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PRATT'S
**GOVERNMENT
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REPORT



**EDITOR'S NOTE: RINGING IN THE
NEW YEAR!**

Steven A. Meyerowitz

**WHEN A VIOLATION OF A RULE
OR REGULATION BECOMES AN FCA
VIOLATION: UNDERSTANDING THE
DISTINCTION BETWEEN CONDITIONS
OF PAYMENT AND CONDITIONS OF
PARTICIPATION**

Robert S. Salcido

**RECENT FALSE CLAIMS
ACT SETTLEMENTS HIGHLIGHT
PHYSICIAN COMPENSATION SCRUTINY**

Hal A. Goldsmith and Anne P. Sharamitaro

**CYBERSECURITY FOR GOVERNMENT
CONTRACTORS: NEW CONTROLLED
UNCLASSIFIED INFORMATION
REQUIREMENTS SLOWLY TAKE SHAPE**

Scott A. Schipma

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Editor's Note: Ringing in the New Year!

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1

When a Violation of a Rule or Regulation Becomes an FCA Violation: Understanding the Distinction Between Conditions of Payment and Conditions of Participation

Robert S. Salcido

3

Recent False Claims Act Settlements Highlight Physician Compensation Scrutiny

Hal A. Goldsmith and Anne P. Sharamitaro

15

Cybersecurity for Government Contractors: New Controlled Unclassified Information Requirements Slowly Take Shape

Scott A. Schipma

19

Federal Contractors Will Have To Provide Paid Sick Time

Francine Esposito and Arielle B. Sepulveda

26

In the Courts

Steven A. Meyerowitz

30

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When a Violation of a Rule or Regulation Becomes an FCA Violation: Understanding the Distinction Between Conditions of Payment and Conditions of Participation

*By Robert S. Salcido**

The author of this article explores the question: “When does a technical violation of a rule or regulation result in a False Claims Act violation?”

A common issue that any person who conducts business with the government confronts is this: When does a perceived rule violation or contractual breach result in potential False Claims Act (“FCA”) violations, subjecting the person to treble damages and substantial civil penalties?

This question is particularly pressing for those participating in Medicare and Medicaid programs. Prior to participation in these programs, health care providers and suppliers must enter into various agreements certifying that they will adhere to various rules and regulations. When submitting claims for payment or cost reports, health care entities must also certify that they complied with various federal and state rules and regulations.

However, some of the rules and regulations to which they certify compliance are trivial in nature and would not, and should not, result in the denial of payment on a claim if the service is covered and otherwise appropriately performed. For example, FCA actions have been predicated upon a company using a rubber-stamped signature rather than the physician’s handwritten or electronic signature¹ or a skilled nursing facility failing to provide residents with nutritional snacks contrary to law.² Most would agree that these transgressions are better addressed through provider education or a corrective action plan rather than denial of payment on the claim plus treble damages plus the imposition of substantial civil penalties. This is especially true when, as one

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¹ See, e.g., *United States ex rel. Keltner v. Lakeshore Med. Clinic*, No. 11-CV-00892, 2013 U.S. Dist. LEXIS 44640, at *17–18 (E.D. Wis. Mar. 28, 2013) (ruling that the FCA would not apply under these circumstances).

² *United States ex rel. Sweeney v. Manorcare Health Services, Inc.*, No. CO3-5320, 2005 U.S. Dist. LEXIS 45216 at *13–*14 (W.D. Wash. Mar. 4, 2005).

court has noted, “Medicare regulations are among the most completely impenetrable texts within human experience,”³ and “anyone examining Medicare regulations would conclude that they are so complicated that the best intentioned plan participant could make errors in attempting to comply with them.”⁴

However, FCA plaintiffs contend that, whenever governmental rules are breached, an FCA claim may be filed based upon the logic that the value of full compliance with law is factored into every claim and that if the government knew it would receive less, it would pay less on the claim, or not at all. Based upon this reasoning, FCA plaintiffs have filed lawsuits when:

- a hospital violates Medicare conditions of participation (such as not having an adequate number of nurses to provide nursing care);
- a skilled nursing facility fails to provide “quality of care;”
- a Medicare supply company violates Medicare Supplier Standards;
- a drug company fails to report an “adverse event” under the FDA’s reporting procedures;
- an end-stage renal disease facility violates conditions of coverage;
- a managed care entity violates marketing regulations;
- an independent diagnostic testing facility breaches regulations regarding physician supervision;
- a healthcare company violates HIPAA;
- a drug company knowingly violates the FDA’s Current Good Manufacturing Practice regulations; and
- health care entities violate state licensing rules or corporate practice of medicine doctrine.⁵

THE PRECISE ISSUE

Thus, the relevant FCA issue is when does a technical violation of a rule or regulation result in an FCA violation?

³ *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 770 (N.D. Tex. 2003) (internal quotation and citation omitted), *aff’d in relevant part*, 2008 U.S. App. LEXIS 17946 (5th Cir. Aug. 19, 2008).

⁴ *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 310–11 (3d Cir. 2011).

⁵ For a detailed discussion of the relevant court precedents illustrating each of these cases, see Robert Salcido, *False Claims Act & Healthcare Industry: Counseling & Litigation* § 2:03 (American Health Lawyers Ass’n Supp. 2014); see generally Robert Salcido, *False Claims Act & Health care Industry: Counseling & Litigation* (2d ed. American Health Lawyers Ass’n 2008).

THE TECHNICALLY CORRECT ANSWER

A violation of a technical rule or regulation results in an FCA violation only when the violation, under the pertinent regulatory scheme, actually causes the government to incur immediate financial detriment, that is, to constitute a “claim” made upon the government. Courts have conceptualized this principle by distinguishing what are known as conditions of participation, which do not result in FCA liability, from conditions of payment, which do potentially trigger FCA liability.⁶

ANALYSIS

This answer flows from the FCA’s title, language, case law, and purpose.

Title and Language

As the FCA’s title makes clear, it is a “False *Claims Act*.” The word “claim,” since 1986, has been a defined term in the FCA, meaning any “request or demand” for “money or property.” The statutory word “false” coupled with the word “claim,” suggests that “an improper claim is aimed at extracting money the government otherwise would not have paid.”⁷ Thus, under its plain terms, the FCA applies only when the alleged breach would result in the government denying or reducing payment.⁸

⁶ Courts find that conditions of participation are those where violations may trigger administrative sanctions (like the imposition of a corrective action plan), but will not necessarily result in the government’s denial of payment, whereas conditions of payment are those where, if the government knew that the condition was not being followed, it would refuse payment. *See, e.g., United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 799 (8th Cir. 2011) (ruling that the relator “must plead and prove that [the defendant’s] allegedly false Certifications were conditions of payment—‘those which, if the government knew they were not being followed, might cause it to actually refuse payment’” and noting that, by contrast, “if the regulatory violations were only conditions of . . . participation, they ‘are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program’”).

⁷ *See United States ex rel. Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001) (“The juxtaposition of the word ‘false’ with the word ‘fraudulent’, plus the meaning of the words comprising the phrase ‘false claim,’ suggest an improper claim is aimed at extracting money the government otherwise would not have paid”).

⁸ *See id.* (“The language of [the FCA] plainly links [a defendant’s] wrongful activity to the government’s *decision to pay*”) (emphasis added); *United States ex rel. Costner v. URS Consultants, Inc.*, 153 F.3d 667, 677 (8th Cir. 1998) (noting in “*United States v. McNinch*, the Supreme Court suggested that a ‘claim’ under the FCA is a ‘demand for money’ that induces the government to disburse funds or ‘otherwise suffer immediate financial detriment’. 356 U.S. 595, 599 . . . (1958)” and that “[e]ssentially, then, only those actions by the claimant *which have the*

Court Precedent

Consistent with the FCA's title and language, FCA case law, in a number of contexts, has underscored the importance of the plaintiff establishing clear linkage between the alleged fraud and the actual claim for payment under which the government experiences immediate financial detriment.

Specifically, courts have focused upon the meaning of the word "claim." As the 9th Circuit has recently noted, "It seems to be a fairly obvious notion that a False Claims Act suit ought to require a false claim."⁹ 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.'"¹⁰ "Therefore, a central question in False Claims Act cases is whether the defendant ever presented a 'false or fraudulent claim' to the government."¹¹ Indeed, multiple courts have pointed out that an "actual false claim is 'the sine qua non of a[n

purpose and effect of causing the United States to pay out money it is not obligated to pay . . . are properly considered 'claims' within the meaning of the FCA") (emphasis supplied). Indeed, in multiple cases, the Supreme Court has been careful to link application of the FCA to actual claims for payment. *See, e.g., United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943) (stating that the purpose of the FCA "was to provide for restitution to the government of *money taken from it by fraud*") (emphasis supplied); *Rainwater v. United States*, 356 U.S. 590, 592 (1958) ("It seems quite clear that the objective of Congress was broadly to *protect the funds and property of the government from fraudulent claims.*") (emphasis supplied); *United States v. Bornstein*, 423 U.S. 303, 309 n.4 (1976) ("[t]he conception of a claim against the government normally *connotes a demand for money or for some transfer of public property.*") (emphasis supplied). Indeed, even in *United States v. Neifert-White*, which is generally cited as the Supreme Court's endorsement of an expansive interpretation of the FCA, because it speaks to the FCA reaching "all fraudulent attempts," the remainder of the oft-quoted passage dramatically limits the FCA by linking the fraudulent attempts to causing "the Government to pay out sums of money." *United States v. Neifert-White Co.*, 390 U.S. 228, 233, 19 L. Ed. 2d 1061, 88 S. Ct. 959 (1968) (False Claims Act reaches to "all fraudulent attempts to *cause the Government to pay out sums of money.*") (emphasis supplied). *See also United States v. McNinch*, 356 U.S. 595, 599 (1958) (the "False Claims Act was not designed to reach every kind of fraud practiced on the Government").

⁹ *United States ex rel. Cafasso v. General Dynamics C4 Sys.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 997 (9th Cir. 2002)); *see also United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1173 (9th Cir. 2006) ("[F]or a false statement or cause of action to be actionable . . . , it is necessary that it involve an actual claim"); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996) ("The FCA . . . requires a false claim").

¹⁰ *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).

¹¹ *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999).

FCA] violation.”¹² Similarly, courts have ruled that FCA plaintiffs cannot state a false statement cause of action, unless they show that the false statement resulted in the submission of a false claim.¹³

Aside from the meaning of the word “claim,” courts have also focused on the FCA’s structure in limiting its application to when the government confronts immediate financial detriment. Specifically, the FCA “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.’”¹⁴ If the FCA were intended simply to apply to fraudulent schemes, without tracing the alleged conduct to discrete claims from which the government would suffer financial loss, then Congress

¹² *Aflatooni*, 314 F.3d at 1002 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002)); see also *Cafasso*, 637 F.3d at 1055; *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 618 F.3d 505, 513 (6th Cir. 2010); *United States ex rel. Rost v. Pfizer, Inc.* 507 F.3d 720, 727 (1st Cir. 2007). See generally *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 71 (D.D.C. 2007) (holding when a relator cannot “point to a single, specific false claim” or sufficiently describe one, he has “failed to create a triable issue of fact”).

¹³ For example, because, in 2009, Congress clarified the meaning of the statutory definition of claim in other respects and the statutory language governing what constitutes an actionable false statement, some plaintiffs asserted that one can assert a violation of the FCA based upon the preparation of a false statement without reference to a false claim as a result of Congress’ 2009 amendments. Courts have rejected this position. See, e.g., *United States ex rel. Folliard v. CDW Gov’t, Inc.*, 722 F. Supp. 2d 20, 35 (D.D.C. 2010) (“Relator is also mistaken that FERA eliminated the need to allege and prove the existence of a false claim.” First, this argument ignores the titular premise of the False Claims Act. Second, the statutory text plainly prohibits the use of a false statement “material to a false or fraudulent claim,” 31 U.S.C. § 3729(a)(1)(B) (West 2010), which presupposes the existence of a claim. Third, even if the statute were unclear, the legislative history clarifies that Congress also presupposed the existence of a claim: “liability under [the revised] section 3729(a) attaches *whenever a person knowingly makes a false claim to obtain money or property*, any part of which is provided by the Government without regard to whether the wrongdoer deals directly with the Federal Government; with an agent acting on the Government’s behalf; or with a third party contractor, grantee, or other recipient of such money or property.” S. Rep. 110-10 at 11 (emphasis added); see also *id.* at 10–11 (seeking to eliminate the “exempti[on] [for] subcontractors *who knowingly submit false claims* to general contractors and are paid with Government funds” (emphasis added)). *Id.* (footnote omitted). See also *United States ex rel. Kester v. Novartis Pharms. Corp.*, 2014 U.S. Dist. LEXIS 74461 at *25–26 (S.D.N.Y. May 29, 2014) (subsection (a)(1)(B) “contains a ‘double falsity’ requirement—the plaintiff must plead both a false statement and a corresponding false claim In short, the submission of a ‘claim’ is an essential element of causes of action under subsections (a)(1)(A) and (a)(1)(B)” (citations omitted)).

¹⁴ *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) (citation omitted).

would not have needed to set forth the specific types of conduct that would result in FCA liability or specifically define the meaning of the word “claim.”

Statutory Purpose

Finally, this construction—requiring that the alleged violation be an actual condition of payment, and not simply a condition of participation—is consistent with not just the statutory language and case law, but also the statutory purpose to protect the federal treasury. An interpretation that the FCA applies to every violation of a rule, regulation or standard regardless of whether it had a direct impact on a governmental determination to pay a claim would transform the FCA into “some super enforcement tool”¹⁵ that is “almost boundless”¹⁶ and that operates as “an all-purpose antifraud statute”¹⁷ intended to enforce every regulation or rule on the books.¹⁸ Such an interpretation, aside from being contrary to the statute and Supreme Court precedent, would simply lead to “more collateral litigation under the False Claims Act,”¹⁹ which relators and the government may seek, but courts would reject.²⁰

¹⁵ See *United States ex rel. Am. Textile Mfrs. Inst. v. Limited, Inc.*, No. C2-97-776, 1997 U.S. Dist. LEXIS 18142 at *42 (S.D. Ohio Nov. 13, 1997) (describing the limited scope of the FCA), *aff’d* 190 F.3d 729 (6th Cir. 1999).

¹⁶ See *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 496 (D.C. Cir. 2004) (rejecting FCA construction that would result in “almost boundless” reach).

¹⁷ See *United States ex rel. Hopper v. Solway Pharms., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009) (noting that the FCA is not “an all-purpose antifraud statute”) (quoting *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). See also *United States ex rel. Campie v. Gilead Sci., Inc.*, No. C-11-0941, 2015 U.S. Dist. LEXIS 1635, at *24 (N.D. Cal., Jan. 7, 2015) (“the FCA is not a catchall anti-fraud provision”) (citation omitted).

¹⁸ *United States v. Sanford-Brown*, 788 F.3d 696, 711 (7th Cir. 2015) (ruling that it would be “unreasonable” for court to hold “that an institution’s continued compliance with the thousands of pages of federal statutes and regulations incorporated by reference into a [Program Participation Agreement] are conditions of payment for purposes of liability under the FCA”) (footnote omitted).

¹⁹ *Totten*, 380 F.3d at 497.

²⁰ The government, for example, before courts, has objected to the distinction between “conditions of payment” and “conditions of participation” and the corresponding analytical framework that distinguishes “legal falsity” from “factual falsity” and “express certifications” from “implied certifications.” However courts have routinely rejected the government’s objections. For example, eight circuits analyze the FCA from the framework of express versus implied certifications; only one circuit has adopted the government’s rejection of this terminology. The eight circuits that have explicitly rejected the government’s preferred approach and have, instead, considered whether express or implied false certifications have been submitted to the government are: *United States ex rel. Badr v. Triple Canopy, Inc.*, 775 F.3d 628, 635–36 (4th Cir. 2015); *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 306 (3d Cir. 2011); *United*

CONCLUSIONS AND APPLICATIONS

Given the above, courts, as they have consistently ruled in countless cases, are correct in insisting that mere regulatory or contractual violations are insufficient to trigger FCA liability.²¹

States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1266–67 (D.C. Cir. 2010); *United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 996–98 (9th Cir. 2010); *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002); *United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 696 (2d Cir. 2001). Indeed, the government's views were rejected, notwithstanding the fact that, in several actions it submitted Statements of Interest advocating a viewpoint different from what the court adopted. *See, e.g.*, Br. for United States, at 35, *United States ex rel. Hobbs v. MedQuest Assocs.*, No. 11-6520 (6th Cir. May 18, 2012); Br. for United States, at 16–17, *United States ex rel. Steury v. Cardinal Health, Inc.*, No. 12-20314 (5th Cir. Aug. 2, 2012); Br. for United States, at 24, *United States ex rel. Absber v. Mommence Meadows Nursing Ctr., Inc.*, Nos. 13-1886, 13-1936 (7th Cir. Sept. 26, 2013). Moreover, contrary to the government's position that distinguishing between conditions of participation and conditions of payment is not a useful exercise to evaluate potential liability under the FCA, as of July 31, 2015, a simple Lexis search of the phrases "conditions of participation" and "conditions of payment" and "False Claims Act" generated 121 citations. The reason for the overwhelming, almost uniform court rejection of the government's position is that consistent with statutory language and purpose, the use of this framework avoids transforming the FCA into "some super enforcement tool" that is "almost boundless" and that operates as "an all-purpose antifraud statute" intended to enforce every regulation or rule on the books.

²¹ *United States ex rel. Dunn v. N. Mem'l Health Care & N. Mem'l Med. Ctr.*, 739 F.3d 417, 419 (8th Cir. 2014); *United States ex rel. Ketrosor v. Mayo Found.*, 729 F.3d 825, 829 (8th Cir. 2013) (no FCA liability because relators alleged "nothing more than regulatory noncompliance"); *United States ex rel. Onnen v. Sioux Falls Indep. School Dist. No. 49-5*, 688 F.3d 410, 414 (8th Cir. 2012) ("The FCA is not concerned with regulatory noncompliance"); *United States ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011) (finding that the FCA is not concerned with regulatory noncompliance, but "serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money") (emphasis supplied); *see also United States ex rel. Urquilla-Diaz v. Kaplan Univ.*, No. 13-13672, 2015 U.S. App. LEXIS at *6 (11th Cir. Mar. 11, 2015) ("Liability under the False Claims Act arises from the submission of a fraudulent claim to the government, not the disregard of government regulations or failure to maintain proper internal procedures") (quoting *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1012 (11th Cir. 2005)); *United States ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 717 (6th Cir. 2013) (noting that the FCA "is not a vehicle to police technical compliance with complex federal regulations" and that the "blunt[ness]" of the FCA's hefty fines and penalties makes them an inappropriate tool for ensuring compliance with technical and local program requirements") (citation omitted); *United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 532 (6th Cir. 2012) (the FCA "is not a vehicle to police technical compliance with complex federal regulations"); *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) ("The FCA is not a general

However, when does a knowing violation of a rule, regulation or standard morph into an FCA violation? One situation is when the relevant rule expressly conditions payment on compliance with the rule. For example, the Medicare Act requires that services be medically necessary and reasonable as a condition of payment, and, if they are not, the government denies payment.²² Under these circumstances, compliance with the statute would be a condition of payment.

Other variations are trickier. For example, at times, the government may state that a condition of participation is a condition of payment.²³ Courts have mainly rejected the general statement that compliance with what is truly a condition of participation can be transformed into a condition of payment if the government in fact does not treat the violation as a condition of payment.²⁴ Of course, where the statute or regulation is silent, and the government has a range of administrative remedies, then, by definition, the rule is a condition of participation, and there is no FCA liability.

Thus, whenever confronting the issue, a defendant should ask: “Does the statute or regulation speak directly to the issue?” If not, and the statutory or regulatory scheme provides the government with a range of administrative remedies, then the violation is a condition of participation and hence not actionable under the FCA, because the government is not placed in immediate

‘enforcement device’ for federal statutes, regulations, and contracts”) (citations omitted).

²² See, e.g., *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (noting that, because the Medicare Act’s medical necessity provision “contains an express condition of payment—that is, ‘no payment may be made’—it explicitly links each Medicare *payment* to the requirement that the particular item or service be ‘reasonable and necessary’” and thus precludes the government from reimbursing a Medicare provider who fails to comply and consequently is a condition of payment when, in fact, the government does reduce payment based upon the alleged infraction).

²³ See, e.g., CMS Enrollment Forms (noting that compliance with conditions of participation are a condition of payment); see generally Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6407, 124 Stat. 119, 769–70 (2010) (mandating as an express “condition of payment” that the physician certify and document in specified fashion a face-to-face encounter with a patient for the patient to be eligible for home health services).

²⁴ See, e.g., *United States ex rel. Parikh v. Citizens Med. Ctr.*, 6:10-CV-64, 2013 U.S. Dist. LEXIS 134693, at *49–55 (S.D. Tex. Sept. 20, 2013) (noting that the relator’s response that the express language of CMS-855A forms states that compliance with conditions of participation are a condition of payment lacked merit, because, if this contractual language could convert a condition of participation into a condition of payment, it would “drastically expand the role of the courts in policing regulations in an area traditionally governed by administrative agencies”); *United States ex rel. Wall v. Vista Hospice Care*, 778 F. Supp. 2d 709, 721 (N.D. Tex. 2011) (same).

financial detriment, and there is, by definition, no “false” “claim.”²⁵ Alterna-

²⁵ For just a general listing of the relevant FCA case law, *see*:

1st Circuit: United States ex rel. Ge v. Takeda Pharm. Co., No. 10-11043, 2012 U.S. Dist. LEXIS 156752 at *19–20 (D. Mass. Nov. 1, 2012) (ruling that the legal requirement that drug companies report adverse events is a condition of participation, because the “FDA has discretion to take a number of different actions should a drug manufacturer violate the adverse-event reporting requirements” and thus because the “relator has not adequately established compliance with adverse-event reporting procedures was a material precondition to payment of the claims at issue, the complaints do not state a claim upon which relief can be granted under Rule 12(b)(6)”), *aff’d other grounds*, 737 F.3d 116 (1st Cir. 2013).

2nd Circuit: United States ex rel. Blundell v. Dialysis Clinic, Inc., No. 5:09 CV 00710, 2011 U.S. Dist. LEXIS 4862, at *54 (N.D.N.Y. Jan. 19, 2011) (finding that defendant’s alleged violation of “Conditions for Coverage for End-Stage Renal Disease Facilities” constituted conditions of participation and not a condition to payment and, hence, did not result in FCA liability).

3rd Circuit: United States ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 308 (3d Cir. 2011) (an allegation that “appellees violated the regulations do[es] not state a plausible claim for relief under the FCA inasmuch as the Government’s payments of appellees’ Medicare claims were not conditioned on their compliance with the marketing regulations”).

5th Circuit: United States ex rel. Wall v. Vista Hospice Care, 778 F. Supp. 2d 709, 721 (N.D. Tex. 2011) (rejecting the relator’s contention that, merely because the defendant hospice’s CMS-855A enrollment form stated that hospice understood that “payment of the claim by Medicare is conditioned . . . on the provider’s compliance with all applicable conditions of participation in Medicare,” compliance with condition of participation became a condition of payment because, “if merely signing this form converts a condition of participation into a condition of payment, then every hospice provider not fully complying with all conditions of participation may be held liable under the FCA, thus undermining the distinction between conditions of payment and participation, as well as Medicare’s internal administrative structure, to deal with violations of conditions of participation. To so hold would burden federal courts with what should be administrative determinations of whether medical services were performed in compliance with Medicare statutes and regulations governing participation. Courts are not the place where such issues are to first be resolved. Therefore, although the CMS-855A form purports to condition payment on compliance with ‘all applicable conditions of participation,’ this Court does not read that form as mandating an extension of FCA liability to every statement certifying compliance with any Medicare statute or regulation relating to conditions of participation”).

6th Circuit: United States ex rel. Hobbs v. MedQuest Assocs. Inc., 711 F.3d 707, 712–13 (6th Cir. 2013) (rejecting the government’s contention that the defendant independent diagnostic testing facility’s (IDTF) violation of the regulation requiring that services mandating a physician’s direct or personal supervision must be supervised by a physician designated as a supervising physician on the IDTF’s CMS enrollment form and its failure to properly enroll in the Medicare program and instead submitting claims under a physician’s billing number, did not violate the FCA, because the regulations violated were conditions of participation and not conditions of payment, and, hence “do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program”); *United States ex rel. Williams v. Renal Care Grp.*, 696 F.3d 518, 531–32

tively, if the statute or regulation does speak to the issue, then the defendant

(6th Cir. 2012) (rejecting the government’s contention that the dialysis supplier’s breach of Medicare’s Supplier Standards because it was only an alleged “billing conduit” breached the FCA because satisfaction of Medicare standards for dialysis suppliers were a condition of participation that provide for an independent sanction, and, hence, there is no FCA liability “irrespective of whether [defendants] in fact violated the regulations”); *United States ex rel. Landers v. Baptist Mem’l Health Care Corp.*, 525 F. Supp. 2d 972, 975, 978–79 (W.D. Tenn. 2007) (finding breaches of conditions of participation for hospitals—such as having an adequate number of nurses and other personnel to provide nursing care; having policies governing surgical care designed to ensure the achievement and maintenance of high standards of medical practice and patient care, and providing a sanitary environment—did not result in FCA liability, because even though “Defendants’ alleged non-compliance with Conditions of Participation may lead to prospective corrective action or even termination, Plaintiff has not presented any evidence that Defendants would have been ineligible to receive payment of its Medicare claims during a potential period of non-compliance,” but the government would, notwithstanding the breach, have continued to reimburse their claims for at least a period of time).

7th Circuit: United States ex rel. Upton v. Family Health Network, Inc., No. 09-cv-6022, 2012 U.S. Dist. LEXIS 141238 at *31–32 (N.D. Ill. Oct. 1, 2012) (dismissing relators’ complaint alleging that defendant, a managed care organization, falsely certified compliance with contractual provisions with a state Medicaid agency providing that defendant would not refuse to enroll Medicaid recipients based upon their medical condition, because they “do not . . . explain how Defendants’ certifications are conditions for payment, nor do they cite any contractual provision that supports that proposition”). *Cf. United States v. Sanford-Brown*, 788 F.3d 696, 711–12 (7th Cir. 2015) (finding that, when the government admits that not all violations of the regulatory scheme would constitute an FCA violation and “the agency’s regulations have at all times provided—and continue to provide—a governmental enforcement mechanism in the form of an administrative proceeding before the subsidizing agency, whereby any evidence of violations of conditions of participation may be considered and adjudicated,” the relator cannot state an FCA cause of action because, compliance should be evaluated and adjudicated by the agency and not by courts).

8th Circuit: Vigil, 639 F.3d at 799–800 (affirming FCA dismissal where an alleged regulatory breach “may have jeopardized” defendant’s “continued *participation* in the various . . . programs,” but “it is implausible to believe, and the Complaint does not even allege, that these past violations would have affected decisions” by the government to pay) (emphasis in original).

9th Circuit: United States ex rel. Campie v. Gilead Sci., Inc., No. C-11-0941, 2015 U.S. Dist. LEXIS 77261 at *18–24 (N.D. Cal., June 12, 2015) (ruling that an alleged failure to obtain FDA approval of an alleged major change in the manufacturing process when the manufacturing source of a previously approved drug was changed to an unregistered and uninspected plant there was no FCA violation, because, although “failure to get the needed supplemental approval may lead to other consequences” for the defendant, the relator “failed to cite to, e.g., a statute, rule, or regulation that makes payment conditioned on *supplemental* approval by the FDA,” and noting that “to determine materiality under the FCA and the ‘but-for cause in the chain of causation’ analysis advocated by Plaintiff, the Court would have to determine whether the FDA would have in fact approved each drug in question. Given the wide range of administrative responses and action that could have been taken by the FDA (e.g., corrective notices, warnings, plan of remediation, requirement of monitoring), the Court would be tasked not only with determining

should inquire into how the government has historically enforced the provision. If the administrative case law reveals that the government did not deny payment based upon the alleged infraction, then the violation is a condition of

whether a falsity was presented to the FDA, but also predicting the institutional response of the FDA and the ultimate outcome of the specialized and complex administrative proceeding. Given the range of actions available to the FDA, this would be a daunting task. The court is ill-equipped to make that kind of prediction. Such an inquiry stands in contrast to the inquiry in a more typical FCA case—determining whether a particular statement or certification made to the payor agency is in fact false and material to the decision to pay. Absent a clear directive from Congress, the Court is unwilling to read into the FCA such an expansive sweep,” that (citation omitted); *United States ex rel. Huey v. Summit Healthcare Ass’n, Inc.*, No. CV-10-8003, 2011 U.S. Dist. LEXIS 26740 at *17 (D. Ariz. Mar. 2, 2011) (rejecting the relator’s allegation that defendant hospital breached FCA because of its nurse supervision practices because in “the Medicare context, . . . conditions of participation, unlike conditions of payment, are insufficiently related to the government’s payment decision to form the basis of an FCA claim”); *Sweeney v. ManorCare Health Servs., Inc.*, No. C03-5320RJB, 2005 U.S. Dist. LEXIS 45216 at *4, *11–14 (W.D. Wash. Mar. 4, 2005) (dismissing the relator’s Medicare FCA complaint where the relator alleged the nursing home did not provide prescribed snacks and nutritional supplements to residents because, notwithstanding plaintiff’s contention that defendant failed to adhere to state and federal regulations concerning the quality of care to be provided to nursing home residents, the relator did not state a cause of action, because the relator did not show that regulatory violations were conditions of payment, but were only “conditions of participation in the Medicare and Medicaid programs. Moreover, there are administrative and other remedies for regulatory violations.”) (internal quotations omitted).

11th Circuit: United States ex rel. Ortolano v. Amin Radiology, No. 5:10-cv-583, 2015 U.S. Dist. LEXIS 9724, at *29–30 (M.D. Fla. Jan. 28, 2015) (vacating the jury verdict in the relator’s favor and entering judgment for the defendant, because violation of Florida law mandating that only a nuclear medicine technologist is authorized to perform the entirety of a PET/CT scan was “at most, a condition of participation, and not a condition of payment,” because there was a “complete absence of any statutory, regulatory, decisional, or other viable authority suggesting that a failure to comply with Florida’s licensing laws with respect to radiation and nuclear medicine testing is a condition of payment under Medicare, Medicaid, or Tricare” and noting that the only way to accept the relator’s theory is by “weaving together isolated phrases from several sections in the complex scheme of Medicare regulations, as well as portions of Florida statutes.” This “cut-and-paste approach is not supported by the structure of the regulatory scheme, and it is not reasonable to expect Medicare, [Medicaid, or Tricare] providers to attempt such an approach to statutory interpretation in their efforts to comply with the FCA”) (internal quotation and citations omitted).

See also United States ex rel. Davis v. District of Columbia, No. 14-7060, 2015 U.S. App. LEXIS 11902, at *12–13 (D.C. Cir. July 10, 2015) (finding where the relator alleged that the defendant, contrary to law, failed to maintain adequate documentation for the audit regarding Medicaid claims because it did not have actual possession of the supporting documentation, the relator’s claim failed, because nothing in the defendant’s “State Plan or the Medicaid regulations on which [the relator] relies conditioned payment on [the defendant’s] *physical possession* of documentation supporting its year-end cost reports”).

participation and there is no FCA liability.²⁶ Moreover, if there are no relevant administrative enforcements to review, then the defendant should request in discovery from the government in cases in which the government has intervened—and inquire with the government in cases in which the government has declined to intervene—the government’s prior enforcement history of the relevant statute or regulation to determine whether the government has treated the alleged breach as a condition of payment or a condition of participation.

By undertaking this type of inquiry into how the government has historically treated the violation, courts and private litigants can ensure that the FCA is maintained within its proper boundaries, as Congress intended, and is not, contrary to congressional intent, transformed into a boundless, super-statute to enforce every rule or regulation on the books, backed by treble damages and massive civil penalties, and enforced by private, financially self-interested litigants.

²⁶ See, e.g., *United States ex rel. Portilla v. Riverview Post Acute Care Ctr.*, No. 12-1842, 2014 U.S. Dist. LEXIS 44002, at *46–47 (D.N.J. Mar. 31, 2014) (noting that, where administrative adjudications revealed that the quality of care regulations the relator claimed were breached resulted in administrative sanctions and not denial of payment, the compliance with those regulations “is a classic condition of participation and not payment” and, hence, not actionable under the FCA).