Key Points

- Learn the latest case law developments regarding what evidence the government or the relator must establish to prove that the defendant "recklessly" interpreted a statute or regulation in violation of the FCA.
- Understand the circumstances under which the defendant's reasonable interpretation of an ambiguous statute or regulation can provide the defendant with a dispositive defense under the FCA.
- Learn the latest case law developments regarding when a health care business is required to remit an overpayment to the government or incur potential liability under the FCA.

Recent Significant Case Law Developments Regarding What Constitutes a Reckless Interpretation of a Law and When Retention of an Overpayment Violates the False Claims Act

Among the most important False Claims Act (FCA) issues to understand in discharging one’s obligations to comply with the law is what, if anything, one must do when the underlying regulatory scheme governing payment from the government is ambiguous. For example, if the company simply adopts a reasonable interpretation of the law and seeks payment, will courts, under FCA precedent, find the company liable under the FCA if, upon review, the company’s reasonable interpretation is wrong? Under these circumstances, will the company be deemed to have acted with “reckless disregard” in violation of the FCA if there is no official governmental guidance that would have warned the company away from its reasonable interpretation of law?

Another vexing issue is determining when a company has a duty to return an overpayment to the government under the FCA’s recently amended reverse false claim provision. For example, does the provision reach merely negligent conduct such that, if a company unreasonably interprets an ambiguous law, but does not act fraudulently or recklessly, is the company liable under the FCA for “knowingly and improperly” “avoiding” or “concealing” an obligation to pay if it does not timely investigate and remit an overpayment?

Two recent 8th Circuit FCA decisions—United States ex rel. Estate of Donegan v. Anesthesia Assocs. of Kan. City, PC1 and United States ex rel. Olson v. Fairview Health Servs., of Minn.2—expressly address

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these questions, finding that a defendant does not act with reckless disregard when it adopts a reasonable interpretation of an ambiguous law and there is no official governmental guidance that would warn the company away from its reasonable interpretation and that the FCA's reverse false claims provision requires that the defendant act fraudulently and not simply negligently when it makes a mistaken, erroneous construction of law to be held liable under the FCA's overpayment rule.

These decisions validate important principles addressed in two prior Salcido Report Public Disclosure Alerts (“Report”) regarding the scope and proper application of the FCA. See Understanding When an Overpayment Can Result in False Claims Act Liability and Why Current Precedent and Regulatory Guidance is Mistaken (“Understanding When an Overpayment Can Result in FCA Liability”) and What Must the Government Prove to Establish that a Defendant Recklessly Interpreted a Statute or Regulation in Violation of the False Claims Act? (“What Must the Government Prove to Establish that a Defendant Recklessly Interpreted a Statute”).

I. A Reasonable Interpretation Of Law Does Not Result In An FCA Violation When There Is No Official Governmental Guidance To Warn Defendant Away From That Interpretation

In What Must the Government Prove to Establish that a Defendant Recklessly Interpreted a Statute, this Report asserted that recent trending FCA case law demonstrates that courts, over the government’s objection, have affirmatively found that the FCA plaintiff cannot satisfy the FCA’s knowledge standard when the government or relator announces a novel interpretation of law in the course of FCA litigation for failing to adhere to an interpretation of a rule or regulation that has never been published.

One case that was selected to illustrate this principle was the district court’s opinion in United States ex rel. Estate of Donegan v. Anesthesia Assocs. of Kan. City, PC.3 Specifically, in Donegan, the governing regulation required that the anesthesiologist must personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, emergence, to bill at a higher rate. The district court concluded that the regulation was ambiguous regarding when “emergence” occurs—that is, whether it occurs primarily in the operating room (the relator’s position) or whether it extended to the recovery room (the defendant’s position). Ultimately, the district court concluded that, because defendant’s interpretation of an ambiguous regulation was reasonable and there was no official guidance to warn defendant away from its reasonable interpretation, the relator could not, as a matter of law, satisfy the FCA’s scienter standard.

The relator then appealed, and the government, as it had in the district court, objected to the district court ruling, stating that the district court had inappropriately “adopted the sweeping rule that a defendant’s reasonable interpretation of an ambiguous regulation precludes FCA liability, regardless of the defendant’s state of mind.”4 The relator, as the government has in other litigation, also contended that a defendant is liable because a defendant, confronting an ambiguous law, has a duty to seek clarification

4 2016 U.S. App. LEXIS 14830, at *10 (emphasis added).
from government employees or otherwise should be liable under the FCA for acting with reckless disregard of the law.

The 8th Circuit rejected both positions. The court stated that the principle that a reasonable interpretation of an ambiguous rule precludes FCA scienter is not so “sweeping” simply because “if a Relator (or the United States) produces sufficient evidence of government guidance that ‘warn[ed] a regulated defendant away from an otherwise reasonable interpretation,’” summary judgment would not be proper on the issue of FCA scienter. In Donegan, however, the FCA plaintiff had failed to submit any relevant evidence that “the government had warned [the defendant] that the agency interpreted [the emergence regulation] differently” and thus, because there had not been sufficient “official government warning,” there was not “sufficient evidence of reckless disregard.” Additionally, the 8th Circuit, like the D.C. Circuit in United States ex rel. Purcell v. MWI Corp., specifically rejected the position that the government’s failure to promulgate a clear rule or regulation thereby creates a duty on those doing business with the government to inquire into the government’s true intent prior to submitting any claim for payment.

Donegan marks the third straight FCA case in which the government has lost in asserting that defendants can be held liable in an FCA case notwithstanding the defendant’s reasonable interpretation of an ambiguous rule and the fact that there is no official governmental guidance to warn the defendant away from its reasonable interpretation. The government has been losing because its viewpoint—that defendant should have correctly guessed what the government’s official position would be if the government were to publish one or else make informal inquiries of government employees—is untenable.

First, the government’s viewpoint that the defendant can act with reckless disregard notwithstanding its reasonable interpretation of law when there is no official guidance to warn the defendant away from its interpretation is illogical. If the defendant demonstrates that it, in fact, has a reasonable interpretation of law and there is no official guidance that would warn it away from that interpretation, then how could it have behaved recklessly, unless it is charged with the duty of being clairvoyant and actually having the duty to predict what official interpretation the government will promulgate at some future date that may be contrary to defendant’s interpretation or be held potentially liable under the FCA? Indeed, this is precisely why the D.C. Circuit rejected the government’s position in Purcell. There, the defendant learned of the

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5 Id. (citation omitted).
6 Id. at *11.
7 807 F.3d 281 (D.C. Cir. 2015).
8 See Donegan, 2016 U.S. App. LEXIS 14830, at *11 (noting plaintiff “argues that summary judgment was improper because [defendant] had a duty to ask [the Centers for Medicare & Medicaid Services (“CMS”) or its local contractors whether its interpretation of ‘emergence’ was proper. We disagree. As the agency had not clarified an obvious ambiguity in its Step Three regulations for decades, [defendant’s] failure to obtain a legal opinion or prior [CMS] approval cannot support a finding of recklessness”) (internal quotation and citation omitted); see also Purcell, 807 F.3d at 290 (finding that there was no guidance from the government that would provide the defendant with any “particular reason to formally inquire about” the legality of the commissions paid).
9 Aside from this case, as noted in the prior Report, the D.C. Circuit in Purcell and the district court in Donegan had expressly rejected the government’s position because the position results in an overly expansive interpretation of the FCA. See Purcell, 807 F.3d 281 (D.C. Cir. 2015); Donegan, 2015 U.S. Dist. LEXIS 74239, at *27-29.
10 807 F.3d at 289-90 (D.C. Cir. 2015).
government's official interpretation of a rule only during the course of a “fraud” action—namely, when the
government asserted it as part of its FCA action. According to the government, notwithstanding the fact
that the defendant formulated a reasonable interpretation of law, it should have instead adhered to the
government's unpublished and unknown interpretation that the government only announced at the time it
filed its lawsuit. 11 Obviously, the court rejected that position.

Second, contrary to the government’s assertion, the government’s failure to write a clear rule should not
thereby create a duty on the defendant to make informal inquiries of government employees to learn what
the government’s true intent is regarding the law. Any company that has followed this route can attest
that, to the extent any informal answer can be obtained from the government’s mid-level managers, the
answers are, at times, not based upon evidence, idiosyncratic or simply wrong. 12 And requiring a
business to engage in this practice of making informal inquiries—for fear of violating the FCA—does not
result in “good” government, but bad government, because this practice is no substitute for notice and
comment rulemaking that clearly defines defendants’ duties so that they can operate their businesses
within the confines of the law.

Finally, frequently in these cases, the government raises a policy argument that the court should find that,
notwithstanding the defendant’s reasonable interpretation of law and the lack of official governmental
guidance, the defendant should potentially be held liable because, otherwise, the defendant will have an
“incentive to violate the law” whenever there is an ambiguous law. The government’s position is wrong
because the government can always enforce the law. If the government believes that the defendant’s
reasonable interpretation is wrong, the government can always sue to enforce its rights, such as an action
for payment by mistake of fact, or unjust enrichment or, if applicable, breach of contract. And, if the
government is right and the defendant is wrong, the government should recover. All that is being stated in
these cases, as the D.C. Circuit articulated best in Purcell, is that, if the government elects to promulgate
a vague or general rule, then, under these circumstances, a fraud action under the FCA (with treble
damages and substantial civil penalties) “may cease to be an available remedy.” 13

II. The FCA’s Overpayment Rule Does Not Apply To Negligent Conduct
In Understanding When an Overpayment Can Result in FCA Liability, the Report contended that the
government’s guidance and court precedent have misconstrued the FCA’s plain statutory language

11 Id.
12 Indeed, the Olson case discussed below at Section II perfectly illustrates this point. The defendant made multiple
inquiries of the government, which resulted in it receiving conflicting guidance from various government employees,
which ultimately resulted in FCA litigation.
13 See Purcell, 807 F.3d at 291. Indeed, the court’s decision is consistent with the principles that the Supreme Court
enunciated in Universal Health Services, Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016). There, the
Court emphasized that the FCA is not a “vehicle for punishing garden-variety breaches of contract or regulatory
violations.” Id. at 2003. And, as the Court “emphasize[d],” the “False Claims Act is not a means of imposing treble
damages and other penalties for insignificant regulatory or contractual violations.” Id. at 2004. Here, if the plaintiff’s
interpretation had prevailed—and defendants are liable for treble damages and substantial civil penalties
notwithstanding the defendant’s reasonable interpretation of law where there is no authoritative contrary
interpretation of the law—then the FCA would be applied to punish “garden-variety breaches of contract or
regulatory violations.”
regarding what knowledge standard applies in determining whether there is an obligation to repay an overpayment. Both CMS and a district court indicated that one could be held liable under the FCA for merely being negligent in failing to report an overpayment.

Significantly, the 8th Circuit, in *Olson*, has set the record straight that the FCA overpayment obligation extends to only fraudulent, not negligent, conduct. Additionally, CMS has issued a Final Rule clarifying that its regulation does not purport, in any fashion, to interpret the FCA’s intent standard, which has been “interpreted by a body of False Claims Act case law.” The 8th Circuit’s ruling in *Olson* and CMS’s statement will help to ensure that the FCA’s overpayment rule is confined to only those instances, consistent with congressional intent that a health care business “knowingly and improperly” (as oppose to negligently) retains an overpayment.

A. The 8th Circuit’s Decision in *Olson*

In *Olson*, the relator alleged that the defendant medical center falsely induced the state Department of Health and Human Services (DHS) to overreimburse it for services provided to Medicaid patients. The relator worked for the DHS and claimed, that as part of his employment, he drafted a legislative amendment reducing Medicaid expenditures for hospital inpatient services by 10 percent. But, the amendment excluded “children’s hospitals” from the reimbursement reduction.

The defendant medical center operated a children’s unit that was not licensed as a children’s hospital. It believed that the children’s unit should be considered a children’s hospital, and, hence, the legislative rate reduction did not apply to the unit, and it lobbied state officials accordingly. Although the relator, as the author of the legislation, opposed these efforts, contending that children units were not children hospitals, the state agency disagreed, retroactively exempted the unit and paid the defendant approximately $500,000 to compensate it for prior admissions that had applied the rate reduction.

The relator disagreed with the exemption and persuaded the DHS Commissioner and Office of Inspector General to investigate. The investigation ultimately resulted in the DHS concluding that the relator was correct that the exemption was erroneous and notifying the defendant that it would be issuing a notice of recovery once the overpayment was calculated.

The relator’s FCA action alleged that the defendant violated the FCA’s reverse false claims provision by “knowingly conceal[ing] an obligation to pay back [Medicaid] monies to the federal and state government,

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17 Id.
18 Id. at *5.
19 Id. at *5-7.
20 Id. at *6-7.
21 Id. at *7.
22 Id. at *8.
that it knew it illegally received.”\(^{23}\) The relator contended that the legislative language was clear and that the defendant knew that the rate reduction was intended to apply to its children’s unit.\(^{24}\) Moreover, the relator contended that the defendant’s interpretation of the law was patently unreasonable because it applied the exemption, not just to children treated in the children’s unit, but to all inpatients younger than the age of 18 treated elsewhere in the hospital (e.g., birth services to newborns and appendectomies for children, which the relator contended would normally not be provided at children’s hospital).\(^{25}\)

The 8th Circuit rejected the relator’s contention. The court noted that, under the 2009 FCA amendment, the relator must demonstrate that the defendant owed an “obligation,” defined as “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-guarantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.”\(^{26}\) The court concluded that the relator failed to demonstrate that the defendant knew that it had an “obligation” to pay back the $500,000 payment that it received. At the time that the DHS issued the defendant’s reimbursement, the defendant, according to the court, did not have an obligation to remit the reimbursement back to the government, but, instead, merely had a potential liability and not an established duty.\(^{27}\)

Significantly, in reaching this conclusion, the court rejected the viewpoint that the FCA’s overpayment provision, which does not, by its terms, require falsity or deception, can apply to nonfraudulent conduct. Specifically, the court noted that the absence of terms such as “false” or “fraudulent” is not dispositive of the nature of the conduct prohibited. The court reasoned that the provision in dispute—“knowingly concealing an obligation to pay money to the government”—included fraud because to “conceal is to fail to disclose,” and the “Restatement (Second) of Contracts § 160 treats concealment as equivalent to a misrepresentation.”\(^{28}\) The court also noted that its “understanding comports with the punitive nature of liability that the FCA imposes. Without fraud, punitive damages—a mandatory penalty of up to $10,000 for each claim and treble damages—would seem an unreasonable levy against individuals guilty of only ‘knowingly receiving an overpayment from the government fisc.’”\(^{29}\) Thus, if “there is no allegation of fraudulent conduct under the FCA, then there can be no reverse liability under § 3729(a)(1)(G).”\(^{30}\)

B. CMS Overpayment Regulation

As the prior Report described, CMS had issued a proposed rule that, contrary to the FCA’s plain language, appeared to apply the FCA merely to negligent conduct. For example, CMS noted that

\(^{23}\) Id. at *19.  
\(^{24}\) Id. at *19.  
\(^{25}\) See id., at *30 (dissenting opinion).  
\(^{26}\) Id. at *19-20 (citation omitted).  
\(^{27}\) The dissenting judge disagreed, asserting that, because the defendant’s contention that the exemption from the 10 percent reduction applied to all children, and not just those in the children’s unit, its interpretation of an ambiguous regulation was “patently unreasonable,” and, hence, it “must have known it was getting overpaid.” Id. at *30.  
\(^{28}\) Id. at *22.  
\(^{29}\) Id. at *23.  
\(^{30}\) Id. at *25.
examples of when a business may fail to discharge its obligation to report an overpayment included “[w]hen there is reason to suspect an overpayment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may be found to have acted in reckless disregard or deliberate ignorance of any overpayment.”

In CMS’s final regulation, however, it specifically clarified that the agency had no such intent to address or interpret the application of the FCA’s intent standard as courts have developed and applied the FCA’s intent standard. Specifically, CMS stated:

We note that in discussing the standard term “reasonable diligence” in the preamble, we are interpreting the obligation to “report and return the overpayment” that is contained in section 1128J(d) of the Social Security Act. We are not seeking to interpret the terms “knowing” and “knowingly”, which are defined in the Civil False Claims Act and have been interpreted by a body of False Claims Act case law.

Instead, CMS clarified that it only sought to elucidate the duty that creates an “obligation” under the FCA and not when one fails to “knowingly and improperly” conceal or avoid that obligation.

Comment: …. Commenters suggested that a failure to report and return an identified overpayment should not lead to reverse FCA liability, unless the provider “knowingly concealed” or “knowingly and improperly avoided” the obligation. Other commenters stated that the proposed rule inappropriately applies the FCA, specifically the “reverse false claims” cause of action, to honest mistakes or inadvertent overpayments.

Response: We are interpreting section 1128J(d) of the Act in this rulemaking, not the FCA. In this rule, our discussion of the FCA is limited to its explicit inclusion in the enforcement provision under section 1128J(d) of the Act, which states that any overpayment retained by a person after the deadline for reporting and returning the overpayment under this rule is an obligation for purposes of the FCA.

Thus, although CMS purports to define what duty a business has to investigate an overpayment, which creates an “obligation” under the FCA, because it does not seek to define when a business is acting with unlawful intent, as set forth in the plain language of the FCA’s overpayment regulation, CMS’s rule does not ultimately determine whether the defendant breached the FCA. The FCA plaintiff will have to establish that evidence independent of CMS’s rule. As a result, CMS’s statement will help to ensure that the FCA’s overpayment rule is confined to only those instances, consistent with congressional intent, that a health care business “knowingly and improperly” (as opposed to negligently) retains an overpayment.

31 77 Fed. Reg. 9179, 9182 (Feb. 16, 2012) (emphasis added). As the Report argued, this formulation—on its face—conflates a negligence standard with a reckless disregard and a deliberate ignorance standard and treats each of these standards as if they were merely interchangeable, which is clearly contrary to law.

32 81 Fed. Reg. at 7661

33 Id. at 7665.
Conclusion
The court’s ruling in Donegan will help to ensure that businesses that seek to understand the complex maze of health care rules and regulations will not be held liable for their reasonable interpretations of law when there is no official governmental guidance to warn them away from that interpretation. The court’s ruling in Olson will help to ensure that, when the law, and its potential scope, is ambiguous, a business will not be held to have unlawfully retained an overpayment if the government later disagrees with the business’s interpretation of law.

Additionally, these 8th Circuit cases confirm current FCA trending case law, including the Supreme Court’s ruling in Escobar, that the FCA should not be applied in “garden-variety” regulatory or contractual disputes, but only when there is fraudulent conduct that warrants the imposition of treble damages and substantial civil penalties.

Read past issues of The Salcido Report:
February 26, 2016 – What Must the Government Prove to Establish that a Defendant Recklessly Interpreted a Statute or Regulation in Violation of the False Claims Act?

December 21, 2016 – Understanding When an Overpayment Can Result in False Claims Liability and Why Current Court Precedent and Regulatory Guidance is Mistaken

October 28, 2015 – 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

October 1, 2015 – When a Violation of a Rule or Regulation Becomes an FCA Violation: Understanding the Distinction Between Conditions of Payment and Conditions of Participation

September 25, 2015 – False Claims Act Public Disclosure Alert

About the Author
Robert Salcido is a leading FCA practitioner.

The United States typically obtains a positive monetary recovery in more than 90 percent of the FCA actions it institutes, see Lessons from Qui Tam Litigation, 114 COLUM. L. REV. at 1991. However, Mr. Salcido has been lead counsel in several FCA actions in which he successfully defended clients in FCA actions the government 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,

- 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 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 relator and 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:

- 2014 Supplement to False Claims Act and the Health care Industry: Counseling and Litigation (American Health Lawyers Ass’n 2014)

Because of his work successfully defending a number of FCA lawsuits, he has been recognized in:
• *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* (2006-2015), in the 2011-2015 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.
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