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What constitutes "reckless disregard" under the FCA?

» The FCA creates substantial liability and compliance obligations in the health care industry.

» A common issue in investigations is whether there may be reckless disregard of fraud or wrongdoing.

» Recent court decisions shed light on what constitutes reckless disregard.

» Seeking advice from legal counsel, disclosure to government regulators, and following industry practices may reduce the risk of a reckless disregard finding.

» By responding accordingly, the risks of potential FCA liability may be mitigated.

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A common issue in compliance investigations is whether the conduct being investigated could lead to a charge that an entity or individual engaged in "reckless disregard" under the FCA (FCA). The FCA generally creates liability for "knowing" violations, which includes "actual knowledge," "deliberate ignorance," or "reckless disregard." Actual intentional fraud and deliberate ignorance of fraud are both relatively rare. However, mistakes and technical violations of rules, regulations, or contracts are more common, particularly in the health care industry, and the line between negligence and reckless disregard can be difficult to discern in many situations. Recent court decisions shed light on what type of conduct constitutes reckless disregard under the FCA and provide guidance on what kinds of facts may allow an entity or individual to achieve a court ruling that a whistleblower or the government has not established reckless disregard. Compliance professionals and counsel should be aware of this, both to assess past conduct and to assess what actions should be considered before and in the midst of potential compliance issues. This article surveys a few of the leading cases on the reckless disregard standard in an effort to discern the key types of evidence relied on by courts to grant summary judgment (or in some cases, a motion to dismiss) in favor of defendants. Compliance professionals and legal advisors should keep these factors in mind as they respond to situations that raise potential liability under the FCA.

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The False Claims Act

The federal FCA creates civil liability upon knowing submission of what is deemed to be a "false claim" to the government, or the making of a false statement that causes the government to pay a claim, or keeping government money that one is not entitled to retain, among other potential violations.[1] Such claims typically arise from government reimbursement or subsidy programs, such as Medicare or Medicaid. Actions under the FCA may be filed by the Attorney General or a private party

whistleblower. A private party's action under the FCA is referred to as a *qui tam* action and the private party is referred to as the relator. Damages under the FCA can reach into the tens of millions of dollars, because they include a potential statutory penalty of $5,500 to $11,000 per false claim, plus three times the amount of actual damages sustained, as well as the costs of suit to recover the damages.[2] Department of Justice statistics show that recoveries under the FCA since 1987 have exceeded $30 billion, and recoveries in 2011 alone exceeded $3 billion—most of it in the health care industry.[3]

A typical action under the FCA has a variety of elements, including that a violation must be done "knowingly," which is defined by the statute as: (1) "actual knowledge of the information" at issue, (2) "deliberate ignorance of the truth or falsity of the information," or (3) "reckless disregard of the truth or falsity of the information." "[N]o proof of specific intent to defraud" is required.[4]

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The reckless disregard standard

In 1986, Congress added the reckless disregard prong to the FCA in order to clarify the standard of intent required for constructive knowledge (other portions of the statute have been amended several times since).[5] The Senate Report accompanying the bill states that the amendment "adopts the concept that individuals and contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek." The Senate Report further "defines this obligation as 'to make such inquiry as would be reasonable and prudent to conduct under the circumstances to ascertain the true and accurate basis of the claim.' Only those who act in 'gross negligence' of this duty will be found liable under the FCA." Finally, the Senate Report explains as follows:

> [T]he constructive knowledge definition attempts to reach what has become known as the 'ostrich' type situation where an individual has 'buried his head in the sand' and failed to make simple inquiries which would alert him that false claims are being submitted. While the Committee intends that at least some inquiry be made, the inquiry need only be 'reasonable and prudent under the circumstances[,'] which clearly recognizes a limited duty to inquire as opposed to a burdensome obligation. The phrase strikes a balance which was accurately described by the Department of Justice as 'designed to assure the skeptical both that mere negligence could not be punished by an overzealous agency and that artful defense counsel could not urge that the statute actually require some form of intent as an essential ingredient of proof.'

Leading court decisions on reckless disregard

Courts have interpreted the reckless disregard standard as requiring various iterations of "extreme" or "aggravated" gross negligence or somewhere "on a continuum between gross negligence and intentional harm."[6]

But what kinds of facts do or do not suffice to establish reckless disregard? Examining the case law, particularly several notable recent decisions, sheds some light on how a compliance professional or counsel can assess the risk of a reckless disregard finding.

In a recent decision from fall 2012, *United States ex rel. Williams v. Renal Care Group, Inc.*, the Sixth Circuit Court of Appeals found that the defendant health care providers had not acted with reckless disregard of the relevant Medicare statutes and regulations.[7] Defendant Renal Care Group, Inc. (RCG) was a dialysis provider that created a wholly-owned subsidiary, Renal Care Group Supply Company (RCGSC), to increase profits. Specifically, the subsidiary supplied in-home dialysis equipment that was reimbursed by Medicare at a higher rate than the parent company received for its services provided at a dialysis facility.

The Sixth Circuit found that the defendants did not act with reckless disregard of the relevant Medicare statutes and regulations because they "consistently sought clarification on the issue, followed industry practice in trying to sort through ambiguous regulations, and were forthright with government officials over [the subsidiary's] structure." Specifically, the Sixth Circuit held that "the defendants were not in reckless disregard of the truth or falsity of their claims" because:

1. The defendants sought legal counsel on this issue.
2. The defendants' legal counsel sought clarification on the rules from CMS officials.
3. The [RCG's outside counsel's] letter referenced a positive conversation with [a HCFA official], and her notes and billing records reflect as such.
4. The defendants were aware of large dialysis providers that had wholly owned subsidiaries filing for Method II reimbursements.
5. Industry publications openly encouraged the use of Method II reimbursements to increase profit.
6. RCGSC was a separately incorporated entity with its own Medicare supplier number; and
7. CMS and OIG knew of RCGSC's ownership structure.

Thus, the Sixth Circuit concluded that "[t]o deem such behavior 'reckless disregard' of controlling statutes and regulations imposes a burden on government contractors far higher than what Congress intended."

Similarly, in *United States ex rel. K & R Ltd. Partnership v. Massachusetts Housing Finance Agency*, 530 F.3d 980 (D.C. Cir. 2008), the D.C. Circuit Court of Appeals affirmed a grant of summary judgment, finding that the defendants did not act with reckless disregard of the relevant mortgage subsidy statutes and regulations where there was nothing to warn defendants away from the view they took of the regulations and the defendants brought the payment at issue to the government's attention.[8] Defendant MassHousing was a mortgage lender that sold tax-exempt bonds to investors to finance housing projects as part of its public mission to support affordable housing for low-income Massachusetts residents. Pursuant to a National Housing Act program, borrowers paid MassHousing 1% interest on their mortgages and MassHousing applied to the government for the difference between 1% and the actual interest on their bonds. In 1993, MassHousing used proceeds from new bonds to redeem or retire mostly higher interest bonds it used to finance mortgages and reaped substantial savings on its debt service, but did not pass along those savings to the government by reducing its claims for payments.

The D.C. Circuit held that MassHousing did not act with reckless disregard of the relevant mortgage subsidy statutes and regulations,

because its interpretation of the mortgage notes at issue was not unreasonable and there was no basis for MassHousing to conclude that it was. The D.C. Circuit explained that, although "the unreasonableness of MassHousing's interpretation is merely evidence, the absence of which does not preclude a finding of knowledge, . . . [the relator] point[ed] to nothing else 'that might have warned [MassHousing] away from the view it took.'"

Additionally, the D.C. Circuit noted that "MassHousing made no secret of the 1993 bond refund and during [a government agency] audit the next year, MassHousing specifically brought the 1993 refund to [the agency's] attention, albeit for a somewhat different issue." Finally, the D.C. Circuit noted that the agency continues to pay claims from MassHousing and although this fact "might not preclude a finding of knowledge, here that fact at least suggests MassHousing did not act with reckless disregard."

Likewise, in another recent decision, from summer 2012, *United States ex rel. Streck v. Allergan, Inc.*,[9] the U.S. District Court for the Eastern District of Pennsylvania partially granted defendants' motions to dismiss, holding that it could not plausibly be inferred that the defendants acted with reckless disregard during a time period when the relevant Medicaid guidance provided "nothing that warned [the defendants] away from the view they took."

Finally, in *United States ex rel. Burlbaw v. Orenduff*, the Tenth Circuit Court of Appeals affirmed a grant of summary judgment, finding that the defendants did not act with reckless disregard of the relevant Department of Defense minority set-aside statutes and regulations because the government authorized the conduct at issue.[10] Defendant New Mexico State University applied for and received Department of Defense set-aside contract grants on the basis that it was a "minority institution," as designated by the Department of Education, although the designation proved to be incorrect. The University relied on the Department of Education's designation "without independently verifying [its] statutory eligibility." The Tenth Circuit held that the University acted with mere negligence of the relevant Department of Defense statutes and regulations, and not reckless disregard, because there was no "scienter-based evidence in the record," "the government knowledge inference" applied, and "the text of the applicable statutory and regulatory scheme" supported the reasonableness of the University's actions. The government knowledge inference applies when the government has knowledge of the facts underlying an allegedly false claim and authorizes the contractor to make the claim. "In such a situation, an inference arises that the contractor has not 'knowingly' presented a fraudulent or false claim."

The Tenth Circuit explained that the government knowledge inference was "well-suited to the facts of this case" because the Department of Education had access to the University's enrollment data, reviewed this data, "repeatedly designated" the University as a minority institution, and based on these designations invited the University to apply for set-aside contracts. Finally, the Tenth Circuit concluded that "the texts of the applicable statutory and regulatory schemes help[ed] highlight the absence of scienter and confirm the reasonableness of defendants' reliance upon the [government's] confirmation of [the University's] eligibility." Specifically, the Tenth Circuit explained that that statutory and regulatory scheme "welcomed" the University's reliance upon the Department of Education's designation because it made the Department of Education responsible for verifying eligibility and made proof of such designation acceptable evidence of eligibility to participate in the set-aside program.

Key types of evidence supporting a finding of no reckless disregard

As set forth above, there is no single factor whose presence or absence can guarantee a particular ruling on the issue of reckless disregard. Instead, courts tend to use more of a totality of the circumstances approach and evaluate all facts in any given case. However, there are several key types of evidence relied on by courts to find that defendants have not violated the "reckless disregard" standard, examples of which are summarized as follows:

- Seeking and relying on advice of legal counsel, particularly outside counsel;
- Disclosure of the relevant facts to government regulators;
- Seeking guidance or clarification from government regulators;
- Approval or authorization by government regulators of the conduct at issue (particularly, as in *Orenduff*, where regulators have sufficient access to the relevant facts);
- The absence of red flags, contrary authority, or other indications of the unreasonableness of the interpretation of applicable regulations; or
- Following industry practice, especially if documented, (e.g., in industry publications).

There is no one factor among these that is required for a finding of no reckless disregard. For example, in the *MassHousing* case, the D.C. Circuit held that "MassHousing's failure to obtain a legal opinion or prior [agency] approval cannot support a finding of recklessness without evidence of anything that might have given it reasons to do so." Rather, the presence of one or more of the factors above would tend to mitigate against a finding of reckless disregard.

Conclusion

The FCA provides a significant source of potential liability for entities and individuals in the health care field. Compliance officers and legal advisors should be aware of the key types of evidence relied on by courts to rule that defendants did not act with reckless disregard. By keeping these factors in mind and responding accordingly, the risks of potential liability under the FCA may be mitigated.

Authors' note: This article is of a general nature and is not intended to be, nor should it be construed or relied upon to be, legal advice.

1. *See* 31 U.S.C. § 3729(a)(1).
2. *See* 31 U.S.C. § 3729(a)(1) & (a)(3); 28 C.F.R. § 85.3(a)(9); *see also United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 525 (6th Cir. 2012) ($86,642,592 in damages awarded at trial court level); *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) ($64 million in damages); *United States v. Bourseau*, 531 F.3d 1159, 1164 (9th Cir. 2008) ($15,688,585 in damages).
3. U.S. Department of Justice Fraud Statistics Overview, October 1, 1987 –September 30, 2011. Available at http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf
4. *See* 31 U.S.C. § 3729(b)(1).
5. *See* S. Rep. 99-345, at 20-21, 1986 U.S.C.C.A.N. 5266, 5285.
6. *See, e.g., United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008) ("Reckless disregard under the FCA is an extreme version of ordinary negligence.") (internal quotation marks omitted); *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 945 n.12 (10th Cir. 2008) ("[A]n aggravated form of gross negligence (i.e., reckless disregard) will satisfy the scienter requirement for an FCA violation."); *United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Grp., Inc.*, 370 F. Supp. 2d 18, 41 (D.D.C. 2005) ("Reckless disregard, as used in the FCA, lies on a continuum between gross negligence and intentional harm.") (internal quotation marks and emphasis omitted).
7. *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518 (6th Cir. 2012).
8. *United States ex rel. K & R Ltd. P'ship v. Mass. Hous. Fin. Agency*, 530 F.3d 980 (D.C. Cir. 2008).
9. *United States ex rel. Streck v. Allergan, Inc.*, 2012 U.S. Dist. LEXIS 92936 (E.D. Pa. July 3, 2012).
10. *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008).