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What Must the Government Prove to Establish That a Defendant Recklessly Interpreted a Statute or Regulation in Violation of the False Claims Act?—Part II

By Robert S. Salcido*

In this two-part article, the author discusses the implications of the U.S. Supreme Court's ruling in Safeco Ins. Co. v. Burr *to the False Claims Act, and provides a detailed analysis of court decisions applying the Supreme Court's precedent to determine when a party's reading of a statutory term is "reckless." The first part of the article, which appeared in the May 2016 issue of* Pratt's Government Contracting Law Report*, analyzed the Court's decision in* Safeco *and discussed recent U.S. Court of Appeals for the D.C. Circuit's application of the Court's* Safeco *rule. This second part of the article examines other court applications of the* Safeco *doctrine in recent False Claims Act cases.*

OTHER COURT APPLICATIONS OF *SAFECO* DOCTRINE IN RECENT FCA CASES

Other courts have also recently studied the issue of what are the FCA implications when the defendant has developed a reasonable interpretation of a rule, but there is no formal authority to warn the defendant away from its interpretation. They have ruled that, under these circumstances, the defendant cannot "knowingly" submit a false claim.

Frensenius

In *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*,[31] the relator alleged that the defendant billed Medicare for overfill—a surplus volume of Epogen and Zemplar contained in vials received from manufacturers—from 2005 through 2006 in violation of Medicare rules and regulations prohibiting reimbursement for drugs that providers receive for free.[32] The court bifurcated

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[31] No. 1:10-CV-1614, 2015 U.S. Dist. LEXIS 156924 (N.D. Ga. Oct. 30, 2015).

[32] *Id.* at *21–22. Regarding overfill, the court noted that manufacturers of Epogen and

the summary judgment briefing schedule to first consider whether the submission of a request for payment for overfill administration satisfied the FCA falsity element—that is, whether overfill administration was reimbursable under Medicare rules and regulations.[33] The court ruled that the defendant was not permitted to bill Medicare for Epogen and Zemplar overfill during the relevant time period and hence submitted false claims.[34] At that point the court did not consider whether the defendant "knowingly" submitted any false claim.

After the parties moved for summary judgment on the FCA's knowledge element, the court ruled that no reasonable jury could find that the defendant acted knowingly or recklessly such that it could be held liable under the FCA.[35] The court primarily relied upon two factors in ruling that the defendant did not act with reckless disregard. First, the court noted that the relevant rules and regulations regarding overfill billing were silent and that no rule or regulation expressly prohibited billing for administered overfill during the relevant time period.[36] Second, viewing Medicare law and policy generally, the court concluded that whether billing was permitted was ultimately ambiguous: "One could have deduced from the Medicare policy on discarded drugs that overfill was free, and thus should not be billed even if administered. But one could alternatively, reasonably assume that by prohibiting overfill billing only when overfill is discarded, Medicare implicitly recognized that overfill can be billed when administered."[37]

Faced with this ambiguity, and notwithstanding that the court had previously ruled that a better interpretation of Medicare law is that the defendant violated the law when billing for overfill, the court found that the defendant did not "recklessly" interpret the law, because the evidence in the record showed that the defendant believed—and its counsel advised—that administered overfill was reimbursable. The court ruled that, whether right or wrong, the defendant's interpretation was plausible, because (1) although some facts existed that could

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Zemplar distribute the drugs in individual vials, with the amount of drug contained in the vial labeled on the vial itself. "However, consistent with industry standards and federal regulations, the manufacturers also include in each vial a surplus volume of each drug, referred to as 'overfill' . . . The overfill ensures that the nurses administering the drug will be able to extract at least the labeled amount from the vial." *Id.* at *11.

[33] *Id.* at *22.

[34] *Id.* at *22–24 (citing *United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.,* 972 F. Supp. 2d 1339 (N.D. Ga. 2013).

[35] *Id.* at *26.

[36] *Id.* at *113.

[37] *Id.* at *113–14.

have led the defendant to conclude that overfill billing was impermissible, the defendant's lawyers believed that billing was permissible and so advised the company;[38] (2) although the defendant never disclosed its billing practice to CMS, the defendant informed the OIG that it was billing for overfill under its Corporate Integrity Agreement and stated that it was utilizing (and implicitly billing for) overfill in its SEC filings;[39] and (3) although simply acting in conformity with others in the industry does not absolve government contractors of FCA liability, the evidence revealed that others in the industry routinely billed overfill and believed that it was permissible, including the relator's own expert.[40]

Ultimately, the court concluded that, although the defendant's interpretation of the rule was wrong, and even negligent, the defendant's interpretation was not recklessly wrong, because it was consistent with its communication to the government and conformed to industry practices:

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[38] *Id.* at *27–34. *See generally United States ex rel. Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1061–62 (11th Cir. 2015) (holding that the defendant school did not act with reckless disregard when the individual testified that, when he signed a certification of compliance with the Rehabilitation Act, even though he had not personally ensured that the company's nondiscrimination policies and grievance procedures complied with the Rehabilitation Act, because he "relied on the opinions of his subordinates, including those charged with compliance, and had no reason to believe that [the defendant's] policies violated the Rehabilitation Act or its implementing regulations" and "while he did not independently review the agreement or specifically review [the defendant's] policies for compliance with the Rehabilitation Act, [the defendant] had hired 'the kind of people that had integrity, that had experience, [and] that had knowledge'; the company also used a system where there were 'experts who ran the departments,' and they were responsible for ensuring [the defendant's] compliance" and the relator "adduced no evidence—either in the district court or on appeal—suggesting (much less showing) that [the individual's] reliance on his subordinates was unreasonable under the circumstances").

[39] *Id.* at *116. *See also United States ex rel. Gonzalez v. Planned Parenthood of L.A.,* 759 F.3d 1112, 1115–16 (9th Cir. 2014) (finding that, where the defendant had exchanged letters with state officials describing its billing process, it was billing at usual and customary rates and not at acquisition cost, and state officials did not object; when state later acknowledged that, regarding the definition of "at cost," the state had provided "conflicting, unclear, or ambiguous misrepresentations . . . to providers," the relator could not set forth a plausible FCA cause of action that the defendant knowingly presented false claims).

[40] *Id.*, *123–24. *See also United States ex rel. Williams v. Renal Care Grp.*, 696 F.3d 518, 531 (6th Cir. 2012) (holding that a defendant is not reckless when, in the face of ambiguous regulations, the defendant follows industry practice, consults and relies on advice of counsel, and was forthright with the government about its conduct). For a detailed history of the FCA's knowledge standard and a description of its case law, *see* Robert Salcido, False Claims Act & Healthcare Industry: Counseling & Litigation § 2:05 (American Health Lawyers Ass'n Supp. 2014); *see generally* Robert Salcido, False Claims Act & Healthcare Industry: Counseling & Litigation (2d ed. American Health Lawyers Ass'n 2008).

Perhaps Relator is correct. Fresenius's exploitation of silence or ambiguity in the Medicare rules or regulations, capitalizing on a loophole in the regulatory fabric, certainly has an unsettling dimension to it. The Court agrees with Relator that "as the recipient of substantial largesse from the Government," Fresenius had an obligation to act with integrity and not abuse its position as government contractor. And the Court credits Relator's position that the presumption in Medicare reimbursement practices is that a provider does not bill for something it received for free. The record thus supports a reasonable inference that Fresenius negligently failed to recognize the relationship between various Medicare principles, rules and regulations, and failed to properly investigate whether overfill was a reimbursable drug product or instead no different than a free sample. Also based on this record, a jury could decide that sophisticated companies such as Fresenius were not blindsided when CMS proposed to prohibit overfill billing. Indeed, issues involving overfill extraction, administration, and billing had bubbled to the surface time and again for decades—in the context of patient safety and reentry protocols, alleged kickbacks and improper marketing, wastage, and of course, billing for overfill administration. And viewed in the light most favorable to Relator, Fresenius knew free items were not reimbursable.

Nonetheless, Fresenius's failure to connect the dots—to fully appreciate that overfill was to be treated just like a free sample for reimbursement purposes—although arguably negligent, does not support a finding of recklessness based on this record. Instead, the record shows that Fresenius adopted a plausible interpretation of the Medicare rules and regulations, consistent with its communications with OIG and CMS and with some in the industry (including Relator's own expert). CMS could presumably have timely and successfully attempted to recover overpayments based on overfill reimbursement prior to 2011. But to expose Fresenius to treble damages in an FCA action would only be appropriate if Fresenius recklessly disregarded or alternatively fraudulently with intent disregarded the fact that overfill was simply not reimbursable. On this record, no reasonable jury could make such a finding.[41]

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[41] *Id.* at *134–36.

Anesthesia Associates of Kansas City

In *United States ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC,*[42] another district court construed what evidence the FCA plaintiff must present to demonstrate that the defendant recklessly interpreted an ambiguous rule or regulation.

In *Anesthesia Assocs.*, the relator contended that the defendant's anesthesiologists violated the "Seven Steps" regulation setting forth the conditions of payment for Medically Directed anesthesia services by failing to personally participate in a patient's emergence from anesthesia in the operating room.[43] Specifically, the regulation provided that the anesthesiologist must personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, induction and *emergence.*[44] If this condition is not satisfied, the procedure must be billed at a lower rate.

The regulation did not define what "emergence" means, or when emergence begins or ends, and neither CMS, in subregulatory guidance, nor its agents defined emergence.[45] The court also pointed out that no national or state anesthesiology organization had defined "emergence," because "emergence is a process, and each patient is different. Some patients take longer than others to recover from the effects of anesthesia, and there are different levels of emergence."[46] The court noted that the University of Kansas Hospital, where some of the defendant's anesthesiologists and CRNAs received their education and training, taught its anesthesiology residents and nurse anesthetist students that emergence occurs over a period of time and may take an hour or more.[47]

In light of this regulatory void, the defendant and the relator offered conflicting definitions of when emergence occurs. For example, the defendant defined "emergence" to include the patient's recovery in the recovery room.[48] The defendant's anesthesiologists attempted to comply with the emergence requirement for each patient, either by visiting the patient during the patient's emergence in the operating room, in the hallway during the patient's transfer to the recovery room or after the patient arrived in the recovery room.[49]

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[42] No. 4:12-CV-0876, 2015 U.S. Dist. LEXIS 74239 (W.D. Mo. June 9, 2015).

[43] *Id.* at *1–2.

[44] *Id.* at *6.

[45] *Id.* at *6, *14–15.

[46] *Id.*

[47] *Id* at *15.

[48] *Id.* at *16.

[49] *Id.* at *16.

The relator, by contrast, viewed emergence as excluding time in the recovery room.[50] In support, the relator proffered two board-certified expert anesthesiologists, who disagreed with the proposition that an anesthesiologist is present at "emergence" if he examines the patient in the recovery room. One expert anesthesiologist, for example, opined that:

> It defies the widespread practice and common sense to argue that an anesthesiologist need NOT be present during . . . emergence in the operation room. This is in direct contrast to the intent and letter of the law, and the general understanding of the law in the anesthesiology community, as it pertains to Medical Direction.[51]

Not surprisingly, for FCA purposes, the parties derived different legal conclusions stemming from the ambiguity regarding the meaning of emergence. For example, the defendant contended that the ambiguity regarding what constitutes emergence demonstrated that the relator cannot establish that the defendant *knowingly* submitted false claims. Specifically, the defendant noted that its interpretation that emergence extends into the recovery room is reasonable and that the U.S. Court of Appeals for the Eighth Circuit has held recently that a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA."[52]

The relator, by contrast, pointed out that the FCA requires it to show only that the defendant submitted a false claim with "reckless disregard" or "deliberate indifference" and that reimbursement regulations do not have to be drafted with impossible specificity or mathematical precision.[53] Instead, the relator contended that "emergence" should be interpreted according to its common meaning in the medical community, and it pointed out that it has placed evidence in the record demonstrating that the government and the medical community understand that being present for emergence means being present in the operating room as the patient is weaned from anesthesia.[54] The relator suggested that, even if the regulation is ambiguous, it need only show that the defendant knew that CMS interpreted the regulation in a certain way

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[50] *Id.*

[51] *Id.* at *16–17. The reason that the issue of where emergence occurred was potentially case-dispositive is that some defendant employees testified that defendant anesthesiologists were almost never present in the operating room for emergence. *Id.* at *17.

[52] *Id.* at *25 (quoting *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013)).

[53] *Id.* at *25.

[54] *Id.* at *25–26.

and that its actions did not comply with this interpretation.[55]

In reaching its ruling, the court engaged in a three-step inquiry: Was the regulation ambiguous? If so, did the defendant have a reasonable (or plausible) interpretation of the ambiguous rule? If so, was there formal guidance that would warn the defendant away from its reasonable (plausible) interpretation?

As to ambiguity, the court concluded that the regulation is ambiguous, because what constitutes "personally participates in . . . emergence" is not clear. Specifically, the court noted:

> "Emergence" is not defined by CMS, a National Coverage Determination, a binding Local Coverage Determination, or any national or state anesthesiology organization. Although there is a consensus within the anesthesiology community that emergence begins in the operating room with the cessation of the delivery of anesthetic agents, there is no agreement on when it *ends.* Relator's two experts and Palmetto GBA, the nationwide Medicare carrier for railroad retirees, view emergence as ending once the patient is turned over to the staff in the recovery room. But it is uncontroverted that anesthesiologists consider emergence to be a process that occurs over a period of time and may take an hour or more to complete, depending on the patient. The absence of a clear definition of when emergence ends means the regulation is ambiguous. *See Ketroser*, 729 F.3d at 831.[56]

As to reasonableness, the court concluded that the defendant's interpretation was reasonable. The defendant defined "emergence" to include the patient's recovery in the recovery room. The court noted that, although the defendant's interpretation of emergence may not be the most widely held or most reasonable definition of "emergence," it was a plausible definition, and, thus, its "view that the regulation is satisfied by seeing the patient in the recovery room is a reasonable interpretation."[57]

Finally, as to formal guidance that would warn the defendant away from its interpretation, the court found that there was none:

> Although exactly what constitutes "deliberate ignorance" or "reckless disregard" is somewhat uncertain, the Eighth Circuit has made clear what does *not* constitute "deliberate ignorance" or "reckless disregard." The Eighth Circuit recently held in *United States ex rel. Ketroser v. Mayo*

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[55] *Id.* at *26.

[56] *Id.* at *29–30.

[57] *Id.* at *30 (footnote omitted).

> *Foundation* that where a regulation is unclear, a defendant's "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." 729 F.3d 825, 832 (8th Cir. 2013). This is consistent with its 2010 decision in *United States ex rel. Hixson v. Health Management Systems, Inc.* that a bill submitted "based on a reasonable interpretation of a statute cannot support a claim under the FCA if there is not authoritative contrary interpretation of that statute. 613 F.3d at 1190. To prevail in an FCA action the relator "must show that there is no reasonable interpretation of the law that would make the allegedly false statement true." *Id.* at 1191.[58]

The court also concluded that its analysis is not altered by the fact that the defendant had a financial motive to reach its interpretation, because, regardless of the defendant's opportunistic interpretation, the relator could not establish the FCA knowledge element:

> Of course, Defendant's interpretation is opportunistic because it has a financial motive to interpret the regulation this way. Under Relator's definition of "emergence," thousands of the procedures Defendant's anesthesiologists performed should have been billed at the lower Medical Supervision rate. But there is "no authoritative contrary interpretation" of the regulation here, and the Eighth Circuit has ruled that "a defendant does not act with the requisite deliberate ignorance or reckless disregard by 'taking advantage of a disputed legal question.' " *Hixson*, 613 F.3d at 1190–91 (quoting *Hagood*, 81 F.3d at 1478). While Relator has arguably put forth a more reasonable interpretation of the regulation, this is not enough. Relator must carry its burden of showing "that there is no reasonable interpretation of the law that would make the allegedly false" claim valid. *Id.*[59]

CONCLUSION

So, what is the teaching of this growing body of FCA case law for those

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[58] *Id.* at *26–27. In a Statement of Interest, the government entered the fray, asserting that "what steps the defendant took to ascertain the government's construction of an ambiguous regulation is also relevant to evaluating whether the defendant acted with knowledge." *Id.* at *28. The court rejected the government's Statement of Interest, noting that its alternate formulation was inconsistent with 8th Circuit case law that "a defendant is not liable under the FCA if the regulation is ambiguous and [the defendant's] statements would be true under a reasonable interpretation of the regulation." *Id.* at *28–29.

[59] *Id.* at *26–27.

operating corporate compliance departments, in-house lawyers advising the company regarding its government contracts and payments, and lawyers defending FCA actions?

First, stay actively abreast of governmental rules and regulations regarding government payment and form a reasonable understanding of what those rules require. *Second*, when applicable, communicate that understanding to the government whenever the issue arises (for example, in informal conversations with government representatives, routine audits, SEC filings or other public reports). *Third*, monitor official governmental pronouncements and court decisions to evaluate whether that guidance contains any information that would "warn" the company "away" from its reasonable interpretation.

This growing body of case law is a paradigm shift. The best defense argument is always that the defendant's conduct conformed to the plain language of the government's rule. However, when the defendant's fallback position has been that the government's rule is ambiguous, but that the defendant relied upon a reasonable interpretation, the Department of Justice's response historically has been, in essence, "Oh my God, if the rule is ambiguous, why did you not seek out guidance from the government instead of interpreting the rule in a fashion that furthered your financial interest? That is the epitome of 'reckless disregard' or 'deliberate ignorance,' which should subject you to liability under the FCA." Now, the courts have offered the defendant a dispositive response when the rule is ambiguous, which is as follows: What formal guidance—in either official agency action or court decision—have you, the government, promulgated that you contend should have warned us away from our reasonable interpretation of an ambiguous rule? If the government cannot identify any, the case law is teaching that the government should receive, if its interpretation of the rule is correct, no more than single damages on an overpayment claim, but not treble damages and substantial civil penalties under the FCA, because, under these circumstances, the government cannot satisfy the FCA's knowledge element.