Tracking 3 Enforcement Trends In Health Care

By **Jaime Jones** (November 27, 2019)

Jaime Jones

According to the statistics published by the U.S. Department of Justice in December 2018, fraud recoveries, including under the False Claims Act, declined in 2018 for the third straight year.

While the majority of the dollars recovered by the government in these actions continues to come from the providers of health care services, technologies that enable those services, the manufacturers of the drugs and devices, and the private insurers who pay for health care, recoveries from the health care sector have also declined.

While we await the official 2019 statistics from the DOJ, we know that this year has continued the Trump administration's trend of decreasing enforcement recoveries. That said, recoveries from the industry continue to be counted in the billions of dollars and outstrip levels seen a decade ago.

While this administration's enforcement priorities have shifted from those of the last, and while the DOJ is taking steps to exercise discretion and preserve its enforcement resources in some matters, both the DOJ and the U.S. Department of Health and Human Services continue to devote substantial resources to aggressively pursuing high-priority enforcement issues, particularly those that potentially impact patient safety and substantially increase costs to the federal health care programs.

Of course, the government's enforcement initiatives focused on combating the opioid epidemic, including through actions brought against participants at every level of the distribution chain, will continue.

Similarly, the DOJ will continue to prosecute violations of the Anti-Kickback Statute — the key driver of so many billions of dollars in recoveries by the DOJ from pharmaceutical and medical device manufacturers and providers in the industry over the last 20 years — both criminally and through actions brought under the False Claims Act where it finds them.

In particular, the DOJ will seek in 2020 to wrap up the spate of cases it has brought in various years against drug manufacturers and vendors in connection with patient assistance programs, alleging violations of the AKS and other laws.

The DOJ also will continue its efforts to combat "upcoding" fraud against the Medicare Advantage program, having now extracted significant settlements from some plans and providers over the last two years.

We also expect to see continued focus on manufacturers and compounding pharmacies that expose patients to harm through failure to comply with current good manufacturing practice requirements, and efforts by the DOJ to leverage those cases for significant civil recoveries under the FCA.

These and other enforcement areas of focus will be shaped by the trends and developments in the law that emerged in 2019. This article explores those that the health care industry can expect to continue in 2020.

DOJ Dismissals of Qui Tam Suits

In January 2018, Michael Granston, then-director of the DOJ's Civil Fraud Section, issued a memo announcing that the DOJ would seek dismissal of whistleblower actions brought under the FCA if the suits do not serve the federal government's interests. The Granston memo clarifies that DOJ lawyers will evaluate whistleblower actions for possible dismissal according to seven considerations:

1. Curbing meritless actions;

2. Preventing parasitic or opportunistic actions;

3. Preventing interference with agency policies and programs;

4. Controlling litigation brought on behalf of the federal government;

5. Safeguarding classified information and national security interests;

6. Preserving government resources; and

7. Addressing egregious procedural errors.

In 2018 we saw department lawyers begin to file Granston memo motions to dismiss cases in pursuit of this objective. This effort was initiated with motions seeking to dismiss a dozen lawsuits filed across the country by an LLC relator formed for the purpose of pursuing allegations that pharmaceutical manufacturers and third-party service providers violated the Anti-Kickback Statute and the FCA by providing various support services for the manufacturers' drugs.

This trend of Granston motions continued in a modestly robust way in 2019, with the DOJ, for example, seeking to dismiss declined qui tam suits filed against a hospital defendant for allegedly falsifying diagnosis codes and defrauding the Medicare Advantage program, and against hospital services companies for allegedly falsely designating outpatient stays as inpatient services, as well as other actions.

In 2019 we received decisions by the courts on these Granston motions, from which a circuit split has emerged. On the one hand we have a heightened standard for dismissal adopted by the U.S. Court of Appeals for the Ninth Circuit[1] and the U.S. Court of Appeals for the Tenth Circuit,[2] as articulated by the former in the Sequoia Orange case.

Under that standard, the government must show a valid purpose for dismissal and a rational relationship between dismissal and that purpose. In contrast, the U.S. Court of Appeals for the D.C. Circuit held in Swift that the government has an "unfettered right to dismiss" an FCA case, and no standard of review applies.

The DOJ won more Granston motions than it lost in 2019, with district courts applying even the heightened Sequoia Orange standard frequently finding the government's interest in preserving resources, avoiding discovery and controlling litigation costs to be legitimate, and dismissing declined cases found to be rationally related to that interest. The DOJ's record is not unblemished, though.

In April, the U.S. District Court for the Southern District of Illinois denied a Granston motion to dismiss filed by the DOJ in one of the dozen patient support services cases referenced

above.[3]

Applying the Sequoia Orange test, that court held an evidentiary hearing focused in particular on the extent of the DOJ's investigation of the LLC relator's allegations before ultimately rejecting the DOJ's assertion that the potential recoveries were unlikely to justify the costs of pursing the case. That decision is on appeal to the U.S. Court of Appeals for the Seventh Circuit, with a ruling expected in 2020.

The DOJ in 2020 is likely to continue to move to dismiss some declined qui tam suits, particularly those that raise the potential for discovery of HHS that could yield evidence that would undermine the DOJ's ability to bring suits and extract settlements from other defendants in other matters.

This concern is of particular weight in the DOJ's balancing test in the post-Escobar world in which defendants will seek to show that HHS knew of the alleged fraud or similar conduct yet continued to pay claims, establishing the alleged fraud to be immaterial to the government's reimbursement decisions and thus not actionable under the FCA.

As it does so, the DOJ may feel or be compelled to do more to demonstrate the robustness of its investigative efforts to succeed on these motions in at least some courts.

Increased Attacks on FCA Cases Premised on Violations of Subregulatory Guidance

This year the U.S. Supreme Court, in a case that did not arise under the FCA, issued a decision vacating a payment policy adopted by HHS' Centers for Medicare and Medicaid Services for its failure to engage in notice-and-comment rulemaking. That case, Azar v. Allina Health Services,[4] considered a 2014 decision by CMS to alter the way in which it calculated payments by Medicare to "disproportionate share" hospitals.

In siding with the plaintiff hospitals, the court held 7-1 that the Medicare Act expressly requires HHS to engage in notice-and-comment rulemaking prior to adopting any substantive legal standard. Specifically, the Medicare Act states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation.[5]

Holding the Administrative Procedure Act's distinction between substantive and interpretive rules to be irrelevant to the application of the Medicare Act's requirement, the court in Allina found it unnecessary to define the precise contours of substantive legal standards that would trigger the required notice-and-comment rulemaking.

Rather, the court noted the government's concession that the Medicare Act does not define the way in which the disproportionate share payment is to be calculated and that the CMS formula was designed to fill that gap as sufficient to trigger that requirement.

Allina has tremendous implications for the DOJ's ability to pursue wide swaths of health care fraud allegations under the FCA. As 2019 drew to a close, we saw those implications play out for the first time in a decision by the U.S. District Court for the Eastern District of Pennsylvania in Polansky v. Executive Health Resources Inc.[6]

Polansky is a declined FCA suit in which the relator alleged that the defendant hospital services company caused hospitals falsely to certify outpatient services as inpatient, triggering false claims for higher reimbursement amounts. Notably, in its decision the court first granted the government's own Granston motion to dismiss the matter before turning — over the parties' objections — to considering whether summary judgment might properly have been granted to the defendant on some or all claims.

In that regard, the Polansky court relied on Allina in holding that the FCA claims premised on a CMS rule articulated in payment manuals and interpreting the standards under which a hospital admission properly is considered "inpatient" must fail because the rule constitutes a substantive legal standard as to which CMS was required (but failed) to establish through notice-and-comment rulemaking.

In reaching this conclusion, the Polansky court offered a definition of "substantive legal standard" missing from Allina: "If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a 'substantive legal standard.'"

As the Supreme Court in Allina pointed out, and as those in the health care industry well know, CMS issues many manuals and other guidance to participants in the Medicare program that affect the right to and amount of reimbursement for covered items and services. Because FCA actions against health care defendants frequently turn on whether or not Medicare would have covered an underlying product or service, Allina has potentially massive implications for these cases going forward.

Whatever the evidence of the alleged underlying fraud in these cases may be, if the relevant rule of reimbursement was issued only in a provider manual or other subregulatory guidance, then Allina dictates the claim should fail as a matter of law.

On Oct. 31, HHS released a memo from top lawyers in its Office of General Counsel articulating how Allina applies to FCA and other enforcement activities. Specifically, the Allina memo states that payment rules and other guidance documents issued by the Center for Medicare that do comply with the standard set forth in Allina cannot form the basis of enforcement actions.

The memo confirms that to the extent guidance is "closely tied to statutory or regulatory requirements, enforcement actions implicating those guidance materials can still be brought."

In addition, the memo notes that nothing in Allina prevents CMS from enforcing payment provisions as a matter of contract law, where appropriate. However, where "guidance [sets] forth payment rules that are not closely tied to statutory or regulatory standards, the government generally cannot use violations of that guidance in enforcement actions, because under Allina, it was not validly issued."

Thus, among other forms of guidance, local coverage determinations issued by Medicare administrative contractors, standing alone, cannot form the basis of an enforcement action.

The memo also states that, consistent with the principles articulated in the DOJ's Section 1-20.000 of the Justice Manual, and the predicate Brand Memo, guidance documents can be relevant to establishing the materiality and scienter elements of a FCA cause of action — even if they cannot alone establish falsity.

This memo is thus another arrow in FCA defendants' quivers to respond to FCA actions premised on subregulatory guidance. The industry should keep a careful eye on how other courts evaluate issues arising under Allina in 2020, and defendants in particular should take note as they develop their advocacy in enforcement and litigation matters.

Pursuit of Investors in the Health Care Industry

This year also brought the first reported settlement by the DOJ of FCA claims against a private equity investor in the health care industry. That matter, U.S. ex rel. Medrano v. Diabetic Care Rx LLC,[7] involved claims against a compounding pharmacy and its private equity fund owner alleging the pharmacy filed claims with Tricare that were rendered false by alleged kickbacks.

The government, relator and defendants settled the matter following a dismissal of the suit for a failure to adequately connect the alleged AKS violations to a false implied or express certification on which payment was conditioned.

However, the court had granted leave to replead, and an earlier recommendation by the magistrate expressly noted that if the pleading deficiency could be addressed, a claim likely could be stated against the private equity fund defendant and its principals based on allegations by the government that (1) the fund had a controlling interest in the pharmacy; (2) that two representatives of the fund served as both board members and officers of the pharmacy; and (3) that these individuals played an active role in the management of the pharmacy.

The government further alleged that the PE fund had acted with the requisite intent, alleging that "[as] an investor in health care companies, [the fund] knew or should have known ... that health care providers that bill federal health care programs are subject to laws and regulations designed to prevent fraud, including the [AKS]."

In support of its position in Medrano, the DOJ cited a decision from a declined case, in which the court held that a private equity fund can be liable "where the submission of false claims by another entity was the foreseeable result of a business practice," and where the private equity fund "members and principals formed a majority of the ... [defendant provider's] Board, and were directly involved in the operations" of its portfolio company mental health facility.[8]

On this record, in September the private equity fund and its portfolio pharmacy in Medrano elected to pay $21 million to resolve the FCA allegations against them. This settlement clarified what was previously understood: Private equity investors are most vulnerable where they actively engage in the management of portfolio companies.

2020 is likely to bring other efforts by the DOJ to reach into the deep pockets of the private equity funds that increasingly are seeking to invest in the health care space.

Conclusion

Whether 2020 will mark the fourth straight year of declining recoveries from providers, manufacturers, payors and investors in the health care industry will be of little interest to those who find themselves on the opposite side of the thousands of civil and criminal enforcement actions that are likely to yield more billions to the federal coffers.

They — and the entities seeking to avoid enforcement activity by refining their compliance

programs and proactively engaging on issues with HHS — will be well served in considering the trends and developments that emerged in 2019.

Jaime L.M. Jones is a partner at Sidley Austin LLP and co-leader of the firm's health care practice.

[1] United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp., 151 F.3d 1139 (9th Cir. 1998).

[2] Ridenour v. Kaiser-Hill Co., Ltd. Liability Co., 397 F.3d 925 (10th Cir. 2005).

[3] United States of America ex rel. Cimznhca, LLC v. UCB, Inc., 2019 U.S. Dist. LEXIS 64267 (S.D. Ill. Apr. 15, 2019).

[4] Azar v. Allina Health Services, 139 S. Ct. 1804 (2019).

[5] 42 U.S.C. § 1395hh(a)(2).

[6] Polansky v. Executive Health Resources, Inc., No. 12-4239, 2019 WL 5790061 (E.D. Pa. Nov. 5, 2019).

[7] U.S. ex rel. Medrano v. Diabetic Care Rx, LLC, Case No. 15-62617-CIV-BLOOM, S.D.Fl.

[8] U.S. ex rel. Martino-Fleming v. South Bay Mental Health Center, Civ. Action No. 15-13065, D. Mass.