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Health Care Enforcement Quarterly Roundup - October 2018

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Introduction

In the latest installment of *Health Care Enforcement Quarterly Roundup*, we examine key enforcement trends in the health care industry that we have observed over the past few months. In this issue, we report on the practical applications of recent guidance from the US Department of Justice (DOJ), a recent blow to DOJ's effort to use the federal False Claims Act (FCA) to attack Medicare Advantage reimbursement, continued enforcement efforts at the state and federal level to combat the opioid crisis, and potential changes to the Stark Law and Anti-Kickback Statute. We also continue our reporting on how the lower courts have interpreted the landmark *Escobar* case.

Government Dismissals of Qui Tams after the Granston Memorandum

This year has seen significant changes in the FCA enforcement landscape. As reported in earlier *Quarterly Roundup* editions, the so-called January 2018 Granston Memorandum directs DOJ trial lawyers to more seriously consider dismissing meritless FCA cases brought by whistleblowers. Specifically, the Granston Memorandum highlights that trial lawyers should consider the FCA's dismissal provision, 31 USC § 3730(c)(2)(A), an "important tool" to "advance the government's interests, preserve limited resources, and avoid adverse precedent."[1] Two recent cases decided after the Granston Memorandum's release demonstrate an emerging split over what the government must prove to warrant dismissal.

Valid Purpose Test

In *United States et al. v. Academy Mortgage Corporation*, the relator, an underwriter at Academy Mortgage Corporation, claimed that the defendant defrauded the government by falsely certifying loans for government insurance.[2] The relator's initial complaint limited the alleged misconduct to a one-year period at the branch where the relator worked, and the government declined to intervene. After the relator filed an amended complaint, the government moved to dismiss under the FCA's dismissal provision, arguing—as directed in the Granston Memorandum—that the lawsuit would drain government resources and was not justified under a cost-benefit analysis.

In response, the relator claimed that the government failed to meet the US Court of Appeals for the Ninth Circuit's burden-shifting approach for adjudicating the dismissal of an FCA action as set forth in *United States ex rel. Sequoia Orange Company v. Baird-Neece Packing Corporation*. *Sequoia* requires that the government first identify "a valid government purpose and demonstrate a rational relation between the dismissal and that purpose."[3] After the government establishes this element, "the burden shifts to the relator to demonstrate that the dismissal is fraudulent, arbitrary and capricious, or illegal."[4] The relator argued that the government did not conduct a sufficient cost-benefit analysis to satisfy its burden under *Sequoia*. In particular, the relator claimed that the government failed to meaningfully assess the potential proceeds from the lawsuit.

The court agreed with the relator and denied the motion to dismiss. Citing *Sequoia*, the court explained that the government failed "to conduct a minimally adequate investigation" because it only reviewed 1.5 years of the alleged misconduct, even though the allegations in the amended complaint spanned a period of six years.[5] The court also noted that even if the government had met the first element of the burden-shifting approach, the relator had met her burden by showing that the government's failure to fully investigate the claim resulted in the motion to dismiss being "fraudulent, arbitrary and capricious, or illegal." The government's appeal of the district court's decision is pending before the Ninth Circuit.[6]

The Government's "Unfettered Right" to Dismiss

In *United States ex rel. Maldonado v. Ball Homes*, the relator sued under the FCA, alleging that the defendants took part in a fraudulent scheme that involved submitting falsified documents to obtain loans issued by the Federal Housing Administration.[7] The government declined to intervene and, several months later, filed a motion to dismiss.

The *Maldonado* court noted that "courts have developed two differing standards for evaluating government requests to dismiss *qui tam* actions," citing to *Sequoia* and *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003).[8] The court explained that while *Sequoia* requires the government to show a valid government purpose that is rationally related to dismissal, *Swift* held that the government has an "unfettered right" to dismiss a *qui tam* action.[9] In granting the government's motion, the court noted the circuit split about whether the government has an unfettered right to dismiss *qui tam* cases or whether it must first show cause to do so. The court took the former stance, holding that the government "has virtually unfettered discretion to dismiss a *qui tam* action" and dismissed the complaint.[10]

Practice Note: Although the Granston Memorandum encourages prosecutors to use the FCA's dismissal provision, there is an emerging split over what the government must prove to warrant dismissal. FCA defendants pushing for dismissal pursuant to the Granston Memorandum should bear in mind the extent of the government's dismissal authority in the applicable jurisdiction.

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[1] DOJ Commercial Litigation Branch, Fraud Division, *Factors for Evaluating Dismissal Pursuant to 31 U.S.C. § 3170(c)(2)(A)* (Jan. 10, 2018).

[2] 3:16-cv-02120, 2018 WL 3208157, (N.D. Cal. June 29, 2018).

[3] *Id*. at *2.

[4] *Id.*

[5] *Id*. at *3.

[6] *United States v. Acad. Mortg. Corp.*, No. 18-1640.

[7] No. CV 5: 17-379-DCR, 2018 WL 3213614 (E.D. Ky. June 29, 2018).

[8] *Id.* at *3.

[9] *Id.*

[10] *Id.*

Court Strikes Down Medicare Advantage Overpayment Regulation, Leveling Playing Field

In a significant decision for Medicare Advantage insurers, the US District Court for the District of Columbia vacated a 2014 Medicare Overpayment Rule earlier this month. *UnitedHealthcare Ins. Co. et al. v. Azar et al.*, No. 1:16-cv-00157 (D.D.C. Sept. 7, 2018). Under the Medicare statute, "actuarial equivalence" is required between CMS payments for health care coverage under Medicare Advantage plans and CMS payments under traditional Medicare. UnitedHealthcare challenged the 2014 Overpayment Rule on a number of grounds, including that it (1) violated the statutory actuarial equivalence requirement, resulting in payments to Medicare Advantage insurers that were not equivalent to payments under traditional Medicare, and (2) improperly resulted in the imposition of a negligence standard under the FCA for Medicare Advantage insurers with respect to retention of overpayments.

The court sided with UnitedHeathcare, finding that the 2014 rule devalued payments to Medicare Advantage insurers and established a system where "actuarial equivalence" cannot be achieved. The Court explained:

> [T]he effect of the 2014 Overpayment Rule, without some kind of adjustment, is that Medicare Advantage insurers will be paid less to provide the same healthcare coverage to their beneficiaries than CMS itself pays for comparable patients. This inequity is inevitable because CMS sets Medicare Advantage rates based on costs that are presumed, based on traditional Medicare diagnosis codes, to be associated with particular health status information that is not verified in underlying patient records. The same unverified diagnosis is, under the 2014 Overpayment Rule, treated as an overpayment that must be repaid, thus reducing the reimbursement to a Medicare Advantage insurer while requiring no such reduction in payment under traditional Medicare.

The court also agreed that from an enforcement standpoint, the Overpayment Rule improperly exposed Medicare Advantage insurers to FCA liability based on a lower standard of proof than the FCA requires. The rule provided that a Medicare Advantage insurer would be deemed to have identified an overpayment that needed to be repaid when the insurer determined, *or should have determined through the exercise of reasonable diligence*, that it received an overpayment. The court held that "reasonable diligence" is a negligence standard, and as such is inconsistent with the FCA's minimum mental state of "reckless disregard." The court observed that CMS has "no legislative authority to apply more stringent standards to impose FCA consequences through regulation."

State and Federal Enforcement Efforts Continue to Combat the Opioid Crisis

Following a string of speeches and announcements in late 2017 and early 2018, the DOJ has remained active in actions to combat the opioid crisis. In August 2018, the DOJ reached a settlement-in-principle with Insys Therapeutics in an FCA suit over the company's marketing of Subsys, a sub-lingual spray form of fentanyl.[11] Insys will pay at least $150 million and up to $75 million more based on "contingent events" to settle the claims. The settlement appears to have helped Insys avoid protracted litigation and company-ending liability.

In contrast to the substantial *Insys* settlement, the DOJ moved the US District Court for the District of Massachusetts to dismiss an FCA suit targeting OxyContin manufacturer Purdue Pharma and several of the drug's distributors.[12] The DOJ asserted that all of the claims in the case were derived from public sources, triggering the FCA's public disclosure bar. This action was consistent with the Granston Memorandum, which guides DOJ to increase use of its authority to dismiss FCA cases.

Reflecting a continued focus on federal enforcement, the DOJ intervened in another set of cases against Reckitt Benckiser and Indivior involving their delivery system for the drug Suboxone.[13] Although the companies marketed their sub-lingual Suboxone film as being less vulnerable to diversion and safer than tablets, the complaint alleged that many patients take the drug in divided doses, leaving unconsumed portions accessible to children.

The DOJ has also pressed cases against individuals that it alleges are responsible for improper opioid marketing and distribution. For example, the Insys settlement does not affect criminal proceedings against 15 former Insys officials for their involvement in the alleged scheme. Indeed, on the same day that the DOJ announced the settlement, a former district sales manager, Jeffrey Pearlman, pled guilty in the US District Court for the District of Connecticut to conspiracy to defraud the United States. In August 2018, in the US District Court for the District of Ohio, the DOJ sought its first-ever restraining order to bar two doctors from prescribing medications after an investigation revealed that they recklessly and unnecessarily distributed painkillers and other drugs.

State and local lawsuits involving opioids have also continued apace. The DOJ's Insys settlement, for instance, does not resolve state civil fraud and consumer protection claims against the company in the same action, including a number of claims under state false claims acts. In addition, a number of other states and municipalities have pressed their own suits against opioid manufacturers and distributors. This includes New York and Oregon, whose state attorneys general have announced lawsuits against Purdue Pharma.[14]

Practice Note: The Trump Administration and the Sessions DOJ have made it clear that federal enforcement efforts to combat the opioid crisis will remain a top priority. Complementing extensive state-level enforcement, the DOJ has indicated that it will intervene where appropriate, push for settlements where swift resolution makes sense, and utilize its most aggressive enforcement tools to send a message to individuals and companies in the opioid distribution network.

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[11] N. Raymond and A. Thibault, Insys to pay $150 million to settle U.S. opioid kickback probe, Reuters (Aug. 8, 2018), https://www.reuters.com/article/us-insys-opioids/insys-to-pay-150-million-to-settle-doj-probe-into-sales-practices-idUSKBN1KT1G5.

[12] J. Overly, *DOJ Urges Toss Of FCA Suit Targeting Opioid Sellers*, Law360, (Aug. 23, 2018), https://www.law360.com/articles/1076065/doj-urges-toss-of-fca-suit-targeting-opioid-sellers.

[13] N. Raymond, *U.S. joins lawsuits against Indivior, Reckitt over drug Suboxone*, Reuters, (Aug. 8, 2018), https://www.reuters.com/article/us-indivior-lawsuit/u-s-joins-lawsuits-against-indivior-reckitt-over-drug-suboxone-idUSKBN1KT2NW.

[14] Press Release, New York State Office of the Attorney General, Attorney General Underwood And Governor Cuomo Announce Suit Against Purdue Pharma For Widespread Fraud And Deception In Marketing Of Opioid Products (Aug. 14, 2018), https://ag.ny.gov/press-release/attorney-general-underwood-and-governor-cuomo-announce-suit-against-purdue-pharma; Press Release, Oregon Department of Justice, Attorney General Rosenblum Sues Purdue Pharma, Maker of OxyContin, (Sept. 13, 2018), https://www.doj.state.or.us/media-home/news-media-releases/attorney-general-rosenblum-sues-purdue-pharma-maker-of-oxycontin/.?

Continued Evolution of Post-Escobar Jurisprudence

As we reported in earlier *Quarterly Roundup* reports, lower courts continue to wrestle with the unanimous landmark decision in *United Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). While most of the case law developing in this area has focused on the Supreme Court of the United States' reinvigorated materiality standard, another aspect of the *Escobar* decision is an essential tool for FCA defendants: the two-part test articulated by the Supreme Court for applicability of implied certification theory.

Implied Certification's Two-Part Test

In *Escobar*, the Supreme Court held that the implied certification theory can be a basis for liability "at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual provisions makes those representations misleading half-truths."[15]

Among a number of other courts, the US Court of Appeals for the Ninth Circuit has held that both conditions outlined by the Supreme Court must be satisfied for an implied certification claim to proceed. *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 901 (9th Cir. 2017).[16] This is important, in part, because some claims do not satisfy the first prong, inasmuch as the allegedly false claims may contain no representation about the goods or services provided. But a more recent three-judge panel of the Ninth Circuit expressed skepticism about the *Escobar* two-part test. *United States ex rel. Rose v. Stephens Institute*, No. 17-15111, 2018 WL 4038194 (9th Cir. Aug. 24, 2018). The *Rose* court questioned whether the two conditions articulated by the Supreme Court were "the *only* way to establish liability under an implied false certification theory."[17] The court stated that it was constrained by prior three-judge panel decisions such as *Gilead*, however, and reluctantly concluded "that Relators must satisfy *Escobar's* two conditions to prove falsity, unless and until our court, en banc, interprets *Escobar* differently."[18]

Materiality

The Ninth Circuit's decision in *Rose* also addressed the issue of materiality, an element of any FCA claim, although its analysis did not hew to *Escobar's* "rigorous" and "demanding" materiality standard. The Supreme Court in Escobar held that whether the government conditions payment on compliance with a regulation or contract term is relevant to the question of materiality, but not

dispositive; the court instead focused heavily on what the government *actually* would have done (or did) with respect to payment or nonpayment of claims had it known of the alleged noncompliance. *Rose* involved allegations that an art school failed to follow an incentive compensation ban that it had pledged to follow in order to receive federal funds. The *Rose* court found the evidence of materiality sufficient to survive summary judgment, stating that beyond conditioning payment on compliance with the "bonus ban" at issue, "[t]here is evidence . . . that the [government] did care about violations of the [bonus] ban and did not allow schools simply to continue violating the ban while receiving Title IV funds."[19] That evidence included the magnitude of the alleged violation and the fact that the government had historically taken some action against schools found to have violated the ban, including by assessing fines and requiring one school to repay $16 million in federal funds.[20]

However, as Judge Smith's dissent on the materiality issue notes, "caring is not enough to make [noncompliance] material under the *Escobar* standard."[21] The dissent went on to opine that the panel gave too much weight to the government's general concern regarding compliance, flouting *Escobar's* admonition that the FCA is not intended to punish "garden-variety breaches of contract or regulatory violations."[22] The dissent emphasized the lack of evidence regarding how the government would respond to the specific violations alleged in that particular case had it known of them, which is ultimately the heart of the "materiality" inquiry.[23] It further suggested that the majority relied too heavily upon compliance as a condition of payment—which *Escobar* held is not dispositive—and in doing so, failed to apply *Escobar's* "rigorous" and "demanding" materiality standard.[24]

We will have to wait and see what happens if the Ninth Circuit has occasion to address the *Rose* panel's treatment of *Escobar's* two-part test and materiality standard *en banc*. The petition for rehearing en banc, if one is filed, is due October 9, 2018.

Latest Updates

In our Q1 issue of the *Quarterly Roundup*, we reported that in *United States ex rel. Ruckh v. Salus Rehabilitation, LLC, et al.*, No. 8:11-cv-1303-T-23 (M.D. Fl. Jan. 11, 2018), the district court overturned a $350 million jury verdict, finding that the relator did not meet the *Escobar* materiality standard. The relator appealed, and the case is currently pending in the US Court of Appeals for the 11th Circuit. On July 20, 2018, the DOJ filed an *amicus* brief in support of the appellant-relator, arguing that the district court had "fundamentally misunderstood" the *Escobar* decision's discussion of when violations are material to the government's payment decision. We will continue to track this case and the 11th Circuit's approach to materiality post-*Escobar*.

In Q2, we reported on the US Court of Appeals for the Sixth Circuit's decision in *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018). Over a vigorous dissent, the panel held that the relator had alleged materiality sufficient to survive a motion to dismiss. On August 23, 2018, the Sixth Circuit issued an order rejecting the defendant's bid to rehear the suit, leaving in place the panel's 2–1 decision.

Practice Note: Practitioners defending FCA cases and investigations should pay close attention to the evolving interpretations of Escobar. If the legal theory advanced by the government or the relator is "implied certification," do the allegations or evidence satisfy the two-part test? Moreover, are the allegations or evidence of materiality sufficient to pass muster? Bear in mind that the latter question is

not limited to implied certification FCA claims; materiality is a necessary element of any FCA claim.

[15] 579 U.S. __, 136 S. Ct. 1989 (2016).

[16] As reported in our inaugural issue, Gilead's petition for *certiorari* is currently pending in the Supreme Court. As we last reported, the Supreme Court invited the solicitor general to file a brief expressing the views of the United States. As of the date of this publication, there has been no new activity in the case, and the solicitor general has not filed a brief.

[17] *Id.* at *4.

[18] *Id.*

[19] *Id.* at 8.

[20] *Id.* at 7–8.

[21] *Id.* at 11 (Smith, J., dissenting).

[22] 136 S. Ct. at 2003

[23] *Id.* at 11-12 (Smith, J., dissenting).

[24] *Id.* at 12.?

Potential Changes to the Stark Law and Anti-Kickback Statute Could Reshape the Enforcement Landscape

As part of the effort to shift to value-based care, HHS recently announced a "Regulatory Sprint to Coordinated Care," led by Deputy Secretary of HHS Eric Hargan.[25] This initiative aims to address regulatory impediments to care coordination in furtherance of the government's interest in paying for quality over quantity. The initiative could result in substantial changes to two laws that generate significant litigation in the health care space: the Stark Law and the Anti-Kickback Statute (AKS).

The Stark Law

The physician self-referral law, commonly referred to as the Stark Law, contains a two-part prohibition: (1) a physician may not make a referral to an entity for designated health services (DHS) if the physician (or an immediate family member) has a financial relationship with that entity, *unless an exception applies*, and (2) the entity may not submit a claim to Medicare for DHS furnished pursuant to a prohibited referral. Violations of the law may result in non-payment penalties, exclusions and overpayment refund obligations.

As providers move towards implementation of value-based care models, the Stark Law has proven to be a regulatory impediment. For example, the Stark Law's requirement that physician compensation meet certain standards—*e.g.*, it must be consistent with fair market value and not take into account referral volume or value of referrals—may come into direct conflict with value-based structures, particularly where these standards are poorly defined and do not acknowledge the potential for payment models that align physician incentives with care patterns. Because the Stark Law is

structured as a strict liability statute and is replete with complex and ambiguous requirements with poorly-defined standards, many FCA cases predicated on Stark claims, however weak or unsupported, have survived motions to dismiss and entered the discovery phase of litigation.

Anti-Kickback Statute

The AKS is a criminal statute that prohibits offering, paying, soliciting or receiving anything of value in exchange for, or to induce a person to make referrals for, items and services that are payable by a federal health care program. The AKS also extends to inducements or rewards to purchase, lease, order or arrange for, or recommend purchasing, leasing or ordering any services or items that may be covered by a federal health care program. Value-based payment models may implicate the AKS because those models often seek to align physician financial incentives with certain practice patterns, resulting in compensation that might not conform to typical fair market value models or otherwise vary with the physician's referrals to a particular entity.

Potential Changes on the Horizon

Seeking reforms to the Stark Law and the AKS has been a priority for many health care stakeholders for several years. Recent developments suggest that meaningful changes to applicable regulations could finally be on the horizon.

In June 2018, CMS issued a request for information (RFI) seeking input from the public on how the Stark Law frustrates efforts to implement value-based care models.[26] CMS sought input on how the Stark Law affects novel financial arrangements and the applicability of existing exceptions to these arrangements. CMS also solicited comments on some of the most fundamental principles for Stark Law compliance, including the concepts of "fair market value," "commercial reasonableness," and "takes into account the volume or value of referrals."

In August 2018, the OIG published an RFI seeking similar input on the AKS.[27] The OIG requested information on a range of topics, including arrangements between parties that participate in alternative payment models or other novel financial arrangements designed to promote care coordination and value, how to understand "value" as a concept, the adequacy of existing fraud and abuse waivers, and specific issues relating to cybersecurity and telehealth services.[28]

The Stark Law and AKS RFIs come on the heels of recent comments from former Secretaries of HHS Kathleen Sebelius and Tommy Thompson that describe the Stark Law and AKS as "remnant[s] of the fee-for-service world" that "harm the very patients they are supposed to protect by deterring more comprehensive patient-centered, coordinated care."[29] CMS's efforts also follow the Senate Finance Committee's 2015 inquiries that resulted in publication of the white paper entitled, *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models*. In the white paper, the Committee concluded that "[t]he Stark law was created to address a risk in an [fee-for-service] payment model," and "[t]he financial incentives that trigger overutilization concerns in an [fee-for-service] payment model are largely or entirely eliminated in alternative payment models." In particular, the Senate Finance Committee noted that health care companies view the Stark Law's strict liability standard and large penalties as a hindrance to implementation of alternative payment reforms.

Impact of Stark Law and AKS Reform on FCA Litigation

The Stark Law and AKS are often used as the basis for *qui tam* lawsuits. For example, the Stark Law is a strict liability statute with an absolute prohibition on DHS referrals if the physician has a financial relationship, unless an exception applies. Therefore, courts generally view Stark Law exceptions as affirmative defenses that a *qui tam* defendant must plead and prove. The practical result of this framework is that Stark Law-based FCA suits often survive motions to dismiss, allowing plaintiffs to pursue discovery. Such was the case for the defendant hospital in *United States ex rel. Bingham v. BayCare Health Systems*, where a relator's questionable Stark Law theory and weak facts survived a motion to dismiss only to be dismissed on summary judgment. Like many *qui tam* defendants facing Stark Law-based FCA litigation, BayCare Health was forced to endure time-consuming and expensive discovery and motions practice to ultimately dispense with a case that was unsupported by the evidence.

If Stark Law reforms result in "bright line" guidance about the law's exceptions, this could prove helpful for defendants trying to defeat weak cases from proceeding to costly litigation. For example, if the reforms result in specific guidance on how to demonstrate fair market value, taking into account the volume or value of referrals, or commercial reasonableness, an FCA defendant may be able to demonstrate that payment arrangements *per se* fall into an exception earlier in the litigation, perhaps even at the motion to dismiss stage.

Practice Note: Lawyers representing health care providers should pay close attention to any changes in the Stark Law or the AKS. Such changes could affect the defense of actions predicated on alleged violations of the Stark Law, the AKS or both. We will continue to monitor developments in this area.

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[25]*See* 83 Fed. Reg. 29,524 (June 25, 2018).

[26] id.

[27] *See* 83 Fed. Reg. 43,607 (Aug. 27, 2018)

[28] The OIG also solicited feedback on the beneficiary inducement prohibition in the Civil Money Penalties Law, which authorizes the imposition of civil money penalties for paying or offering any remuneration to a Medicare or Medicaid beneficiary that the offeror knows or should know is likely to influence the beneficiary's selection of a particular provider or supplier of Medicare or Medicaid payable items. This prohibition is also implicated by many value-based care models.

[29] K. Sebelius & T. Thompson, *Overcoming health-care challenges by moving from volume to value*, The Hill (July 17, 2018), https://thehill.com/opinion/healthcare/397433-overcoming-health-care-challenges-by-moving-from-volume-to-value.

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