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COMMENT

IMPLIED CERTIFICATION AND MATERIALITY SHOULD BE DISTINCT ELEMENTS WHEN ASSESSING FALSE CLAIMS ACT LIABILITY

Robert B. Vogel, M.D.

I. INTRODUCTION

Health law attorneys who defend pharmaceutical manufacturers against fraud allegations find themselves confronted with new and vexing problems. The once stalwart division between classic healthcare fraud and fraud due to the violation of drug manufacturing regulations is gone, and defense attorneys are scrambling to respond.1

1. In October of 2010 GlaxoSmithKline agreed to plead guilty to charges relating to the manufacturing of adulterated drugs at its SB Pharmco Puerto Rico, Inc. ("SB Pharmco") facility in Puerto Rico. Press Release, Department of Justice Office of Public Affairs, GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010), http://www.justice.gov/opa/pr/2010/October/10-civ-1205.html [hereinafter GlaxoSmithKline Settlement]. The final settlement, which included criminal and civil penalties, totaled $750 million dollars. Id. The Department of Justice (DOJ) determined that several of SB Pharmco’s pharmaceuticals were contaminated with microorganisms, thus violating the Food, Drug and Cosmetics Act (FDCA) that prohibit delivering drugs that are adulterated. Id. “Under the FDCA, a drug is deemed adulterated if the methods used in, or the facilities or controls used for, its manufacturing, processing, packing or holding did not conform to or were not operated or administered in conformity with current good manufacturing practice . . . .” Id. This case had been filed in federal court in Massachusetts as a qui tam action and netted the whistleblower $96 million. Id. The U.S. Attorney Carmen Ortiz said of the case, the industry has an obligation to ensure that all rules, regulations and law are complied with[. . . . To do less erodes the public confidence and compromises patient safety. As this investigation demonstrates, we will not tolerate corporate attempts to profit at the expense of the ill and needy in our society—or those
The case of *United States ex rel. Rostholder v. Omnicare*\(^2\) is illustrative of this new and emerging genre of False Claims Act (FCA) cases.\(^3\) The plaintiff, a former employee of a pharmaceutical company wholly owned by Omnicare, alleged that the defendant violated the Food, Drug, and Cosmetic Act’s (FDCA) Current Good Manufacturing Practices (CGMP) regulation that prohibits the repackaging of penicillin alongside other pharmaceuticals.\(^4\) The crux of the matter was this: did the defendants violate the FCA by impliedly certifying that they would comply with the CGMP regulation regarding penicillin when they filed claims to federal and state health care programs for reimbursement?\(^5\)

The answer to this question has ramifications for the future of healthcare fraud enforcement that cannot be overstated. Because the FDA recognizes that these regulations apply to a spectrum of manufacturers, the regulations “provide[] [a] framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device.”\(^6\) Additionally the United States Food and Drug Administration (FDA) can issue warning letters or initiate other regulatory actions against a company that fails to comply with the CGMP regulations.\(^7\) In light of this, defense attorneys today are asking the

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who cut corners that result in potentially dangerous consequences to consumers.

*Id.*


4. *United States ex rel. Rostholder*, 2012 WL 3399789, at *5. The FDCA is located at 21 U.S.C. §§ 301–99 and the CGMP regulations are located at 21 C.F.R. 211. The regulation pertaining to penicillin packaging is located at 21 C.F.R. § 211.42. See 21 C.F.R. § 211.42(d) (2004) (“Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.”).


7. U.S. Food and Drug Administration, *Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations*, FDA (Sep. 7, 2012), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm. The FDA has a variety of administrative remedies available to it when there is the suspicion of wrongdoing. This includes
following question: If the regulations are meant as “guidelines” for the pharmaceutical companies to essentially write their own rules and the FDA can levy administrative remedies, then why are these companies being charged with violations of the FCA?

The answer to the defense attorneys’ question has high stakes. The FCA is the government’s leading weapon against healthcare fraud. The Department of Justice (DOJ) recovered $4.1 billion in fiscal year 2011 from FCA cases, which included $2.4 billion from the health care arena. A total of $6 billion in health care dollars has been recovered via the FCA since January of 2009. For financial and political reasons, the government seeks to open these new avenues to prosecute fraud and abuse in the Medicare and Medicaid systems. Implied compliance to the regulatory framework is

sight visits and a warning letter (a so-called 483 action). Id. The FDA website explains 483 actions this way:

When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter. The Warning Letter identifies the violation, such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use. The letter also makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform FDA of its plans for correction. FDA then checks to ensure that the company’s corrections are adequate.


9. Id.

10. Id. Attorney General Eric Holder said,

This report reflects unprecedented successes by the Departments of Justice and Health and Human Services in aggressively preventing and combating health care fraud, safeguarding precious taxpayer dollars and ensuring the strength of our essential health care programs[.] We can all be proud of what’s been achieved in the last fiscal year by the department’s prosecutors, analysts and investigators – and by our partners at HHS. These efforts reflect a strong, ongoing commitment to fiscal accountability and to helping the American people at a time when budgets are tight.
arguably the most lucrative new mechanism to hold pharmaceutical companies liable under the FCA.11

The most controversial aspect of answering the defense attorneys' question is: How should a court determine if the pharmaceutical company certified compliance with a regulation (express or implied certification theory)? And if the government had known of the false compliance, would it have paid the claim and/or excluded the company from participation in the program (materiality)? The answer comes by understanding what constitutes a legally false claim under the FCA and considering the criteria the government uses to decide if it should or should not pay claims. Part II of this Comment provides a short primer on the FCA, and Part III provides an exhaustive review of the circuit splits surrounding these issues. Lastly, in Part IV this Comment argues that courts should make a sequential determination of whether a claim is legally false and then whether that falsity would have been material to the government's decision to pay the claim. Part IV of this Comment argues that by separately assessing certification and materiality courts will be following Congress' lead on how this issue should be addressed. Congress is signaling its intention to retain "certification" as a distinct element of FCA liability by explicitly linking the Anti-Kickback Statute (AKS) to the FCA in the Patient Protection and Affordable Care Act (PPACA) and by tightening the connection between the Stark Law and the FCA.

II. THE FALSE CLAIMS ACT

In order to understand and evaluate the controversy concerning implied certification and materiality, one needs to understand where these elements fit into the larger context of the FCA. To succeed in an FCA action, the plaintiff must show by a preponderance of the evidence that the defendant (1) made a claim (2) that was false or fraudulent (3) "knowingly" (4) seeking payment or approval from the United States government.12

Id. Secretary of Health and Human Services Kathleen Sebelius said,

    Fighting fraud is one of our top priorities and we have recovered an unprecedented number of taxpayer dollars[.] Our efforts strengthen the integrity of our health care programs, and meet the President's call for a return to American values that ensure everyone gets a fair shot, everyone does their fair share, and everyone plays by the same rules.

Id.

12.  31 U.S.C. § 3729(a)(1)(A)-(G) (2012). Sections 3729(a)(1)(A)-(B) are the most commonly utilized. 31 U.S.C. § 3729(A) says, "knowingly presents, or causes to be presented,
The FCA defines "claim" as "any request or demand, whether under a contract or otherwise, for money or property" from the United States government. Because a request for reimbursement from Medicare or Medicaid constitutes a "claim," this element is rarely in dispute within the context of healthcare cases. This Comment focuses on the second element, that the claim was false or fraudulent, and the fourth element, that the falsity would have been material to the government's decision to pay the claim. A claim can be false or fraudulent in two ways. First, there are so-called "factually false" claims, where the goods or services that the defendant contracted with the government to provide have not been rendered. Second, there are the two "legally false" claims that violate a contract term, statute, or regulation with which the claimant has either expressly or impliedly certified compliance.


Interpreting the last word of the phrase is fairly easy. The False Claims Act states that a claim 'includes any request or demand for money or property' where the government provides any portion of the money or property requested. 31 U.S.C.A. §3729(c). In other words the False Claims Act at least requires the presence of a claim—a call upon the government fisc—for liability to attach.

Id. See also United States v. Krizek, 111 F.3d 934, 940 (D.C. Cir. 1997) (holding that the number of claims submitted on HCFA-1500 forms, Medicare reimbursement claim forms, was equal to the number of claims under the Act). Congress has determined that fraud against the government occurs when the claim is filed and that the government need not sustain damages or pay for claim to have been considered filed. S. REP. NO. 99-345, at 8 (1986), reprinted in 1986 U.S.C.C.A.N. 5266. In 1986 Congress stated, "The United States is entitled to recover such forfeitures solely upon proof that false claims were made, without proof of damages. A forfeiture may be recovered from one who submits a false claim though no payments were made on the claim." Id.

15. See infra Parts III–IV (discussing false and fraudulent claims presented under the FCA).

16. United States ex rel. Mikes v. Strauss 274 F.3d 687, 696–704 (2d Cir. 2001). The discussion of the "worthless services claim" is essentially a discussion of the "factually false" claim because instead, "[A] worthless services claim asserts that the knowing request of federal reimbursement for a procedure with no medical value violates the Act irrespective of any certification." Id. at 702. Legally false claims are those where express or implied certification is implicated. Id. at 697–700.
Suppose a law school wishes to ensure compliance with a school policy that prohibits students from cheating on final exams.\textsuperscript{17} As a means of compliance, the law school instructs each student to sign an affidavit at the end of an exam stating that the student did not give or receive help. By signing, the student has \textit{exactly} attested to his honesty. But what if the law school's student handbook states that there shall be no cheating on final exams? Has not any law student who merely hands in an exam \textit{implicitly} attested to his honesty?

Logically, a claim will be deemed false when the product or service at issue fails to comply with contractual requirements between the parties.\textsuperscript{18} In these cases, the vendor has \textit{expressly} certified to the government that the product or service conforms to the agreed upon specifications.\textsuperscript{19} The issue becomes more complex when the vendor violates a statute or regulation but was not bound by an identifiable contract term to comply with that statute or regulation. Like the law student bound by the handbook, has the vendor \textit{implicitly} certified compliance with the applicable contract term, statute or regulation just by virtue of the fact that he has made a claim to the government? In the perfect world there would be no need for implied certification because government agencies would require vendors to \textit{expressly} certify compliance with all applicable statutes and regulations in the contract itself. But this is not the case.\textsuperscript{20} Implied certification theory, used in this way, has the potential to significantly broaden FCA liability by forcing the vendor to comply with statutes or regulations that were not explicitly part of his contract.

\textsuperscript{17} This hypothetical is modeled after the one discussed by the court in \textit{United States v. Kellogg Brown \& Root Services, Inc.} See \textit{United States v. Kellogg Brown \& Root Servs., Inc.}, 800 F. Supp. 2d 143, 154–55 (D.D.C. 2011).

\textsuperscript{18} See \textit{United States v. Aerodex, Inc.}, 469 F.2d 1003 (5th Cir. 1972). In \textit{Aerodex}, false claims liability was assessed against a manufacturer of ball bearings, who knowingly supplied non-conforming goods to the government. \textit{Id.} at 1006. Aerodex, Inc. claimed that, although the ball bearings did not meet the agreed upon specifications, it supplied the military with the same basic performance characteristics as a conforming product. \textit{Id.} at 1007. Aerodex did not deny that the bearings that it supplied to the government were reworked versions of another bearing that rendered the two indistinguishable to the naked eye. \textit{Id.} Industry standards allowed either ball bearing to be used in the specific engine that was the subject of the contract. \textit{Id.} The court, nevertheless, found that Aerodex's deliberate mislabeling of a part specifically named in the contract compelled a finding of liability under the FCA. \textit{Id.} at 1012.

\textsuperscript{19} \textit{Id.}

In 2009, as part of the Fraud Enforcement and Recovery Act (FERA), Congress amended the FCA to expressly include a "materiality" requirement. The revised FCA defined "materiality" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." By adding the "materiality" requirement in § 3729(a)(1)(B) and defining it, Congress helped to resolve part of the circuit split on this issue. As will be reviewed in Part III, prior to the FERA amendments that defined "materiality," there were circuits that declined to read a materiality element into the statute at all. This Comment argues that even though Congress added the "materiality" element under FERA it did not intend to envelope false certification theory under the materiality umbrella.

The FCA contains several _qui tam_ provisions that enable a private party, known as a relator, to file a lawsuit on behalf of the government. The government might never detect certain fraudulent activity were it not for cases initiated by current or former employees of companies who have information by virtue of their insider status.

21. _Compare_ 31 U.S.C. § 3729(a)(2) (2006) ("knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government") with 31 U.S.C. § 3729(a)(1)(B) (2010) ("knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim"). It should be noted that the word "material" is found in § 3729(a)(1)(B) but not in § 3729(a)(1)(A). This is because § 3729(a)(1)(A) is used for claims that are factually false, and it is assumed that these claims would be "material" to the government's decision to pay the claimant.


23. See United States _ex rel._ A+ Homecare Inc. v. Medshares Mgmt. Grp. Inc., 400 F.3d 428, 445 (6th Cir. 2005) (stating that "[t]he circuits which have addressed the issue of materiality are inconsistent on the standard to be used"). See discussion infra Part III.


25. The term "_qui tam_" is "short for the Latin phrase _qui tam pro domino rege quam pro se ipso in hac parte sequitur_, which means 'who pursues this action on our Lord the King's behalf as well as his own.'" Vermont Agency of Natural Resources v. United States _ex rel._ Stevens, 529 U.S. 765, 768 n.1 (2000).


27. See S. REP. No. 99-345, at 3–4 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5268–69 ("[M]ost fraud goes undetected due to the failure of Governmental agencies to effectively ensure accountability on the part of program recipients and Government contractors . . . . Detecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity.").
Part III of this Comment is a comprehensive presentation of the key cases from each circuit that invoke both express and implied certification theory. The charts included in this Comment catalog the cases and important holdings from the decisions in each circuit. These charts are meant to serve as an initial reference for the reader who wishes to understand the circuits' positions, and who may then delve into Part III for a brief on the particular case.

III. BACKGROUND

A. False Certification

1. Express False Certification

   a. First Circuit

      (1) United States ex rel. Hutcheson v. Blackstone Medical, Inc.29

      The relator alleged that Blackstone engaged in a nationwide kickback scheme to induce hospitals and physicians to submit materially false or fraudulent claims to Medicare.30 He argued that compliance with the Anti-Kickback Statute (AKS)31 is a precondition for Medicare reimbursement and that causing doctors and hospitals to submit claims that did not comply with the AKS made the claims false or fraudulent.32 The court rejected the relator's argument that, in the absence of express legal representation or factual misstatement, a claim can only be false or fraudulent if it fails to comply with a precondition of payment expressly stated in a statute or regulation.33 The court refused to adopt the construct of express or implied certification as a way of addressing such an argument.34 Instead it chose to look at this issue by determining if the claim misrepresented compliance with a precondition of payment and then addressed whether those

28. See infra Chart 1, Chart 2.
30. Id. at 378.
31. 42 U.S.C. § 1320a–7b (2012). The AKS prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. Id.
32. United States ex rel. Hutcheson, 647 F.3d at 379.
33. Id.
34. Id.
misrepresentations were material. In this case the “misrepresentations” were adequate to trigger FCA liability. The court concluded, “[t]his holding is consistent with those of other courts that have found claims false or fraudulent for non-compliance with a contract term.” Refusing to label this “express compliance,” the court nonetheless looked at the contract terms and determined that they were adequately specific to demand compliance.

(2) New York ex rel. Westmoreland v. Amgen, Inc.

In this case, decided soon after Blackstone, the relator alleged that Amgen, Inc. employed a kickback scheme that induced physicians to file false or fraudulent claims to the states’ Medicaid programs. The court employed the same analysis as it did in Blackstone, refusing to adopt the term “express certification.” The court looked closely at the regulatory regime governing each of the Medicaid programs in question and decided that “the absence of such kickbacks is a precondition of being entitled to payment under these Medicaid programs, [and that] the reimbursement claims submitted to the four programs ‘represented that there had been compliance with a material precondition of payment that had not been met.” The court dismissed the relator’s claims referable to the Georgia Medicaid regime, however, because no language was found that preconditioned payment on alleged kickbacks. While eschewing the term “express certification,” the First Circuit tied the express wording of regulatory language to certification of false claims.

35. Id. at 392.
36. Id. at 392–93. The court looked specifically at the Provider Agreement and the Hospital Cost Report Forms that the providers signed as a prerequisite to payment from Medicare. Id. at 381. The Provider Agreement required, inter alia, that the provider “understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with [Medicare’s] laws, regulations, and program instructions.” Id. The Agreement specifically mentioned AKS as one of the regulations. Id.
37. Id. at 394.
38. Id. at 393.
40. Id. at 105.
41. Id. at 109–15.
42. Id. at 113 (quoting United States ex rel. Hutcheson, 647 F.3d at 392).
43. Id. at 116.
b. Second Circuit

(1) United States ex rel. Mikes v. Strauss

In Mikes, a physician brought a *qui tam* suit against her former partner physicians for submitting fraudulent Medicare claims. The relator’s cause of action was that the defendants submitted false claims for reimbursement for unreliable spirometry services. Dr. Mikes claimed that the spirometers were improperly calibrated; therefore, the results of the test were unreliable. The relator claimed that when the defendants submitted claims to Medicare they expressly certified compliance with the terms set out on the reimbursement form. The court agreed that an expressly false claim is “a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.” Nevertheless, the court did not agree with Dr. Mikes that the reliability of the spirometry measurements were expressly required by the wording of the reimbursement form.

c. Third Circuit

(1) United States ex rel. Kosenske v. Carlisle HMA, Inc.

In Kosenske, anesthesiologists brought a *qui tam* action under the FCA against the Carlisle Hospital and Health System alleging that the defendants submitted outpatient claims to Medicare falsely certifying that the claims were in compliance with the Stark and Anti-Kickback Acts. In finding for the relator, the court concluded that “[f]alsely certifying compliance with the Stark or Anti-Kickback Acts in connection with a claim submitted to a federally funded insurance program is actionable under the FCA.”

44. United States ex rel. Mikes v. Strauss 274 F.3d 687 (2d Cir. 2001).
45. *Id.* at 693.
46. *Id.*
47. *Id.* at 694.
48. *Id.* at 698. The “Form HCFA-1500 expressly says: ‘I certify that the services shown on this form were medically indicated and necessary for the health of the patient . . . .’” *Id.*
49. *Id.*
50. *Id.* at 699.
52. *Id.* at 88.
53. *Id.* at 94.
(2) United States ex rel. Wilkins v. United Health Group, Inc. 54

More recently in United States ex rel. Wilkins v. United Health Group, Inc. the Third Circuit affirmed that there is express false certification liability under the FCA, citing Kosenske. 55 The Wilkins court stated, "Under the 'express false certification' theory, an entity was liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." 56

d. Fourth Circuit

(1) Harrison v. Westinghouse Savannah River Co. 57

In Harrison, the relator brought a claim alleging that the defendants misrepresented both the need for a subcontractor and the price of the subcontract for work they were doing for the Department of Energy (DOE). 58 Westinghouse Savannah River Company (Westinghouse) also falsely certified that no conflict of interest existed between itself and the subcontractor. 59 The relator claimed this was done in order to get approval from the DOE for the subcontract work. 60 The court said, "The False Claims Act is intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." 61 The Harrison court went on to say that the False Claims Act is violated "when a government contract or program required compliance with certain conditions as a prerequisite to a government benefit, payment or program; the defendant failed to comply with those conditions; and the defendant falsely certified that it had complied ...." 62 The court held that Harrison sufficiently alleged that Westinghouse made intentional misrepresentations to the government and

55. Id. at 306.
56. Id. at 305 (citing Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008)).
58. Id. at 780.
59. Id.
60. Id.
61. Id. at 788 (citing United States v. Neifert-White Co., 390 U.S. 228, 232 (1968) (internal quotation marks omitted)).
62. Id. at 786.
submitted a certification known to be false about matters that were material to the decision to grant a subcontract.\textsuperscript{63}

(2) United States\textit{ ex rel.} Godfrey\textit{ v.} KBR\textsuperscript{64}

In\textit{ Godfrey,} the relator alleged that KBR violated the FCA by paying inflated invoices submitted to it by subcontractors and then seeking payment from the government based on these increased payments.\textsuperscript{65} The court here agreed with the\textit{ Harrison} court that express certification was operative when the defendant failed to comply with conditions that served as prerequisites to obtaining a government payment.\textsuperscript{66} In this case, however, the relator failed to support his claim of improper billing, and he failed to demonstrate that KBR made payments with knowledge that the recipients were not entitled to such payments.\textsuperscript{67}

e. Fifth Circuit

(1) United States\textit{ ex rel.} Thompson\textit{ v.} Columbia/HCA Healthcare Corp.\textsuperscript{68}

In\textit{ Thompson,} the relator alleged that the defendants falsely certified that annual cost reports were in compliance with the Anti-Kickback and Stark Statutes.\textsuperscript{69} The court distinguished claims for service that violate statutes, which do not necessarily constitute false claims under the FCA,\textsuperscript{70} from false certifications of compliance when certification is a prerequisite for obtaining a government benefit.\textsuperscript{71} The court stated, "[W]here the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation."\textsuperscript{72} The court did not agree with Thompson that in this case the retention of any payment received prior to

\begin{itemize}
\item \textsuperscript{63} Id. at 794.
\item \textsuperscript{64} United States\textit{ ex rel.} Godfrey\textit{ v.} KBR, 360 F. App'x 407 (4th Cir. 2010).
\item \textsuperscript{65} Id. at 408.
\item \textsuperscript{66} Id. at 412.
\item \textsuperscript{67} Id.
\item \textsuperscript{68} United States\textit{ ex rel.} Thompson\textit{ v.} Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).
\item \textsuperscript{69} Id. at 900–01.
\item \textsuperscript{70} Id. at 902.
\item \textsuperscript{71} Id.
\item \textsuperscript{72} Id.
\end{itemize}
submission of the annual report was conditioned on the certification of compliance with Medicare statutes.73

(2) United States ex rel. Steury v. Cardinal Health, Inc.74

In Steury, the relator alleged that the defendant submitted a false or fraudulent claim within the meaning of the FCA by accepting payment from the government after selling the Veteran Administration an unsafe intravenous fluid infusion device.75 Although this case was presented by the relator on the implied certification theory, the court relied on Thompson, reaffirming the Fifth Circuit's view on express certification.76

f. Sixth Circuit

(1) Chesborough v. VPA, P.C.77

In Chesborough, the relator was a radiologist who provided x-ray interpretation services to the defendant, a home health provider.78 Chesborough alleged that VPA filed false or fraudulent claims because the tests "were either not properly documented as to indication, were performed with equipment that did not conform to industry standards[,] or were administered by inadequately trained radiology technologists."79 The court noted that Chesborough was not bringing these claims because "VPA expressly certified that its studies complied with industry standards."80 The court notes that situations do exist where the FCA covers failure to comply with a regulation submitted to the government.81 "When a claim expressly states that it complies with a particular statute, regulation, or contractual term that is a prerequisite for payment, failure to actually comply would render the claim fraudulent."82

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73. Id.
75. Id. at 265–66.
76. Id. at 267–68.
77. Chesborough v. VPA, P.C., 655 F.3d 461 (6th Cir. 2011).
78. Id. at 464.
79. Id. at 465.
80. Id. at 467 (emphasis added).
81. Id.
82. Id. (quoting Mikes v. Straus, 274 F.3d 687, 697–99 (2d Cir. 2001)).
g. Seventh Circuit

(1) United States ex rel. Gross v. Aids Research Alliance-Chicago\textsuperscript{83}

In Gross, the relator was a participant in a National Institutes of Health (NIH) research study conducted by the defendants.\textsuperscript{84} Gross claimed that "[i]ndividually, and in cumulative effect, the forms, written reports, and study results submitted by the defendants constituted certifications of compliance with all requirements and conditions of the research grant."\textsuperscript{85} The court found that Gross had not pleaded with the specificity necessary to state a claim because his complaint failed to describe how any of the "forms" that the defendants filed related to payments of grant money from the NIH.\textsuperscript{86} The court stated that "where an FCA claim is based upon an alleged false certification of regulatory compliance, the certification must be a condition of the government payment in order to be actionable."\textsuperscript{87}

(2) United States ex rel. Yannacopoulos v. Gen. Dynamics\textsuperscript{88}

In Yannacopoulos, the relator claimed that the defendants violated the FCA by making false statements to the government to obtain payment for the sale of F-16 fighter planes to Greece.\textsuperscript{89} The sale of the planes was conducted under the United States' Foreign Military Financing Program.\textsuperscript{90} Under that program, Greece bought the fighters directly from General

\textsuperscript{83} United States ex rel. Gross v. Aids Research Alliance-Chi., 415 F.3d 601 (7th Cir. 2005).
\textsuperscript{84} Id. at 603.
\textsuperscript{85} Id. at 604 (quoting from the plaintiff's second amended complaint).
\textsuperscript{86} Id. at 604–05.
\textsuperscript{87} Id. at 605 (citing United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013 (7th Cir. 1999)). While discussing regulatory violations that do not rise to the level of an FCA violation the court says: "[T]hat minor technical regulatory violations do not make a claim 'false' for purposes of the FCA; the existence of mere technical regulatory violations tends to undercut any notion that a prior representation of regulatory compliance was knowingly and falsely made in order to deceive the government." Id. at 604 (citing Lamers, 168 F.3d at 1019). The court also cites to United States ex rel. Luckey v. Baxter Healthcare Corp. Id.; United States ex rel. Luckey v. Baxter Healthcare Corp., 183 F.3d 730 (7th Cir. 1999).
\textsuperscript{88} United States ex rel. Yannacopoulos v. Gen. Dynamics, 652 F.3d 818 (7th Cir. 2011).
\textsuperscript{89} Id. at 821–23.
\textsuperscript{90} Id. at 821.
Dynamics, but it did so using funds that were loaned by the United States. Before the United States government would release funds to General Dynamics, it required the company to sign a certification agreement containing representations regarding the Greek sale. On the invoices to the government for payment of the Greek sale, General Dynamics certified compliance with its contract and the certification agreement. The court pointed out that in the Seventh Circuit, a breach of contract claim does not give rise to FCA claims. Nevertheless, if the defendant falsely claims to be in compliance with a contract to obtain payment, it may be an actionable claim under the FCA. Such a statement would be a "legally false request for payment" after an express certification of compliance with a contract.

h. Eighth Circuit

(1) United States ex rel. Vigil v. Nelnet

In Vigil, the relator alleged that Nelnet—a company formed to perform collection services and present claims to the Department of Education (DOE) for interest subsidies, special allowances, and insurance payments on defaulted student loans—filed false claims to the government. Participation in this program was conditioned on compliance with DOE regulations. Vigil claimed that Nelnet’s claims for reimbursement under these programs “included materially false certifications of compliance with [DOE] regulations that were conditions of payment for those claims.”

91. Id.
92. Id. at 824.
93. Id.
94. Id. (citing United States ex rel. Garst v. Lockhead-Martin Corp., 328 F.3d 374 (7th Cir.2003)).
95. Id. (citing United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163 (10th Cir. 2010)). In noting this important contrast the court here cites to two Tenth Circuit cases. See Lemmon, 614 F.3d at 1163; United States ex rel. Conner v. Salina Regional Health Center, Inc., 543 F.3d 1211 (10th Cir. 2008).
96. Id. (quoting Lemmon, 614 F.3d at 1168).
97. Id.
99. Id. at 794–95.
100. Id. at 795.
101. Id. at 797 (internal quotation marks omitted). The certification by Nelnet read: “The information in this claim is true and accurate and that the loan(s) included in the claim was (were) made, disbursed . . . and serviced in compliance with all federal regulations and appropriate guarantor rules. Id.
The court made a distinction between regulatory violations that were conditions only of participation in the programs and false certifications that were conditions of payment. The court said that express false certification is "actionable under the FCA only if it leads the government to make a payment which it would not otherwise have made." The court noted that "absent actionable false certifications upon which funding is conditioned, the False Claims Act does not provide such a remedy."  

i. Ninth Circuit  

(1) United States ex rel. Hopper v. Anton  

In Hopper, the relator was the employee of a school district that allegedly was conducting evaluations of special education students in violation of the California Education Code. The court found that the forms the school district submitted for payment did not contain any certification of regulatory compliance. Therefore, false certification theory did not apply because liability is only created "when certification is a prerequisite to obtaining a government benefit." The Ninth Circuit endorsed the express certification theory but held that it was not applicable to this case.  

(2) United States ex rel. Hendow v. University of Phoenix  

In Hendow, the defendant was charged with filing false claims that violated subsidies under Title IV and the Higher Education Act. The relator alleged that when the University of Phoenix entered into the Program Participation Agreement with the Department of Education it agreed to "abide by a panoply of statutory, regulatory, and contractual requirements. One of these requirements is a ban on incentive compensation: a ban on the institution's paying recruiters on a per-student basis." The court affirmed the Ninth Circuit's approach to express

102. Id. at 799.  
103. Id. (quoting United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1219 (10th Cir.2008)).  
104. United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996).  
105. Id. at 1263.  
106. Id. at 1267.  
107. Id. at 1266.  
108. Id. at 1266–67. The court notes that "absent actionable false certifications upon which funding is conditioned, the False Claims Act does not provide such a remedy." Id. at 1267.  
109. United States ex rel. Hendow v. Univ. of Phx., 461 F.3d 1166 (9th Cir. 2006).  
110. Id. at 1168–69.  
111. Id.
certification as discussed in Anton. It stated, "[T]he question is merely whether the false certification—or assertion, or statement—was relevant to the government’s decision to confer a benefit." The court held that eligibility for payment under Title IV and the Higher Education Act was explicitly conditioned on compliance with the incentive compensation ban. In upholding the express certification theory as it applied to the University of Phoenix, the court noted that "[t]hese are not ambiguous exhortations of an amorphous duty. The statute, regulation, and agreement here all explicitly condition participation and payment on compliance with, among other things, the precise requirement that relators allege that the University knowingly disregarded."

j. Tenth Circuit

(1) United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.

In Conner, the relator was an ophthalmologist who claimed that the defendant hospital expressly certified compliance with Medicare laws and regulations and violated those certifications by filing false annual cost reports. Because Medicare law did not contain a provision that required compliance with the annual cost report, Conner proceeded under an express certification theory, even though he conceded that the Medicare laws did not contain a condition of compliance within the annual cost report. Conner urged the court to look at the annual cost reports standing alone and the explicit certifications found in them that conditioned payment on Medicare statutes and regulations. The court rejected this expansive view of false express certification and said: "When an [sic] the express certification does not state that compliance is a prerequisite to payment, we must look to the underlying statutes to surmise if they make the certification a condition of payment." The court rejected Conner's
argument that "any failure by SRHC to comply with any underlying Medicare statute or regulation during the provision of any Medicare-reimbursable service renders this certification false, and the resulting payments fraudulent." The court concluded that express certification leads to actionable claims under the FCA only if it "leads the government to make a payment which it would not otherwise have made." Put another way, the "false statement must be material to the government’s decision to pay out moneys to the claimant." Thus, Conner’s allegations concerning the annual reports failed.

(2) United States ex rel. Lemmon v. Envirocare of Utah, Inc.

In Lemmon, the relator alleged that Envirocare of Utah, Inc. ("Envirocare") violated its contractual and regulatory obligations to the federal government by improperly disposing of waste. The false claims arose when Envirocare submitted invoices for payment that contained certifications that it had fulfilled its obligations under the contract. The court noted that the express certification theory makes a claim actionable under the FCA only if it "leads the government to make a payment which, absent the falsity, it may not have made." Here, the relator’s claims were dismissed because of failure to state legally sufficient claims with the requisite specificity.

121. Id. at 1219 ("[L]iability [under the FCA] does not arise merely because a false statement is included within a claim, but rather the claim itself must be false or fraudulent." (quoting United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp., Inc., 400 F.3d 428, 443 (6th Cir. 2005))).

122. Id.

123. Id. (quoting United States ex rel. Hendow v. Univ. of Phx., 461 F.3d 1166, 1172 (9th Cir. 2006)). The court goes on to make the distinction between conditions of program participation and conditions of payment. Id. at 1220 (citing United States ex rel. Gross v. AIDS Research Alliance-Chi., 415 F.3d 601, 604 (7th Cir. 2005); Mikes v. Straus, 274 F.3d 687, 701-02 (2d Cir. 2001)). The court’s distinction is that conditions of participation are enforced through administrative mechanisms, while conditions of payment might cause the government to actually refuse payment, if it knew the conditions were not being followed. Id.

124. Id. at 1121.


126. Id. at 1166.

127. Id.

128. Id. at 1169.

129. Id. at 1173.
k. Eleventh Circuit

There are no applicable cases from the Eleventh Circuit.

l. D.C. Circuit

(1) United States v. Science Applications International Corp.\textsuperscript{130} 

In this case, the government alleged that Science Applications International Corporation (SAIC) violated contractual obligations that required it to "forego entering into consulting or other contractual arrangements with any firm or organization, the result of which may give rise to a conflict of interest with respect to the work being performed under the contract."\textsuperscript{131} Additionally, the contract required that SAIC would certify adherence to regulations that required the listing of any potential conflicts of interest.\textsuperscript{132} SAIC was hired by the Nuclear Regulatory Commission (NRC) to provide expertise to support the agency's rulemaking concerning recycled, radioactively contaminated materials from nuclear facilities.\textsuperscript{133} The court denied the government's claims with respect to express certification on two grounds.\textsuperscript{134} First, the reports submitted by SAIC made no reference to whether the company had complied with conflict of interest requirements.\textsuperscript{135} Second, the government never stated that SAIC's "separate express contractual certifications were themselves request[s] or demand[s] for money so as to fall within the statute's definition of claim."\textsuperscript{136} This case was decided on implied certification theory.\textsuperscript{137}

(2) United States v. Kellogg Brown & Root Services, Inc.\textsuperscript{138} 

In this case, the government charged that Kellogg Brown & Root (KBR) knowingly billed for the cost of private security contractors in Iraq, an

\textsuperscript{130} United States v. Sci. Applications Int'l Corp., 626 F.3d 1257 (D.C. Cir. 2010).
\textsuperscript{131} Id. at 1262 (quoting the 1992 contract between the government and SAIC).
\textsuperscript{132} Id. 48 C.F.R. § 2009.570-3(b) (1999) lists the potential conflicting "situations and relationships." Id.
\textsuperscript{133} Id. at 1261-62.
\textsuperscript{134} Id. at 1267.
\textsuperscript{135} Id.
\textsuperscript{136} Id. (internal quotation marks omitted).
\textsuperscript{137} Id. at 1268–71.
expense that the government had expressly forbidden in its contract. The court stated that "express false certification occurs when the claimant explicitly represents that he or she has complied with a contractual condition, but in fact has not complied." In this case, the court ruled that the government's express false certification theory arguments were really routine breach of contract claims. According to the court, the government conflated claims that were "false" with claims that were simply "disallowed" by the contract. This case was decided on implied certification theory.

m. Federal Circuit

There are no applicable cases in this circuit.

2. Implied False Certification

a. Early cases exemplifying implied false certification

(1) United States ex rel. Pogue v. American Healthcorp, Inc.

An early case that concerned the notion of implied certification was United States ex rel. Pogue v. American Healthcorp, Inc. In Pogue, the qui tam plaintiff alleged that a scheme existed involving the referral of Medicare and Medicaid patients to the defendant's hospital in violation of the Anti-Kickback and Self-Referral statutes. The relator argued that even though the claims for which the defendant sought payment were correctly billed and medically necessary, the fact that they submitted a Medicare claim carried the implied certification that that were complying with all aspects of the federal Medicare statutes.

139. Id. at 147.
140. Id. at 154 (quoting Mikes v. Straus, 274 F.3d 687, 698 (2d Cir. 2001)). The court fashions an informative analogy saying that express false certification is like a student who hands in a signed essay expressly certifying that it was his own work and yet it was taken from another source. Id. at 154–55. Implied false certification is when the same essay is handed in, but the falsity lies not on the fact that he signed it, but that a school guideline requires that all submissions be the student's own work. Id.
141. Id. at 154.
142. Id. at 155.
143. Id. at 155–59.
145. Id. at 1508.
146. Id. at 1509.
The court agreed with Pogue and said that not disclosing violations of the other statutes demonstrated the intent to cause the government to pay claims that it would not have paid had it been aware of the violations.\textsuperscript{147} For the first time in the Medicare context, the court agreed that a provider submitting facially correct claims could be held liable under the FCA because of a violation of a second, related federal statute.\textsuperscript{148} The court agreed that Pogue stated a claim under the FCA when he argued that "the defendants concealed their illegal activities from the government in an effort to defraud the government into paying Medicare claims it would not have otherwise paid."\textsuperscript{149}

b. First Circuit

(1) United States \textit{ex rel.} Hutcheson \textit{v.} Blackstone Medical, Inc.\textsuperscript{150}

The relator alleged that Blackstone engaged in a nationwide kickback scheme to induce hospitals and physicians to submit materially false or fraudulent claims to Medicare.\textsuperscript{151} The relator argued that compliance with the Anti-Kickback Statute (AKS) is a precondition for Medicare reimbursement and that causing doctors and hospitals to submit claims that did not comply with the AKS made the claims false or fraudulent.\textsuperscript{152} The court rejected the argument that in the absence of express legal misrepresentation or factual misstatement, a claim can only be false or fraudulent if it fails to comply with a precondition of payment expressly stated in a statute or regulation.\textsuperscript{153} But, the court refused to adopt the construct of express or implied certification as a way of addressing such an argument. Instead the court looked at this issue by determining if the claim misrepresented compliance with a precondition of payment and then by addressing whether those misrepresentations were material.\textsuperscript{154} The court said the claims in this case "represented that there had been compliance with a material precondition of payment that had not been met. We do not

\textsuperscript{147} Id. at 1513.
\textsuperscript{148} Id.
\textsuperscript{149} Id.
\textsuperscript{150} United States \textit{ex rel.} Hutcheson \textit{v.} Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011).
\textsuperscript{151} Id. at 378.
\textsuperscript{152} Id.
\textsuperscript{153} Id. at 379.
\textsuperscript{154} Id. at 392.
categorize this representation as one of law or fact, nor do we categorize it as either express or implied." The court went on to say that it "first address[ed] whether the claims at issue here misrepresented compliance with a precondition of payment so as to be false or fraudulent and then address[ed] whether those misrepresentations were material." In this case the "misrepresentations" were adequate to trigger FCA liability.

c. Second Circuit

(1) United States ex rel. Mikes v. Strauss

In Mikes, a physician brought a qui tam action against her former partner physicians for submitting fraudulent Medicare claims. Mikes alleged that the defendants submitted false claims for reimbursement for unreliable spirometry services. Mikes claimed that the spirometers were improperly calibrated and, therefore, the results of the test were unreliable. Mikes claimed that when the defendants submitted claims to Medicare they expressly certified compliance with the terms set out on the reimbursement form. The court agreed that an expressly false claim is a claim that falsely certifies compliance with a particular statute, regulation, or contractual term where compliance is a prerequisite to payment. Nevertheless, the court disagreed that the reliability of the spirometry measurements was expressly required by the reimbursement form.

Mikes also asked the court to address these claims under the theory of implied false certification. In its analysis, the court recounted the holding

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155. Id.
156. Id.
157. Id. at 392–93. The court looked specifically at the Provider Agreement and the Hospital Cost Report Forms that the providers signed as a prerequisite to payment from Medicare. Id. at 381. The Provider Agreement required, inter alia, the provider "understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with [Medicare's] laws, regulations and programs instructions." Id. The Agreement specifically mentioned AKS as one of the regulations. Id.
159. Id. at 693.
160. Id.
161. Id. at 698. The Form HCFA-1500 expressly says: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient . . . ." Id.
162. Id.
163. Id. at 699.
164. Id.
of the Federal Claims Court in *Ab-Tech Construction v. United States*. In *Ab-Tech Construction*, the court upheld the concept of implied certification in the context of a federal small business statutory program. The *Mikes* court distinguished *Ab-Tech* by saying that the *Ab-Tech* rationale "did not fit comfortably into the health care context" and "the False Claims Act was not designed as a blunt instrument to enforce compliance with all medical regulations—but rather only those that are a precondition to payment." The *Mikes* court then stated, "Specifically, implied certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." The court concluded that "liability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing—as that term is defined by the Act—that payment expressly is precluded because of some noncompliance by the defendant.

The court’s ruling on Mikes’s specific allegations are instructive in understanding how the court applied these criteria. Mikes alleged implied certification of claims with reference to two Medicare statutes—§§ 1395y(a)(1)(A) and 1320c-5(a). The § 1395 statute states that “no payment may be made under [the Medicare statute] for any expenses incurred for items or services.

The § 1320 statute states, “[I]t shall be the obligation of a practitioner who provides a medical service for which payment may be made... to

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166. *Id.* at 433–34.
167. *Mikes*, 274 F.3d at 699. Interestingly, the court premised this argument on the idea of federalism. *Id.* at 700. The *Mikes* court said that governments at the state and local level are the best places to resolve health care issues of this type. *Id.*
168. *Id.*
169. *Id.* at 700 (citation omitted).
170. *Id.*
171. *Id.*
172. *Id.* (internal quotation marks omitted).
assure compliance with the section.”173 The court said that here “the structure of the statute informs us that § 1320c-5(a) establishes conditions of participation, rather than prerequisites to receiving reimbursement.”174 Thus under the Mikes formulation, it is the express condition of payment of claims based on certification with a regulation, not conditions of participation in the program, that is the key to assessing FCA liability.175

(2) United States ex rel. Kirk v. Schindler Elevator Corp.176

The Second Circuit again addressed implied certification in Kirk, this time in a non-medical claims setting. In Kirk, the qui tam plaintiff claimed that his former employer, Schindler Elevator Corporation, obtained government contracts under the Vietnam Era Veterans Readjustment Assistance Act (“VEVRAA”)177 and then either failed to file or falsified VETS-100 reports.178 The applicable statute, 31 U.S.C. § 1354(a)(1), provides that “no agency may obligate or expend funds” to enter a contract covered by VEVRAA when the contractor has not submitted a VETS-100 report.179 The Kirk court firmly adopted the Mikes court’s formulation of implied certification, agreeing that “implied certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.”180 Kirk stated a valid claim because 31 U.S.C. § 1354(a)(1) did expressly state that, in order to be paid in compliance with VETS-100, reporting was required, and Schindler had impliedly certified compliance when it accepted the contract.181

173. Id. at 701.
174. Id. at 701–02.
175. Id. at 702.
177. Id. at 100. 38 U.S.C. § 4212 requires contractors doing business with the federal government to submit annual “VETS-100 Reports” to the Secretary of Labor providing information about the number of veterans employed by the contractor. Id. at 99.
178. Id. at 98.
179. Id. at 115.
180. Mikes, 274 F.3d at 700.
(3) United States ex rel. Feldman v. City of New York\textsuperscript{182}

\textit{Feldman} is a recently decided case from the Southern District of New York, within the Second Circuit, that applies the implied certification principles of \textit{Mikes} and \textit{Kirk} in the healthcare setting. In \textit{Feldman}, the United States government—acting intervenor in this \textit{qui tam} action—alleged that the City of New York filed false claims in administration of the Personal Care Services ("PCS") program under Medicaid.\textsuperscript{183} The court carefully parsed the language of the applicable statute and decided that the payment was expressly predicated on the compliance with the Department of Health Regulation that addressed PCS.\textsuperscript{184} The defendants here argued that they, like the \textit{Mikes} defendants, should be exonerated because they filed reimbursement forms that did not expressly implicate implied certification with the applicable regulation.\textsuperscript{185} The \textit{Feldman} court disagreed, stating that "the Government allegations here relate not to whether a medical provider provided the appropriate level of care [as in \textit{Mikes}], but whether the City impliedly represented its compliance with the fundamental procedural requirements governing the approval of PCS benefits under New York State Law."\textsuperscript{186}

d. Third Circuit

(1) United States \textit{ex rel.} Wilkins v. United Health Group, Inc.\textsuperscript{187}

The Third Circuit adopted express false certification liability under the FCA in its 2009 decision in \textit{United States ex rel. Kosenske v. Carlisle HMA},

\begin{itemize}
  \item \textsuperscript{182} United States \textit{ex rel.} Feldman v. City of New York, 808 F. Supp. 2d 641 (S.D.N.Y. 2011).
  \item \textsuperscript{183} \textit{Id.} at 644–48.
  \item \textsuperscript{184} \textit{Id.} at 651. The PCS program regulations are found in Department of Health Reg. § 505.14.18. N.Y. COMP. CODES R. & REGS. tit. 18, § 505.14 (2012). The court here specifically mentions § 505.14(b). \textit{Feldman}, F. Supp. 2d at 651. This section is called "Criteria and authorization for provision of services." N.Y. COMP. CODES R. & REGS. tit. 18, § 505.14. Section 505.14(b)(1) reads, "When the local services department receives a request for services, that department shall determine the applicant's eligibility for medical assistance." \textit{Id.} Section 505.14(b)(2) reads, "The initial authorization for personal care services must be based on the following." \textit{Id.} (emphasis added). It is this "based on" language in this regulation that the \textit{Feldman} court uses to state: "[U]nder federal law, a claimant is entitled to PCS benefits only if those benefits are, in fact, "based on" the considerations enumerated in DOH Reg. § 505.14(b)(2)." \textit{Feldman}, F. Supp. 2d at 651.
  \item \textsuperscript{185} \textit{Id.} at 652.
  \item \textsuperscript{186} \textit{Id.} at 654.
  \item \textsuperscript{187} United States \textit{ex rel.} Wilkins v. United Health Grp., Inc., 659 F.3d 295 (3d Cir. 2011).
\end{itemize}
Inc.\textsuperscript{188} The court in Wilkins reaffirmed the ruling in Kokenske and addressed implied certification for the first time in the Third Circuit.\textsuperscript{189} Wilkins alleged that United Health Group violated the FCA by claiming compliance with Anti-Kickback Statutes and marketing regulations inherent in Medicare Advantage ("MA") plans.\textsuperscript{190}

The Third Circuit adopted the concept of implied false certification for liability under the FCA after noting that a majority of other circuits had done so.\textsuperscript{191} But the court also put limitations on how expansively it was willing to apply the implied certification theory, especially in the federally funded health care arena.\textsuperscript{192} The court agreed with the Mikes court formulation and chose to limit implied certification to "only those regulations that are a precondition to payment . . ."\textsuperscript{193} The court summarized its holding by saying that "under this theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims."\textsuperscript{194} The court concluded that Wilkins's complaint met these implied certification standards.\textsuperscript{195} The court said that United Health Care knowingly received

\begin{itemize}
\item \textsuperscript{188} United States ex rel. Kokenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009).
\item \textsuperscript{189} Wilkins, 659 F.3d at 306.
\item \textsuperscript{190} Id. at 306.
\item \textsuperscript{191} Id. at 306. The court notes that as of June, 2011, the Second, Sixth, Ninth, Tenth, Eleventh, and District of Columbia Circuits had adopted implied certification. Id. The court gives two reasons for adopting implied certification theory. First, the court says that the express, Congressionally stated purpose for the FCA was to ferret out all attempts to cause the government to pay out money for property or services that were not delivered. Id. The court stated that "a false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specifications, statute or regulation . . . ." S. Rep. No. 99-345, at 9 reprinted in 1986 U.S.C.C.A.N. 5266, 5274. The second justification for adopting the implied certification theory was a comparison between 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2). The Third Circuit said that "section 3729(a)(1), when compared with section 3729(a)(2), indicates that a plaintiff can bring a claim under the FCA even without evidence that a claimant for Government funds made an express false statement in order to obtain those funds." Wilkins, 659 F.3d at 306-07 (emphasis added).
\item \textsuperscript{192} Wilkins, 659 F.3d at 307.
\item \textsuperscript{193} Id. (quoting United States ex rel. Mikes v. Strauss, 274 F.3d 687, 699 (2d Cir. 2001)).
\item \textsuperscript{194} Id.
\item \textsuperscript{195} Id. at 313.
\end{itemize}
payment from the government in violation of the AKS, which they deemed an explicit precondition to payment under Medicare.\textsuperscript{196}

e. Fourth Circuit

(1) United States \textit{ex rel.} Berge v. Bd. of Trustees of Univ. of Ala.\textsuperscript{197}

Pamela Berge was a graduate student at the University of Alabama-Birmingham (UAB) when she brought this \textit{qui tam} suit against the University alleging that it had violated the False Claims Act by making false statements to the National Institutes of Health (NIH) in an annual progress report for its grant.\textsuperscript{198} The Fourth Circuit decided this case based on what it called the "materiality" of the claims.\textsuperscript{199} The court defined materiality as "whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action."\textsuperscript{200} The court here reversed the lower court, finding that Berge failed to carry her burden of showing that UAB's statements were material to NIH's decision to supply grant money.\textsuperscript{201}

(2) United States \textit{ex rel.} Hererra v. Danka Office Imaging Co.\textsuperscript{202}

Danka Office Imaging Company ("Danka") held a federal contract that obligated it to pay the government a "Fee for Service" (FFS) percentage based on all sales made under the contract.\textsuperscript{203} Hererra claimed that Danka violated the False Claims Act by failing to file its quarterly FFS reports to

\begin{itemize}
\item \textsuperscript{196} \textit{Id.}
\item \textsuperscript{197} United States \textit{ex rel.} Berge v. Bd. of Trs. of Univ. of Ala., 104 F.3d 1453 (4th Cir. 1997).
\item \textsuperscript{198} \textit{Id.} at 1456.
\item \textsuperscript{199} \textit{Id.} at 1459. In this case, the court does not refer to certification as a means of determining whether the allegedly false statements made by UAB were utilized by the NIH to influence payment. The court looked to the criminal law to determine that "materiality" should be applied in civil cases. \textit{Id.} The court goes on to say that the determination of whether a fact is "material" is a matter of law and not one for the jury. \textit{Id.} at 1459–60.
\item \textsuperscript{200} \textit{Id.} (quoting United States v. Norris, 749 F.2d 1116, 1122 (4th Cir. 1984) (internal quotation marks omitted)).
\item \textsuperscript{201} \textit{Id.} at 1462. "Assuming arguendo that all of Berge's allegations were true and UAB had made these false statements, it is hard to imagine that NIH's decision-making would have been influenced by them." \textit{Id.}
\item \textsuperscript{202} United States \textit{ex rel.} Hererra v. Danka Office Imaging Co., 91 Fed. Appx. 862 (4th Cir. 2004).
\item \textsuperscript{203} \textit{Id.} at 862–63.
\end{itemize}
the government.\textsuperscript{204} Herrera’s first theory of liability was that each invoice that Danka submitted to the government was a “direct false claim” because they included the FFS that Danka was ultimately not going to pay.\textsuperscript{205} The court disagreed that this represented a false claim because, while Danka was required to include the FFS on all its statements and the failure to pay the FFS may have been a breach of contract, the inclusion of the FFS on the invoice was not a false claim.\textsuperscript{206}

The court also disagreed with Hererra that Danka’s submissions were false by implied certification theory.\textsuperscript{207} The court emphasized that, in order for implied certification to validly apply, the false claim must be a prerequisite for the government’s decision to pay.\textsuperscript{208} The court said that the government’s decision to pay Danka was not predicated on the condition that Danka remit the FFS payment.\textsuperscript{209} The court, referring to its ruling in \textit{Harrison v. Westinghouse Savannah River Company},\textsuperscript{210} stated, “We have previously noted that claims of implied certification were ‘questionable’ in this circuit. Given our resolution of this issue we need not decide whether claims for implied certification are viable under the False Claims Act.”\textsuperscript{211}

\begin{itemize}
  \item \textsuperscript{204} \textit{Id.} at 863.
  \item \textsuperscript{205} \textit{Id.} at 864.
  \item \textsuperscript{206} \textit{Id.} The court utilized the “direct false claim” formula from \textit{Harrison v. Westinghouse Savannah River Co.} \textit{Id.} (citing Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784–85 (4th Cir. 1999)). The claimant must show the defendant “made a claim for payment or approval by the government, that the claim was false or fraudulent, that [Danka] acted ‘knowingly’ in presenting the false claim, and that the falsity was material.” \textit{Id.} (quoting \textit{Harrison}, 176 F.3d at 784–85).
  \item \textsuperscript{207} \textit{Id.} at 865.
  \item \textsuperscript{208} \textit{Id.} at 864.
  \item \textsuperscript{209} \textit{Id.} at 865. The court utilized the implied certification analysis from \textit{Harrison v. Westinghouse Savannah River Co.} \textit{Id.} (citing \textit{Harrison}, 176 F.3d at 786, 786 n.8). Quoting \textit{Harrison}, the court said that “[t]o the extent that the theory is valid, the theory of implied certification creates liability under § 3729(a)(1) where ‘submission of invoices and reimbursement forms constituted implied certifications of compliance with the terms of the particular government program.’” \textit{Id.} at 864 (quoting \textit{Harrison}, 176 F.3d at 786, 786 n.8). The court looked to the D.C. Circuit ruling in \textit{United States ex rel. Siewick v. Jamieson Sci. & Eng’g Inc.} \textit{Id.} (citing United States ex rel. Siewick v. Jamieson Sci. & Eng’g Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000) (emphasizing that the claimant must show that certification was a prerequisite to government payment)).
  \item \textsuperscript{210} \textit{Harrison}, 176 F.3d at 786 n.8.
  \item \textsuperscript{211} \textit{Hererra}, 91 Fed. Appx. at 865 n.3.
\end{itemize}
(3) United States ex rel. Godfrey v. KBR

In Godfrey, the relator alleged that KBR violated the False Claims Act by paying inflated invoices submitted to it by subcontractors and then seeking payment from the government based on these increased payments. The court agreed with the Harrison court that express certification was operative when the defendant failed to comply with conditions that served as prerequisites to obtaining a government payment. The court rejected Godfrey's allegation of implied certification.

f. Fifth Circuit

(1) United States ex rel. Steury v. Cardinal Health, Inc.

In Steury, the relator alleged that the defendant submitted a false or fraudulent claim within the meaning of the FCA by accepting payment from the government after selling the Veteran Administration an unsafe intravenous fluid infusion device. The court noted that it had never previously adopted the theory of implied certification and that it did not need to decide that issue here because the relator had failed to provide sufficient allegations for implying false certification. The court distinguished between mere breaches of contract and claims under the FCA that have a prerequisite requirement. The court made an important distinction when it failed to recognize this prerequisite requirement as part


213. Id. at 408.

214. Id. at 411–12 (citing Harrison, 176 F.3d at 786).

215. Id. The court, referring to its analysis in Harrison, said, "Godfrey did not allege that LOGCAP, the contract between KBR and the government, made payment contingent on compliance with any particular conditions, nor did he allege any facts to support his conclusory assertion that KBR in fact certified compliance." Id. The court also looked to the Seventh Circuit in emphasizing that when false certification is alleged, certification must be a condition of the government's requirement for payment. Id. (citing United States ex rel. Gross v. AIDS Research Alliance-Chi., 415 F.3d 601, 605 (7th Cir. 2005)).


217. Id. at 266.

218. Id. at 268. The court noted that it had previously declined to adopt implied false certification in United States ex rel. Marcy v. Rowan Cos. Inc. Id. (citing United States ex rel. Marcy v. Rowan Cos., 520 F.3d 384, 389 (5th Cir. 2008)).

219. Id. "We have thus repeatedly upheld the dismissal of false-certification claims (implied or express) when a contractor's compliance with federal statutes, regulations, or contract provisions was not a 'condition' or 'prerequisite' for payment under a contract." Id.
of the materiality prong of the FCA.\textsuperscript{220} While noting that the definition of “material” had been broadened,\textsuperscript{221} the court said that the claim must first be analyzed as to “whether it is fair to find a false certification or false claim for payment in the first place.”\textsuperscript{222} The court concluded that “a false certification of compliance, without more, does not give rise to a false claim for payment unless payment is conditioned on compliance.”\textsuperscript{223}

The court found that in this case the government’s payment for the intravenous infusion device was not conditioned on Cardinal Health’s compliance with the warranty of merchantability.\textsuperscript{224} The relator did not allege that the contract between the parties contained a warranty of merchantability, and the court narrowly construed the applicable regulation.\textsuperscript{225} The court did say that a knowing delivery of defective goods to the government or a knowing attempt to deceive the government about the nature of commercial items may violate the FCA.\textsuperscript{226}

\begin{footnotesize}
\begin{enumerate}
\item[220.] \textit{Id.} at 269.
\item[221.] \textit{Id.} The Fraud Enforcement and Recovery Act of 2009 ("FERA") defines “material” as “a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” 31 U.S.C. § 3729(b)(4) (2012).
\item[222.] \textit{Steuery,} 625 F.3d at 269.
\item[223.] \textit{Id.} The court went on to say:

As already discussed, when payment is not conditioned on a certification of compliance, it is not fair to infer such certification from a mere request for payment. Similarly, even if a contractor falsely certifies compliance (implicitly or explicitly) with some statute, regulation, or contract provision, the underlying claim for payment is not “false” within the meaning of the FCA if the contractor is not required to certify compliance in order to receive payment.

\textit{Id.} “As we have recognized in the past, whether payment is conditioned on compliance will depend on the specific statutes, regulations, and contracts at issue in a particular case.” \textit{Id.} at 271 n.4.
\item[224.] \textit{Id.}
\item[225.] \textit{Id.} at 269–70. The relator referred the court to the Federal Acquisition Regulations (FAR)(48 C.F.R. § 12.404(a)). \textit{Id.} at 269. The court notes that under the FAR the government has as remedies the right to accept the noncompliant item, initiate price reduction or replace the noncompliant item. \textit{Id.} “That the government may accept (and pay) for noncompliant commercial items under the FAR confirms that payment is not conditioned on compliance with the warranty of merchantability.” \textit{Id.} at 270.
\item[226.] \textit{Id.} at 270. \textit{United States v. Aerodex, Inc.} is an example of such a case decided by the Fifth Circuit. See \textit{United States v. Aerodex, Inc.}, 469 F.2d 1003 (5th Cir. 1972). In Aerodex, false claims liability was assessed against a manufacturer of ball bearings, who knowingly supplied non-conforming goods to the government. \textit{Id.} at 1006. Aerodex, Inc. claimed that although the ball bearings did not meet the agreed specifications, it supplied the military
\end{enumerate}
\end{footnotesize}
g. Sixth Circuit

(1) United States ex rel. Augustine v. Century Health Servs.\textsuperscript{227}

Century Health Services ("Century") established an Employee Stock Ownership Plan (ESOP) and named two of its top officers as the plan's trustees.\textsuperscript{228} Century was eligible for reimbursement of ESOP funds by the Health Care Financing Administration (HCFA).\textsuperscript{229} Based on submissions made by Century, in which it certified compliance with the applicable rules for reimbursement, it received money from HCFA, deposited the money, and immediately withdrew the money from the ESOP accounts.\textsuperscript{230} The trustees failed to replace the promissory notes with appropriately valued stock.\textsuperscript{231}

The court's precedent cases broadly construed the meaning of "false or fraudulent" claims.\textsuperscript{232} The Sixth Circuit affirmed the lower court's analysis with the same basic performance characteristics as a conforming product. \textit{Id.} Aerodex did not deny that the bearings it supplied to the government were reworked versions of another bearing which rendered the two indistinguishable to the naked eye. \textit{Id.} at 1008. Industry standards allowed either ball bearing to be used in the specific engine that was the subject of the contract. \textit{Id.} The court, nevertheless, found that Aerodex's deliberate mislabeling of a part specifically named in the contract compelled a finding of liability under the FCA. \textit{Id.} at 1012. The court also found that Aerodex breached its express warranty to supply the specific ball bearing called for in the contract. \textit{Id.} The court stated that it was irrelevant that government inspectors had initially failed to inspect the bearings before accepting and installing them. \textit{Id.}

\textsuperscript{227} United States \textit{ex rel.} Augustine \textit{v.} Century Health Servs., 289 F.3d 409 (6th Cir. 2002).
\textsuperscript{228} \textit{Id.} at 411.
\textsuperscript{229} \textit{Id.} at 412.
\textsuperscript{230} \textit{Id.}
\textsuperscript{231} \textit{Id.}
\textsuperscript{232} \textit{Id.} at 413. For example, in the Sixth Circuit case of \textit{United States \textit{ex rel.} Compton \textit{v.} Midwest Specialties, Inc.}, the contract specifically called for testing to be conducted on the brake shoes that Midwest was to supply for Army vehicles. See \textit{United States \textit{ex rel.} Compton \textit{v.} Midwest Specialties, Inc.}, 142 F.3d 296, 297–98 (6th Cir. 1998). Midwest was aware of an express production-testing requirement and knowingly violated it. \textit{Id.} at 304. The court ruled that this was an FCA violation because the "manufacturer knowingly supplies nonconforming goods to the government, based on a belief that the nonconforming goods are just as good as the goods specified in the contract." \textit{Id.} The court found that the Army's consequential damages were equal to the entire contract price, since all of the brake shoes had to be removed after they were found to be nonconforming. \textit{Id.} at 304–305. The court said that "the general rule recognized in the Uniform Commercial Code [is] that a buyer may reject goods outright' if the goods or the tender of delivery fail in any respect to conform to the contract." \textit{Id.} at 305. The court then concluded, "[w]e stress that the government did not
of implied certification—the defendants impliedly certified compliance with Medicare regulations governing reimbursement for ESOP contributions by knowingly filing false cost reports. The defendants alleged that the claims were not expressly false when they were filed and therefore did not satisfy this aspect of FCA analysis. The court disagreed, holding that “liability can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned. We adopt this theory of liability [implied certification], and conclude that the district court did not err in finding it applicable in this case.”

(2) Chesborough v. VPA, P.C.

In Chesborough, the relator, a radiologist, provided x-ray interpretation services to the defendant, a home health provider. Chesborough alleged that VPA filed false or fraudulent claims because the tests “were either not properly documented as to indication, were performed with equipment that did not conform to industry standards, or were administered by inadequately trained radiology technologists.” The court noted that Chesborough was not bringing these claims because “VPA expressly certified that its studies complied with industry standards.” The court noted that situations do occur when FCA liability exists for failure to comply with a regulation.

Chesborough did not identify a specific Medicare or Medicaid regulation indicating compliance was required but generally stated that “appropriate diagnostic testing on Medicare beneficiaries” was indicated for proper reimbursement. The court did not accept this as a sufficient standard for implied certification.

bargain only for plug-welded brake shoes that could withstand a certain amount of force; they also bargained for the confidence that comes with a product that has been subjected to production testing.” Id. at 305 n.8.

234. Id. at 415.
235. Id.
237. Id. at 464.
238. Id. at 465 (internal quotation marks omitted).
239. Id. at 467 (emphasis added).
240. Id.
241. Id. at 468.
242. Id. In this 2011 case, the Sixth Circuit reiterated its holding from United States ex rel. Augustine v. Century Health Servs., Inc., embracing the concept of implied certification. Id.
(3) United States v. Villaspring Health Care Ctr., Inc.\textsuperscript{243}

In this Eastern District of Kentucky case, arising from the Sixth Circuit, the United States became aware of potential violations of Medicare and Medicaid claim violations after state officials investigated potential criminal neglect at the Villaspring owned nursing homes.\textsuperscript{244} The court agreed that the United States had properly pleaded implied certification because the government appropriately alleged that Villaspring had violated its Medicare provider agreement.\textsuperscript{245}

h. Seventh Circuit

(1) United States \textit{ex rel.} Abner v. Jewish Hospital Health Care Servs., Inc.\textsuperscript{246}

In this Southern District of Indiana case, arising in the Seventh Circuit, the relators alleged healthcare fraud via billing irregularities by their


\textsuperscript{244} \textit{Id.} at *2-*3.

\textsuperscript{245} \textit{Id.} at *22. When Villaspring enrolled in Medicare it was required to submit a form (HCFA-855) in which it agreed to a certification statement. \textit{Id.} The language of the Certification Statement signed [by Bortz] on behalf of Villaspring, provides:

I understand that payment of a claim by Medicare or other federal health care programs is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions . . . and on a provider/supplier being in compliance with any applicable conditions of participation in any federal health care program.

\textit{Id.} (citation omitted) (internal quotation marks omitted). The court decided that based on this language it was reasonable for the government to assert that a violation of a Medicare statute or regulation could give rise to liability under an implied certification theory. \textit{Id.} at *22-*23.

employer hospital. The court granted summary judgment for the defendants because the relators failed to allege that a false claim that was actually submitted.

i. Eighth Circuit

(1) United States ex rel. Kappenman v. Compassionate Care Hospice of the Midwest, L.L.C.

In this district court case from the Eighth Circuit, the relator alleged that false claims were filed to the Center for Medicare and Medicaid Services by her employer Compassionate Care Hospice (CCH), an entity that provided hospice care. The court explained its theory of implied certification stating that the relator "must show that if the government had been aware of the defendant's violations of the Medicare laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." The court found that Kappenman had shown sufficient factual support that CCH had impliedly certified compliance with Medicare regulations.

j. Ninth Circuit

(1) United States ex rel. Ebeid v. Lungwitz

In Ebeid, the relator alleged that Lungwitz, who owned three health care businesses, engaged in the "unlawful corporate practice of medicine" and

247. Id. at *1.
248. Id. at *8--9. There is no mention of "certification" here. Id. at *8. The Seventh Circuit has not yet explicitly adopted or rejected implied certification.
250. Id. at *4.
251. Id. at *13. (quoting Wilkins v. United Health Grp., Inc., 659 F.3d 295, 307 (3d Cir. 2011)).
252. Id. at *14--15. The Medicare statute related to this implied certification claim stated: "[N]o payment may be made under Part A or B of this subchapter for any expenses incurred for items or services in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness." Id. at *13 (quoting 42 U.S.C. § 1395y(a)(1)(C) (2012)). The court said that this section of the code is an express condition of payment that links Medicare payments to the requirement that each claim be reasonable and necessary. Id. at *14--15 (citing United States ex rel. Mikes v. Straus, 274 F.3d 687, 700 (2d Cir. 2001) (internal quotation marks omitted)).
253. United States ex rel. Ebeid v. Lungwitz, 616 F.3d 993 (9th Cir. 2010).
that referrals among her businesses were unlawful.\textsuperscript{254} Ebeid alleged that Lungwitz maintained an illegal corporate structure, that the entities exhibited a prohibited amount of control over physician medical decision-making, and that they made illegal patient referrals amongst themselves.\textsuperscript{255} Ebeid claimed that Lungwitz submitted claims to the government for reimbursement while violating federal rules that were a precondition for payment.\textsuperscript{256} The Ninth Circuit explicitly adopted, for the first time, the theory of implied certification.\textsuperscript{257} The court looked to the Stark Act and related Medicare regulations for language to support Ebeid's claim.\textsuperscript{258} 

\textsuperscript{254} Id. at 995.
\textsuperscript{255} Id. at 995–96.
\textsuperscript{256} Id. at 996.
\textsuperscript{257} Id. at 995–96. The Ninth Circuit adopted an implied certification theory most closely associated with the Second Circuit's ruling in United States ex rel. Mikes v. Straus. Id. at 998. The court said that the ruling in Mikes was most closely in keeping with its precedent of accepting express certification. Id.; United States ex rel. Hendow v. Univ. of Phx., 461 F.3d 1166, 1173 (9th Cir. 2006) (holding that the materiality element of an FCA claim included certification, which was an assertion relevant to the government's decision to confer a benefit.); United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) (holding that "violations of laws, rules and regulations alone do not create a cause of action under the FCA[ and that i]t is the false certification of compliance which creates liability when certification is a prerequisite to obtaining a government benefit") (emphasis in original).

Despite the generalized agreement with the ruling in Mikes, the court here notes that it would not specifically decide if in the Medicare context the underlying statute must "expressly" condition payment on compliance. Ebeid, 616 F.3d at 1001 n.3 (internal quotation marks omitted).

The court said that, express certification simply means that the entity seeking payment certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted. Implied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule or regulation, and that obligation is implicated by submitting a claim for payment even though certification of compliance is not required in the process of submitting the claim. Id. at 998.

\textsuperscript{258} Id. at 999–1001. The court notes that the Stark Act expressly conditions payment on compliance with the Act: "No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of [42 U.S.C. § 1395nn(g)(1)]." Id. at 1000 (quoting 42 U.S.C. § 1395nn(g)(1)). The court said that this would have been an effective use of implied certification, had Ebeid pleaded it sufficiently. Id. Ebeid also pointed to Medicare regulations dealing with home health care and hospice care. Id. The court agreed with Ebeid that these regulations did provide a precondition for payment. Id. at 1001. The court said, "we look to the specific text of the regulation, which
k. Tenth Circuit

(1) Shaw v. AAA Eng'g & Drafting, Inc.\textsuperscript{259}

In Shaw, the relator accused her employer, AAA Engineering and Drafting, Inc. ("AAA"), of falsely inflating numbers on word orders and using those numbers to support equitable adjustment claims.\textsuperscript{260} The relator also claimed that AAA did not comply with its contractual obligation to dispose of silver, used fixer, and other photographic chemicals in accordance with Environmental Protection Agency (EPA) guidelines.\textsuperscript{261} The United States, in amicus curiae supporting the relator's claims, said that AAA had submitted monthly invoices to the government in which it impliedly certified that it complied with the silver recovery provisions in the contract.\textsuperscript{262} The court made a clear distinction between the ability of implied certification to support a claim under 31 U.S.C. § 3729(a)(1), but not claims brought under § 3729(a)(2).\textsuperscript{263} The court agreed with the lower court that provides that 'Medicare ... pays for home health services only if a physician certifies and recertifies' the need for home health care services." Id. (emphasis added) (citing 42 C.F.R. § 424.22 (2012)). "A physician in a prohibited financial relationship may not certify or recertify such need. Id. "Therefore, certification of compliance with the ban on financial relationships prohibited under § 424.22(d) may be inferred by the submission of a related Medicare claim for home health services." Id.

\textsuperscript{259} Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519 (10th Cir. 2000).

\textsuperscript{260} Id. at 523. An equitable adjustment claim was a clause in the contract between AAA and the government that allowed for increased payment if the amount of work performed was more than contemplated at the time the contract was signed. Id. at 524–25. Certification theory was not addressed in this aspect of the case. Id.

\textsuperscript{261} Id.

\textsuperscript{262} Id. at 531. Since AAA was being paid not only for photographic services but also for the environmental compliance, the relator stated that AAA implied certification with the contract's environmental clauses is a violation of the FCA. Id. The court did not discuss whether implied certification is based here on the contractual violation itself or the underlying EPA regulations implicit in the contract. Id. It did make reference to a Senate Committee statement that said false claims under the FCA "may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." Id. (quoting S. REP. NO. 99-345 at 9, reprinted in 1986 U.S.C.C.A.N. at 5274). Thus, the court infers that implied certification theory would extend to the underlying "statute or regulation." Id.

\textsuperscript{263} Id. at 531–32. Because the language of 31 U.S.C. § 3729(a)(2) requires a "false record or statement to get a false or fraudulent claim paid or approved" and § 3729(a)(1) has no requirement of the "false record or statement," FCA liability arising under implied certification can only be brought under 3729(a)(1) claims because no "affirmative or express false statement by the government contractor" is required. Id.
the relator presented sufficient evidence that AAA knowingly failed to comply with the environmental aspects of its contract.264

(2) United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.265

In Conner, the relator was an ophthalmologist who claimed the defendant hospital expressly certified compliance with Medicare law and regulation and violated those certifications by filing false annual cost reports.266 Conner claimed that his allegations proceeded under express certification theory,267 although he conceded that the Medicare laws do not contain a condition of compliance within the annual cost report.268 Conner urged the court to look at the annual cost reports standing alone and find that they contained explicit certification that conditioned payment on Medicare statutes and regulations.269 The court rejected this expansive view of false express certification and said, “When... the express certification does not state that compliance is a prerequisite to payment, we must look to the underlying statutes to surmise if they make the certification a condition of payment.”270 Although Conner proceeded under an express certification theory that the court rejected, the court recognized its precedents did allow for implied certification.271 The court said implied certification is when “the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government's payment.”272

264. Id. at 533.
266. Id. at 1214.
267. Id. at 1218.
268. Id.
269. Id.
270. Id.
271. Id.
272. Id. The court looked at the annual cost report regulation in 42 C.F.R. § 413.24(f)(4)(iv) and found it to “contain[] only general sweeping language [that] does not contain language stating that payment is conditioned on perfect compliance with any particular law or regulation.” Id. at 1219. The court also rejected any sweeping use of implied certification by saying that a failure to comply with Medicare regulations when supplying Medicare services was too broad to be supported by implied certification theory. Id. The court also emphasized the need to distinguish between conditions of the Medicare program’s participation and conditions of payment. Id. at 1220.
(3) United States ex rel. Lemmon v. Envirocare of Utah, Inc.\textsuperscript{273}

In \textit{Lemmon}, the relator alleged that Envirocare of Utah, Inc. ("Envirocare") violated its contractual and regulatory obligations to the federal government by improperly disposing of waste.\textsuperscript{274} The false claims arose when Envirocare submitted invoices for payment that contained certifications that it had fulfilled its obligations under the contract.\textsuperscript{275} The court noted that express certification theory makes a claim actionable under the FCA only if it "leads the government to make a payment which, absent the falsity, it may not have made."\textsuperscript{276} Here the relator's claims were reinstated after they had been dismissed at the lower court for failure to state legally sufficient claims with the requisite specificity.\textsuperscript{277}

The court also assessed Lemmon's claims with respect to implied certification, referring to the rule in \textit{Shaw}. "[W]e found that the pertinent inquiry for such claims is not whether a payee made an 'affirmative or express false statement,' but whether, through the act of submitting a claim, a payee knowingly and falsely implied that it was entitled to payment."\textsuperscript{278} It found Lemmon's claims were sufficient because Lemmon sufficiently pleaded the contract-based claims.\textsuperscript{279}

1. Eleventh Circuit

(1) McNutt ex rel. U.S. v. Haleyville Med. Supplies\textsuperscript{280}

In \textit{McNutt}, the \textit{qui tam} relator alleged that the defendant, a medical device supplier, violated the Anti-Kickback Statute by paying pharmacists for referrals.\textsuperscript{281} The parties agreed that compliance with the Anti-Kickback

\begin{footnotesize}
\textsuperscript{273} United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163 (10th Cir. 2010).
\textsuperscript{274} Id. at 1166.
\textsuperscript{275} Id.
\textsuperscript{276} Id. at 1169.
\textsuperscript{277} Id. at 1173.
\textsuperscript{278} Id. at 1169. (quoting Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 532–33 (10th Cir. 2000)). This court assessed implied false certification by determining whether the government would have paid the claim had it known of its falsity. Id. The \textit{Lemmon} court also faulted the lower court for ruling that the plaintiff needed to tie the alleged incidents to identifiable certification of regulatory compliance. Id. at 1170.
\textsuperscript{279} Id. The court held that the plaintiff had sufficiently pleaded contract-based claims, and the regulatory breaches had not been exclusively relied upon. Id.
\textsuperscript{280} McNutt ex rel. United States v. Haleyville Med. Supplies, 423 F.3d 1256 (11th Cir. 2005).
\textsuperscript{281} Id. at 1258.
\end{footnotesize}
Statute was a condition of payment by the Medicare program because violation of the statute would be grounds for disqualification from the program.282 The defendant argued that the government had failed to identify any false claims.283 The court stated, “[W]hen a violator of government regulations is ineligible to participate in a government program and that violator persists in presenting claims for payment that the violator knows the government does not owe, that violator is liable, under the Act, for its submission of those false claims.”284

(2) United States ex rel. Freedman v. Suarez-Hoyas285

In this district court case from the Eleventh Circuit, the relator alleged that the defendant, a pathologist who owned a pathology laboratory, violated the Anti-Kickback Statute.286 The government alleged that Dr. Suarez-Hoyas enticed a local dermatologist to refer patients by allowing him to bill Medicare for the professional component of the reimbursement, despite the fact that the dermatologist did no work to support this arrangement.287 The court relied on the Eleventh Circuit’s ruling in McNutt288 and agreed with the government that an Anti-Kickback Statute violation was sufficient to state a claim for FCA liability based on implied false certification theory.289

m. D.C. Circuit

(1) United States v. Science Applications International Corp.290

In this case the government alleged that Science Applications International Corporation (SAIC) violated contractual obligations that required that they “forego entering into consulting or other contractual

282. Id. at 1259.
283. Id.
284. Id.
286. Id. at 1272.
287. Id. at 1273.
288. McNutt, 423 F.3d at 1256.
289. Freedman, 781 F.Supp.2d at 1278–79. The Freedman court states that its theory of implied certification is that “where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds contained an implied certification of compliance with the law or regulation and was fraudulent.” Id. (citing United States ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F. Supp. 2d 28, 33 (D.D.C. 2003)).
arrangements with any firm or organization, the result of which may give rise to a conflict of interest with respect to the work being performed under the contract." 291 Additionally, the contract required that SAIC certify to codified regulations that listed relationships that could lead to conflicts of interest. 292 SAIC was hired by the Nuclear Regulatory Commission (NRC) to provide expertise to support the agency’s rulemaking concerning recycled, radioactively contaminated materials from nuclear facilities. 293 The court denied the government’s claims with respect to express certification on two grounds. 294 First, the reports submitted by SAIC made no reference to whether the company had complied with conflict of interest requirements. 295 Second, the government did not claim that SAIC’s “separate express contractual certifications were themselves request[s] or demand[s] for money so as to fall within the statute’s definition of claim.” 296

This case was decided on implied certification theory. 297 The court here adopted what it called the “materiality approach.” 298 It explained that this approach required the plaintiff to show that “the contractor withheld information about its noncompliance with material contractual requirements.” 299 The court went on to say, “The existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not, as SAIC argues, a necessary condition. 300 The plaintiff may establish materiality in other ways, such as through testimony demonstrating that

291. Id. at 1262 (quoting the 1992 contract between the government and SAIC).
292. Id. 48 C.F.R. § 2009.570-3(b) lists the potential conflicting “situations and relationships.” Id.
293. Id. at 1261.
294. Id. at 1267.
295. Id.
296. Id. (internal quotation marks omitted).
297. Id. at 1268–71.
298. Id. at 1269–71. The court stated that the approach it adopted was the same as that adopted by the Ninth and Tenth Circuits. See Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010); United States ex rel. Lemmon v. Envirocare of Utah, Inc., 614 F.3d 1163, 1169 (10th Cir. 2010); Shaw v. AAA Eng’g & Drafting, Inc., 213 F.3d 519, 531–32 (10th Cir. 2000). The court also contrasts this “materiality approach” with the approach taken by the Second Circuit that “recognized an express condition precedent requirement for implied certification.” Sci. Applications Int’l Corp., 626 F.3d at 1269–70 (quoting United States ex rel. Mikes v. Strauss, 274 F.3d 687 (2d Cir. 2001)).
299. Sci. Applications Int’l Corp., 626 F.3d at 1269.
300. Id.
both parties to the contract understood that payment was conditional on compliance with the requirement at issue." The court defined materiality as "evidence that compliance with the legal requirement in question is material to the government's decision to pay." It also stressed that violations of "minor contractual provisions that are merely ancillary to the parties' bargain are neither false nor fraudulent." In this case, the court found that SAIC did impliedly certify compliance with NRC regulation, and the trial court jury found that the contract violations were not minor.

n. Federal

(1) Ab-Tech Constr., Inc. v. United States

Ab-Tech Construction, a minority owned business, was awarded a subcontract by the Small Business Administration (SBA) pursuant to Section 8(a) of the Small Business Act. In order to qualify under Section 8(a), a firm has to be owned and controlled by "socially and economically disadvantaged individuals." Ab-Tech signed a "Statement of Cooperation" in which it expressed understanding of the parameters that constituted compliance with the program. Ab-Tech failed to obtain approval from the SBA for a subcontracting arrangement they formed with Pyramid Construction Company and then attempted to conceal the arrangement. Because Pyramid had a "substantial voice" in the project, the SBA would not have approved the subcontract had it known of the arrangement.

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301. Id.
302. Id. at 1271.
303. Id.
304. Id.
308. Id. at 432. The regulations of the Section 8(a) program said that termination from the program would occur if there was "$f[ailure by the [small business] concern to obtain prior SBA approval of any management agreement, joint venture agreement or other agreement relative to the performance of a section 8(a) subcontract." Id. (citing 13 C.F.R. § 124.209(a)(16) (1993)).
309. Id. at 432–33.
310. Id. at 433.
The court stated that the vouchers submitted for progress payments by Ab-tech were false claims under the FCA because they "represented an implied certification by Ab-Tech of its continuing adherence to the requirements for participation in the 8(a) program." The court went on to explain that "Ab-Tech not only dishonored the terms of its agreement with that agency but, more importantly, caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the 8(a) program." It further explained that the essence of a false claim is withholding "information critical to the decision to pay."

IV. IMPLIED CERTIFICATION AND MATERIALITY

A. Introduction and Premise

It is this Comment's contention that the concepts of "implied certification" and "materiality" are distinct entities that must be decided by courts with separate analyses. The belief that implied certification is a distinct element of the FCA comes partly from revisions to the FCA that are included within the Patient Protection and Affordable Care Act (PPACA). In the PPACA, Congress has codified the connection of the Anti-Kickback Statute (AKS) to the FCA. Congress ended any doubt about this connection by providing that "a claim that includes items or services resulting from a violation of the [AKS] constitutes a false or fraudulent claim for the purposes of [the FCA]." It should be noted that this construct does not say that the claim must necessarily be material to the government's decision to pay—it says that a violation of the AKS is a "false or fraudulent claim for the purposes of [the FCA]." This ended the debate about this issue that dated back to Pogue in 1996 and was still raging in

311. Id. at 434.
312. Id.
313. Id.
315. Id. at § 6402(f)(1).
316. Id.
317. Id. at § 6402(g).
By ending the debate about the connection of the AKS to the FCA, Congress has explicitly announced that implied certification is a distinct element of the FCA, because the connection between the AKS and FCA is itself based on implied certification. The fact that a Stark Law violation is now more closely tied to the FCA also bolsters this view. How could one square the fact that violations of the AKS and Stark Law are now statutorily linked to FCA liability with the fact that implied compliance with other statutes and regulations is not?

In 2009, Congress passed the Fraud Enforcement and Recovery Act (FERA) and revised the FCA statute to add “materiality” into 31 U.S.C. § 3729(a)(1)(B). The definition of materiality is “the natural tendency to influence, or be capable of influencing, the payment or receipt of money or property” from the government. The inclusion of this definition in FERA shows that Congress meant for courts to retain a materiality component in FCA analyses. This broad definition of materiality reveals that Congress meant to allow the courts to broadly construe its meaning. This construct can also be of great benefit as the courts wrestle with so-called “quality of care” cases.

B. Implied Certification Analysis

In United States ex rel. Pogue v. American Healthcorp, Inc., the qui tam plaintiff alleged that the physicians referred their Medicare and Medicaid patients to the defendant’s hospital in violation of the Anti-Kickback and self-referral statutes. Pogue contended that, even though the claims were correctly billed and medically necessary, the fact that the defendants submitted Medicare claims carried the implied certification that they were complying with all federal statutes related to Medicare, including the AKS.

320. See discussion supra Part II.A.1, II.B.1.(a), and III (discussing Pogue and Hutcheson).
325. Id. at 1509.
The Court agreed with Pogue and said that by not disclosing its violations of the AKS, American Healthcorp demonstrated its intent to cause the government to pay claims that it would not have paid had it been aware of these violations.326 For the first time, in the context of Medicare, a court agreed that a provider submitting facially correct claims can still be held liable under the FCA because of a violation of a second, related federal statute.327

In United States ex rel. Hutcheson v. Blackstone Medical, Inc.,328 the relator alleged that Blackstone engaged in a nationwide kickback scheme to induce hospitals and physicians to submit materially false or fraudulent claims to Medicare.329 The relator argued that compliance with the AKS was a precondition for Medicare reimbursement and that failing to comply with the AKS made the claims false or fraudulent.330 The court rejected this argument; however, it also refused to adopt the construct of express or implied certification as a way of addressing such an argument.331 Instead, it chose to look at this issue by determining if the claim misrepresented compliance with a precondition of payment and then addressing whether those misrepresentations were material.332 The court “first address[ed] whether the claims at issue here misrepresented compliance with a precondition of payment so as to be false or fraudulent and then address[ed] whether those misrepresentations were material.”333 In this case, the “misrepresentations” were adequate to trigger FCA liability.334

These two cases—separated by fifteen years—illustrate how courts have wrestled with implied certification analysis within the context of the AKS. The

326. Id. at 1513.
327. Id.
329. Id. at 378.
330. Id.
331. Id. at 379.
332. Id. at 392.
333. Id.
334. Id. at 392.
335. Id. at 392–93. The court looked specifically at the Provider Agreement and the Hospital Cost Report Forms that the providers signed as a prerequisite to payment from Medicare. Id. The Provider Agreement required, inter alia, that the provider “understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with [Medicare’s] laws, regulations and programs instructions.” Id. The Agreement specifically mentioned AKS as one of the regulations. Id.
AKS makes it a criminal offense to “knowingly and willfully” offer, pay, solicit, or receive any remuneration in connection with referring an individual for medical items or services for which payment may be made by any federal health care program, including Medicare and Medicaid. 336 Section 6402 of the PPACA makes two changes to the AKS. 337 The PPACA makes any violation of the AKS a “false or a fraudulent claim” under the FCA. 338 No cases have yet to be adjudicated under this revision of the AKS. 339 It will be interesting to see if courts, especially those that have emphasized a materiality element, interpret this PPACA provision to mean that the claim is false granting automatic FCA liability, or whether the AKS violation will render a claim “false” and then trigger a materiality analysis. 340 This Comment argues for the latter method. Because “implied certification” and “materiality” should be distinct legal analyses, the PPACA revision to the AKS should satisfy the “falsity” element only, leaving courts to determine if the violation at hand was material to the government’s decision to pay. This would allow the courts to use the Hutcheson construct. 341 In Hutcheson, the content of the Provider Agreement and Hospital Cost Reports led the First Circuit to determine that the materiality element was


337. Section 6402 of the Patient Protection and Affordable Care Act amends the Social Security Act by inserting after section 1128I a new section called 1128J. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402, 124 Stat. 119 (2010). Section 1128J(f)(1) is named “Kickbacks” and reads:

Section 1128B of the Social Security Act (42 U.S.C. 1320a-7b) is amended by adding at the end of the following new subsection: (g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of subchapter III of chapter 37 of title 31, United States Code. The other change to the AKS is to the intent requirement that is outside the scope of this Comment.

Id. (emphasis added).

338. Id. at § 6402(f)(1).

339. See United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011). The court in Hutcheson mentions the revision to the AKS made in the PPACA. Id. at 392. The court characterized the changes in the PPACA as “establish[ing] that AKS compliance is, without more, a precondition to Medicare payment.” Id. The court then refused to address the case before it in light of this revision. Id. The court held that the Provider Agreement and Hospital Cost Reports that Blackstone had submitted contained sufficient identification to the AKS to make it clear that violation of the AKS was a precondition of payment. Id.

340. Id.

341. Id. at 392–97.
satisfied. Nevertheless, one can envision scenarios where a court determines that the AKS has been violated but the materiality element is not clear. In these cases the court should undertake a separate materiality analysis.

The Stark Law forbids a physician from referring to an entity, for a designated health service, if the physician has a financial relationship with that entity, and the entity may not present a Medicare claim for payment as a result of a prohibited referral. If the entity violates the Stark Law and receives a payment, a so-called overpayment has occurred. The FERA provision known as the “reverse false claims provision” says,

[A]ny person who . . . knowingly makes, uses, or causes to be used, a false record or statement material to an obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government . . . .

The term “obligation” is defined as “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment . . . .” The term “obligation” is now defined to mean “overpayment,” which links the FCA reverse claims provision more directly to Stark. Thus, there is a link

342. Id. The First Circuit notes that the Provider Agreement drafted by CMS specifically identifies the AKS as one of the two enumerated examples of “laws, regulations and program instructions.” Id. at 392–93. The court concluded that “[t]his language makes it clear that the federal Medicare program will not pay claims if the underlying transaction that gave rise to the claim violated the AKS.” Id.


344. 42 U.S.C. 1395nn(g)(2) (2012) (“If a person collects any amounts that were billed in violation of [the Stark Law], the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected.”). See also 42 C.F.R. 411.353(d) (2012).


347. Before FERA, high dollar amount settlements were reached that linked 31 U.S.C. 3729(a)(1) and (a)(2) to the Stark Law. See United States ex rel. Moilan v. McAllen Hosps. L.P., No. M-050-CV-263, (S.D. Tex 2009); United States ex rel. Reimche v. Tulare Local Healthcare Dist., No. CV 08-00543CAS, (C.D. Cal.). Moilan was settled on October 30, 2009 for $27.5 million. See Press Release, Department of Justice Office of Public Affairs, Texas Hospital Group Pays U.S. $27.5 Million to Settle False Claims Act Allegations (Oct. 30, 2009),
between the Stark Law and the FCA that was strengthened by the FERA revision of the reverse claims provision.

The PPACA has also more closely linked the Stark Law to the FCA.\textsuperscript{348} Under the “Reporting and Returning of Overpayments” section, the “Enforcement” provisions establish that “any overpayment retained by a person after the deadline for reporting and returning the overpayment [under paragraph 2] is an obligation.”\textsuperscript{349}

These revisions are evidence that Congress has sought, through FERA and the PPACA, to strengthen the link between the FCA and both the AKS and the Stark Law.\textsuperscript{350} The implication is clear: Congress meant to codify the element of “implied certification” needed to link these laws and, by reference, has retained implied certification theory as a viable and continued element of FCA analysis.

C. Materiality Analysis

The continued usage of a materiality analysis is less controversial. In determining whether a claim or statement is false or fraudulent, most courts have required an additional factor commonly known as “materiality” in order to find liability under the FCA. There is a circuit conflict over the proper test for materiality that essentially falls into two groups: (1) those that required a higher standard of materiality (the “prerequisite to payment” test)\textsuperscript{351} and (2) those that required a lower standard (“natural tendency to influence” test).\textsuperscript{352}


\textsuperscript{349} Id. (referring to 31 U.S.C. §3729(b)(3)).

\textsuperscript{350} See discussion supra Part IV.A.

\textsuperscript{351} The “prerequisite to payment” test is most commonly associated with the Second Circuit’s decision in \textit{United States ex rel. Mikes v. Straus}, where the court held, “Specifically, implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.” \textit{United States ex rel. Mikes v. Straus}, 274 F.3d 687, 700 (2d Cir. 2001).

\textsuperscript{352} 31 U.S.C. § 3729(b)(4) (2012). This language is taken directly from the FERA definition of “material.” \textit{Id.} Material is defined as: “having the natural tendency to influence,
In *United States ex rel. Mikes v. Straus*, the Second Circuit provided the classic "prerequisite to payment" test for materiality, which was dependent on whether the claim "specifically[] implied certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." In *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, the Fourth Circuit applied a lower standard, which based materiality on the "potential effect of the false statement when it is made." This Comment urges that the "materiality" standard adopted by a court should first be cleanly severed from its implied certification analysis. Then, the court should recognize that when Congress enacted FERA it meant to lower the "materiality" standard. Therefore, courts should adopt the "natural tendency to influence" test.

D. "Quality of Care" Cases

Courts should also consider using the implied certification construct and the broader "materiality" standard as a means of assessing so-called "quality of care" cases. For example, in *Mikes*, the court considered the plaintiff's worthless services claim. The court said, "An allegation that defendants violated the Act [FCA] by submitting claims for worthless services is not predicated upon false certification theory. Instead, a worthless services claim asserts that the knowing request of federal reimbursement for a procedure with no medical value violates the Act irrespective of any or capable of influencing, the payment or receipt of money or property." *Id.* Many courts have interpreted this definition as strongly limiting FCA liability to false statements that directly affect the government's payment decision, and several courts have held that violations of "conditions of participation" in a federal healthcare program did not result in FCA violations. See, e.g., *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, Inc., 543 F.3d 1211 (10th Cir. 2008) (adopting the "prerequisite to payment" standard); *United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, 525 F. Supp. 2d 972 (W.D. Tenn. 2007) (holding that non-compliance could lead to exclusion from participation in Medicare but this would not effect current payment of claims).


certification." The \textit{Mikes} court adopted the same paradigm as the court in \textit{United States ex rel. Lee v. SmithKline Beecham, Inc.}, holding that "a worthless services claim is a distinct claim under the Act. It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided." \footnote{358}

But what of claims under the FCA that are not "worthless," but are of diminished quality? Do these represent factually false claims, and how should they be assessed? In \textit{United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc.}, the government claimed that Community Psychiatric Centers (CPC) was liable under the FCA by not providing its patients with a "reasonably safe environment" and for "submitting bills, [in which] CPC implicitly certified that it was abiding by applicable statutes, rules and regulations requiring provision to patients of appropriate quality of care a safe and secure environment." \footnote{360} The court rejected CPC's assertion that it could not abide by the "vague standards" found in the governing rules. \footnote{361} The court stated that "a problem of measurement should not pose a bar to pursing an FCA claim against a provider of substandard health care services under the appropriate circumstances." \footnote{362} The court then viewed this as a problem of materiality, although it did not explicitly use that term. It stated, "[S]tatutes and regulations governing the Medicaid program clearly require health care providers to meet quality of care standards, and a provider's failure to meet such standards is a ground for exclusion from the program." \footnote{363} Thus, once determining that the services were not worthless, the \textit{Aranda} court used an

\footnote{356}{\textit{Id.} at 702.}

\footnote{357}{United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048 (9th Cir. 2001). In \textit{Lee} the relator alleged that the defendant who operated clinical laboratories falsified laboratory test data. \textit{Id.} at 1050. The Ninth Circuit held that a worthless services claim was the most appropriate way to assess this scenario. \textit{Id.} at 1053. The court held that certification theory was not necessary in assessing worthless services claims. \textit{Id.}}

\footnote{358}{\textit{Mikes}, 274 F.3d 687 at 703.}


\footnote{360}{\textit{Id.} at 1487.}

\footnote{361}{\textit{Id.} at 1488.}

\footnote{362}{\textit{Id.}}

\footnote{363}{\textit{Id.} (internal quotation marks omitted). The court cites to 42 U.S.C. § 1320a-7(b)(6)(B), which states that the secretary may exclude anyone who furnishes patient services "of a quality which fails to meet professionally recognized standards of health care." \textit{Id.}}
implied certification analysis and then a materiality analysis. The court used a three-prong path of analysis. First, was the service that was rendered worthless? Second, did CPC impliedly certify compliance with the relevant statutes and regulations that govern health care quality in psychiatric centers (implied certification analysis)? Third, was the quality of care so inferior that had government known of the substandard care it would not have paid the claim or excluded the entity from participation in the program (materiality analysis)? This Comment deems this to be the proper path of analysis. By separately analyzing the "materiality" of a claim the court is able to assess a question that is very different than the question posed by implied certification.

V. CONCLUSION

In the "Introduction," this Comment presented the hypothetical healthcare defense attorney who was faced with the prospect of defending his client, a large pharmaceutical company, against allegations that it failed to comply with regulations that were not explicitly part of its contract. In United States ex rel. Rostholder v. Omnicare, Inc. the defense won the first

364. Id.
365. Id. at 1488–89.
366. Id.
367. Id. Compare the analysis in Aranda to the analysis in United States ex rel. Swan v. Covenant Care, Inc. United States ex rel. Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212 (E.D. Cal. 2002). In Swan, the relator alleged that Covenant Care (CC) falsified records to conceal inadequate care at their nursing homes. Id. at 1216. The court first assessed whether this represented a worthless services claim. Id. at 1221. It held that it was not worthless because CC was paid on a per diem basis and not per services basis. Id. The court then purported to assess the false certification status of the claims and noted that the Ninth Circuit had not adopted this form of implied certification. Id. The Swan court held that, under United States ex rel. Hopper v. Anton, "regulatory violations do not give rise to a viable FCA action government payment is expressly conditioned on a false certification of regulatory compliance." Id. at 1266 (citing United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996)); United States ex rel. Mikes v. Strauss, 274 F.3d 687, 699 (2d Cir. 2001). Thus, the Swan court does not do a separate "implied certification" and "materiality" analysis in this quality of care case. Swan, 279 F. Supp. 2d at 1221–22.
368. See discussion supra Part I.
369. United States ex rel. Rostholder v. Omnicare, Inc., No. CCB–07–1283, 2012 WL 3399789, at *1 (D. Md. August 14, 2012). In a confusing opinion, the court sought to analyze the claim by invoking implied certification analysis followed by materiality. Id. at *13–14 (noting that the Fourth Circuit had not yet adopted the implied certification doctrine). The court then stated that Rostholder, at oral argument, asked the court only to consider the
battle. It will be interesting to see how cases like *Rostholder* will fare in circuits with a more delineated implied certification theory.\textsuperscript{370} This Comment urges courts that hear these cases to rigorously apply implied certification analysis to the claim and assess materiality in a separate and distinct manner.

\textsuperscript{370} See case briefs *supra* Part III (in particular, note cases from the Second, Third, Sixth, Ninth, Tenth and DC circuits with strongly implied certification theory). See also *supra* note 1.
CHART 1. CIRCUIT BY CIRCUIT STATUS OF FALSE CERTIFICATION:
EXPRESS CERTIFICATION

FIRST CIRCUIT: Rejects certification construct.

United States ex rel. Hutcheson v. Blackstone, 647 F.3d 377 (1st Cir. 2011).


SECOND CIRCUIT: An expressly false claim is one that certifies compliance with a statute, regulation, or contract term where compliance is a prerequisite to payment.


THIRD CIRCUIT: Express certification is falsely certifying compliance with regulations, which are prerequisites to claim for payment.


FOURTH CIRCUIT: When a government program requires compliance as a prerequisite to a benefit or payment and there is failure to comply, there is false certification to induce the benefit.


FIFTH CIRCUIT: A false or fraudulent claim is when a claimant falsely certifies compliance with applicable statutes or regulations.

United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).

United States ex rel. Steury v. Cardinal Health, Inc., 625 F.3d 262 (5th Cir. 2010).

SIXTH CIRCUIT: A claim is fraudulent if it expressly states that it complies with a particular statute, regulation, or contractual term that is a prerequisite for payment and does not so comply.

Chesborough v. VPA, P.C., 655 F.3d 461 (6th Cir. 2011).

SEVENTH CIRCUIT: FCA claims based on false certification of compliance with a statute or regulation requires that it be a condition of or a prerequisite to government payment.


EIGHTH CIRCUIT: Express false certification requires proof that the certifications were conditions of payment and had the government known would have refused to payment.


NINTH CIRCUIT: False certification creates liability when certification is a prerequisite to obtaining a government benefit.

United States ex rel. Hopper v. Anton, 91 F.3d 1261 (9th Cir. 1996).
United States ex rel. Hendow v. Univ. of Phx., 461 F.3d 1166 (9th Cir. 2006).

TENTH CIRCUIT: Express certification applies when there is false certification of compliance with a statute, regulation, or contractual term where compliance is a prerequisite to payment.


ELEVENTH CIRCUIT:

No applicable cases.

D.C. CIRCUIT: Express false certification occurs when a claimant explicitly represents that he has complied with a contractual term and in fact has not.


FEDERAL CIRCUIT:

There are no applicable cases in this circuit.
CHART 2. CIRCUIT BY CIRCUIT STATUS OF FALSE CERTIFICATION: IMPLIED CERTIFICATION

FIRST CIRCUIT: Rejects the construct but recognizes that the condition of payment may be implied in statutes, regulations, or other sources.

United States ex rel. Hutcheson v. Blackstone, 647 F.3d 377 (1st Cir. 2011).

SECOND CIRCUIT: Implied certification occurs when a statute expressly conditions payment on compliance with a given statute or regulation.


THIRD CIRCUIT: Implied certification liability attaches when claimant seeks payment without compliance with regulations that affect eligibility for payment.


FOURTH CIRCUIT: Has not accepted implied certification theory. If the theory is valid it only is to the extent that submission for reimbursement constitutes certification of compliance with the terms of the particular government program.

United States ex rel. Berge v. Bd. of Trs. of Univ. of Ala., 104 F.3d 1453 (4th Cir. 1997).


FIFTH CIRCUIT: Has not accepted implied certification theory. The act of submitting a claim for reimbursement implies compliance with governing federal rules that are preconditions of payment.

United States ex rel. Steury v. Cardinal Health, Inc., 625 F.3d 262 (5th Cir. 2010).

SIXTH CIRCUIT: Implied certification exists even if the claim was not expressly false when it was filed. Violations can exist if payment is conditioned on continuing duties to comply.

United States ex rel. Augustine v. Century Health Servs., 289 F.3d 409 (6th Cir. 2002).

Chesborough v. VPA, P.C., 655 F.3d 461 (6th Cir. 2011).


SEVENTH CIRCUIT: Has not accepted or rejected implied certification theory.


EIGHTH CIRCUIT: Has not accepted or rejected implied certification theory.

NINTH CIRCUIT: Implied certification occurs when a claimant expressly undertook to comply with a law, rule, or regulation and submits a claim for payment and that obligation is implicated by submitting a claim even though certification of compliance is not required.

United States ex rel. Ebeid v. Lungwitz, 616 F.3d 993 (9th Cir. 2010).

TENTH CIRCUIT: The pertinent inquiry is whether through the act of submitting a claim a payee knowingly and falsely implied that it was entitled to payment.

Shaw v. AAA Eng’g & Drafting, Inc., 213 F.3d 519 (10th Cir. 2000).


ELEVENTH CIRCUIT: Has not directly addressed implied certification, but held that there can be a false claim without an express statement.


D.C. CIRCUIT: To show that a claim is false or fraudulent on basis of implied certification, the plaintiff must show contractor withheld information about its noncompliance with material contractual terms.

FEDERAL CIRCUIT: Has not addressed the concept of implied certification but has held that a claim implies continuing compliance with the requirements of participation and can be false without an express statement.