Lack of Materiality as a Defense in False Claims Act Cases

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The False Claims Act (the "Act") imposes liability on those who "'knowingly' present, or cause to be presented, 'a false or fraudulent claim for payment or approval'" to the government.[1] Persons who act in "deliberate ignorance" of or in "reckless disregard" for the truth or falsity of a claim have the requisite level of knowledge to be liable under the Act.[2] No specific intent to defraud must be shown to impose liability.

The False Claims Act has been an especially effective hammer for the government against health care companies that seek payment under federal programs such as Medicare and Medicaid. In 2009, the government instituted its Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative. Since 2009, the Department of Justice has recovered a total of more than $23.8 billion through False Claims Act cases, with more than $15.2 billion of that amount recovered in cases involving fraud against health care programs.

The Materiality Standard Under the False Claims Act

The False Claims Act was never intended to address every conceivable fraud against the government. As noted by the United States Supreme Court:

> The False Claims Act was originally adopted following a series of sensational congressional investigations into the sale of provisions and munitions to the [government]. Testimony before Congress painted a sordid picture of how the United States had been billed for nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed in purchasing the necessities of war. Congress wanted to stop this plundering of the public treasury. At the same time it is equally clear that the False Claims Act was not designed to reach every kind of fraud practiced on the Government.[3]

For heavily regulated companies, such as health care companies, there are thousands of applicable laws, regulations and guidelines, and no company can be expected to comply with every law, regulation and guideline at all times. Courts have developed a mechanism to differentiate which violations actually go to the heart of a claim for federal money and which violations are inconsequential to a federal funding decision. This mechanism is known as "materiality."

Most Courts implicitly recognize that materiality is an element of False Claims Act liability. "If previously unclear, we now make explicit that the current civil False Claims Act imposes a materiality requirement."[4] Materiality is an element of liability that must be proved by the plaintiff by a preponderance of the evidence; it is not an affirmative defense that must be pled or waived.[5]

The U.S. Supreme Court has clarified that liability under Sections 3729(a)(2) and 3792(a)(3) of

1 31 U.S.C. § 3729(a)(1).
2 Id. § 3729(b).
3 *United States v. McNinch*, 356 U.S. 595, 599 (1958).
4 *United States ex rel. Berge v. Board of Trustees of University of Alabama*, 104 F.3d 1453, 1459 (4th Cir. 1997); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 679 (5th Cir. 2003) (en banc) (Jones, J., concurring) ("There should no longer be any doubt that materiality is an element of a civil False Claims Act Case. Our past precedent and every circuit that has addressed the issue have so concluded.").
5 *United States ex rel. Watson v. Connecticut General Life Ins. Co.*, 2003 U.S. Dist. LEXIS 2054 at *44 (E.D. Pa. Feb. 11, 2003).

the Act require that false statements be "material" to the government's decision to pay the claim.[6] "If a subcontractor or another defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim 'by the Government.' In such a situation, the direct link between the false statement and the Government's decision to pay or approve a false claim is too attenuated to establish liability."[7]

Initially, Courts defined "materiality" to be an actual prerequisite to payment such that an inaccuracy in a statement or claim would be considered "false" only if the government would not have paid the claim if it knew of the inaccuracy. More recently, the government has argued that the inaccuracy is material, and thus false, if it has a "natural tendency" to influence the government.[8] Under this standard, an inaccuracy could be considered material if it was deemed capable of influencing payment, even if the government would have paid the claim notwithstanding the alleged inaccuracy.

> As one commenter has noted:
>
> Prior to 1986, when the [Act] was enforced almost entirely by the Justice Department, most [False Claims Act] complaints relied on what may be referred to as 'traditional' fraud—claims for substandard products, claims based on timecard mischarging, claims in contracts procured by bribery, etc. In most such cases, there was no question that the agency would not have paid the claims had it known of the fraud, so materiality was never an issue.
>
> After 1986, when [False Claims Act] enforcement was significantly expanded to affirmatively encourage enforcement by private parties, qui tam relators (and to a lesser extent the expanded Justice Department) began pushing the application of the [False Claims Act] beyond the more traditional areas of enforcement. In this new era, [False Claims Act] cases began to be based on allegations that claims to the government contained 'certification' (either express or implied) of compliance with other laws, regulations, guidelines, or standards."[9]

In May 2009, the Fraud Enforcement and Recovery Act ("FERA") was signed into law. FERA amended the False Claims Act, by, among other things, making the "materiality" requirement explicit for two subsections of the Act, and by defining "materiality" as "having a natural tendency to influence, or by capable of influencing, the payment or receipt of money or property" in Section 3729(b)(4). Despite the "natural tendency" definition of materiality in FERA, recent decisions in a growing number of circuits have emphasized that there must be a knowing violation of a clear prerequisite to payment in order to establish a False Claims Act violation under FERA.[10]

Examples of Court Rulings on Whether Fraud Was "Material" Under the Act

As discussed above, the Act "imposes liability not for defrauding the government generally; it instead only prohibits a narrow species of fraudulent activity: present[ing] or caus[ing] to be presented, . . . a false or fraudulent claim for payment or approval."[11] The Act "attaches liability not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'"[12]

If the government in a False Claims Act case cannot show that the defendant's alleged violation of a statute, regulation, contract or standard of conduct was a condition of payment, rather than a condition of participation in the government program, such a claim cannot survive as a matter of law under most circuits. For example, the following allegations were determined by the Courts to be insufficient to maintain a cause of action under the Act:

1. Allegations that a hospital that violated Medicare conditions of participation did not state a claim under the Act because the government would have continued to reimburse the hospital's claims for at least some period of

6 *Allison Engine v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2126-31 (2008).
7 *Id.* at 2130.
8 *United States v. Southland Mgmt. Corp.* 326 F.3d 669, 679 (5th Cir. 2003); United States v. Rogan, 517 F.3d 449 (7th Cir. 2008).
9 John T. Boese, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS, § 2.04[A] (2014 Supplement).
10 *United States ex rel. Hobbs v. MedQuest Assoc.*, 711 F.3d 707 (6th Cir. 2013); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295 (3d Cir. 2011); *United States ex rel. Steury v. Cardinal Health, Inc.,* 625 F.3d 262 (5th Cir. 2010).
11 *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 501 F.3d 493, 504 (6th Cir. 2007) (citations omitted).
12 *Id.* (quotations omitted).

time.[13]

2. Allegations that defendant companies overcharged federal health care programs for substandard care were not actionable under the Act because the alleged false certifications in defendants' Medicaid reports were conditions of participation rather than of payment.[14]

3. Allegations that a Medicare supply company violated Medicare supplier standards did not state a claim under the Act because the satisfaction of the Medicare standards was a condition of participation under Medicare, not a condition of payment.[15]

4. Allegations that a drug company failed to report an adverse event under FDA reporting procedures did not establish a claim under the Act because the "relator has not adequately established that compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue. . . ."[16]

5. Allegations that a managed care company violated marketing regulations did not state a claim under the Act because "the Government's payments of appellees' Medicare claims were not conditioned on their compliance with the marketing regulations."[17]

6. Allegations of unnecessary surgeries did state a claim for liability under the Act where the alleged false certifications were not material to the government's payment system under a capitated payment system.[18]

7. Allegations that a diagnostic testing facility breached regulations regarding physician supervision did not establish a claim under the Act because such regulations were conditions of participation and "do not mandate the extraordinary remedies of the [Act] and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program."[19]

Conclusion

As the cases above demonstrate, there is an important distinction between regulations that are prerequisites to payment and those that are merely conditions of participation in a federal program. A claim is in violation of the Act if it "is aimed at extracting money the government otherwise would not have paid."[20] Because the False Claims Act is "aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced that government's decision to pay. Accordingly, . . . it does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions."[21]

13 *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, 525 F. Supp. 2d 972, 978-79 (W.D. Tenn. 2007).
14 *United States ex rel. Lacy v. New Horizons, Inc.*, 2008 WL 4415648 (W.D. Okla. Sept. 25, 2008).
15 *United States ex rel. Williams v. Renal Care Group, Inc.*, 696 F.3d 518, 532 (6th Cir. 2012).
16 *United States v. Takeda Pharm Co.*, No. 10-11043-FDS (D. Mass. Nov. 1, 2012), *aff'd other grounds*, 737 F.3d 116 (1st Cir. 2013).
17 *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 308 (3d Cir. 2011).
18 *United States ex rel. Zemplenyi v. Group Health Coop.*, 2011 WL 8214261 (W.D. Wash. Mar. 3, 2011).
19 *United States ex rel. Hobbs. v. MedQuest Assocs.*, 711 F.3d 707, 713 (6th Cir. 2013).
20 *United States ex re. Mikes v. Strauss*, 274 F.3d 687, 696 (2d Cir. 2001).
21 *Id.* at 697.

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