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Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards

John T. Brennan, Jr. and Michael W. Paddock

ABSTRACT: The False Claims Act (FCA) is established as the federal government's prosecutorial weapon of choice in combating fraud and abuse in healthcare today. The FCA's substantial penalties present potential defendants with daunting risks should they elect to put the government's case to the test at trial. The government and relators have sought to extend the contours of the FCA's coverage beyond actions involving "factually false" claims to pursue cases involving alleged violations of other laws that give rise to "legally false" claims. This article considers the viability of the legal bases upon which the FCA may be used in this regard, with specific attention to the appropriateness of implied and express false certification liability theories to punish violations of the Medicare Conditions of Participation. It is the thesis of this article that on both sound legal and policy grounds, the FCA is not an appropriate tool for punishing the failure to provide quality care, unless the quality of care provided is so substandard as to result in a factually false claim (e.g., the services billed were not actually rendered).

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LIMITATIONS ON THE FALSE CLAIMS ACT

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Introduction

The False Claims Act¹ (FCA) is established as the federal government’s prosecutorial weapon of choice in combating fraud and abuse in healthcare today. The scope of the FCA’s potential coverage is broad, its “knowingly” intent element is generous, and its “preponderance of the evidence” burden of proof provides a favorable advantage to federal enforcement authorities and whistleblowers suing under the statute’s qui tam provisions. The FCA’s enormous penalties—up to \$11,000 per claim, plus three times the damages the government sustains—present potential defendants with daunting risks should they elect to put the government’s case to the test at trial. It is no wonder, given these advantages, that false claims-based cases in the healthcare field frequently settle and often involve huge payments.

The success of the FCA in terms of swelling the coffers of the federal government and the pockets of qui tam relators is stunning. From 1987 through 2005, total FCA settlements and judgments exceeded \$15 billion.² These recoveries are expected to increase, as the government’s average FCA caseload has grown by nearly 25 percent from the

1 31 U.S.C. §§ 3729–3733.

2 Letter from L. Ekstrand, Director, Homeland Security and Justice, to Hon. F. Sensenbrenner, Jr., Chairman, Committee on the Judiciary, at 1 (Jan. 31, 2006), available at www.gao.gov/new.items/d06320r.pdf [hereinafter *Ekstrand Letter*].

late 1980s to the early twenty-first century.³ The healthcare industry has become particularly subject to FCA scrutiny: The Department of Health and Human Services (HHS) was named the defrauded agency in 12 percent of FCA complaints filed in 1987; by 2005, it was the named agency in over 49 percent of filed FCA complaints.⁴

Equally remarkable is the success of qui tam relators utilizing the statute to their own (and the government's) benefit. From 1987 to 2005, the aggregated relators' share of FCA settlements and judgments in favor of the federal government exceeded \$1.6 billion.⁵ During that same period, the average FCA recovery in a qui tam case eclipsed \$10 million—with recoveries in healthcare fraud cases tracking larger, on average, than in non-healthcare cases.⁶ The average FCA relator's share was over \$1.7 million—again, with recoveries in healthcare cases larger than in other cases.⁷ Relators in healthcare cases also are more likely to win Department of Justice (DOJ) intervention as compared to relators in non-healthcare cases. This is an important consideration, because data shows that government intervention leads to a better chance of reward—and of a *greater* reward—as compared to cases where the government declines to intervene.⁸

Following on this success in applying the FCA to allegations of healthcare fraud, the government and relators have sought to extend the contours of the FCA's coverage to actions and activities far removed from the "falsity" of the claim for payment itself (that is, "factually false" claims). Through the rubric of "false certification" theories, the government and relators have employed the FCA to pursue cases involving alleged violations of other laws ("legally false" claims) far removed from the data or information included on the claim itself—or even from the actions of the claimant. As federal regulatory agencies such as the Centers for Medicare & Medicaid Services (CMS) focus on performance concerns, prosecutors remain vigilant for ways to apply the FCA to regulatory failings of emerging interest to these federal agencies.

Thus, it is no wonder that the quality of care rendered by providers participating in federal healthcare programs has drawn increasing attention from federal enforcement agencies and qui tam relators, who seek creative ways to employ the FCA as a tool to enforce quality standards. This article considers the viability of the legal bases upon which the FCA may be used in this regard, with specific attention to

3 See GAO, *Information on False Claims Act Litigation, Briefing for Congressional Requesters* 1, 25 (Dec. 15, 2005) [hereinafter *GAO Report*], available at www.gao.gov/new.items/d06320r.df.

4 See *id.* at 26.

5 See *Ekstrand Letter*, at 1.

6 See *GAO Report*, 31.

7 See *id.* at 13, 32.

8 See *id.* at 29, 36.

the appropriateness of false certification liability theories to punish violations of quality standards such as the Medicare Conditions of Participation (COPs). Based on this review, it is the thesis of this article that on both sound legal and policy grounds, the FCA is not an appropriate tool for punishing quality of care violations, unless the quality of care provided was so substandard as to result in a factually false claim (e.g., the services billed were not actually rendered) and/or the claim seeks payment for “worthless services.”

Roles of the States and the Federal Government in Promoting and Policing Quality Healthcare

Because this article focuses on the use of the FCA as a tool for policing healthcare quality, it is appropriate to establish the general context by examining the historical role of the government in enforcing healthcare standards of care.

The traditional role of the states

Traditionally the states, not the federal government, have maintained the authority to monitor, regulate, and enforce the health and safety of the citizenry in general, and healthcare quality of care standards in particular. States have delegated their police powers to regulatory bodies, assigning the right to survey and license nearly all healthcare providers—hospitals, physicians, pharmacies, surgery centers, clinics, nursing facilities, and others. These regulatory bodies are authorized to investigate, sanction, and penalize healthcare providers, including revoking licenses when appropriate. State regulatory bodies and licensing boards routinely summon their police powers to establish quality standards, and to monitor and enforce quality care expectations upon the discovery of substandard care. A contemporary example of states’ role is the enactment of public reporting laws that require reports of “never events,” i.e., medical outcomes that should “never” occur.⁹

The role of the federal government

While not historically vested with the states’ broad police power over healthcare services and providers, as the federal government has grown to be by far the largest payor for medical care, it naturally has become attentive to the quality of the care it purchases for its beneficiaries. Accordingly, through various federal insurance programs such as Medicare, the federal government has established conditions of par-

9 See, e.g., Minn. Adverse Health Care Events Reporting Act of 2003, MINN. STAT. §§ 144.706–7069; Ill. Adverse Health Care Events Reporting Law of 2005, 410 ILL. COMP. STAT. 522/10-1–10-50.

ticipation for providers and suppliers who wish to provide and receive payment for services to covered beneficiaries.¹⁰ To participate in the Medicare program, the provider applicant—a hospital, for example—must undergo initial surveys to determine whether it meets the relevant COPs and other requirements for providing a safe environment and quality care for Medicare beneficiaries.¹¹ If the hospital meets the relevant requirements, CMS certifies the hospital and the hospital enters into a provider agreement with CMS.

If, after a hospital qualifies as a Medicare provider, the federal government or an agency acting on its behalf detects quality of care deficiencies, the hospital must establish and implement, with government oversight, a corrective action plan. During this time, the hospital continues to qualify for Medicare reimbursement.¹² Ultimately, if deficiencies remain uncorrected and/or serious risks to patient welfare or safety arise, CMS may terminate the hospital's certification.¹³ However, payment for services rendered continues up through termination and for 30 days after.¹⁴ Through these regulatory methods, and by virtue of its powerful payor status, the federal government now plays a role equal to the states in the monitoring and enforcement of quality standards.

The federal government's concern regarding healthcare quality spiked significantly, intensifying the government's role with respect to quality standards, in the wake of the Institute of Medicine's 1999 and 2003 reports on the systemic problems in our nation's healthcare system and the staggering number of resultant patient deaths.¹⁵ The reports prompted Congress, in 2003 and again in 2005, to enact legislation authorizing CMS to develop and implement pay-for-performance (P4P) reimbursement methodologies for services rendered

10 For example, the Conditions of Participation for Hospitals deal with subjects such as the governing board (42 C.F.R. § 482.12); patient's rights (*id.* § 482.13); quality assessment and performance improvement (*id.* § 482.21); nursing services (*id.* § 482.23); pharmaceutical services (*id.* § 482.25); radiologic services (*id.* § 482.26); food and diabetic services (*id.* § 482.28); infection control (*id.* § 482.42); discharge planning (*id.* § 482.43); and organ, tissue and eye procurement (*id.* § 482.45). Other COPs address "optional hospital services" (*id.* § 482.51) and "requirements for specialty hospitals" (*id.* § 482.68). Additional Conditions of Participation for psychiatric hospitals can be found at 42 C.F.R. §§ 482.60–62. Conditions of Participation for nursing homes can be found at 42 C.F.R. § 483.30.

11 42 U.S.C. § 1395aa; 42 C.F.R. §§ 488.10, .11. An applicant may be "deemed" to meet certain COPs if it is accredited by the Joint Commission on Accreditation of Hospitals. 42 U.S.C. §§ 1395(e); 1395bb(c).

12 42 C.F.R. § 488.28(a).

13 *Id.* § 489.53(c).

14 *Id.* § 489.55. In addition to the COPs, other statutes and regulations establish quality of care obligations for participating providers. For example, 42 U.S.C. § 1320c-5 obligates Medicare providers to meet professionally recognized standards of care.

15 See INST. OF MED., MEASURING THE QUALITY OF HEALTH CARE 1 (Feb. 1, 1999); INST. OF MED., HEALTH PROFESSIONS EDUCATION: A BRIDGE TO QUALITY 1 (Apr. 8, 2003).

to Medicare beneficiaries—particularly hospital services.¹⁶ Under this legislation, Congress directed CMS to craft methodologies that not only would provide monetary bonuses to hospitals that satisfy numerous quality indicators, but also restrict payments to hospitals that treat “hospital-acquired conditions.” As discussed below, it remains to be seen how more precise grafting of payment conditions on clinical performance may affect false-claims based theories of liability for Medicare providers.

As Congress and CMS each have come to express growing concerns about quality of care issues, and as the federal government’s health-care payments continue to skyrocket, the DOJ has become increasingly involved as an enforcement agency in substandard quality of care cases, often working in tandem with CMS and its administrative enforcement agency, the Department of Health and Human Services’ Office of Inspector General (OIG). The DOJ’s efforts in this regard first focused primarily on nursing homes.

As early as 1996, the U.S. Attorney’s Office for the Eastern District of Pennsylvania executed a settlement agreement with the owner and manager of a nursing home.¹⁷ Through a \$25,000 settlement agreement, the government agreed to drop its claims that the nursing home violated the FCA by billing Medicare and Medicaid for “grossly inadequate” nutritional services and wound care services.¹⁸ Soon after, the same U.S. Attorney’s Office filed an FCA claim against three separate nursing homes, alleging that the facilities violated the law by submitting claims for care rendered to beneficiaries who suffered injuries resulting from “nutritional, wound care and nursing services that were not adequately rendered.”¹⁹ The government settled these allegations for \$500,000.²⁰

In 2000, in *United States v. NHC Health Care Corporation*, a case perhaps better known for its legal analysis than its factual underpinnings, the federal government alleged that a Missouri nursing home violated the FCA by submitting claims for payment for services that were “so insufficient and negligent that the claims . . . amounted to fraud.”²¹ The allegedly insufficient services were purported to arise, at least in part,

16 See Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), § 501. See also Deficit Reduction Act of 2005 (DRA), P.L. 109-171, §§ 5001(b) and (c).

17 See *United States v. GMS Mgmt.-Tucker, Inc.*, No. 96-1271 (E.D. Pa. Mar. 6, 1996).

18 See *id.*

19 Complaint at ¶ 17, *United States v. Chester Care Center*, No. 98-CV-139 (E.D. Pa. Feb. 2, 1998).

20 *United States v. Chester Care Center*, No. 98-CV-139 (E.D. Pa. January 1, 1998) (consent order approving settlement), available at <http://clearinghouse.wustl.edu/chDocs/public/NH-PA-0003-0001.pdf>.

21 *United States v. NHC Health Care Corp.*, 163 F. Supp. 2d 1051, 1053 (W.D. Mo. 2001).

from staffing shortages.²² As will be discussed in more detail below, the government's theory in *NHC* survived the nursing home's motion for summary judgment, with the court finding that a reasonable jury could conclude that the nursing home operators "should have known if they were failing to provide all necessary care."²³

Nursing homes have continued to be the subject of heightened scrutiny. In 2005, the DOJ reached a \$2.5 million settlement resolving allegations that Life Care of Lawrenceville, a Georgia nursing home, violated the FCA by providing deficient care. Specifically, the DOJ asserted that one resident died of toxic poisoning because the nursing home administered Coumadin® without checking for blood clotting, a second resident repeatedly fractured her hip after falling four times in one year, and a third resident died of larvae infestation after the failure to provide basic oral hygiene care allowed maggots to develop in her mouth.²⁴ In a 2007 case, the Department of Justice settled allegations that Ciena Healthcare Management, a provider of management services to 32 Michigan-based nursing homes, violated the FCA for \$1.25 million. In that case, the DOJ claimed that Ciena had submitted "false" claims for services at four facilities that provided, among other allegations, insufficient nutrition and hydration, assessment and evaluation, medication management, and other basic care.²⁵ Outside of the nursing home context, federal prosecutors recently have stated that the false claims theory of quality care remains viable for application to other participating providers.²⁶

Although these nursing home cases resulted in settlement, rather than judicial evaluation of the government's underlying false claims theory, the government's successful interjection of the FCA into quality care cases cannot be ignored, especially in light of the potentially significant settlement value of the typical FCA case. On the other hand, no federal court has found a provider liable for violating the FCA by submitting

22 See *id.* at 1053–54.

23 *Id.* at 1058.

24 See Press Release, U.S. Attorney's Office, N. Dist. of Ga., *Lawrenceville Nursing Home to Pay \$2.5 Million to Settle Allegations of Gross Neglect of Residents* (Dec. 22, 2005), www.usdoj.gov/usao/gan/press/2005/12-22-2005.html. The complaint was originally filed by a whistleblower.

25 See Press Release, Office of the Attorney Gen., Cox & U.S. Attorney Announce \$1.25 Million Health Care Fraud Settlement for Major Nursing Home Operators (Aug. 20, 2007), www.michigan.gov/ag/0,1607,7-164-34739-174472--,00.html; HHS Office of Inspector Gen., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CIENA HEALTHCARE MANAGEMENT, INC., MOHAMMAD QAZI, ANIS KHAN, AND DENISE MAHNKE-PUGH (Aug. 2, 2007), www.oig.hhs.gov/fraud/cia/agreements/ciena_healthcare_management_inc_08022007.pdf.

26 See *In the Hands of Strangers: Are Nursing Home Safeguards Working?*, Hearing Before the H. Subcomm. on Oversight & Investigations, Comm. on Oversight & Commerce (May 15, 2008) (statement of Lewis Morris, Chief Counsel to the Inspector Gen., Office of Inspector Gen., Dep't of Health & Human Servs.), available at energy-commerce.house.gov/cmte_mtgs/110-oi-hrg.051508.Morris-Testimony.pdf.

claims for reimbursement for substandard services. These observations notwithstanding, the case law is replete with government and *qui tam* efforts to articulate legal bases on which quality of care violations can lead to FCA liability. As the balance of this article will discuss, the government may well establish such a connection when the care provided is so substandard as not to comprise care at all. However, where plaintiffs simply allege a connection between, for example, failures to conform to Medicare Conditions of Participation or other quality standards and a “false certification,” such efforts have properly failed.

The False Claims Act

Congress enacted the FCA in 1863, after well-publicized instances of Civil War procurement fraud.²⁷ The FCA’s *qui tam* provisions, which allow private citizens—relators—to institute civil actions on behalf of the government, were part of the original statute.²⁸ The FCA, intended to punish any form of fraud upon the government, was a more punitive statute than it is now, calling for double damages and a \$2,000 penalty for each false claim submitted.²⁹ (A penalty of \$2,000 in 1863 equates to a penalty of more than \$41,000 in 2008.) In addition, and for 80 years after the FCA’s passage, a relator could file an FCA suit even if the government was aware of the alleged fraud—or had succeeded in obtaining criminal indictments for the fraud.³⁰

In 1943, Congress amended the FCA so that government knowledge of the allegations in an FCA complaint acted as a complete bar to jurisdiction.³¹ *Qui tam* cases declined after the 1943 amendments until 1986, when Congress amended the FCA to clarify, among other things, that the requirement that a person act “knowingly” does not mean that the person must act with specific intent to defraud the government.³² Since 1986, the government must demonstrate only that the FCA defendant had actual knowledge of the information, acted in deliberate ignorance of the information, or acted in reckless disregard of the truth of the information—a lesser burden than in common law fraud claims.³³ By lowering the FCA’s scienter requirement, Congress sought to “adopt[] the concept that individuals and contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek.”³⁴

27 See Act of March 2, 1863, ch. 67, 12 Stat. 696–98.

28 See *id.*

29 See *id.* § 3.

30 See U.S. *ex rel.* Marcus v. Hess, 317 U.S. 537 (1943), *reh’g denied*, 318 U.S. 799 (1943).

31 See U.S. *ex rel.* LaValley v. First Nat’l Bank of Boston, 707 F. Supp. 1351, 1354–55 (D. Mass. 1988).

32 *Contra* United States v. Mead, 426 F.2d 118 (9th Cir. 1970).

33 See 31 U.S.C. § 3729(b).

34 S. Rep. No. 99-345, at 20 (1986).

As part of the 1986 amendments to combat fraud, Congress extended the FCA's limiting period beyond six years in certain instances, i.e., up to ten years if the government failed to detect the falsity of the claim upon submission.³⁵ Congress also increased the damages multiplier from two to three, allowing an exception for double damages in instances where the defendant has cooperated with the government's investigation.³⁶ The 1986 amendments increased the per-claim monetary penalty from \$2,000 to \$10,000³⁷ and greatly enhanced a relator's ability to file, prosecute, and reap the rewards of an FCA qui tam suit.³⁸

Today, the FCA remains nearly identical to its 1986 form. However, at the time of this writing, the False Claims Act Correction Act of 2007—which would call for expansions to the FCA rivaling those of the 1986 amendments—remains before Congress.³⁹

The FCA provides that any person who

- (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
- (2) 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;
- (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
- (4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;
- (5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

35 See 31 U.S.C. § 3731(b).

36 See 31 U.S.C. § 3729(a).

37 See *id.* See also The Federal Civil Penalties Inflation Adjustment Act of 1990, P.L. 101-410, which requires federal agencies to adjust, at least every four years, the amount of civil penalties at their disposal; and 28 C.F.R. § 85.3 (Department of Justice regulation inflating range of penalties for FCA violations from \$5,000–\$10,000 to \$5,500–\$11,000 per claim). See also 64 Fed. Reg. 47,099 (Aug. 30, 1999) (implementing inflated range of penalties).

38 See 31 U.S.C. § 3730(d). On July 16, 2008, the bill reported favorably out of the U.S. House Judiciary Committee.

39 S. 2041.

- (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or
- (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person....⁴⁰

Subsections (a)(1) and (a)(2) of the FCA are the most commonly applied sections. In the typical healthcare-based FCA action involving an (a)(1) or (a)(2) violation, the plaintiff alleges that the defendant either has submitted a claim to the government for services not rendered, or has submitted a claim to the government that requests reimbursement in an amount greater than allowed. In these straightforward cases, the information provided on the claim is alleged to be fraudulent or a lie. In other words, the claim is alleged to be factually false.⁴¹

Theories of “False Certification”

A less straightforward (a)(1) and (a)(2) FCA-based theory of liability, increasingly advanced by the government and relators alike, is the theory of “false certification.” Under this theory of liability, the plaintiff does not assert that the information provided in a claim is false or fraudulent. Instead, the plaintiff alleges that the claimant, in certifying a claim to the government, has falsely attested—impliedly or explicitly—that it provided or performed services in adherence to certain statutory or regulatory requirements.⁴²

The certification language for claims for Medicare reimbursement varies. Claimants typically file a CMS-1500 form (for physicians’ and certain other services), a UB-04 (for certain hospital services), and/or a CMS-2552 form (the annual hospital cost report). The CMS-1500 form requires the claimant to certify that the services listed on the form were “medically indicated and necessary for the health of the patient and were personally furnished by [the physician] or were furnished incident to [his or her] professional service by [his or her] employee”⁴³

40 31 U.S.C. § 3729(a).

41 Many FCA actions are based on subsection (a)(7), the “reverse false claim” provision. “Reverse false claims” complaints also typically allege that the record or statement used to conceal a debt owed to the government is false.

42 See, e.g., *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776 (4th Cir. 1999).

43 NAT’L UNIFORM CLAIM COMM., 1500 CLAIM FORM, available at nucc.org/images/stories/PDF/cms_1500_sample.pdf.

The UB-04 certification provides that “[s]ubmission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts.”⁴⁴ The CMS-2552 hospital cost report, submitted to verify the appropriateness of payments for services still paid on the basis of cost reimbursement (e.g., organ procurement services, blood clotting factors, and services provided by certain specialty hospitals), requires the hospital administrator or CFO to certify that, to the best of his or her “knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted,” and further that he or she is “familiar with the laws and regulations regarding the provision of healthcare services, and that the services identified in this cost report were provided in compliance with such laws and regulations.”⁴⁵

Although the case law on false certification theory as applied to healthcare providers is not a paragon of clarity, the cases, coupled with policy considerations, lead to the following framework for applying false certification theories to quality of care cases:

1. Under the theory of implied certification, providers certify their compliance only with statutes or regulations that provide that conformance is a condition of payment. The Medicare COPs themselves do not state that compliance with the COPs constitutes a condition of payment.
2. Under the theory of express certification, if a claim form does not explicitly require certification of compliance with a particular statute, but rather requires the claimant to sweepingly certify its compliance with “all applicable laws and regulations,” or words to that effect, providers certify their compliance only to statutes or regulations material to the government’s decision to pay. Medicare COPs are not explicitly referred to in the relevant claims’ certifications, and have not been determined to be material to the payment decision on any ad hoc, case-by-case basis.
3. Substandard care may be so extreme as to lead to factually false claims, or claims for worthless services. Use of the FCA to punish such transgressions is appropriate. These cases are not based upon theories of false certification, however.

44 The UB-04 is available by subscription on the National Uniform Billing Committee website at www.nubc.org/subscribers/subscribers.html.

45 The Hospital Cost Report is available on the CMS website for download at www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp#TopOfPage.

Implied false certification

The theory of implied false certification is based on the notion that a claimant for reimbursement is vouching that its performance has complied with certain statutes or regulations not identified in the claim itself. A review of cases considering this theory supports the conclusion that it should not be employed successfully against a claimant who has failed to comply with certain Medicare COPs.

The general theory of implied false certification was successfully advanced in the non-healthcare case, *Ab-Tech Construction v. United States*.⁴⁶ In *Ab-Tech*, the court held that the defendant-claimant’s submission of payment vouchers “impliedly certified” ongoing adherence to federal Small Business Administration program requirements. Although the payment vouchers made no express mention of the requirements as a condition of payment, the claimant was required to execute a separate agreement to abide by certain minority business requirements. By contracting management control of its business to a non-minority entity, the defendant failed to meet these requirements. The court found that Ab-Tech’s active concealment of this disqualifying fact was “vital” to the integrity of the program and its decision to pay. Failing to qualify as a minority business, lying about it, and seeking payment as if the claimant was so qualified comprised “the essence of a false claim.”⁴⁷

We submit that the basic parameters of the implied false certification theory as applied to healthcare reimbursement can be gleaned from four decisions reached between 1996 and 2002:

- *United States ex rel. Aranda v. Community Psychiatric Center of Oklahoma*,⁴⁸
- *United States v. NHC Health Care Corporation*,⁴⁹
- *United States ex rel. Mikes v. Straus*,⁵⁰ and
- *United States ex rel. Pogue v. Diabetes Treatment Centers of America*.⁵¹

We suggest further, however, for reasons discussed below, that *Aranda* and *NHC* must be applied with great care. The reasoning in these cases is best reserved for instances where the allegations of substandard care are exceedingly grave. This leaves *Mikes* and *Pogue* as the keys to the analysis of how to apply the FCA to allegations of sub-standard care.

46 *Ab-Tech Constr. v. United States*, 31 Fed. Cl. 429 (1994), *aff’d.*, 57 F.3d 1084 (Fed. Cir. 1995).

47 *Id.* at 434.

48 *United States ex rel. Aranda v. Community Psychiatric Ctr. of Okla.*, 945 F. Supp. 1485 (W.D. Okla. 1996).

49 *United States v. NHC Health Care Corp.*, 163 F. Supp. 2d 1051 (W.D. Mo. 2001).

50 *United States ex rel. Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001).

51 *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258 (D.D.C. 2002).

Aranda and *NHC*: qualified application in quality of healthcare cases

In *Aranda*, the government alleged that the claimant violated the FCA by submitting claims for payment for its CPC Southeast Hospital while “knowingly failing to provide ... government insured patients with a reasonably safe environment.”⁵² This amounted to a false claim, under the government’s theory, because:

1. CPC submitted bills to the government for inpatient psychiatric care to Medicaid patients;
2. by submitting these bills, CPC “implicitly certif[ied] that it was abiding by applicable statutes, rules and regulations” requiring that patients be provided with “appropriate quality of care and a safe and secure environment”; and
3. CPC “knew that it was not providing to its patients appropriate quality care and a safe and secure environment.”⁵³

The complaint also identified a number of significant specific threats to patient safety at the facility, including the failure to take precautions against suicide and sexual abuse.⁵⁴

Ruling on the defendant’s motion to dismiss (an important consideration, given the plaintiff’s relatively light burden at that stage in the proceedings), the court permitted the case to go forward, declining to hold that the allegations, if proved, could not form the basis for an FCA claim.⁵⁵ Before reaching this decision, however, the *Aranda* court offered an observation that suggests a weakness in the court’s analysis. First, the court pointed to the import of quality-based standards to the claims submission by cataloging other enforcement techniques available for dealing with quality of care deficiencies: (“... [s]tatutes and regulations governing the Medicaid program clearly require healthcare providers to meet quality of care standards, and a provider’s failure to meet such standards is a ground for (other penalties... and exclusion...)”).⁵⁶ In our view, the availability of other enforcement approaches (which, incidentally, the government had not pursued in this case) clearly seems to cut against the rationale that quality deficiencies are a proper basis for false claims prosecution. The presence of other remedies easily could suggest that when quality deficiencies arise, the government does not deny payment, but instead undertakes other remedial and, if necessary, punitive actions. Accordingly, if the government does not deny

52 945 F. Supp. at 1487, citing Second Amended Complaint at ¶ 35.

53 *Id.*, citing Second Amended Complaint at ¶¶ 101–02.

54 See *id.* at 1488.

55 *Id.*

56 *Id.*

payment in the face of quality deficiencies, it should not be able later to assert that claims for payment are fraudulent.

As to the legal theory of implied certification, it is not clear that the *Aranda* court truly relied on this theory in denying the motion to dismiss. For example, the court observed that the allegations were analogous to situations involving “contractors who furnished inferior goods”⁵⁷—a concept that suggests the potential of a factually false or worthless service approach. However, the court did observe:

It may be easier for a maker of widgets to determine whether its product meets contract specifications than for a hospital to determine whether its services meet “professionally recognized standards for health care”... a problem of measurement should not pose a bar to pursuing an FCA claim against a provider of sub-standard healthcare services under appropriate circumstances.⁵⁸

It is not clear what those “appropriate circumstances” might be. Unless they comprised no care or worthless services—reasoning not quite reached in *Aranda*—it is fair to say that the *Aranda* decision, although flawed in its reasoning and reached at a preliminary stage, does stand for the premise that the theory of implied false certification could apply to claims for payment for healthcare services of inferior quality. We suggest, however, that the weight of this holding is overwhelmed by the more reasoned analyses of *Mikes* and its progeny, as well as public policy reasons that weigh against a broad application of implied certification.

In circumstances similar to those presented in *Aranda*, the government in *NHC* alleged that the operators of a long-term care facility failed to comply with the standard of care when providing services to Medicare and Medicaid clients.⁵⁹ The government’s complaint included examples of the poor care rendered to residents, who allegedly suffered bedsores and other medical difficulties as the result of NHC’s inattention. The government asserted that NHC had significant staffing shortfalls, that the state agency had received numerous complaints of poor care at the NHC facility, and that patients generally were not given care meeting the standards of the Medicare and Medicaid programs. Thus, the government maintained, NHC submitted false claims for payment for these services.⁶⁰

57 *Id.*

58 *Id.*

59 See *United States v. NHC Health Care Corp.*, 163 F. Supp. 2d 1051 (W.D. Mo. 2001).

60 See *id.*

Perhaps hoping to take advantage of a weak legal theory, the defendants sought to characterize the plaintiff's argument—and argue against it—as if it were based upon implied certification. As the court summarized the parties' posturing:

Implied certification essentially means that the Government alleges liability based on the proposition that a healthcare provider implicitly certified in its claim for reimbursement that it would adhere to the prevailing standard of care when providing services to its Medicare and Medicaid residents. Defendants argue that the majority of courts have rejected this theory in healthcare cases. Defendants further argue that the Court has erroneously adopted an implied certification standard when assessing liability against NHC. Plaintiff counters that it is not seeking liability against the Defendants under a theory of implied certification and if anything, Defendants expressly certified compliance with the standard of care.⁶¹

The *NHC* court, possibly recognizing the analytical difficulty inherent in any certification-based false claims argument, refused to adopt either party's approach. Although noting that the theory of implied certification was appropriate in "some" healthcare cases, "when the standard of care, is at the *heart of the agreement* between the parties,"⁶² the court concluded that implied certification was not relevant in *NHC* because the defendants were sued not "simply" because they violated the standard of care, but instead "because they failed to provide the services they billed for."⁶³ In other words, the court measured the care quantitatively, rather than qualitatively, focusing not on how the services were performed (a conformance with standards-type test) but whether services were performed at all (a service-by-service tally approach).⁶⁴ In this quantitative context, the *NHC* court questioned whether the nursing home had provided the essence of "quality of life"—the "heart of the agreement" with the government. In its previous ruling on a motion to dismiss, the *NHC* court had further contrasted the facts before it to instances where the standard of care was alleged to have been unmet by virtue of defective procedures, by observing that "the government utilizes the standard of care as a measuring stick to demonstrate that not all necessary medical acts that were billed for were actually paid."⁶⁵

61 *Id.* at 1055.

62 *Id.* (emphasis added).

63 *Id.*

64 *Id.* at 1053.

65 *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1156, n.4 (W.D. Mo. 2000).

The *NHC* court concluded, “[W]hether implied certification is proper in the health care arena and whether the facts of the case fall under this theory is mainly irrelevant.”⁶⁶ Dismissing both parties’ focus on the “certification obligation,” the court found that the allegations supported a factually fraudulent false claims argument:

At some very blurry point, a provider of care can cease to maintain this [quality] standard by failing to perform the minimum necessary care activities required to promote the patient’s quality of life. When the provider reaches that point, and still presents claims for reimbursement... the provider has simply committed fraud....⁶⁷

We believe, then, the court’s focus in *NHC* ultimately fell on the factual nature of what services were billed for versus what services were provided, concluding that the government and its beneficiaries were not provided the very basics of the services expected. Certification-based theory, implied or otherwise, is not at issue when the liability stems from the defendant’s falsely billing the government for procedures it did not perform.

Thus, in circumstances where a claimant was alleged to have provided woefully—even dangerously—substandard care, the *Aranda* and *NHC* courts took divergent approaches on the theory of implied false certification. The *Aranda* court concluded, at the motion to dismiss stage, that the plaintiff potentially could assert FCA liability on the basis that a claimant “impliedly certified” government conformance with quality-related standards. The *NHC* court, however, although acknowledging that if the substandard care were at the “heart of the agreement” between the parties, left room for applying the implied false certification theory in quality-based cases. However, the *NHC* court demurred from considering the case on this basis, deftly choosing, in our view, a more straightforward, factually false analysis.

In contrast to the obviously substandard—even dangerous—clinical environments addressed in *Aranda* and *NHC*, the analysis is more difficult if the claimant’s alleged failure to meet quality of care standards such as Medicare Conditions of Participation is alleged as the basis for implied certification liability. In other words, beyond the government’s expectation that, if billed for, a service actually must have been provided, what further quality of care expectations must a claimant meet before filing a claim for payment?

⁶⁶ United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051, 1056 (W.D. Mo. 2001).

⁶⁷ *Id.*

***Mikes v. Straus*: Implied certification applies only to violations explicitly tied to payment**

The Second Circuit Court of Appeals case, *Mikes v. Straus*,⁶⁸ sets forth the most comprehensive healthcare-related analysis of the implied false certification theory. We submit that *Mikes* establishes a well-reasoned, well-defined framework for the application of the implied false certification theory in quality of care-related cases.

In *Mikes*, the relator alleged that a group of physicians had filed false claims to Medicare for spirometry tests because, in part, the tests were performed with equipment not properly calibrated and by staff not properly trained. Based on these deficiencies, *Mikes*, the relator, claimed that the defendants failed to satisfy clinical guidelines promulgated by the American Thoracic Society. Thus, *Mikes* argued, the defendants' claims for payment were false because they sought payment for negligently performed tests.⁶⁹

The relator also alleged that the defendant violated 42 U.S.C. § 1320c-5(a), which establishes Medicare Conditions of Participation for physicians. The statute states that it shall be the obligation of "any health care practitioner ... who provides health care services for which payment may be made ... to assure ... [the services] will be of a quality which meets professionally-recognized standards of care."⁷⁰ *Mikes* argued that compliance with this obligation is a requirement for reimbursement under the Medicare program, and therefore a violation of these quality of care-based "legal requirements" also rendered the defendants' claims per se false under the theory of implied false certification.⁷¹

The Second Circuit acknowledged the potential for an implied false certification argument on the basis that Congress intended the FCA to reach all "kinds of 'legally false' claims,"⁷² along with the Supreme Court's conclusion that the FCA was intended to reach all forms of fraud that might cause financial loss to the government.⁷³ Seeking to establish the scope of the FCA's reach on the basis of implied false certification, the *Mikes* court considered *Ab-Tech* and concluded that the earlier decision should be read with caution. The *Mikes* court found that the *Ab-Tech* reasoning (that the filing of a claim implicitly certifies adherence to certain statutes or regulations):

... does not fit comfortably into the health care context because the False Claims Act was not designed for use

68 United States *ex rel.* *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001).

69 *Id.* at 701.

70 42 U.S.C. § 1320c-5(a)(2).

71 42 U.S.C. § 1320c-5(b)(1)(3).

72 274 F.3d at 700 (*citing* S. Rep. No. 99-345 at 9, *reprinted in* 1986 U.S.C.C.A.N. 5264, 5266).

73 *Id.* at 700 (*citing* United States *v.* Neifert-White Co., 390 U.S. 228, 232 (1968)).

as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment—and to construe the impliedly false certification theory in an expansive fashion would improperly broaden the Act’s reach. Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the federal government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that “the regulation of health and safety matters is primarily, and historically, a matter of local concern.”⁷⁴

The Second Circuit expressed policy concerns, for example, that permitting:

qui tam plaintiffs to assert that the defendant’s quality of care failed to meet medical standards would promote federalization of medical malpractice as the federal government or qui tam plaintiff would replace the aggrieved plaintiff.... Beyond that, we observe that the courts are not the best forum to resolve medical issues concerning levels of care. State, local or private medical societies are better suited for quality of care issues.⁷⁵

Having addressed *Ab-Tech* and policy concerns, the *Mikes* court sharpened its framework for the application of the implied false certification theory of liability in healthcare cases:

[W]e think a medical provider should be found to have implicitly certified compliance with a particular rule as a condition of reimbursement in limited circumstances. 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.⁷⁶

However, the court cautioned, “[j]ust as clearly, a claim for reimbursement made to the government is not legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation or contract that is only tangential to the service for which reimbursement is sought.”⁷⁷

74 *Id.* at 699–700 (citing *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985)); accord *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996).

75 *Id.* at 700.

76 *Id.* (emphasis added).

77 *Id.* at 697.

Based on this analytical framework, the *Mikes* court rejected the plaintiff's claims. Analyzing the § 1320c-5(a)-based prong of the plaintiff's allegations, the Second Circuit acknowledged that the statute did establish a quality standard of applicability to the defendant, but ruled that the provision constituted a "prospective obligation" that a claimant must meet in order to "be eligible to participate in the Medicare program."⁷⁸ The court contrasted the provision to 42 U.S.C. § 1395y(a) (1) (A),⁷⁹ which expressly conditions payment of a claim on the medical necessity of the services (but which the court concluded was not relied upon by the relator). The court noted that the overall structure of § 1320c-5(a) "further informs us that (the statute) establishes conditions of participation, rather than prerequisites to reaching reimbursement," through its reference to peer review organizations to monitor compliance, corrective action procedures, sanctions, and other mechanisms.⁸⁰ Ultimately, the court concluded:

Since § 1320c-5(a) does not expressly condition payment on compliance with its terms, defendants' certifications are not legally false. Consequently, defendants did not submit impliedly false claims by requesting reimbursement for spirometry tests that allegedly were not performed according to recognized states of health care.⁸¹

In sum, the *Mikes* court sifted through the case law, policy considerations, and various theories of false claims liability, including the theory of implied false certification, and in our view, propounded two key principles for the application of this theory in healthcare cases:

1. The implied false certification theory should not apply unless the statute or regulation allegedly falsely certified to is a condition of payment, as articulated in the statute or regulation itself; and
2. As discussed below, the Medicare Conditions of Participation are not conditions of payment, and thus a claimant's lack of conformance with a COP does not serve as a viable ground for an implied false certification challenge.

Pogue: The "materiality" test and potential reconciliation with *Mikes*

In *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, Judge Lamberth of the D.C. Circuit Court dubbed the *Mikes* framework

⁷⁸ *Id.* at 701.

⁷⁹ The Court also concluded that the relator's obligations did not assert that the services in question were not "medically necessary," but rather were performed inappropriately. See *id.* at 698.

⁸⁰ *Id.* at 701 (emphasis added).

⁸¹ *Id.* at 702.

a “parsimonious” implied certification test.⁸² In *Pogue*, the court suggested a broader view of the scope of implied certification applicability: An evaluation of the materiality of the violation to the payment decision must be conducted.⁸³ In reaching this determination, the *Pogue* court took a broader and kinder view of *Ab-Tech* than did the *Mikes* court:

[T]he theory of implied certification, as set out in *Ab-Tech*, 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 from those funds contained an implied certification of compliance with the law or regulation and was fraudulent.... The implied certification theory essentially requires a materiality analysis. Certification of compliance with the statute or regulation alleged to be violated must be so important to the contract that the government would not have honored the claim presented to it if it were aware of the violation.⁸⁴

In *Pogue*, the relator alleged violations of the physician self-referral law (Stark Law)⁸⁵ and/or the federal healthcare program anti-kickback statute.⁸⁶ Evaluating the relationship of these alleged violations to an implied false certification claim, the court found sufficient connections between the payment decision and conformance with the federal self-referral and anti-kickback statutes. With regard to the Stark Law, the court’s task was easy—language in the statute itself makes clear that claims submitted in violation of the law are illegal (thus satisfying even the “parsimonious” *Mikes* test).⁸⁷

The court’s evaluation of the connection between an anti-kickback statute violation and the Medicare payment decision required a broader search for support. The D.C. court reviewed an earlier Tennessee court’s conclusion⁸⁸ that the *Pogue* relator successfully connected anti-kickback statute violations to an FCA action. According to the D.C. court, the earlier court had concluded that compliance with the anti-

82 United States *ex rel.* *Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 264 (D.D.C. 2002).

83 See *id.* at 264.

84 *Id.*

85 42 U.S.C. § 1395nn.

86 42 U.S.C. § 1320a-7b(b).

87 See 42 U.S.C. § 1395nn(g)(1).

88 The case had been transferred from Tennessee to the District of Columbia for multi-district litigation purposes. United States *ex rel.* *Pogue v. Am. Healthcorp*, 914 F. Supp. 1507 (M.D. Tenn. 1996).

kickback statute was material to the contract.⁸⁹ The D.C. Court also relied on the fact that after 2001 (the Tennessee decision occurred in 1996), the form signed by applicants seeking certification as a Medicare provider included a statement affirming the provider's understanding that "payment of a claim by Medicare or other health care program is conditioned on the claim and the underlying transaction complying with such laws, regulations and program instructions (including the anti-kickback and the Stark Law)."⁹⁰ These facts were sufficient for the D.C. *Pogue* court to permit the anti-kickback statute allegations to survive not only the defendant's Motion for Judgment on the Pleadings, but also its motion for summary judgment.⁹¹ Most recently, the *Pogue* court highlighted the importance of materiality in an implied certification analysis, reiterating that the 2001 claim form had "evidentiary value ... proving that the government would not have paid the claims had it known of the alleged violations."⁹²

In reconciling the *Mikes* and *Pogue* tests for articulating the span of the implied certification theory, it appears that the *Mikes* court, if anything, would view materiality as a second hoop through which an implied false certification plaintiff would need to jump, provided the plaintiff first could show noncompliance with a quality-related statute or regulation explicitly tied to the payment decision: "We add that although materiality is a related concept.... We rule simply that not all instances of regulatory compliance will cause a claim to become false. We need not and do not address whether the Act contains a [] materiality requirement."⁹³

The *Pogue* court, however, would reverse the analysis and focus simply on the broad question of materiality as the key to an implied certification analysis.

We believe that the *Mikes* approach to the theory of implied false certification—requiring that the statute or regulation in question provide explicit "no payment" language—is more appropriate. As elucidated below, we suggest that the question of materiality is applied more correctly where a plaintiff initially points to certification of compliance language explicitly embracing a broad range of statutes and regulations as a means of identifying those statutes and regulations

89 United States *ex rel.* Pogue v. Diabetes Treatment Ctrs. of Am., 238 F. Supp. 2d 258, 264 (D. D.C. 2002).

90 *Id.* (emphasis added).

91 *See id.*; see also United States *ex rel.* Pogue v. Diabetes Treatment Centers of America, et al., No. 99-3298 (RCL) (D. D.C. July 21, 2008) (granting defendant's motion for summary judgment as to Stark Law claims, but not as to anti-kickback statute claims).

92 Pogue v. Diabetes Treatment Centers of America, et al., No. 99-3298 (RCL) (D. D.C. July 21, 2008).

93 United States *ex rel.* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001).

truly in play in the act of making a certification. However, where the certification language contains no statutory or regulatory reference at all, and where implied certification is the plaintiff’s best contention, we assert that the plaintiff must allege something more—specific statutory language prohibiting the payment of a claim.

Subsequent to *Mikes*, additional support has emerged for that court’s articulation of the contours of the implied false certification theory’s applicability. At least two courts have addressed the specific question whether Medicare Conditions of Participation violations may form the basis for an implied certification challenge. Both courts concurred with the *Mikes* analysis and concluded that COP violations may not form the basis for such a challenge. In *United States ex rel. Conner v. Salina Regional Health Center*,⁹⁴ the court rejected the relator’s false certification argument, concluding, as did the *Mikes* court, that “the regulations on which [the relator] relies, 42 C.F.R. §§ 482.1 *et. seq.* set out the conditions of participation for hospitals. The statutory basis for these regulations is 42 U.S.C. § 1395x(e). Neither [the regulations nor the statute] expressly conditions payment on certification with these requirements.”⁹⁵

Similarly, in *Sweeney v. ManorCare Health Services*,⁹⁶ the relator accused a nursing home of violating relevant COPs. Granting the defendant’s motion to dismiss, the court made the same distinction between conditions of participation and conditions of payment: “[Relator] does not allege that the regulatory violations were conditions of payment. The regulation violations [Relator] points to are conditions of participation in the Medicare and Medicaid programs.... Absent actionable false certifications upon which funding is conditioned, the FCA does not provide a remedy for regulatory violations.”⁹⁷

In *United States ex rel. Swan v. Covenant Care*,⁹⁸ an implied false certification case containing allegations of violations of Medicare and Medicaid Conditions of Participation, the court rejected the legal appropriateness of false claims actions that “[police] technical compliance with administrative regulations.”⁹⁹ In *United States ex rel. Cooper v. Gentiva Health Services*,¹⁰⁰ the defendant won its motion for summary judgment in a case alleging substandard care. The court observed, as did the *Mikes* court, that allowing the case to proceed would “promote

94 *United States ex rel. Conner v. Salina Reg’l Health Ctr.*, 459 F. Supp. 2d 1081 (D. Kan. 2006).

95 *Id.* at 1087.

96 *Sweeney v. ManorCare Health Servs.*, No. C03-5320RJB (W.D. Wash. Mar. 4, 2005).

97 *Id.*, under II.C.1.

98 *United States ex rel. Swan v. Covenant Care*, 279 F. Supp. 2d 1212 (E.D. Cal. 2002).

99 *Id.* at 1220–21.

100 *United States ex rel. Cooper v. Gentiva Health Servs.*, No. 01-508 (W.D. Pa. Nov. 4, 2003).

federalization of medical malpractice,” finding that state and local agencies were “better suited to monitor quality of care cases.”¹⁰¹

More recently, the Seventh Circuit adopted *Mikes*’ “express condition of payment” test.¹⁰² In a false claims case based upon alleged violations of federal regulations relating to clinical studies, the Court of Appeals held that technical violations of a statute or regulation were insufficient to establish false claims liability.¹⁰³ Even if the alleged violations were more than technical, the court continued, a connection between the violation and the payment decision must be shown.¹⁰⁴

Express false certification

In contrast to situations where the government and/or a relator may allege that a claimant’s submission of a claim impliedly certified compliance with a statute or regulation unspecified on the claim form itself, in express false certification cases, plaintiffs assert liability based on the specific certifying language accompanying the claim. For example, the CMS Medicare Cost Report (Form 2552) requires that the claimant certify that:

[The Cost Report is] to the best of my knowledge and belief... a true, correct, and complete statement prepared from the books and records of the provider in accordance with applicable instructions except as noted. I further certify that *I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in conformance with such laws and regulations.*¹⁰⁵

At first blush, it would seem that certification language such as that presented on Form 2552 would offer a basis upon which to assert the falsity of a claim in cases where the claimant signs the certification and has violated any healthcare law or regulation.¹⁰⁶ However, courts have shown an unwillingness to hold such broad language against a certifying claimant under the express false certification liability theory. Instead, a plaintiff must be able to sift through the range of laws covered by such certification language and show that the claimant falsely certified compliance with a statute or regulation to which the government

101 *Id.* under Analysis § A.1.

102 United States *ex rel.* Gross v. AIDS Research Alliance-Chi., 415 F.3d 601, 604 (7th Cir. 2005).

103 *See id.*

104 *See id.* at 605.

105 The Hospital Cost Report is available on the CMS website at www.cms.hhs.gov/costreports/02_hospitalcostreport.asp.

106 *See* footnotes 43–45, *supra*, and according text (detailing specific certifications within CMS forms).

considers conformance essential or material to the obligation to pay. Simply stated, in express certification analysis, not all false statements made on a claim lead to false claim liability. The court in *United States ex rel. A+ Homecare v. Medshares Management Group*¹⁰⁷ articulated this distinction as follows:

Liability does not arise merely because a false statement is included within a claim, but rather the claim itself must be false or fraudulent. A false statement within a claim can only serve to make the entire claim itself fraudulent if that statement is material to the request or demand for [payment].¹⁰⁸

The Fifth Circuit Court of Appeals thoroughly analyzed this concept of materiality in a case involving false claims allegations against Southland Management Corporation.¹⁰⁹ The procedural history of the *Southland* case is complex, but the case ultimately illustrates how the concept of materiality applies to the kind of broad certification language found, for example, in Form 2552. In *Southland*, the United States brought a false claims action on behalf of the Department of Housing and Urban Development (HUD), alleging that apartment complex owners knowingly presented false claims for housing assistance payments based on false statements—that is, that the conditions of their apartments were “decent, safe and sanitary.” The district court granted summary judgment to the defendants, finding that the government could not prove the materiality necessary to pursue a false claims case; there was no proof that the false certifications were likely to have had a material influence on the government’s payment decision.¹¹⁰

On appeal, the Fifth Circuit Court of Appeals agreed that materiality was a required element of an FCA cause of action. Reversing the district court’s decision in favor of the defendants, however, a majority of the court concluded that finding a false certification material to the payment decision (a concept the majority called “outcome materiality”) was irrelevant. Instead, the majority concluded that as a matter of law, a false certification of compliance alone can give rise to liability if the “certification is a prerequisite to obtaining a government benefit.”¹¹¹ Stated another way, in assessing the falsity of the claim, the majority did not measure materiality based on the regulatory subject matter of the certification statement and the impact of those regulations on payment. Instead, the court looked to the import of the certification itself.

107 *United States ex rel. A+ Homecare v. Medshares Mgmt. Group*, 400 F.3d 428 (6th Cir. 2005).

108 *Id.* at 443.

109 *United States v. Southland Mgmt. Corp.*, 288 F.3d 665 (5th Cir. 2002).

110 *See id.*

111 *Id.* at 679.

This majority encountered a strong dissent from Judge Jones. She disagreed with the conclusion that when a “certification of statutory or regulatory compliance is an express prerequisite to receiving a benefit from the government, a false certification is material and renders the claim false as a matter of law.”¹¹² In her lengthy critique of the majority’s analysis, Judge Jones interpreted prior case law differently: “[T]his court [has previously] stated that to create liability under the FCA, a false certification of compliance must be a ‘prerequisite’ to obtaining a government benefit. Unlike the majority, I interpret this language as requiring more than a formalistic connection to the payment decision.”¹¹³ Judge Jones concluded her dissent by observing that “[t]he majority decision is unfortunate for the owners It is even more unfortunate for future government contractors or beneficiaries who must reckon with the threat of punitive sanctions for breach of vague provisions in complex regulatory schemes; for non-material certifications of compliance; and for false claims the government knowingly (and non-collusively) paid.”¹¹⁴

The *Southland* appeal was reheard en banc by the Fifth Circuit. On rehearing, the Court found that Southland’s claims for payment had been filed while the alleged deficiencies were subject to correction actions. Utilizing a new contract-based approach, the court examined the defendants’ contract with HUD, and concluded that the agreement permitted the government to make housing assistance payments during periods in which HUD is working with the claimant to correct potential deficiencies. Thus, the Court concluded, no false claims for payment were submitted as a matter of law.

This time, in a concurring opinion joined by four of her brethren, Judge Jones expressed displeasure that the case was decided on contractual grounds. Chiding the majority for basing its decision on a “narrow” ground (a theory never put forth below), Judge Jones returned to the question of materiality. Noting “past precedent and every circuit that has addressed the issue have so concluded,” Judge Jones reiterated, “there should no longer be any doubt that materiality is an element of a civil False Claims case.”¹¹⁵ Taking issue, however, with how the government had framed the materiality question, Judge Jones wrote:

[T]he government asserts, however, that whenever it conditions payment for services rendered upon a certification of certain conditions by the payee, a false certification constitutes a material false state-

112 *Id.* at 691.

113 *Id.* at 694 (citing *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. Tex. 1997)).

114 *Id.* at 701–02.

115 *Id.* at 679.

ment as a matter of law and renders the entire claim actively false. *This position is overbroad and unsupported by relevant law.*¹¹⁶

Disagreeing with this view, Judge Jones asserted that “where the facts demonstrate that an agency, though formally requiring certification, did not condition payment on its veracity, the certification is not material, and the certified statement will not give rise to false claims liability.” Further, “were a court to hold that any kind of government certification required in connection with federal government payment ... is material as a matter of law, the government could erase the crucial distinction between punitive FCA liability and minor breaches of contract by the simple expediency of requiring broad, boilerplate certifications.”¹¹⁷

A concurring opinion in *Southland* looked beyond the mere act of certification and determined that the express false certifications were not material. The concurrence pointed to the facts that:

1. HUD never had previously informed the owners of deficiencies under the relevant contractual standards, nor sought any remedy for the deficiencies;
2. under HUD’s normal processes, owners continued to receive subsidies while they worked on deficiencies, rather than experiencing withheld payments;
3. there was no evidence of misapplication of funds or mismanagement;
4. HUD itself controlled the mortgage payments for the apartment complexes, and could have used the funds to enhance project quality if HUD wished; and
5. the only materiality evidence evinced by the government—a bureaucrat’s deposition—included a statement that the government would refuse to pay a voucher only if the certification were not signed.¹¹⁸

The views of Judge Jones and the concurring judges set forth a materiality framework now widely followed in express false certifications cases. The *Southland* analysis is instructive in terms of how the theory might apply—or might not apply—to COP violations challenged under the express certification theory of liability; especially when considered along with *Mikes’* impact on implied certification analysis. The notion that a mere false certification of compliance with unspecified laws, standing alone, could as a matter of law be considered material

116 *Id.* (emphasis added).

117 *Id.*

118 *Id.*

for FCA liability purposes, simply is not viable.¹¹⁹ Instead, for such a false express certification allegation to succeed, the plaintiff must show a material connection between the specific statutes and regulations falsely certified to and the government's payment decision. Where, as in the HUD regulatory scheme, the government has alternative methods of dealing with the alleged deficiencies that can be implemented concurrent with payment, a strong inference arises that the alleged failure to comply is not material to payment.

Convincing support for the conclusion that invocation of broad-based certification language does not satisfy the materiality standard was provided in the memorable analogy set forth by Mr. Justice (then Judge) Breyer in *United States v. Data Translation*.¹²⁰ In that case, the court considered whether a broad disclosure requirement formed the basis for false claims allegations. (The disclosure form at issue was analogous to the "kitchen sink" certification language found in the Form 2552.) Judge Breyer was not impressed with the government's reliance on such a broad-based conformance as the basis for its false certification allegation:

We concede the circumstance to which the Government points with pride, namely, the exhaustiveness of the disclosure that the language literally demands. But, it is that very circumstance that creates a problem. Exaggerating to explain our point, we find the Government's interpretation a little like that of, say, a park keeper who tells people that the sign "No Animals in the Park" applies literally and comprehensively, not only to pets, but also to toy animals, insects and even chicken sandwiches. If one met such a park keeper, one would find his interpretation so surprisingly broad that one simply would not know what he really meant or what to do.... [N]o reasonable person ... could have believed that the Government really wanted the complete and total disclosure for which the language seems to ask.¹²¹

Breyer's common sense approach can and should apply in the case of certification language such as that found, for example, in the Form 2552 certification. From a practical perspective, it is impossible that such a representation could be made honestly by any certifier, thus

119 When the claim's certification explicitly identifies a statute for which compliance is required, such as the current claim form does for the Stark Law, 42 U.S.C. § 1395nn, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), materiality can be implied. *See, e.g., United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 238 F. Supp. 2d 258, 264 (D. D.C. 2002).

120 *United States v. Data Translation*, 984 F.2d 1256 (1st Cir. 1992).

121 *Id.* at 1261.

belying the import of the language to the government payor. In reality, given the punitive nature of the False Claims Act, if the language of the broad 2552 certification truly were understood to be meaningful as written, no one ever would agree to sign the claims form.

The common-sense considerations famously enunciated by Judge Breyer 16 years ago, together with the now well-accepted concept of materiality as an essential element in any false claims case as articulated by Judges Jones in *Southland*, can lead only to the conclusion that neither the government nor qui tam relators may rely on Form 2552-type express certification language to convert alleged COP violations into false claims.

To be fair, the government and/or qui tam relators have not been completely unsuccessful in using Form 2552’s certification language to attack violations of law where the underlying statute does not mention a connection to payment. However, in the key case so holding, *United States ex rel. Thompson v. Columbia Healthcare Corporation*,¹²² the circumstances actually support our notion that under false certification theory, the plaintiff must show a material connection between the statute violated and the payment decision, even if the certification language expressly certifies compliance with statutes and regulations in general.

In *Thompson*, as in *Pogue*, the relator based an FCA case upon alleged underlying violations of the Stark Law and the federal anti-kickback statute. As noted earlier, the Stark Law explicitly states that claims filed in violation of its requirements are illegal and shall not be paid, thus clearly passing the “payment materiality” test. However, the anti-kickback statute provides no such language. For the anti-kickback portion of its false claims case, the relator in *Thompson* pointed to the certification language of Form 2552, arguing that the form’s broad statutory and regulatory reference covered violations of the anti-kickback statute, thereby rendering the certifier’s assertion of conformance false.

To support the relator’s case, the government took the unusual step of offering into evidence the Declaration of the Acting Chief of the Department of Health and Human Services Health Care Financing Administration, David Goldberg. Not surprisingly, Goldberg testified via affidavit that:

- Every cost report contained a certification that must be signed;
- HCFA “understood that the certifier was representing that the services provided in the cost report were not infected by kickback”; and

122 *United States ex rel. Thompson v. Columbia Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex., 1998).

- HCFA conditions both payment and provider eligibility on the veracity of the statements in the cost report.¹²³

Armed with Goldberg's post-claims, post-Complaint, sworn affidavit of the government's reliance on the 2552 certification, the court concluded, at least at the motion to dismiss stage, that:

Plaintiffs have stated a claim for violation of the FCA by Defendants' alleged false certification that the Medicare services identified in the annual hospital cost reports complied with the laws and regulations dealing with the provision of health services.... Plaintiffs have provided evidence in the declaration of David Goldberg that HCFA relied on the certifications in determining the issues of payment and retention of payment as well as continued eligibility....¹²⁴

Despite the Goldberg "save" in *Thompson*, it would be unlikely—and inappropriate—for future courts to permit the government to "declare by personal affidavit," on a case-by-case basis, what statutes it considers material to its payment decision. Although it is hard to imagine the DOJ would find it difficult to identify a witness with authority over claims who is willing to express shock at a defendant's statutory transgression and assert that "had we only known ... we would not have paid this claim," we believe federal courts will find such testimony unpersuasive. Such post-complaint articulations, where the connection between certification and payment is not explicitly set forth in either the law or the certification language, serve as the thinnest reed of support for asserting the violation/payment decision relationship. Indeed, with respect to the facts before it, the *Pogue* court's most recent decision held that materiality could not be proven by government affidavit.¹²⁵

In sum, our analysis of the case law leads to the following conclusions:

- Under the theory of implied false certification, quality-based standards should not form the basis for false claims unless either the standards themselves establish the relationship between compliance and payment, or the allegations support consideration of a determination that no services or worthless services were provided.

¹²³ See *id.* at 1041–42.

¹²⁴ *Id.* at 1046.

¹²⁵ United States *ex rel.* Pogue v. Diabetes Treatment Centers of America, et al., No. 99-3298 (RCL) (D. D.C. July 21, 2008).

- Under the theory of express false certification, broad pledges of conformance with any and all statutes and regulations will not lead to a successful false claim argument, unless the plaintiff can demonstrate the materiality of a violation to the payment decision through extrinsic evidence found either in the standard itself, or in some other explicit form knowable to the claimant prior to the certification of the claim at issue.

The COPs Do Not Support a False Certification Challenge Because They Are Not Connected to Payment Decisions

The Medicare Conditions of Participation are not preconditions or material to the government's decision to pay a claim. The COPs include no language connecting a provider's obligation to comply with the government's decision to pay. In fact, the regulatory framework for addressing COP nonconformance suggests strongly that there is no such connection. The Medicare Program's decision to establish the Conditions of Payment as distinct from the Conditions of Participation further attenuates the connection between the government's payment decision and providers' adherence to the COPs.

Providers have been put on notice that conformance or nonconformance with Medicare's Conditions of Participation is not tied to the government's decision to pay a claim. CMS' instructions to its fiscal intermediaries—the entities charged with receiving and paying claims submitted by participating hospitals—explicitly state that whether COPs are met is not a consideration in paying a hospital's claims. Specifically, section 1.1.3 of CMS' Medicare Program Integrity Manual states:

Potential quality of care issues are not the responsibility of the [Medical Review] unit, but are the responsibility of the QIO, State licensing/survey and Certification agency, or other appropriate entity in the service area. Contractors should refer quality of care issues to them. See Chapter 3, § 1, for a discussion on how contractors should handle situations where providers are non-compliant with Medicare conditions of participation.¹²⁶

¹²⁶ CMS, MEDICARE PROGRAM INTEGRITY MANUAL, QUALITY OF CARE ISSUES, Rev. 229, § 1.1.3 (Nov. 23, 2007), available at www.cms.hhs.gov/manuals/downloads/pim83c01.pdf.

In 2004, CMS issued specific instructions to fiscal intermediaries concerning the relevance of COP conformance to payment decisions:

The Conditions of Participation (COP) requirements cannot be used as a basis for denying payment. The COPs define specific quality standards that providers must meet to participate in the Medicare program. A provider's compliance with the COPs is determined by the CMS regional office (RO) based on the State survey agency recommendation. In cases where you believe that the COPs are not being met or when problems have been identified, you should notify your RO and the appropriate State survey agency so that they can initiate appropriate action.¹²⁷

Wholly separate from the Conditions of Participation, Medicare has established explicit Conditions of Payment that hospitals and other providers must meet to receive reimbursement.¹²⁸ For example, the Conditions of Payment state that Medicare will reimburse a hospital for inpatient services “only if” it obtains a physician's signature as to the reasons for the hospitalization.¹²⁹ The Conditions of Payment also provide that, “[a]s a basis for Medicare payment,” the services for which payment is claimed must be:

- covered services,
- provided to an individual who is eligible for Medicare benefits,
- necessary, and
- claimed within prescribed timeframes.¹³⁰

This explicit language makes clear that a provider's satisfaction of the Conditions of Payment is connected materially to the government's decision to pay the claim.

In sum:

- The COP statutes and regulations themselves do not create a nexus between compliance and the government's payment decision.
- Conditions of payment—as distinct from COPs—are explicitly identified by statute and regulation.
- Instructions to fiscal intermediaries explicitly provide that potential COP violations are *not* to be considered in making payment decisions.

127 Pub. 100-08, Transmittal 64, Change 3042 (Jan. 30, 2004) (emphasis in original).

128 See, e.g., 42 U.S.C. § 1395f(a); see also 42 C.F.R. §§ 424.1–424.555 (2008).

129 See 42 U.S.C. § 1395f(a) (emphasis added); see also 42 C.F.R. § 424.13 (emphasis added).

130 42 C.F.R. § 424.5 (emphasis added).

- Provisions for identifying quality-based deficiencies are well-established, establishing plans for corrective action and, if necessary, sanctions, including program exclusions—all while the government continues to pay claims to the provider (and indeed, for 30 days following exclusion).

Given this review of statutory and regulatory underpinnings, and based on the courts' interpretation of the legal theories of liability, we conclude that a provider's failure to meet a Medicare Conditions of Participation should not form the basis for application of either the implied or express false certification theory of liability under the FCA.

The emerging issue of value-based purchasing

The analysis set forth above is of course not static, and the current disconnect between quality-based standards (COPs or otherwise) and the government's decision to pay a claim may become connected—and sooner rather than later. The federal government continues to focus on improving the quality of the nation's healthcare services; both Congress and CMS have examined the plausibility of implementing a pay-for-performance or value-based purchasing reimbursement methodology. In the Deficit Reduction Act of 2005, Congress specifically directed CMS to develop value-based purchasing of hospital services by implementing quality indicators and instituting payment bonuses and penalties for adherence and noncompliance, respectively; and by minimizing or eliminating payment for eight listed hospital-acquired conditions.¹³¹ These hospital-acquired conditions are loosely referred to as “never events,” as they encompass serious but preventable conditions, such as foreign objects left in the body after surgery, administration of incompatible blood, catheter-associated urinary tract infections, and other similar occurrences.¹³²

These programs, as well as CMS' recent Medicare Hospital Value-Based Purchasing Plan to Congress,¹³³ have not yet been fully finalized or implemented. Accordingly, it remains to be seen how FCA liability might impact a claimant who improperly seeks reimbursement for a quality-based performance bonus, seeks to avoid a quality-based reimbursement penalty, or seeks reimbursement for treating a never event. Depending on how—let alone whether—CMS implements value-based purchasing, improper reimbursement requests arguably may constitute either factually false claims or false certifications of compliance

131 See D.R.A., P.L. 109-171, at § 5001(c).

132 See *id.*

133 See www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINAL-SUBMITTED2007.pdf (last visited July 28, 2008).

with quality standards.¹³⁴ For now, it is safe to say that as the federal government “is rapidly transforming ... from being a passive payer of claims to an active purchaser of higher quality, more efficient health care for Medicare beneficiaries,”¹³⁵ and moves closer to connecting its decision to pay a claim with the provider’s assurances that services were provided in a quality manner, providers would similarly move closer to risking FCA liability by claiming (or retaining) reimbursement for poor quality services.

Policy Considerations

Policy reasons also call into question the appropriateness of employing the False Claims Act for policing quality care. It is useful to recall that “[v]iolations of laws, rules or regulations alone do not create a cause of action under the [False Claims Act].”¹³⁶ Instead, the purpose of the FCA is to “provide restitution for money taken from [the government] by fraud.”¹³⁷ Considering this, as well as the FCA’s striking punitive impact, one must consider whether public policy supports reliance on the panoply of other, far more effective measures for enforcing quality care standards available to the government.

In contrast to other available quality enforcement devices, a successful false claims action does not necessarily resolve underlying quality issues. Although cash may flow to the government and/or the relator, the proceeds from a successful litigation (or settlement) will be deposited directly into the Medicare Trust Fund (or the Health Care Fraud and Abuse Control Fund), and be converted into resources available for “combating health fraud.”¹³⁸ The likelihood is virtually nil that any beneficiary potentially harmed by the allegedly substandard quality of care will enjoy any benefit from the settlement.

134 Although discrete instances of “never events” may be identifiable as assuredly inferior service, allegations of poor quality may be factually intensive, subject to interpretations of the standard of care, and generally difficult to prove—much like allegations of medical malpractice. Accordingly, even assuming the embrace of value-based purchasing, another hurdle for false claims allegations based on inferior quality would be recent jurisprudence, such as *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 378 (4th Cir. 2008), in which the court stated that

While the “phrase ‘false or fraudulent claim’ in the False Claims Act should be construed broadly,” ... it just as surely cannot be construed to include a run-of-the-mill breach of contract action that is devoid of any objective falsehood. An FCA relator cannot base a fraud claim on nothing more than his own interpretation of an imprecise contractual provision. To hold otherwise would render meaningless the fundamental distinction between actions for fraud and breach of contract.

135 73 Fed. Reg. 23,528, 23,561 (Apr. 30, 2008) (proposing to include nine additional diagnoses as “never events” for which Medicare payment should not be made).

136 *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996).

137 *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551 (1943).

138 See 42 U.S.C. § 1395i(k)(2)(C)(iv).

Beyond these concerns, use of the False Claims Act to monitor and police healthcare quality also has broader implications for the appropriate authority and power of the federal government in such matters. The government's interest in being charged fairly by its contractors as a customer of services for program beneficiaries is important and well understood; the government wants to pay a fair price for services and should not be cheated.

When quality of care becomes a substantive consideration, however, the federal government adopts a role for which neither it nor reviewing courts are well suited—that is, to serve as the arbiter of what constitutes appropriate medical care. As noted above, this basic police power has been best left to the states, which are far better equipped with the experience and authority to license, oversee, and discipline healthcare providers. The insinuation of federal courts and federal prosecutors—or worse, whistleblowers—into this role, and the punitive use of the FCA in addressing quality concerns, presents a far less optimum, and we submit a far less appropriate, approach to monitoring and policing healthcare quality.

Conclusion

Until a precondition of government payment is that healthcare services be performed in a high quality manner, or until such quality is at least material to the government's decision to pay claims, the great weight of the law, emerging trends in jurisprudence, and sound policy considerations suggest strongly that when put to the legal test, neither the FCA-based theories of implied nor express certification should be considered a viable approach to enforce quality care standards, particularly not the Medicare Conditions of Participation.

