Health Care Enforcement Quarterly Roundup - April 2018

Friday, April 20, 2018

Introduction

Over the past 18 months, we have closely monitored the Trump administration’s approach to health care enforcement issues, with a particular focus on whether prosecution of the False Claims Act (FCA) remains a priority under the new administration. We have tracked these developments and have discussed observations with our clients. In an effort to share those insights more broadly, we are pleased to introduce the inaugural issue of our Health Care Enforcement Quarterly Roundup. This quarterly roundup will provide an overview of the key enforcement trends our team of seasoned litigators and regulatory experts are seeing in the health care industry.

From continued interpretation of the US Supreme Court’s landmark Escobar decision, to the issuance of new policies from US Department of Justice (DOJ) leadership, to expanded use of the FCA, the first quarter of 2018 set the tone for a busy year in health care enforcement.

Courts Continue to Interpret Escobar Favorably for FCA Defendants

One of the most significant developments in FCA litigation in recent years was the Supreme Court’s unanimous 2016 ruling in Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). Escobar held that the “implied certification” doctrine can be a basis for FCA liability but that, among other things, any falsity must be “material” to the government’s decision to pay that claim.

The implied certification theory of FCA liability is based on the notion that in submitting a claim for payment, the claimant implicitly certifies compliance with statutory, regulatory or contractual requirements. If the claimant has not complied with such a requirement, so the theory goes, the claim is false. The Supreme Court held in Escobar that for this theory to be viable, several hurdles must be surmounted by a relator or the government: (1) there must be an express representation about the goods or services provided on the claim for payment; (2) compliance with the provision at issue must be “material” to the government’s decision to pay that claim; and (3) the defendant must know it is material. In its decision, the Supreme Court elaborated on the meaning of what it described as a “demanding” and “rigorous” materiality standard. Among other things, the Court stressed that “if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.” The Court also made clear that materiality is an appropriate issue for consideration at the motion to dismiss stage. Thus, after Escobar, materiality is an important tool that defendants can use at multiple stages of FCA litigation.

Over the course of 2017 and into the first quarter of 2018, we have been watching how the lower courts interpret and apply Escobar’s demanding and rigorous materiality standard. In 2017, there was a remarkable series of district and appeals court decisions demonstrating that the Escobar standard has teeth, and that many courts were not hesitant to dispose of cases where the materiality of the alleged fraud was in doubt.[1]

The first quarter of 2018 indicates that this trend of favorable materiality rulings continues. For instance, in the first few months of the year, several district courts dismissed implied certification FCA complaints because they did not sufficiently allege materiality.[2] These cases demonstrate a willingness by the lower courts to assess materiality on the pleadings and without the benefit of fact discovery, an approach endorsed by the Supreme Court. Historically, FCA plaintiffs typically argued that materiality was too “fact intensive” to resolve on a motion to dismiss, but the Supreme Court rejected this notion in Escobar.[3]

Materiality has also proved to be the death-knell of FCA cases at later stages of litigation. In a highly publicized case early in the quarter, a district court overturned a $350 million jury verdict, finding that the relator did not meet the Escobar materiality standard at trial because the government had long continued payments to the defendant, a nursing home, despite knowing about the nursing home’s alleged record-keeping deficiencies. United States ex rel. Ruckh v. Salus Rehabilitation, LLC, et al., No. 8:11-cv-1303-T-23 (M.D. Fl. Jan. 11, 2018).

Of the many issues to emerge after Escobar, the one tackled by Ruckh has been the source of much litigation. Most courts agree with the proposition, which derives from the Supreme Court’s opinion, that if the government continues to pay a provider’s claims after becoming aware that the provider did not comply with applicable law or contract provisions, the relator (or, as the case may be, the government) simply cannot prove that the noncompliance was material under Escobar.

But not all courts are aligned on the reach of the Supreme Court’s “continued payment” guidance. In United States ex rel. Campie v. Gilead Sciences, Inc., 862 F.3d 890 (9th Cir. 2017), the relators alleged that Gilead concealed information regarding its compliance with certain FDA regulations. Gilead argued on a motion to dismiss that because the government continued to pay for the drug after learning of Gilead’s FDA violations, those violations were not material to the government’s payment decision. The district court dismissed the case, citing Escobar. But the Ninth Circuit reversed, holding that the relators had pleaded sufficient factual allegations to support materiality at the early stage of the case, despite continued payment by government payors such as Medicare and continued approval by the FDA. The court observed that “the parties dispute exactly what the government knew and when” and that “the issues raised by the parties are matters of proof, not legal grounds to dismiss relators’ complaint.”

In late December 2017, Gilead filed a cert. petition in the United States Supreme Court. Over the first quarter, the parties briefed this petition, and the case was considered at the Supreme Court’s April 13, 2018 conference—where the Court invited the Solicitor General to express the views of the United States in the case. Without question, Gilead is an important case to watch in 2018, as the Supreme Court may decide to clarify the application of the materiality standard after Escobar.

Practice Note: To date, cases interpreting the Escobar materiality standard have been largely favorable to FCA defendants. The issue of materiality should be considered at the outset of any FCA investigation or qui tam litigation, and every FCA complaint should be assessed to determine whether it adequately pleads this essential element. If the complaint survives a motion to dismiss, discovery should be used to develop
the materiality defense for use on summary judgment. In short, whether at the front-end or at later stages of litigation, the materiality standard is a potent weapon in the defense arsenal.

[1] See United States ex rel. D’Agostino v. ev3 Inc., 845 F.3d 1, 7 (1st Cir. 2016) (holding that the district court properly granted defendant’s motion to dismiss because CMS’s continued reimbursement for a particular device under the relator alleged it violated FDA requirements “casts serious doubt on the materiality of the [alleged] fraudulent representations.”); United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481, 490 (3d Cir. 2017) (affirming dismissal of FCA claims because relator failed to sufficiently plead materiality where he essentially conceded that CMS would reimburse claims even with actual knowledge of the alleged deficiencies); Abbott v. BP Exploration & Production, Inc., 851 F.3d 384, 388 (5th Cir. 2017) (holding that district court correctly granted summary judgment where, after a “substantial investigation into Plaintiffs’ allegations,” the allegedly non-compliant activities were allowed to continue).


DOJ Leadership Reaffirms Expanded Enforcement of the FCA to Combat Opioid Epidemic

In his March 2018 confirmation hearing, President Trump’s nominee to head DOJ’s Civil Division, Joseph “Jody” Hunt, signaled that DOJ would continue with its aggressive enforcement of the FCA. In fact, Hunt said that he and the Trump administration are focused on “vigorously enforcing the [FCA]” and “aggressively” combating the opioid epidemic by using the FCA as one of its enforcement tools. Mr. Hunt commented that the Civil Division will focus on holding accountable “opioid manufacturers, distributors, and others in the distribution and prescription chain.” Mr. Hunt signaled that he will deploy all civil and criminal remedies to accomplish these enforcement goals. [1]

Mr. Hunt’s comments follow DOJ’s announcement of the Prescription Interdiction and Litigation (PIL) Task Force on February 27, 2018. [2] In a speech by Attorney General Jeff Sessions, DOJ announced that the Task Force “will use criminal and civil actions to ensure that distributors and pharmacies are obeying federal regulations created to prevent the improper prescribing of medications.” [3] The Task Force plans to use the FCA as one of a number of enforcement tools to “crack down on pain-management clinics, drug testing facilities, and physicians that make opioid prescriptions.” [4] The Task Force will look at every level of the opioid distribution system, from manufacturer to distributor, and will coordinate with multiple agencies, including the Drug Enforcement Agency (DEA) and the Food and Drug Administration (FDA). It will also consider a wide array of enforcement approaches, including the FCA, among other civil, criminal and regulatory enforcement measures.

In a separate speech before the Federal Bar Association’s Qui Tam Conference on February 28, 2018, Deputy Associate Attorney General Stephen Cox echoed the Attorney General’s statements, emphasizing the power of the FCA to reach all levels of the opioid distribution chain. [5] Cox highlighted DOJ’s September 2017 settlement with Galena Biopharma, in which the company paid $7.55 million to settle claims that it paid kickbacks to physicians for prescribing a fentanyl-based opioid. [6] At the time, the Acting United States Attorney for the district where the charges were brought also characterized the prosecution as part of the battle against opioids. Cox noted that two of the physicians involved in the Galena case were tried, convicted, and sentenced to prison for, among other things, prescribing opioids outside the usual course of professional practice.

On February 27, 2018, Attorney General Sessions also announced that DOJ intended to file a statement of interest in multidistrict litigation currently pending in the United States District Court for the Northern District of Ohio (17-MD-2804). In early March, DOJ filed a statement identifying several potential recovery statutes and other legal considerations, and sought 30 days to decide whether to participate in the proceedings. DOJ followed up on April 2, 2018, filing a motion seeking to “(1) to participate in forthcoming settlement discussions . . . and (2) to participate as friend of the Court by providing information to the Court and the parties to facilitate effective non-monetary remedies to address problems arising from the national opioid crisis.”

It is also important to note that state and local governments are likely to pursue a similar approach to combatting the opioid crisis through enforcement actions under state false claims acts. In November, the St. Louis County Minnesota Board of Commissioners authorized a lawsuit on its behalf in state court. On March 14, the county filed a 10-count complaint alleging, among other things, violations of the state’s FCA. [7]

Practice Note: The national opioid crisis is a public health emergency that will be a top law enforcement priority for the foreseeable future. DOJ has steadily increased its public statements about the crisis and, with the establishment of the PIL Task Force, has indicated that it intends to investigate every level of the opioid distribution system. DOJ’s insertion into the Ohio MDL may be a harbinger of what is to come—greater involvement from DOJ in existing cases and increased volume of government investigations and litigation.

[3] Id.
[4] Id.

Guidance Memoranda Continue to Be Used by DOJ Leadership to Endorse Enforcement Priorities and Protocols

DOJ has long used guidance memoranda to reflect enforcement priorities and provide specific guidance to its prosecutors. This remains true in the Trump administration. In the first quarter of 2018, the new administration put its stamp on how it intends to handle FCA enforcement in the coming years.

The Granston Memo
On January 10, 2018, DOJ’s Civil Division issued a memorandum to prosecutors handling *qui tam* FCA cases outlining circumstances under which the United States should seek dismissal of cases that “lack substantial merit.” Authored by Michael Granston, the director of the Civil Division’s Fraud Section, the so-called “Granston Memo” outlines seven factors that prosecutors should consider in determining whether to exercise DOJ’s statutory authority to dismiss *qui tam* matters pursuant to 31 USC § 3730(c)(2)(A).

These factors include: (1) curbing meritless *qui tams*, “either because the legal theory is inherently defective, or the relator’s factual allegations are frivolous;” (2) preventing parasitic or opportunistic *qui tam* actions, where *qui tam* cases duplicate pre-existing government investigations and “add no useful information;” (3) preventing interference with agency policies and programs; (4) *avoiding* the risk of unfavorable precedent; (5) safeguarding classified information and national security interests; (6) preserving government resources; and (7) addressing egregious “procedural errors.” In particular, the Granston Memo also notes that cases may be dismissed where the action is “both lacking in merit and raises the risk of significant economic harm that could cause a critical supplier to exit the government program or industry.” What remains to be seen is how aggressively the United States intends to aid FCA defendants in these efforts.

While DOJ asserts that the Granston Memo merely reiterates existing statutory authority, the memo’s detailed guidance opens the door for FCA defendants to advocate for the dismissal of frivolous relator cases.

**The Brand Memo**

Shortly after issuance of the Granston Memo, then-Associate Attorney General Rachel Brand issued a memorandum mandating that “[DOJ] litigators may not use noncompliance with guidance documents as a basis for proving violations of applicable laws in [affirmative civil action] cases.” [1] Agency guidance is not law. It does not have the force or effect of a statute or regulation. Nonetheless, for years, relators have cited the failure to comply with agency guidance as grounds for pursuing FCA claims.

The “Brand Memo” seeks to limit this trend, at least where the United States is considering intervention in a case. The memorandum effectively directs DOJ lawyers to limit the use of agency guidance as the sole basis for seeking authority to pursue an FCA enforcement action. [2] While the Brand Memo provides some flexibility for prosecutors to use agency guidance—e.g., using evidence that a defendant read guidance to prove knowledge—it generally represents a positive move for FCA defendants. It forces DOJ line attorneys to be more skeptical of the purported merits of *qui tam* suits that appear to rely on regulatory nitpicking by *qui tam* relators.

Once again, the ultimate effect of this memorandum on existing and future cases is not yet clear. Without question, the Brand Memo should have an effect on how DOJ thinks about and implements intervention decisions. But it has limits. Because it only controls the behavior of DOJ attorneys, it may not reduce the number of *qui tam* complaint filings that rely on regulatory missteps to establish the falsity of the claim. And, as with all DOJ guidance memos, the Brand Memo does not obligate the courts.

**Practice Note:** It is too soon to measure the full impact of the recently issued Granston and Brand memos. What is clear, however, is that the Trump administration is putting its own stamp on FCA enforcement. While the Granston Memo provides additional ammunition to FCA defendants, it is not yet clear whether it will result in the dismissal of more cases. In contrast, the Brand Memo has more defined parameters and is likely to result in an adjustment in the types of cases in which the DOJ intervenes.

DOJ Maintains Focus on FCA Enforcement against Individuals

In September 2015, DOJ issued the well-known “Yates Memo” (named for then-Deputy Attorney General Sally Yates), which focuses on individual accountability for corporate wrongdoing. In the years since issuance of the Yates Memo, DOJ has codified its policy around individual accountability for corporate wrongdoing in the US Attorney’s Manual. Despite early commentary that raised questions about whether DOJ would continue to emphasize enforcement against individuals, cases over the past 15 months reflect a continued focus on individual accountability. In a recap of FCA enforcement in Fiscal Year 2017, DOJ announced that it had “continued to ensure individual accountability for corporate wrongdoing by pursuing FCA and other civil remedies to redress fraud by individuals as well as corporations.” [3]

DOJ highlighted several settlements with individual defendants, including the following cases:

- To resolve United States ex rel. Delaney v. eClinicalWorks LLC, eClinicalWorks and three of the company’s founders agreed to a combined $155 million settlement. [2] Additionally, three lower level employees (a developer and two project managers) were required to pay smaller amounts to resolve the individual claims against them ($15–50,000 each). [3]

- In United States ex rel. Meehan v. Medstar Ambulance Inc., et al. the owners of Medstar Ambulance Inc. and the company agreed to a combined $12.7 million settlement. [4]

The trend continued in the first quarter of 2018. In February 2018, DOJ secured a $124 million settlement with Horizons Hospice, LLC and its owner to resolve FCA allegations that the company fraudulently billed Medicare and Medicaid for patients ineligible for hospice care. [5] In addition to settlements, DOJ had several recent trial victories against individual defendants accused of FCA violations. In late January 2018, nearly three years after the United States intervened, the ex-CEO and two marketing consultants at Health Diagnostics Laboratory were found liable by a DSC jury for over $17 million in Medicare fraud, which is automatically trebled under the FCA to over $51 million and is subject to as yet to be determined FCA penalties of $5,500 to $11,000 per claim. Health Diagnostics Laboratory previously settled with DOJ in 2015 for $47 million, but the government chose to pursue additional claims against individual defendants. [6]

At this point in 2018, the DOJ pipeline of individual liability cases that pre-dated the Trump administration is dwindling and the resolution of matters over the course of this year may be a significant indicator of the true direction FCA enforcement may take under this administration.

**Practice Note:** In the first quarter of 2018, DOJ continued its push to impose FCA liability on individuals. Based on cases we are seeing across the health care industry, we expect this trend to continue.

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**Private Equity Sponsor Named as FCA Defendant**

DOJ also made news in February 2018 when it named a private equity firm as a co-defendant in 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.). The case involves allegations that Patient Care America (PCA), a Florida compounding pharmacy, paid illegal kickbacks to induce prescriptions for drugs reimbursed by TRICARE.

While DOJ routinely targets company executives—particularly in recent years—the addition of a private equity sponsor of a health care company as an FCA defendant is noteworthy. Here, the United States’ complaint in intervention names as defendants PCA, two of its executives, and PCA’s private equity sponsor (and ultimate owner). Discovery and motion practice—and potentially a trial—will determine whether the government can prove its allegations and theories in this case.

**Practice Note:** While it is too early to tell whether the inclusion of a private equity sponsor as a defendant in Medrano is an outlier or is representative of a growing trend, this case is noteworthy. We will continue to monitor this case and any others that follow.

**DOJ Continues Action against Medicare Advantage Plans, Showing Increased Focus on Intersection of the FCA and Managed Care**

Last year, DOJ intervened in United States ex rel. Poehling v. UnitedHealth Group., Inc. (C.D. Cal.). In this case, DOJ alleged FCA violations relating to Medicare Advantage “risk adjustment” scores. Risk adjustment alters payments to MA plans to reflect expected costs associated with the health status of Medicare beneficiaries enrolled in MA plans.

In a ruling on a motion to dismiss in February 2018, the presiding judge in Poehling dismissed allegations that UnitedHealth had falsely attested to the accuracy of the risk adjustment scores. The judge allowed the case to proceed on a theory that the defendant had improperly avoided an obligation to refund the government for risk-adjustment related overpayments.

**Poehling** is one of several pending cases brought by DOJ and relators in district courts across the country in which MA plans are defendants.

**Practice Note:** DOJ’s intervention in Poehling reflects a shift towards government enforcement against MA plans. With enrollment in MA plans steadily increasing, it is likely that this trend will continue. We will continue to monitor Poehling and other cases pending in district court and report back in subsequent roundups.

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