

The Salcido Report: False Claims Act Public Disclosure Alert

Akin Gump
STRAUSS HAUER & FELD LLP

False Claims Act - Year In Review: Five Decisions That Will Affect the Future of FCA Litigation

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Key Points:

- False Claims Act plaintiff cannot use discovery to satisfy Fed. R. Civ. P. 9(b).
- Payment of fair market value is a dispositive defense in FCA actions alleging a violation of the Anti-Kickback Statute.
- *Qui tam* plaintiffs cannot proceed with separate claims or against separate defendants once the government intervenes unless the government intervenes in the relator's additional claims.
- CMS's most recent Stark law interpretation significantly diverges from recent Stark law/FCA court decisions.
- Subregulatory guidance that is not tethered to a statute or regulation cannot serve as the foundation to an FCA action.

The Department of Justice (DOJ) recorded another banner year of over \$3 billion in False Claims Act (FCA) recoveries in 2019.¹ The health care industry, as usual, bore the brunt of the recoveries with DOJ registering over \$2.6 billion in recoveries.²

Aside from FCA recoveries, 2019 also produced significant new FCA case law. During the year, 781 cases addressed the FCA.³ Of these, 164 addressed Fed. R. Civ. P. 9(b), failure to state fraud with specificity; 119 referenced Section 3730(h), the whistleblower retaliation provision; 105 also cited *Universal Health Servs. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016), the Supreme Court's FCA materiality decision; and collectively, 110 cases referenced either Medicare or Medicaid kickbacks or the Stark law.

Most cases reiterate longstanding precedent.⁴ But a few cases dramatically break from existing precedent or address a common issue in a novel fashion that impacts the manner in which lawyers bring and defend FCA actions and how health care entities operate their compliance programs.

During 2019, courts issued a handful of cases that will have a lasting impact on FCA procedural and substantive issues. As to FCA process, in *U.S. ex rel. Wride v. Stevens-Henager College, Inc.*,⁵ a court, after undertaking a comprehensive review of

Contact Information

If you have any questions concerning this alert, please contact:

Robert Salcido

Partner

rsalcido@akingump.com

Washington, D.C.

+1 202.887.4095

the FCA's text and structure, restricted the relator's ability to assert additional allegations and name additional defendants once the government intervenes in the *qui tam* action. The case, consistent with the FCA, reaffirms the United States' primacy in *qui tam* litigation and protects defendants' from meritless lawsuits.

Additionally, as to process, in *Bingham v. HCA, Inc.*,⁶ the 11th Circuit affirmed the district court's decision to strike allegations based upon information relator obtained during discovery while defendant had a pending Rule 9(b) motion. The decision will ensure that relators, who presumably have inside information, cannot use the discovery process to bring *qui tam* actions but, consistent with the statute, can only proceed if they possess specific information regarding purported fraud before filing their actions.

Substantively, several cases will impact the government's and relator's ability to invoke the FCA without a sufficient foundation to warrant its use. In *Polansky v. Exec. Health Res., Inc.*,⁷ a district court ruled that the Centers for Medicare & Medicaid Services' (CMS) subregulatory guidance cannot serve as the predicate to an FCA action when the guidance constitutes a substantive legal standard that should have been promulgated pursuant to notice and comment rulemaking.

Also, substantively, courts issued important decisions regarding the use of the Anti-Kickback Statute (AKS) and Stark law in FCA actions. In *Bingham v. HCA, Inc.*,⁸ the 11th Circuit ruled that there is no unlawful remuneration exchanged in violation of the AKS when payments are at fair market value. And, in *U.S. ex rel. Bookwalter v. UPMC*,⁹ the 3rd Circuit applied a broad theory of Stark law liability, but the conceptual underpinning for the court's decision was directly undermined by CMS's proposed rulemaking to revise the Stark law.

Finally, in *United States v. AseraCare, Inc.*,¹⁰ the 11th Circuit cemented existing precedent that reasonable clinical judgment cannot be "false" as a matter of law. Significantly, the court also endorsed limits regarding how evidence demonstrating that the defendant purportedly knowingly tendered false claims must be linked, in time and place, to the actual false claims to serve as evidence of an FCA violation.

Set forth below is a discussion of each of these cases, the court's reasoning and the reasons the cases will have a lasting impact on FCA procedural and substantive issues.

The Relator Cannot Pursue Separate Claims and Defendants Once the Government Intervenes: *U.S. ex rel. Wride v. Stevens-Henager College, Inc.*

Historically, in *qui tam* actions, the relator freely added defendants or claims even after the government intervened. Courts frequently assumed that this practice is permitted.¹¹

In *U.S. ex rel. Wride v. Stevens-Henager College*, the court considered whether, after the government's intervention, the relator may file amended complaints to pursue additional claims or defendants when the government did not intervene in the relator's additional claims.¹²

The court found that the FCA's plain language, structure and legislative history dictated that once the government intervenes in a lawsuit, the relator cannot pursue separate defendants and causes of action. Instead, the court concluded that there can

only be one operative complaint and one lead plaintiff, not two or more operative complaints and multiple lead plaintiffs.¹³

As to the FCA's plain language, the court noted that a relator "may bring a civil action for the person and for the United States Government."¹⁴ After review, "the Government shall (A) *proceed with the action*, in which case *the action shall be conducted by the Government*; or (B) notify the court that *it declines to take over the action, in which case the [relator] shall have the right to conduct the action*."¹⁵ In short, the court reasoned that the FCA authorizes the government to either intervene in "the action" or decline to take over "the action."¹⁶ There is no third alternative that permits the government to proceed with some claims or causes of action but not others.

The court also noted that in multiple respects the FCA's structure further demonstrates that the relator cannot pursue separate allegations once the government intervenes. First, Section 3730(c)(1) provides that if the government intervenes, it has "the primary responsibility for prosecuting the action, and shall not be bound by an act of the [relator]."¹⁷ The court pointed out that allowing relators to pursue the non-intervened claims is in direct conflict with this provision because the government would not have "primary responsibility" for conducting the action if, after the government files a complaint in intervention, a relator's complaint remained operative and the relator retained the right to amend that complaint, adding parties and claims to the government's action.¹⁸

Second, the court also pointed to the FCA provisions addressing awards to relators as demonstrating that Congress did not contemplate that relators would be entitled to recover regarding non-intervened in causes of action. Sections 3730(d)(1) and (d)(2) contemplate only two scenarios. Section 3730(d)(1) anticipates that the government will proceed with the action "[i]f the Government proceeds with an action brought by a [relator] under subsection (b), such [relator] shall ... receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim." Section 3730(d)(2) contemplates that the relator will proceed with the action "[i]f the Government does not proceed with an action under this section, the [relator] ... shall receive ... not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement." The court pointed out that there is no provision that attempts to compute what portion of the recovery the relator will obtain when the government intervenes in a portion of the civil action and declines as to a portion of the civil action because Congress never anticipated that result.¹⁹

Third, the court pointed out that if the relator were allowed to proceed with separate claims after the government intervenes, the FCA's fee-shifting provision would be undermined. Section 3730(d)(4) provides that "[i]f the Government does not proceed with the action and the [relator] conducts the action," the court may award reasonable attorney's fees "if the defendant prevails in the action and the court finds that the claim of the [relator] was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." Specifically, the court noted that if the relators, after the government intervenes, are allowed to add defendants and claims to the action, the attorney fee provision is undermined because the relators' new claims could prove frivolous, and the defendants would nevertheless be precluded from recovering attorney fees because the government "proceed[ed] with the action."²⁰ The court reasoned that the attorney fee provision envisions that the government, when it intervenes, takes responsibility for the entire action, and it does not contemplate a situation in which a relator continues to add claims or defendants to the action.²¹

Fourth, the court noted that under the FCA when the government intervenes, the relator can continue as a party, but that right is narrowly defined in the statute and does not include the right to conduct the action and it does not encompass the right to add defendants and claims to the action.²² Instead, Section 3730(c)(2)(C) contemplates the rights that a relator would have as a party to the action. It provides that the court, after the government has intervened, can limit the number of witnesses a relator may call, limit the testimony of those witnesses and limit the relator's cross-examination of other witnesses.²³ Thus, while it is clear Congress anticipated that relator's may call witnesses, and took measures to limit that participation when contrary to the government's interest, Congress neither in this provision nor elsewhere indicated that it anticipated that beyond calling witnesses the relator would be adding causes of action or defendants once the government intervened.²⁴

Further, Section 3730(c)(2)(D) authorizes a court to limit a relator's "participation during the course of litigation" if the defendant shows that the relators' participation "would cause the defendant undue burden or unnecessary expense."²⁵ The court reasoned that if "Congress truly intended that the right to continue as a party to the action included the right to add defendants and claims to the action, Congress would not have given courts the ability to limit a relator's 'participation' upon a showing that the defendant would suffer undue burden or unnecessary expense."²⁶ Instead, the court concluded that Section 3730(c)(2)(D) contemplates that the right to continue as a party to the action is more limited (e.g., calling and cross-examining witnesses and engaging in discovery), and the provision suggests that Congress did not intend to let relators maintain the non-intervened portion of an action.²⁷ Consistent with this interpretation, the court noted that the legislative history indicated that the relator would only possess limited rights once the government intervened.²⁸ For example, "the Senate Bill provided relators the right to request 'copies of all pleadings filed in the action and copies of all deposition transcripts'", and furnished relators the right to "file objections with the court and petition for an evidentiary hearing to object to any proposed settlement or to any motion to dismiss filed by the Government'."²⁹

In sum, the Court found that both the FCA's plain language and the legislative history suggest that Congress envisioned that a relator, as a party to the action, could (1) call witnesses, (2) cross examine witnesses, (3) request to receive pleadings and deposition transcripts, (4) object to proposed settlements, and, (5) at the most, conduct discovery.³⁰ But neither the statute nor the legislative history suggests that a relator, as a party to an action, can add defendants and claims to the action.³¹ The Court concluded that if "Congress intended to give relators such rights, one would imagine that either the statute or the legislative history would reflect its intent to do so. But neither does."³²

The relators contended that the court's interpretation will lead to a perverse outcome because relators will simply "file separate complaints – perhaps for each defendant, each cause of action, or both."³³ But the court responded that the FCA's first-to-file bar—which provides that "[w]hen a person brings an action under this subsection, *no person other than the Government may ... bring a related action* based on the facts underlying the pending action"³⁴—would prevent such conduct because the plain language of the first-to-file bar prevents a relator from commencing a second action that is based on the facts underlying the first.³⁵ The relators also contended that "a construction that eliminates partial intervention will simply lead the Government and relators to sever the nonintervened claims into separate actions during the seal

period.”³⁶ Again, the court responded that it failed to discern how “this is possible when relators cannot file a second action that is based on the underlying facts of the first action.”³⁷

As a result of the court’s reasoning, it concluded that in the action, the government’s complaint superseded the relators’ complaint and became the operative pleading and the relators then lost the right to add defendants and claims to the action. It ruled that any pleading the relators filed after the government elected to intervene lacked legal effect. The court concluded that, at most, the relators could have persuaded the government to amend its complaint to include additional claims, allegations or defendants. But “the relators were unable to take the steering wheel from the Government, adding new claims, allegations, and defendants to the Government’s action.”³⁸ Accordingly, the court struck the relators’ second, third and fourth amended complaints because they had no legal effect.³⁹

This case may significantly limit many *qui tam* lawsuits. The relator, historically, had pursued additional defendants and causes of action that the government elected not to pursue, which has significantly increased the cost of litigation. If other courts confronting this issue adopt *Wride*’s reasoning, the number of FCA claims will be reduced. Additionally, the case may result in the United States pursuing fewer *qui tam* actions. If the United States only wants to pursue a single defendant or single claim, and the relator believes that many defendants engaged in the same conduct, the United States and relators may agree that the United States should not intervene so the relator can pursue those additional claims. Given the relator’s record of very limited success when litigating without the government’s assistance, this result should inevitably also benefit defendants.

Relator Cannot Use Discovery to Satisfy Rule 9(b) and Payment at FMV is a Dispositive Defense in an FCA Case Predicated Upon an AKS Violation: *Bingham v. HCA, Inc.*

Frequently, relators will file *qui tam* actions that do not identify specific claims that the defendant submitted to the government.⁴⁰ As a result, defendants commonly move to dismiss under Fed. R. Civ. P. 9(b), pointing out that the relator failed to identify even a single claim with specificity.

Once defendants move to dismiss under Rule 9(b), most courts will not permit discovery.⁴¹ The logic underlying staying discovery is twofold: (1) permitting the relator to obtain evidence of fraud for the first time during discovery directly undermines the purpose of Rule 9(b) which is that the relator obtain a sufficient quantum of evidence of fraud before suing for fraud and tarnishing the defendant’s reputation in the community⁴²; and (2) ensuring that the government, consistent with the FCA, has sufficient evidence that the relator has supplied before deciding whether it is in the government’s interest to intervene in the lawsuit.⁴³ But, at times, some courts, in order to move their dockets, will not, as a matter of practice, delay discovery while they consider the defendant’s motion to dismiss.

The issue raised in *Bingham* is what should occur when the court elects not to stay discovery, and the relator then obtains discovery and amends his complaint to supply sufficient specificity to satisfy Rule 9(b).

Another frequently arising issue in FCA actions alleging an AKS violation is whether evidence that defendant paid fair market value (FMV) is a dispositive defense. In

Bingham, the 11th Circuit ruled that relator cannot use discovery to surmount Rule 9(b) and a FMV payment is a dispositive defense under the AKS.

Rule 9(b) and FCA Discovery:

In *Bingham*, after denying defendant's motion to stay discovery in light of defendant's anticipated motion to dismiss, the relator received discovery and used that discovery to amend the complaint.⁴⁴ The defendant moved to strike new facts in relator's amended complaint that stemmed from discovery, which the district court granted.⁴⁵ The 11th Circuit affirmed, ruling that "the goals of applying Rule 9(b) to False Claims Act cases are advanced by striking information in Relator's [amended complaint] that was learned through discovery, prior to a final decision on the motion to dismiss" when the initial Complaint does not satisfy Rule 9(b).⁴⁶ The court's rationale was that (1) "it is important to discourage plaintiffs from being able to learn the complaint's bare essentials through discovery which could needlessly harm a defendants' ... goodwill and reputation by bringing a suit that is, at best, missing some of its core underpinnings, and, at worst, are baseless allegations used to extract settlements" and (2) "allowing a relator to amend a complaint after discovery would force the government to decide whether or not to intervene in the case without complete information."⁴⁷

FMV and the AKS:

In *Bingham*, the relator claimed that defendant violated the AKS by providing sweetheart deals to certain physicians who leased space in medical office buildings the defendant developed in exchange for patient referrals from these physicians.⁴⁸ The court concluded that the relator did not show that defendant paid any remuneration to physician tenants because the relator set forth no evidence at summary judgment demonstrating that the physicians' and hospital agreements conferred any benefit in excess of fair market value.⁴⁹

The court based its conclusion that remuneration must include something more than fair market value based upon dictionary definitions and the definition of remuneration in a related statutory provision. Specifically, in *Bingham*, the 11th Circuit noted that an AKS violation "requires that there be 'remuneration' offered or paid in the transaction at issue."⁵⁰ In defining remuneration, the court looked to Black's Law Dictionary, which construes "remuneration" in pertinent part as "[p]ayment; compensation."⁵¹ Compensation, in turn, "cannot be given unless some sort of benefit is conferred."⁵² In light of these definitions, remuneration is only provided when there is a benefit and "the value of a benefit can only be quantified by reference to its fair market value."⁵³ The court also noted that this "understanding of 'remuneration' is supported by the definition of 'remuneration' in 42 U.S.C. § 1320a-7a(i)(6), which relates to civil monetary penalties in connection with medical fraud."⁵⁴ The court noted that although this definition of remuneration is in a different section of the statute, "it also defines 'remuneration' to include the 'transfer[] of items or services for free or for other than fair market value' and thus is consistent with our view of the correct definition."⁵⁵

Given the dictionary definition of remuneration and its definition in a related statutory provision, the court concluded that "the issue of fair market value is not limited to" defendant's safe harbor defense, "but is rather something Relator must address in order to show that [the defendant] offered or paid remuneration to physician tenants."⁵⁶ The court affirmed the district court's grant of summary judgment because the relator

did not show that any of the arrangements conferred any benefit in excess of fair market value.⁵⁷

The decision is important because it reinforces the need to stay discovery once a motion to dismiss is filed and will deter relators from participating in discovery and attempting to use the fruits of discovery to overcome Rule 9(b) deficiencies in those cases in which courts permit discovery to proceed.⁵⁸ The decision is also significant in reiterating to compliance personnel the importance of carefully documenting FMV because it can provide a dispositive defense and will provide an avenue to obtain dismissal of the lawsuit without having to address the parties' underlying intent in entering into the arrangement.

Subregulatory Guidance That Determines Payment Cannot Serve as the Foundation for an FCA Claim: *Polansky v. Exec. Health Res., Inc.*

The Medicare Program extensively relies upon subregulatory guidance to determine Medicare payments. As the Supreme Court recently noted in *Azar v. Allina Health Servs.*, the Provider Reimbursement Manual itself exceeds 6,000 pages.⁵⁹ Historically, courts have been split regarding the extent to which subregulatory guidance may serve as the predicate to an FCA violation. However, a chain of recent decisions have cast the issue in a new light and dictates that where the subregulatory guidance determines payment, the guidance, by itself, is insufficient to serve as the foundation of an FCA violation.

The issue most recently arose in *Polansky v. Exec. Health Res., Inc.*⁶⁰ There the court considered whether subregulatory guidance CMS issued in Manuals for hospitals to determine the inpatient status of patients for purposes of seeking reimbursement under the Medicare Act could serve as the basis for determining whether claims are false under the FCA.

In *Polansky*, the relator alleged that the defendant caused hospitals to fraudulently bill Medicare and Medicaid by falsely designating patient admissions as inpatient when they should have been billed as outpatient.⁶¹ The court noted that the Medicare Act sets parameters for reimbursement of Medicare claims, requiring that a service be “reasonable and necessary for the diagnosis or treatment of illness or injury” to qualify for reimbursement.⁶² But the Medicare Act itself does not define what is “reasonable and necessary.”⁶³ To assist health care providers determine whether inpatient admissions satisfies the Medicare Act’s “reasonable and necessary” requirement, CMS issued guidance in its Manuals.⁶⁴ In 1981, a Manual introduced the concept of a 24-hour standard (that is, if the patient’s stay is expected to be less than 24 hours, the stay should be billed as outpatient).⁶⁵ A 1989 Manual provision instructed that physician should use the 24-hour period as a benchmark (that is, the physician should order an admission if the patient is expected to need hospital care for 24 hours or more).⁶⁶ But none of these policies went through notice and comment rulemaking. They were merely communicated in Manual guidance.⁶⁷

In *Polansky, Inc.*, the court, after hearing oral argument on a motion to dismiss, ordered, *sua sponte*, that the parties brief the potential applicability of the Supreme Court’s recent decision in *Azar v. Allina Health Servs.*⁶⁸ The court noted that unrelated to the reimbursement regime, the Medicare Act requires that CMS provide the public with advance notice and an opportunity to comment before adopting a “rule,

requirement, or other statement of policy ... that establishes or changes a *substantive legal standard*.”⁶⁹

The district court noted that the Supreme Court declined to define the full scope of what constitutes a “substantive legal standard” under the Medicare Act. But the court noted that the D.C. Circuit in *Allina Health Servs. v. Price*,⁷⁰ had articulated a definition for “substantive legal standard.”⁷¹ In *Allina*, the D.C. Circuit ruled that the term substantive legal standard “at a minimum includes a standard that creates, defines, and regulates the rights, duties, and powers of parties.”⁷² The district court adopted the D.C. Circuit’s definition of “substantive legal standard.”⁷³

Applying this definition, the district court concluded that CMS’ Manual guidance constituted a substantive legal standard “and therefore required notice and comment rulemaking procedures.”⁷⁴ The court noted that substantive legal standards determine reimbursement.⁷⁵ If a policy affects the right to, or amount of reimbursement, it is more likely to be deemed a “substantive legal standard.” Because the 24-hour policy affects a hospital’s right to payment because it sets the standard by which a hospital’s entitlement to the higher reimbursement rate for inpatient claims is assessed, it is a “substantive legal standard” under the Medicare Act and should have been promulgated under notice and comment. The court concluded that because the policy was not promulgated under notice and comment rulemaking, there was not a binding rule and hence there could be no FCA liability.⁷⁶

The issue is very significant in FCA enforcement. To determine that a claim is “false” in the first instance, there must be a breach of some underlying statute, regulation or contractual provision.⁷⁷ If the underlying statute, regulation or contractual provision is vague or ambiguous and defendant adopts a reasonable interpretation of the provision, that is a dispositive defense under the FCA.⁷⁸

Thus, to surmount this hurdle, the government or relator will frequently cite to subregulatory guidance as the standard that renders the underlying claim to be “false.” For example, in *Polansky*, instead of stating that the hospital’s admissions are false because those admissions did not satisfy the vague medical necessity mandate in the Medicare statute, the relator states the claims are false because, in light of the diagnoses, the physician could not have anticipated that the patient would be admitted for more than 24 hours under the CMS Manual provisions.

But the district court, relying upon Supreme Court and D.C. Circuit authority, ruled that if the FCA plaintiff wants that subregulatory guidance to be the operative standard to assess whether a claim is false, CMS needs to undertake notice and comment rulemaking.⁷⁹ As the Supreme Court pointed out in *Allina*, in one “way or another Medicare touches the lives of nearly all Americans” and “even a seemingly modest modification[] to the program can affect the lives of millions.”⁸⁰ Given this, “a rational Congress could have thought those benefits [associated with notice and comment rulemaking] especially valuable when it comes to a program where even minor changes to the agency’s approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate.”⁸¹ And where subregulatory guidance is invalid on this ground, and consistent with CMS’s and DOJ’s guidance, the subregulatory guidance cannot form the foundation of an FCA action.

Judicial Stark Law Interpretations Conflict with CMS’ Latest Guidance: *U.S. ex rel. Bookwalter v. UPMC*

Major hospitals systems have literally thousands of financial relationships with physicians that are subject to the Ethics in Patient Referrals Act, better known as the Stark law. The FCA is the chief enforcement mechanism for the Stark law. Over the last six years, the government and relators have consummated several multimillion-dollar settlements alleging that defendants violated the FCA based upon an underlying Stark law violation.⁸² Significant FCA/Stark law decisions can dramatically affect how hospital systems negotiate and administer their physician contracts. In this regard, the 3rd Circuit's decision in *U.S. ex rel. Bookwalter v. UPMC*⁸³ and CMS' recent proposed rulemaking revising critical components of the Stark law will have a significant impact on hospital/physician relationships.

On December 20, 2019, the 3rd Circuit issued its decision in *Bookwalter*.⁸⁴ According to the relators, the health system paid its physicians a base salary and an annual work unit quota (based on work Relative Value Units or wRVU's).⁸⁵ If the physicians failed to meet their annual yearly quota, their employer could lower their future base salary. If they exceeded their quota, they earned a \$45 bonus for every extra work unit.⁸⁶

The relator asserted that the physicians artificially boosted their work units by mischaracterizing their role in the surgery or the medical necessity of the procedure and that the financial relationship, in which many of the surgeons were in the top 10 percent in compensation and productivity, violated the Stark law.⁸⁷

The defendants asserted that the Stark law did not apply because their relationship fell within the Stark law bona fide employment, personal services, fair market value and indirect compensation exceptions.⁸⁸ The court noted that all four exceptions have two elements in common—that is, that the physicians' compensation does not take into account the volume or value of referrals and that the compensation not exceed fair market value.⁸⁹

Ultimately the court concluded that the relators' complaint plausibly pled that the compensation took into account the volume or value of referrals and was not set at fair market value. A central component to the court's conclusion that the payments plausibly, for purposes of Fed. R. Civ. P. 12(b)(6), took into account referrals and exceeded fair market value is that the health system paid more money to the physicians than it received in reimbursement from the physicians' professional services. Specifically, the court noted:

Compensation for personal services above the fair market value of those services can suggest that the compensation is really for referrals. This is just common sense. Healthcare providers would not want to lose money by paying doctors more than they bring in. They would do so only if they expected to make up the difference another way. And that way could be through the doctors' referrals.⁹⁰

The court observed that payment to physicians exceeded collections in two respects. First, some surgeons' base pay exceeded their collections, a practice the court characterized as "suspicious."⁹¹ Second, aside from base salary, the court noted that surgeons' bonus per work unit exceeded what the defendants collected on most of those work units.⁹² The court concluded that this "is yet another sign that the surgeons' pay took referrals into account."⁹³

Ultimately, the court concluded that there is enough "smoke" that "makes fire plausible".⁹⁴

So aggregate compensation that exceeds fair market value is smoke. It suggests that the compensation takes referrals into account. And the relators here plead five facts that, viewed together, make plausible claims that the surgeons' pay exceeded their fair market value. First, some surgeons' pay exceeded their collections. Second, many surgeons' pay exceeded the 90th percentile of neurosurgeons nationwide. Third, many generated Work Units far above industry norms. Fourth, the surgeons' bonus per Work Unit exceeded what the defendants collected on most of those Work Units. And finally, the government alleged in its settlement agreement that the Medical Center had fraudulently inflated the surgeons' Work Units. That much smoke makes fire plausible.⁹⁵

Approximately, one month after the 3rd Circuit issued its initial September 2019, which contained the same quoted language as the December 2019 revised decision discussed above, CMS promulgated a proposed rule construing the scope of the Stark law that directly undermined the 3rd Circuit's reasoning in *Bookwalter*.⁹⁶ Consistent with its stated goals to ensure that the Stark law is not construed to discourage providers, suppliers and physicians "from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower cost (or slow their rate of growth)," CMS provided new definitions of commercial reasonableness, fair market value and the meaning of what entails taking into account volume or value of referrals.⁹⁷ These definitions directly undermined the 3rd Circuit's reasoning in *Bookwalter*.

Whereas the 3rd Circuit had concluded that "providers would not want to lose money by paying doctors more than they bring in," which is "suspicious," CMS, in its preamble statements, pointed out at length why in fact it would be reasonable for a health system to enter into such an arrangement and proposed regulatory language in its definition of commercial reasonableness to codify its understanding.⁹⁸ Specifically, CMS reviewed comments from industry which pointed out that contracts in which physicians were paid more than the professional revenue they generate may reasonably exist to satisfy community need, provide timely access to health care, satisfy licensure and regulations requirements, improve quality and health outcome and also noted that some service lines typically lose money, such as psychiatric and burn units. CMS, based upon its expertise and knowledge of the industry, found these comments from industry "compelling":

[C]ommenters shared numerous examples of compensation arrangements that they believed would be commercially reasonable despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received. Commenters also explained that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. These commenters explained some of the reasons why parties would enter into such transactions, such as community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of

quality and health outcomes. One commenter suggested that entire hospital service lines, with their needed management and other physician-provided services, are illustrative for operating at a loss and identified psychiatric and burn units as examples of such service lines. According to this commenter, with changes in reimbursement, more service lines will operate at a loss in the future. The commenter urged that these services are of vital need to communities and, unless CMS addresses the definition of “commercial reasonableness,” health care providers may be prohibited from providing these services to their communities as a result of a fear of violating the commercial reasonableness standard. We find these comments and the concerns they highlight compelling.⁹⁹

To provide further legal effect to its conclusion, CMS proposed adding specifically to its definition of commercial reasonableness that an “arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.”¹⁰⁰

Similarly, whereas the 3rd Circuit found inherently suspicious compensation at the high end of survey data, CMS expressly found that such compensation could satisfy its definition of fair market value when the physician is highly qualified has good results and there is strong demand. CMS concluded that, under these circumstances, “compensation substantially above” survey data may be fair market value:

Extenuating circumstances may dictate that parties to an arm’s length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject transaction. By way of example, assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of \$450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be \$450,000 per year, this particular physician commands a significantly higher salary and the general market value (or market value) of the transaction may, therefore, be well above \$450,000. The statute requires that the compensation is the value in an arm’s length transaction, but that value must also be consistent with the general market value (or market value) of the subject transaction. In this example, compensation *substantially* above \$450,000 per year may be fair market value.¹⁰¹

Finally, whereas the 3rd Circuit had concluded that that the physicians’ compensation took into account, in part, the physicians’ referrals became the physicians’ compensation exceeded collections, CMS, as noted, in its proposed rule agreed that there are a number of “compelling” reasons regarding why this would occur that are completely unrelated to physician referrals.¹⁰²

Finally, also equally significant from an FCA perspective, CMS reassured industry that in the absence of agency guidance, a reasonable interpretation of a statutory or

regulatory requirement of the physician self-referral law is satisfactory when asserting compliance with the requirement.¹⁰³

CMS's regulatory guidance will stick a dagger in the heart of many FCA/Stark actions. A common theme in many FCA/Stark cases is the allegation that the mere fact that the hospital knows that there is a financial loss in the employment of the physician tends to prove that the hospital knows that it is paying the physician in excess of fair market value in violation of the Stark law.¹⁰⁴ CMS's interpretation of the Stark law directly undermines this contention for several reasons. *First*, as CMS pointed out, there are multiple reasons why a hospital would employ a physician while knowing that it will incur a loss, including the need to provide timely access to health care, satisfy licensure and regulatory requirements, and improve quality and health outcomes. *Second*, CMS's revised interpretation of what constitutes fair market value should provide flexibility to hospital systems to not be handcuffed by misleading survey data in negotiating payment arrangements with physicians. *Third*, CMS's statement regarding reasonable interpretation of the Stark law providing a dispositive defense will align the Stark law with the FCA defense that a reasonable interpretation of an ambiguous rule is a dispositive defense when the government does not provide any official guidance to warn the defendant away from its reasonable interpretation.¹⁰⁵

Reasonable Clinical Judgment Does Not Result in “False” Claims and Bad Intent Evidence Must Be Linked to Specific False Claims: *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019)

As noted in a prior Salcido Report, *11th Circuit's Decision in AseraCare: Important in Determining When Clinical Judgment Regarding Medical Necessity Can Result in an Overpayment and How Evidence Regarding Corporate Knowledge Must be Tied to Claims to Establish False Claims Liability* (Oct. 10, 2019), the 11th Circuit in *AseraCare* addressed two key issues that arise in FCA litigation regarding when, if ever, reasonable clinical judgment can form the basis of an FCA violation and the extent to which an FCA plaintiff can use random e-mails and other communications unconnected to any false claim as proof of an FCA violation.

Specifically, the first issue is when can clinical judgment be deemed “false” for purposes of the FCA. On that issue, the 11th Circuit concurred with the district court that a mere reasonable disagreement among clinicians is insufficient to establish FCA falsity. The court concluded that absent a showing of an objective and knowing falsehood, the FCA is not an appropriate instrument to serve as the government's primary line of defense against questionable claims for reimbursement.

This decision has significant ramifications both in defending FCA cases and in health care entities' internal reviews and audits. The court's ruling will significantly deter the government from bringing such lawsuits when all that exists is a mere battle of experts. Additionally, the court's ruling may also result in health care entities transforming the manner in which they conduct medical reviews. Many entities evaluate clinical judgment as either being “right” or “wrong” in light of the medical documentation. If the judgment appears wrong, the entity may believe that there is a duty to remit an overpayment to the government. But, as the 11th Circuit correctly concluded, this approach is overly simplistic and wrong because at times there can be two or more reasonable opinions, with none of them being false or wrong.

The second issue is when can the FCA plaintiff use scattered communications within a company regarding generalized alleged misconduct to establish that discrete claims are “knowingly” false. On this issue, the court concluded that the government must actually tie evidence of improper practices, by place and time, to the specific claims at issue to establish FCA liability. This is significant because the FCA plaintiff, at trial and the summary judgment stage, frequently will seek to take scattered e-mails and texts reflecting a corporate strategy to be profitable and regulatory lapses to assert that unrelated claims are “knowingly” false. Importantly, the court in *AseraCare*, joining a growing list of other courts, rejected this approach.¹⁰⁶

Conclusion

As 2020 unfolds, FCA plaintiffs, no doubt, will pursue expansive, aggressive FCA theories of liability in the hope of reporting record year-end recoveries. But several cases issued in 2019 will provide speedbumps. *Wride* will limit the relator’s ability to name new defendants and causes of action once the government intervenes if the government does not join relator’s claims. *Polansky* will limit the use of subregulatory guidance that is not closely tied to a statute or regulation as the foundation for an FCA lawsuit. *HCA* will limit the relator’s ability and desire to use discovery to add specificity to otherwise vague FCA allegations. Finally, although historically FCA plaintiffs have aggressively pursued FCA claims based upon alleged lack of medical necessity or violations of the AKS or Stark law, court decisions in *AseraCare*, *HCA*, and CMS’s Stark law regulatory guidance in the aftermath of *Bookwalter*, will impose important limits on overly expansive plaintiff theories. Ultimately only time will tell whether these speedbumps courts constructed will slow the rush of recoveries or whether plaintiffs will speed on through.

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About the Author

Robert Salcido is a leading FCA practitioner.

Mr. Salcido has been lead counsel in several FCA actions in which he successfully defended clients in FCA actions that the government or relator filed at trial or summary judgment. Some of those cases include:

- Mr. Salcido was lead counsel for Golden Living in an FCA action where the federal government had sued Golden Living's predecessor company, Beverly Enterprises ("Beverly"), for \$895 million, alleging that Beverly had engaged in an unlawful kickback scheme with McKesson Corp. in violation of the Anti-Kickback Act and the FCA. After 14 days of trial, the court ruled that Beverly and McKesson did not violate the FCA or the Anti-Kickback Act because their business negotiations were fair, reasonable and conducted in good faith. *See United States of America ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683 (N.D. Miss. 2012).
- Mr. Salcido was lead counsel for Aegis Therapies and a Golden Living skilled nursing facility where the federal government had alleged that defendants provided medically unnecessary rehabilitation therapy. The district court granted defendants' summary judgment motion, ruling that the government had used the wrong standard to assess whether the services were medically necessary and failed to prove that defendants' certification regarding medical necessity was objectively false. *See United States ex rel. Lawson v. Aegis Therapies, Inc.*, 2014 U.S. Dist. LEXIS 45221 (S.D. Ga. Mar. 31, 2015).
- Mr. Salcido was lead counsel for defendants, an operator of a chain of skilled nursing companies and a rehabilitation company, during a five-week FCA jury trial. Based upon the trial record, the district court entered judgment for the defendants ruling that the relator did not establish FCA materiality at trial as a matter of law. *See United States ex rel. Ruckh v. Salus Rehab., LLC*, 304 F. Supp. 3d 1258 (M.D. Fla. 2018).
- Mr. Salcido was lead counsel for a defendant physician and multispecialty group practice that the government accused of FCA violations. The district court dismissed all the government's claims on summary judgment. Ultimately, because the United States' action lacked "substantial justification," the United States was ordered to pay defendants more than \$500,000 in legal fees. In making the ruling, the court ruled that Medicare fraud law is an area of expertise and ruled that it was undisputed that Mr. Salcido possessed such expertise. *See United States v. Prabhu*, 442 F. Supp. 2d 1008 (D. Nev. 2006).
- Mr. Salcido was lead counsel for Golden Living in an action where the relator and the government sued multiple defendants alleging that they violated the FCA because they knowingly created and operated a supply company in violation of

Medicare Supplier Standards. The district court granted defendants' FCA summary judgment motion regarding the Supplier Standards allegations, finding that the government's prior administrative proceedings demonstrated that the defendant supply company was entitled to payment. See *United States ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664 (N.D. Miss. 2011).

Mr. Salcido has authored a number of books and chapters in leading publications (including the American Health Lawyers Association, BNA Books and Bloomberg BNA) regarding the application of the FCA, including:

- *False Claims Act & the Health Care Industry: Counseling & Litigation* (3d ed. American Health Lawyers Ass'n 2018).
- "The False Claims Act in Health Care Prosecutions: Application of the Substantive, Qui Tam and Voluntary Disclosure Provisions" in *Health Care Fraud and Abuse: Practical Perspectives*, Ch. 3 (3d ed. BNA Books 2013) (with annual supplements).
- "False Claims Act: Health Care Applications and Defenses" in *Bloomberg BNA Health Law and Bus. Series No. 2650* (2012).

Because of his work successfully defending a number of FCA lawsuits, Mr. Salcido has been recognized in:

- *The National Law Journal* in its 2019 inaugural list of Health Care Law Trailblazers recognizing those who have made an impact through new strategies or innovative court cases for several notable FCA wins.
- *The National Law Journal* in its 2018 Winning Litigators for obtaining a successful trial verdict in an FCA lawsuit.
- *The National Law Journal* in its 2014 Litigation Trailblazers & Pioneers as one of 50 "people who have made a difference in the fight for justice" for his outstanding work in defending FCA lawsuits.
- *Chambers USA: America's Leading Lawyers for Business* (2006-2019), in the 2011-2019 editions of Chambers USA, listed under Health Care: Regulatory and Litigation, Leading Individuals (Nationwide) (Band 1) and as Health Care Leading Individuals (District of Columbia) (Band 1).
- *Law360*, which selected Mr. Salcido as one of the four Health Care MVPs for 2012 based upon a successful trial verdict obtained in the Golden Living FCA/Anti-Kickback Act lawsuit.

Before entering private practice, Mr. Salcido served as trial counsel for the U.S. Department of Justice Civil Fraud Section, which has nationwide jurisdiction over the FCA, where he led several successful prosecutions of the FCA on the United States' behalf.

¹ See Justice Department Recovers Over \$3 Billion From False Claims Act Cases in Fiscal Year 2019, U.S. Dep't of Justice (Jan. 9, 2019), <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>.

² Id.

³ Specifically, according to a LEXIS search of all cases issued in calendar year 2019, and used the phrase "False Claims Act."

⁴ For a description of the general issues arising under FCA cases addressing Rule 9(b), whistleblower retaliation and Escobar, see Robert Salcido, *False Claims Act & the Health Care Industry: Counseling & Litigation* (3d ed. American Health Lawyers Association 2018) at §§ 3:09; 3:07; 2:06, respectively (2020 Supplement forthcoming).

⁵ 359 F. Supp. 3d 1088 (D. Utah 2019).

⁶ 783 Fed. Appx. 868 (11th Cir. 2019).

⁷ No. 12-CV-4239, 2019 U.S. Dist. LEXIS 192332 (E.D. Pa. Nov. 5, 2019).

⁸ 783 Fed. Appx. 868 (11th Cir. 2019).

⁹ No. 18-1693, 2019 U.S. App. LEXIS 38367 (3d Cir. Dec. 20, 2019).

¹⁰ 938 F.3d 1278 (11th Cir. 2019).

¹¹ Robert Salcido, *False Claims Act & the Healthcare Industry: Counseling & Litigation* (3d ed. American Health Lawyers Ass’n 2018) at § 3:02 (discussing case law).

¹² 359 F. Supp. 3d 1088 (D. Utah 2019).

¹³ *Id.* at 1116 (after intervention, while “a relator retains a limited right to continue as a party to the action, that right does not allow the relator to amend his or her complaint to add defendants and claims to the Government’s action. Those rights necessarily belong to the party with the primary responsibility for conducting the action – in this case the Government. Consequently, the Government’s complaint in intervention superseded the relators’ amended complaint, and any pleading subsequently filed by the relators lacked legal effect”).

¹⁴ *Id.* at 1116-17 (quoting 31 U.S.C. § 3730(b)(1)).

¹⁵ *Id.* at 1117 (quoting § 3730(b)(4) (emphasis added)).

¹⁶ The court also rejected the government’s view that Congress used the word “action” to mean “cause of action” rather than “civil action.” *Id.* at 1118. The court ruled that the FCA’s plain language undermined the government’s contention:

First, § 3730(b)(1) unambiguously shows that Congress used “action” to mean “civil action.” The first sentence provides that a relator may bring a “civil action,” and the following sentence explains that the “action” (i.e., the civil action) shall be brought in the name of the Government. § 3730(b)(1). The next sentences provides that “[t]he action [i.e., the civil action] may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.” § 3730(b)(1).

Second, other provisions show that Congress used “action” to mean something other than “cause of action.” “The court shall dismiss an action or *claim* under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or *claim* were publicly disclosed.” § 3730(e)(4)(A) (emphasis added). If “action” means “cause of action,” the words “or claim” would be superfluous. See *Cause of Action*, BLACK’S LAW DICTIONARY (10th ed. 2014) (suggesting that one review the definition of “claim” for more information on the definition of “cause of action”). That is, interpreting

“action” to mean “cause of action” runs afoul of the rule that courts must “give effect, if possible, to every clause and word of a statute.”

Id. at 1118 (citation and footnote omitted).

¹⁷ Id.

¹⁸ Id. at 1121.

¹⁹ Id. The court also pointed out that nothing in the legislative history describing the provision suggests that “Congress intended for courts to apply the damages provision for intervened actions to the claims that the Government prosecuted and then apply the damages provision for non-intervened actions to the claims that the relators prosecuted.” Id. at 1121-22.

²⁰ Id. at 1123.

²¹ Id.

²² Id. at 1124-25.

²³ Id. at 1125.

²⁴ Id.

²⁵ Id.

²⁶ Id.

²⁷ Id.

²⁸ Id. at 1125-26.

²⁹ Id. But the court was required to grant an evidentiary hearing only “upon a showing of substantial and particularized need.” Id. The court noted that the Senate Judiciary Committee explained that the proposed Senate Bill gave relators “increased involvement in suits brought by the relator but *litigated by the Government*.” Id. (quoting S. Rep. No. 99-345, at 13 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5278 (emphasis added)). By contrast, the court noted that the House Bill proposed to expand the “role of the relator so that when the Government enters the action ..., the relator remains a party to the suit with the same rights as if he had been an intervenor of right under Rule 24(a), Federal Rules of Civil Procedure.” Id. at 1126. The court noted that while the House Bill defined the relators’ rights by express reference to the rights of an intervenor of right under Federal Rules of Civil Procedure, the FCA’s final language did not. The court concluded that this severely undercuts the relators’ argument that the court must look to the Federal Rules of Civil Procedure to ascertain what rights a relator has as a “party to the action.” Id.

³⁰ Id.

³¹ Id.

³² Id. (footnote omitted).

³³ Id. at 1119, n. 12.

³⁴ § 3730(b)(5) (emphasis added).

³⁵ *Id.* at 1119, n. 12.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* at 1127.

³⁹ *Id.*

⁴⁰ A “claim” is a defined term in the FCA, meaning generally a demand or request for money or property. See 31 U.S.C. § 3729(b)(2). It is important to identify a “claim” in an FCA action because, as many courts have noted, it is “a fairly obvious notion that a False Claims Act suit ought to require a false claim.” *U.S. ex rel. Cafasso v. Gen. Dynamics C4 Sys.*, 637 F.3d 1047, 1055 (9th Cir. 2011). Indeed, the “central question” in an FCA case is “whether the defendant ever presented a false or fraudulent claim to the government.” *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999). This is because the “[FCA] attaches liability, not to the underlying fraudulent activity or to the government’s wrongful payment, but to the ‘claim for payment’.” *Cafasso*, 637 F.3d at 1055 (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)); see also *In re: Baycol Prods. Litig.*, 732 F.3d 869, 875 (8th Cir. 2013) (same).

⁴¹ Robert Salcido, *False Claims Act & the Health Care Industry: Counseling & Litigation* (3d ed. American Health Lawyers Association 2018) at § 3:09 (discussing case law).

⁴² See, e.g., *U.S. ex rel. Atkins v. McInteer*, 740 F.3d 1350, 1359 (11th Cir. 2006) (“[t]he particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim”) (internal quotation marks omitted).

⁴³ See, e.g., *U.S. ex rel. Estate of Donegan v. Anesthesia Assocs. of Kan. City, PC*, 4:12-CV-0876-DGK, 2015 U.S. Dist. LEXIS 74239, at *21-23 (W.D. Mo. June 9, 2015) (“[a] relator may not assert new theories of liability based on information learned during discovery.... [P]ermitting a relator to assert new theories of liability after conducting discovery would enable the relator to conduct an end-run around the heightened pleading standard, effectively allowing the relator to file a flimsy lawsuit subjecting the defendant to time-consuming and expensive discovery in the hope of uncovering an unknown wrong or extracting a settlement from the defendant”).

⁴⁴ 783 Fed. Appx. at 875.

⁴⁵ *Id.*

⁴⁶ *Id.* at 876.

⁴⁷ *Id.* (citations and internal quotation omitted).

⁴⁸ *Id.* at 870-71.

⁴⁹ *Id.* at 874.

⁵⁰ *Id.* at 873.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.* at 874.

⁵⁸ For example, the challenge the relator confronts at this stage if the court permits discovery is that the relator could spend both time and money engaging in full-scale discovery, but that time and money will be for naught if the court decides the relator's initial complaint does not satisfy Rule 9(b) and the relator cannot use the information obtained in discovery to amend the deficient complaint.

⁵⁹ 139 S. Ct. 1804 (2019). As the dissent pointed out, CMS also issues more than a dozen other manuals encompassing tens of thousands of additional pages of instructions. See *id.* at 1823 (noting CMS "also publishes more than a dozen other manuals, with tens of thousands of additional pages of instructions governing 'the scope of benefits, the payment for services, [and] the eligibility' for benefits or services. § 1395hh(a)(2). These include the Medicare General Information, Eligibility and Entitlement Manual; the Medicare Claims Processing Manual; the Medicare Benefit Policy Manual; the Medicare Secondary Payer Manual; the Medicare Program Integrity Manual; the Medicare Prescription Drug Benefit Manual; and many others").

⁶⁰ No. 12-CV-4239, 2019 U.S. Dist. LEXIS 192332 (E.D. Pa., Nov. 5, 2019).

⁶¹ *Id.* at *2. "Medicare generally pays about \$4,500-\$5,000 more for inpatient services ... than it does when the same services are provided to a patient classified as outpatient observation." *Id.* at *3, n.3.

⁶² *Id.* at *34 (citing 42 U.S.C. § 1395y(a)(1)(A)).

⁶³ *Id.*

⁶⁴ *Id.* at *35-36.

⁶⁵ *Id.* at *36.

⁶⁶ *Id.* at *36-37.

⁶⁷ The court noted that subsequently, effective October 1, 2013, CMS published a final rule regarding the Two Midnight Rule after notice and comment. *Id.* at *4 (citing 78 Fed. Reg. 50,496 (Aug. 19, 2013), codified at 42 C.F.R. § 412.3(d)(1)).

⁶⁸ *Id.* at *10 (citing 139 S. Ct. 1804 (2019)).

⁶⁹ *Id.* at *34-35 (citing 42 U.S.C. § 1395hh(a)(2)) (emphasis supplied).

⁷⁰ 863 F.3d 937, 943 (D.C. Cir. 2017).

⁷¹ 2019 U.S. Dist. LEXIS 192332, at *40.

⁷² *Id.*, 863 F.3d at 943.

⁷³ 2019 U.S. Dist. LEXIS 192332, at *40.

⁷⁴ *Id.* at *40-41.

⁷⁵ *Id.* at *41.

⁷⁶ *Id.* at *45 (“Since the 24-hour policy was contained in agency manuals that had not been promulgated pursuant to notice and comment, *Allina* compels the conclusion that there can be no FCA liability on Relator’s Phase I claims”).

⁷⁷ A claim cannot be false as a matter of law unless there is some breach of a rule, regulation, standard, or duty that would render the defendant’s statement false. See, e.g., *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003) (“[W]hether a claim is valid depends on the contract, regulations, or statute that supposedly warrants it. It is only those claims for money or property to which a defendant is not entitled that are ‘false’ for purposes of the False Claims Act”) (citation omitted) (en banc); see also *U.S. ex rel. Troxler v. Warren Clinic, Inc.*, 630 F. App’x 822, 825 (10th Cir. 2015) (finding no FCA violation because plaintiff did not “identify a statute, regulation, or contract” that required compliance as a condition to payment); *U.S. ex rel. Thulin v. Shopko Stores Operating Co.*, 771 F.3d 994, 998-1000 (7th Cir. 2014) (noting that a “claim may be false for purposes of the FCA if it is made in contravention of a statute, regulation, or contract” and ruling that relator’s complaint must be dismissed under Rule 12(b)(6) when relator could not establish that defendant’s conduct breached any law); *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (“when a supplier complies with the existing regulations, it is entitled to represent to the government (and the world) that it has done so, without facing a claim of deception”); *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006) (“Claims are not ‘false’ under the FCA unless they are furnished in violation of some controlling rule, regulation or standard”) (citation omitted).

⁷⁸ See, e.g., *United States v. Allergen, Inc.*, 746 F. App’x 101, 109-10 (3d Cir. 2018) (concluding that although the court was not prepared to find that the defendants had the best interpretation of the statute, it found that the plaintiff had failed to plead an FCA cause of action because the defendants had a reasonable interpretation of an ambiguous statute, and the relator did not plead that the government had published any official guidance that would “warn” defendants away from their reasonable interpretation); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015) (stating that the defendant did not knowingly submit false claims when there was no “‘guidance from the courts of appeals’ or relevant agency ‘that might have warned [the defendant] away from the view it took’”) (citation omitted); see also *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 880 (8th Cir. 2016) (affirming dismissal because the relator had failed to submit any relevant evidence that “the government had warned [the defendant] that the agency interpreted [the relevant regulation] differently” than defendant’s interpretation and thus because there had not been sufficient “official government warning,” there was not “sufficient evidence of reckless disregard”); *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 831–32 (8th Cir. 2013).

⁷⁹ CMS has come to the same conclusion. In a recent internal memorandum its Chief Legal Officer opined that “to the extent that [CMS Manuals] and similar guidance set 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.” Kelly M. Cleary, Brenna E. Jenny, *Impact of Allina on Medicare Payment Rules*, Department of Health and Human Services at p. 2 (Oct. 31, 2019), https://d1198w4twoqz7i.cloudfront.net/wp-content/uploads/2019/12/05141151/CMS-Memo_Impact-of-Allina-on-Medicare-Payment-Rules.pdf. Separately, DOJ had previously arrived at the same conclusion. See Memorandum from The Assoc. Attorney Gen. to the Heads of Civil Litig. Components and U.S. Attorneys (Jan 25, 2018) (Department of Justice “litigators may not use noncompliance with guidance documents for a basis for proving violations of applicable law”). Before *Allina*, courts had split regarding whether instructions furnished in CMS manuals are sufficient to trigger FCA liability if they are not followed. See, e.g., *In re Cardiac Devices Qui Tam Action*, 221 F.R.D. 318, 353 -54 (D. Conn. 2004) (“To adopt defendants’ position that interpretive rules are not binding would effectively nullify the Medicare manuals in their entirety and would allow defendants to submit claims for any and all types of non-covered services that clearly were not reasonable or necessary... . Thus, we disagree with defendants’ position that an interpretive rule cannot form the basis of a claim under the FCA. However, that is not to say that a violation of a Manual provision is a per se violation of the FCA. As discussed above, the FCA requires the submission of a false claim to have been done ‘knowingly,’ as that term is defined by the Act”), *rev’d other grounds, remanded*, 469 F.3d 263 (2d Cir. 2006); see also *United States v. R&F Properties of Lake Cty., Inc.*, 433 F.3d 1349, 1357 (11th Cir. 2005) (carrier manual provision can be consulted to understand meaning of ambiguous regulation); *U.S. ex rel. Suter v. Nat’l Rehab Partners, Inc.*, 2009 U.S. Dist. LEXIS 88630 at *16 (D. Idaho Sept. 24, 2009) (noting that CMS manuals do not have the effect of statutes and regulations but that courts have allowed plaintiffs to predicate FCA actions on the non-binding guidance where the non-binding guidance merely interprets specific language in an existing statute or regulation and ruling that because the CMS Manual Provisions and preamble statements in the Federal Register at issue interpret regulations, the relevant language and statements can form the basis for FCA liability); but cf. *U.S. ex rel. Jamison v. McKesson*, 784 F. Supp. 2d 664, 677 n. 10 (N.D. Miss. 2011) (“To the extent the Government seeks to introduce the OIG Special Advisory Bulletin ... as evidence of Supplier Standard non-compliance, the Court deems such evidence as improper” because the document was merely “agency interpretations of regulations” and thus lack “the force of authoritative law” and is “not binding on this Court”); *U.S. ex rel. Swafford v. Burgess Med. Ctr.*, 98 F. Supp. 2d 822, 827-28 (W.D. Mich. 2000) (ruling that the Carriers Manual, which “is merely a guide for fiscal intermediaries between Medicare and physicians, and lacks the binding effect of law or regulation” would not be used to “judge the truth or falsity of defendants’ representations”) (citation omitted) *aff’d*, 24 Fed. Appx. 491 (6th Cir. 2001); *U.S. ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 41 n.3 (D. Mass. 2000) (ruling that Carrier Manual guidance constituted merely an “interpretive rule” and hence did “not command providers to structure their tests in any particular manner, and, despite the government’s contrary suggestion, measures taken to avoid the application of the Rule are not necessarily illegitimate”).

⁸⁰ 139 S. Ct. at 1808.

⁸¹ *Id.* at 1816.

⁸² Among the several Stark/FCA settlements over the last half dozen years in the tens of million dollar range include, *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*,

792 F.3d 364 (4th Cir. 2015), where the 4th Circuit affirmed the district court's FCA judgment awarding plaintiffs \$237,454,195 (which later settled for more than \$72 million, purportedly based upon Tuomey's ability to pay). Also, Halifax Hospital Medical Center and Halifax Staffing agreed to pay \$85 million to resolve allegations that they violated the FCA and Stark Law after long-standing litigation construing several provisions of the Stark Law. The government has consummated several other FCA/Stark Law multimillion dollar settlements, including one with North Broward Hospital District, a special taxing district in Florida, which operates hospitals, for \$69.5 million and Pacific Alliance Medical Center, Inc., for \$42 million.

⁸³ No. 18-1693, 2019 U.S. App. LEXIS 38367 (3d Cir. Dec. 20, 2019).

⁸⁴ The court issued its initial decision on September 17, 2019. See *U.S. ex rel. Bookwalter v. UPMC*, 938 F.3d 397 (3d Cir. 2019). After a petition for rehearing and rehearing en banc, the court panel issued, on December 20, 2019, a significantly revised panel opinion and denied UPMC's petition for rehearing en banc. See *Bookwalter v. UPMC*, No. 18-1693 (3d Cir. Dec. 20, 2019).

⁸⁵ 2019 U.S. App. LEXIS 38367, at *5.

⁸⁶ *Id.* at *6.

⁸⁷ *Id.* at *6-7. Ultimately, the government intervened in the portion of the lawsuit related to the allegation that the physicians mischaracterized their role in surgery or the necessity of the surgery and settled those allegations for \$2.5 million. The government declined to intervene in the claims related to Stark law violations. *Id.* at *8.

⁸⁸ *Id.* at *11.

⁸⁹ *Id.* at *11-12.

⁹⁰ 2019 U.S. App. LEXIS 38367, at *18.

⁹¹ *Id.* at *20 (observing that "[p]aying a worker more than he brings in is suspicious.").

⁹² *Id.* at *22-23.

⁹³ *Id.* at *23.

⁹⁴ *Id.* at *20.

⁹⁵ *Id.* at *19-20. As noted below, CMS's interpretation of the Stark law related to the reasonableness of paying physicians more than their collections dissipates some of the court's "smoke" indicating that there is a fire. Moreover, some of the other smoke appears to be just that, smoke. As to the physicians being paid at the 90th percentile, as another court concluded, there is nothing inherently problematic with a prominent institution paying a physician at the 90th percentile, especially when the physician is highly productive. See, e.g., *U.S. ex rel. Villafane v. Solinger*, 543 F. Supp. 2d 678, 691-92 (W.D. Ky., 2008) (rejecting relator's contention that payment at 90th percentile and 75th percentile were inherently above fair market value and noting that doctors appear "to be highly qualified and arguably at or near the top of his profession" and relator's expert's "findings suggest only that Defendant physicians were paid at a level consistent with their abilities, not that they were paid at an unreasonably high level"). The court, more generally, also noted that any "definition of fair market value that would automatically deem anything over the median or indeed, anything at the 80th

percentile, as necessarily not being fair market value would seem illogical. After all, any distribution of salaries in a marketplace will show some higher or lower than others.... The Court suspects this is in part why the rulemakers opted against defining fair market value in terms of standard deviations and other statistical measurements....” *Id.* at 691, n. 13. Indeed, the true smoke would appear if the physician were paid at the 90th percentile but her productivity was at a much lower percentile, which apparently here was not the case. Similarly, the \$2.5 million settlement with the government can hardly qualify as smoke. If the government proceeds with an FCA action, it is highly unlikely that even a meritless FCA case will be dismissed at the pleading stage but, instead, will proceed through discovery. Where the allegations include a substantial number of patient charts, including surgical records, and the necessity of services and identifying who performed surgical services at specified times, the cost of litigation would be exorbitant. For example, in one FCA litigation with a short trial, the relator requested a petition of fees and costs of over \$19 million. See *U.S. ex rel. Harman v. Trinity Indus.*, 872 F.3d 645, 651 (5th Cir. 2017). (The case was ultimately reversed on appeal, see *id.*) Given that and the substantial risk associated with any FCA action in which the government intervenes, a \$2.5 million FCA settlement with the government at the start of litigation involving multiple claims, an extended time-period and that is document intensive, would be perceived as a settlement of nuisance value, and at far less than the ultimate costs of litigation, rather than smoke of any type. Indeed, because the government would be aware of these facts as well and still settled at only \$2.5 million, the relatively small settlement amount is a strong indicator that the government also perceived its case as weak.

⁹⁶ See 84 Fed. Reg. 55766 (Oct. 17, 2019).

⁹⁷ *Id.* at 55767-68.

⁹⁸ These statements also existed in the 3rd Circuit’s initial decision in September, which pre-dated CMS’s proposed rule. See 938 F.3d at 412.

⁹⁹ 84 Fed. Reg. at 55790.

¹⁰⁰ *Id.* at 55840.

¹⁰¹ *Id.* at 55799 (emphasis supplied).

¹⁰² Compare 2019 U.S. App. LEXIS 38367, at *18 *with* 84 Fed. Reg. at 55790.

¹⁰³ 84 Fed. Reg. at 55798. CMS’s Stark law guidance, by its own admission, is replete with ambiguity, having undergone several rounds of rulemaking. See, e.g., Physician Ownership of, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services, 57 Fed. Reg. 8588 (Mar. 11, 1992); Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements, 60 Fed. Reg. 41,914 (Aug. 14, 1995); Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 63 Fed. Reg. 1659 (Jan. 9, 1998); Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase I), 66 Fed. Reg. 856 (Jan. 4, 2001); Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054 (Mar. 26, 2004); Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012 (Sept. 5, 2007); Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 48,434

(Aug. 19, 2008); Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,170 (Nov. 29, 2010); Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70,886 (Nov. 16, 2015).

¹⁰⁴ See Robert Salcido, *Minimizing Exposure to Stark Law Liability in False Claims Act Cases by Isolating Those Who Determine Fair Market Value From Those Who Measure Contribution Margin or Other Similar Operational Data* (Oct. 28, 2015) <https://www.akingump.com/en/news-insights/minimizing-exposure-to-stark-law-liability-in-false-claims-act.html>.

¹⁰⁵ See, e.g., *Allergen, Inc.*, 746 F. App'x at 109-10; *MWI Corp.*, 807 F.3d at 289; see also *Donegan*, 833 F.3d at 880; *Ketroser*, 729 F.3d at 831-32. The significance of CMS' statement is just as in FCA jurisprudence where a reasonable interpretation of ambiguous law is a dispositive defense unless the government has issued official guidance to warn defendant away from its reasonable interpretation, a reasonable interpretation of CMS' ambiguous guidance regarding the Stark law is also a dispositive defense.

¹⁰⁶ See, e.g., *U.S. ex rel. Ruckh v. Salus Rehabilitation, LLC*, 304 F. Supp. 3d 1258, 1268-69 (M.D. Fla. 2018) (finding that the relator must offer evidence of a top down directive and noting that the relator had failed to establish the existence of a scheme as against the "Management Entity" – an LLC that sat atop the specialized nursing facilities alleged to have submitted false claims – because the relator had set forth only "a scattering of claims in a smattering of facilities [which] is a wholly insufficient basis from which to infer the existence of a massive, authorized, cohesive, concerted, enduring, top-down, corporate scheme to defraud the government"); *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-604, 2016 U.S. Dist. LEXIS 80160, at *64 (N.D. Tex. June 20, 2016) ("Relator seemingly suggests she is only required to prove Defendants operated with reckless disregard as to falsity, and not that the certifications or claims were actually false or fraudulent. This view reflects a misunderstanding of the FCA's falsity element, confusing the FCA's scienter requirement—which requires knowledge or reckless disregard—with the necessity to show that records or claims were false. The FCA's knowledge element is an independent, additional hurdle for Relator, not a shortcut around proof of falsity. Without evidence linking Relator's 'scheme' evidence to the 291 patients whose files Dr. Steinberg analyzed, there is no evidence that the certifying physicians for the 291 patients were not exercising their best clinical judgments nor that they did not believe the subject patients were terminally ill when they certified them as such, and thus there is no evidence of the falsity required to establish liability"); *cf. U.S. ex rel. Oberg v Pa. Higher Educ. Assistance Agency*, 912 F.3d 731, 735-36 (4th Cir. 2019) (noting that the district court did not error in excluding audit at trial when the audit found that the defendant had paid excessive salaries and bonuses to its executives and managers and the relator sought to show that the findings tended to establish FCA scienter—that is, that the desire for personal gain motivated defendant's officers to submit false claims—because as "the district court correctly explained: 'it doesn't really make any difference whether they were operating well or not well or whatever. The only issue in this case is: Did they commit fraud and file a false claim?'").

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