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QUALITY OF CARE AS A BASIS FOR FALSE CLAIMS ACT LIABILITY: IS THE PROOF INSURMOUNTABLE?

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I. INTRODUCTION

Health care fraud enforcement continues to remain a top priority for federal government officials. Indeed, the U.S. Department of Justice ("DOJ") recently announced that it recovered $2 billion in settlements and judgments in fiscal year 2007 pursuing allegations of fraud against all federal government programs, and, continuing a recent trend, the lion's share of that amount — $1.54 billion — came from the health care industry.[1]

Through the Deficit Reduction Act of 2005 ("DRA"), the federal government is also helping state governments ramp up their health care fraud enforcement activities. Signed into law on February 8, 2006, the DRA directs the Center for Medicare & Medicaid Services ("CMS") to create a Medicaid Integrity Program that is similar to its Medicare counterpart, and it substantially increases funding, staffing, and contract resources at CMS to help states combat Medicaid fraud and abuse.[2]

As prosecutors at all levels of government focus their efforts on health care fraud enforcement, some prosecutors (and private plaintiffs in *qui tam* actions) have begun to employ (and others are continuing to employ) the False Claims Act ("FCA") as a vehicle to regulate quality of care. Prosecutors often justify deficient quality of care claims under the FCA by invoking what is commonly referred to as the "implied certification" theory. The basic premise behind this theory is that when providers submit claims for reimbursement from a government funded health care program, they implicitly certify that they have complied with all applicable statutes, regulations, and standards regarding the quality of care provided.[3] Prosecutors further argue that by submitting claims for reimbursement based, at least in part, on care that violates an applicable quality of care standard, providers have submitted a false claim to the government and should be subject to FCA liability.[4]

In the health care context, FCA actions based on the implied certification theory raise interesting and difficult questions for prosecutors, defense attorneys, judges, and health care providers. The most fundamental question is whether the FCA can or should be used as a vehicle to regulate quality of care. While some prosecutors seemingly take acceptance of the theory for granted, defense attorneys strongly disagree, particularly in situations where the underlying quality of care laws include comprehensive enforcement provisions that are less draconian than the penalties available under the FCA.

Assuming for the sake of argument that the FCA is an appropriate vehicle for regulating health care quality, however, one of the more challenging issues facing courts and litigants is the

1 *See* Press Release, U.S. DOJ, Justice Department Recovers $2 Billion for Fraud Against the Government in FY 2007; More Than $20 Billion Since 1986 (Nov. 1, 2007) (*available at:* http://www.usdoj.gov/opa/pr/ 2007/November/07_civ 873.html).
2 *See* DRA Section 6034.
3 *See generally* John R. Munich and Elizabeth W. Lane, *When Neglect Becomes Fraud: Quality of Care and False Claims*, 43 St. Louis L. J. 27 (1999); Robert Fabrikant and Gelnn E. Solomon, *Application of the Federal False Claims Act to Regulatory Compliance Issues in the Health Care Industry*, 51 Ala. L. Rev. 105 (1999).
4 *Id.*

burden of proof that prosecutors must show to justify the imposition of treble damages and civil penalties. Health care providers are subject to countless quality of care laws and regulations, and the standards used to measure quality of care rarely lend themselves to an objective assessment of whether the standards were met or not. In fact, in most cases, a provider's level of compliance with a particular quality of care standard will fall somewhere on a continuum between full compliance and no compliance at all. This reality begs an obvious question — how egregious must a quality of care violation be in order to justify FCA liability?

The first section of this article discusses the government's burden of proof in a traditional FCA enforcement action, and it concludes with a brief discussion of why these cases often settle. The next section discusses the government's burden of proof in an FCA quality of care action based on the implied certification theory. Unfortunately, as long as courts deem these actions an acceptable way of regulating the quality of health care — as some have — this section concludes that the burden of proof in such cases will remain a moving target. Finally, this article concludes with summaries of judgments and settlements that illustrate the evolution of the implied certification theory in FCA quality of care actions.

II. ELEMENTS AND BURDEN OF PROOF IN A TRADITIONAL FCA ENFORCEMENT ACTION

The FCA imposes civil liability on:

> any person who - (1) knowingly presents, or causes to be presented, to . . . the United States Government . . . 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; [or] (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid. . . .[5]

In order to prevail in an FCA enforcement action, courts generally agree that the government must establish these FCA elements, at a minimum, by a preponderance of the evidence.[6]

First, the government must show that the defendant submitted or caused another person to submit a claim for payment to the federal government. The FCA defines a "claim" as:

> any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.[7]

Although proof of this element is rarely the subject of significant dispute, the breadth of the definition strongly suggests that that physicians and other providers who submit claims to the federal government indirectly — through a state government or a private contractor, for example — may expose themselves to FCA liability.[8]

Second, FCA liability will attach only if the government shows that the defendant's claim for payment was false or fraudulent, or that the defendant used a false or fraudulent record or

5 31 U.S.C. Section 3729(a)(1)-(3) (2000). Unless otherwise indicated, all references to the United States Code are to the version published in 2000.
6 31 U.S.C. Section 3731(c) ("In any action brought under [the FCA], the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.").
7 31 U.S.C. Section 3729(c).
8 *See, e.g., United States ex rel. Luther v. Consolidated Industries, Inc.*, 720 F. Supp. 919 (N.D. Ala. 1989). The U.S. Supreme Court heard argument on February 26, 2008 in a case that should clarify what is required to satisfy this element with respect to certain "indirect" claims. *See Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 491 (2007) (*cert. granted*). Specifically, in *Allison Engine*, the Court will likely determine whether a subcontractor must "present" its claims to the government as a condition of FCA liability, or whether liability may attach if a subcontractor is paid by a general contractor with funds originally provided by the government.

statement to obtain payment or approval of the claim. Because the FCA does not define "false" or "fraudulent," courts must determine the meaning of these terms on a case-by-case basis, and that analysis is almost always at the center of FCA disputes. In the health care context, false or fraudulent claims typically involve situations where providers allegedly sought reimbursement for services: (a) that were never provided or were not medically necessary; (b) that were not eligible for reimbursement under the government program at issue; or (c) without adequate documentation of the services performed or the amount of time spent performing those services.

Third, although specific intent to defraud is not an element of an FCA claim, the government must show that the defendant "knowingly" submitted a false or fraudulent claim.[9] The FCA's knowledge requirement is satisfied if the defendant submitted the claim: (a) with actual knowledge of the false information; (b) in deliberate ignorance of the truth or falsity of the information; or (c) in reckless disregard of the truth or falsity of the information.[10]

In addition to these three basic elements, there is some debate as to whether the government must show a final element — damages — in order to prevail under the FCA. Some courts have suggested that FCA plaintiffs are not required to show damages in order to prevail.[11] Other courts have suggested the opposite,[12] however, the FCA seems to support this view.[13]

Notwithstanding the apparent disagreement regarding proof of damages as a required element of FCA liability, it is clear the government must make some showing of damages if it aims to subject a defendant to the full brunt of the FCA's enforcement provisions. And, once FCA liability is established, the consequences can be staggering. To begin, any person found to have violated the FCA may be liable for treble damages, or three times the amount of damages actually sustained by the government as a result of the violation.[14] Before treble damages can be imposed, however, the government must introduce sufficient proof to enable a reasonable estimate of actual damages incurred by the government as a result of the false or fraudulent claim.[15] In addition to treble damages, courts may impose civil penalties against any person found to have violated the FCA in an amount equal to $5,000 to $10,000 per violation.[16] As long as the government shows that the FCA has been violated, proof of actual damages is not necessarily required as a basis for civil penalties.[17] Finally, in addition to damages and civil penalties, health care providers that violate the FCA may be subject to the ultimate penalty — exclusion from the underlying government health care program.[18]

Damages incurred by the government as a result of traditional FCA violations can be particularly difficult to prove due to the complexity of healthcare transactions involving a government payor. Moreover, damages per false claim are often small, at least in relative terms, and the government must support treble damage claims with proof that is sufficient to permit a reasonable estimate of the total damages sustained.[19]

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9 *See* 31 U.S.C. Section 3729(b).
10 *See* 31 U.S.C. Section 3729(b).
11 *See, e.g., United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (affirming district court judgment finding failure to show actual damages did not preclude recovery under the FCA without explicitly addressing the issue); *see also United States ex rel. Schumer v. Hughes Aircraft Co*., 63 F. 3d 1512, 1525 (9th Cir. 1995) (stating that the "lack of a determination of harm ... does not preclude a claim under the [FCA]"); *United States v. Ridglea State Bank*, 357 F. 2d 495, 497 (5th Cir.1966); *Toepleman v. United States*, 263 F.2d 697, 699 (4th Cir. 1959), *cert. denied sub nom. Cato v. United States*, 359 U.S. 989 (1959) (noting that the investigation necessary to detect a false or fraudulent claim costs the government money even if no money is paid on the claim); *United States v. Rohleder*, 157 F. 2d 126, 129 (3rd Cir. 1946); *United States v. Kensington Hosp*., 760 F. Supp. 1120, 1127 (E.D. Pa. 1991) (listing cases).
12 *See, e.g., Young-Montenay, Inc. v. Untied States,* 15 F.3d 1040, 1043 (5th Cir. 1994); United States ex rel. Stinson v. Provident Life & Accident Ins. Co., 721 F. Supp. 1247, 1258-59 (S.D. Fla. 1989) (stating that the FCA requires that the government suffer damages as a result of the submission of a false or fraudulent claim); *Blusal Meats, Inc. v. United States*, 638 F. Supp. 824, 827 (S.D.N.Y. 1986), *aff'd*, 817 F. 2d 1007 (2nd Cir. 1987).
13 *See* note 6, *supra*.
14 31 U.S.C. Section 3729(a)(A)-(C).
15 *See, e.g., United States v. Rogan*, 459 F. Supp. 2d 692, 720 (N.D. Ill. 2006) ("The computation of damages [under the FCA] does not have to be done with mathematical precision but, rather, may be based upon a reasonable estimate of the [government's] loss."), *aff'd*, 517 F. 3d 449 (7th Cir. 2008); *AB-Tech Const., Inc. v. United States*, 31 Fed. C. 429, 434 (1994) (holding government is not entitled to treble damages under the FCA if it offers no proof of actual damages resulting from the alleged FCA violation), *aff'd*, 57 F. 3d 1084 (Fed. Cir. 1995).
16 31 U.S.C. Section 3729(a).
17 *See, e.g., Rogan*, 459 F. Supp. 2d at 720 ("The United States does not need to prove actual damages in order to recover . . . statutory penalties [under the FCA]. The United States may recover penalties upon a showing that the claims were false, even if no damage is proved."), *aff'd*, 517 F. 3d 449; *United States ex rel. Rudd v. Schimmels*, 85 F. 3d 416, 419 n. 1 (9th Cir. 1996) ("In addition to treble damages, the FCA requires a court to award not less than $5,000 and not more than $10,000 for each false claim or statement submitted to the government, even if no damages were caused by the false submissions.").
18 *See* 42 U.S.C. Section 1320a-7(a).
19 *See* note 15, *supra*.

FCA actions based on a number of claims submitted over a period of time for care provided to different individuals can be particularly difficult to prove. In such cases, the government should be required to introduce evidence of damages incurred as a result of each and every claim, which necessarily requires proof of the coding used to support each claim, the coding that should have been used to support each claim, and the reimbursement rates attributed to those codes under the reimbursement plan(s) at issue. Prosecutors often seek to avoid these complexities by introducing summaries of allegedly false or fraudulent claims and the damages incurred as a result, which defendants necessarily challenge as speculative.

Despite the challenges of proving traditional FCA claims, providers often prefer to settle such cases because of the risks and uncertainty of trial and the disastrous consequences of an adverse judgment.[20] As noted above, the monetary damages and civil penalties that can result from FCA liability are staggering. More importantly, however, providers found to have violated the FCA can be excluded from participation in government-funded health care programs, which often sounds the death knell for providers who rely on serving individuals covered under such programs.

III. ELEMENTS AND BURDEN OF PROOF IN AN FCA QUALITY OF CARE ACTION BASED ON THE "IMPLIED CERTIFICATION" THEORY

The basic elements of an FCA action based on the "implied certification" theory are the same as those of a traditional FCA action. In sum, the government must show that: (a) the defendant submitted or caused another person to submit a claim for payment to the federal government; (b) the claim for payment was false or fraudulent, or the defendant used a false or fraudulent record or statement to obtain payment or approval of the claim; and (c) the defendant submitted the false or fraudulent claim "knowing" that it was false.

FCA actions based on implied certification are different from traditional FCA actions in the sense that they are not based on outright falsehoods, such as reimbursement claims for services that were never provided. Instead, such actions are based on the premise that, by submitting a claim for reimbursement to a government-funded health care program, health care providers implicitly certify that they have complied with all applicable statutes, regulations, and standards regarding the quality of care provided. If one accepts this premise, the logic of the implied certification theory continues that by submitting a claim for reimbursement to the government for services that did not meet an applicable quality of care requirement, the claim is inherently "false" or "fraudulent," the provider "knew" it, and FCA liability should attach.

Whether prosecutors can or should rely on the implied certification theory as a basis for establishing liability under the FCA remains the subject of significant dispute. Unfortunately, the U.S. Supreme Court has contributed to the debate by rendering conflicting interpretations of the scope and breadth of the FCA itself. On the one hand, the Court has encouraged implied certification theorists by broadly stating that the FCA "reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money."[21] On the other hand, the Court has encouraged defendants by stating that the FCA "was not designed to reach every kind of fraud practiced on the Government."[22]

If the implied certification theory takes hold, the ramifications for health care providers and their attorneys will be significant. Indeed, taken to the extreme, the theory has the potential to sweep virtually every quality of care standard to which providers are subject under the umbrella of the FCA, and it would allow violations of those standards to be prosecuted as FCA violations with all of the associated consequences (*i.e.*, damages, civil penalties, and exclusion from the underlying program).

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20 *See* Stephanie L. Trunk, *Sounding the Death Toll for Health Care Providers: How the Civil False Claims Act Has a Punitive Effect and Why the Act Warrants Reform of its Damages and Penalties Provision*, 71 Geo. Wash. L. Rev. 159 (2003).
21 *United States v. Niefert-White Co.*, 390 U.S. 228, 233 (1968).
22 *United States v. McNinch*, 356 U.S. 595, 599 (1958).

Although not exhaustive, likely sources of quality of care standards that could be used to form the basis of an FCA action under an implied certification theory include:

1. **Medicare and Medicaid.** Various provisions in the Medicare and Medicaid laws require health care providers to provide services consistent with "professionally recognized standards of health care."[23] At trial, this standard would require a battle of medical experts to establish the professionally recognized standard of care, which would depend on the circumstances of each allegedly false or fraudulent claim and could vary depending on: the age or health status of the patient; the type of provider(s) involved in the patient's care; the medical specialty of the provider(s); and the geographic location of the patient(s) or provider(s).

2. **The Social Security Act.** The Social Security Act requires skilled nursing facilities to provide each resident with the "necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being, in accordance with [their] comprehensive assessment and plan of care."[24] At trial, this standard would require courts to analyze each comprehensive assessment and plan of care at issue and determine whether the care and services provided were consistent with the overall goal of helping the patient attain or maintain the highest practicable physical, mental, and psychological well-being.

3. **The Nursing Home Reform Act.** The Nursing Home Reform Act requires nursing facilities to comply with quality of care standards similar to those included in the Social Security Act. Specifically, a nursing facility "must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident."[25] Moreover, such facilities are obligated to "provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care . . . ."[26]

4. **Quality of Care Standards Promulgated by Medical Professional Associations.** Some plaintiffs have brought FCA actions based, at least in part, on alleged violations of standards promulgated by medical professional associations. In these cases, plaintiffs have argued that such standards are the "professionally recognized standards of care" to which providers agree to conform as a condition of participating in and receiving payments under the government-sponsored health care program.

5. **Provider Agreements.** Written agreements between providers and government entities at the local, state, or federal level may incorporate quality of care standards that could be used to buttress an FCA action based on the implied certification theory.

Unfortunately, these and other quality of care standards like them are extremely vague and do not lend themselves to an objective assessment of whether the standard was met or not. Instead, quality of care standards generally describe an optimal level of care, and judges and juries may use

23 *See, e.g.*, 42 U.S.C. Section 1320a-7(b)(6)(B) (authorizing the government to exclude providers from any federal health care program if they furnish patient services "of a quality which fails to meet professionally recognized standards of health care"); *Id.* at Section 1320c-5(a)(2) (requiring providers participating in federal health care programs to certify that services provided "will be of a quality that meets professionally recognized standards of health care"); *Id.* at Section 1396a(a)(30)(A) (requiring state Medicaid programs to proscribe methods and procedures relating to the utilization of, and payment for, services that are sufficient to "assure that payments are consistent with . . . quality of care"); 42 C.F.R. Section 455.2 (defining "abuse" to mean, among other things, "provider practices that are inconsistent with sound . . . medical practices . . . or fail to meet professional recognized standards for health care.").

24 42 C.F.R. Section 483.25; *see also* 42 U.S.C. Section 1395i-3(b)(2) ("A skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care.").

25 42 U.S.C. Section 1396r(b)(1)(A).

26 42 U.S.C. Section 1396r(b)(2).

these standards as a baseline against which to measure and compare the actual quality of care provided. The subjective results of these comparisons will fall somewhere on a continuum between full compliance and no compliance at all, and they will always be impacted by context and the experience of the fact finder.

How egregious must a provider's quality of care violation be in order to justify an FCA action based on the implied certification theory? The answer to this fundamental question is likely to vary from jurisdiction to jurisdiction, from judge to judge, and from jury to jury.

IV. CASE STUDIES

The following case studies suggest that in determining whether providers can or should be subject to FCA liability for providing deficient quality of care, many courts are willing to impose practical limits on the implied certification theory and the reach of the FCA. Interestingly, the courts tend to focus on the statutory or contractual requirements of payment, rather than on the delivery of care. Nonetheless, these case studies also suggest that liability (or an out-of-court settlement) should result in such cases only when the alleged quality of care violations are particularly egregious.

A. United States ex rel. Aranda v. Community Psychiatrics Ctrs. of Okla., Inc.[27]

Aranda was one of the first cases to recognize that potential validity of the implied certification theory in the health care context. The defendant hospitals in *Aranda* allegedly submitted claims for government reimbursement for services provided to psychiatric patients knowing that the quality of care provided was substandard and the hospital environment unsafe. The government specifically alleged that understaffed shifts, lack of monitoring equipment, and inappropriate housing assignments caused physical injury to and sexual abuse of government-insured patients.[28] In a motion to dismiss, the hospitals argued that they could not be subject to FCA liability because: (a) the government program's billing and reimbursement requirements did not subject the hospital to objective quality of care or safety standards; (b) without objective standards, health care providers could not knowingly fail to comply; and (c) the existence of a comprehensive scheme to regulate providers' compliance with quality of care standards should preclude additional liability under the FCA.[29]

In denying the defendant's motion to dismiss, the court held that a provider's failure to meet applicable quality of care and safety standards could form the basis of FCA liability under appropriate circumstances.[30] Interestingly, the court also stated that the difficulties of comparing "professionally recognized standards of health care" with the actual care provided should not preclude FCA claims against the providers of allegedly substandard health care services.[31]

B. United States ex rel. Mikes v. Straus.[32]

In *Straus*, the federal district court in the Southern District of New York soundly rejected a *qui tam* plaintiff's attempt to invoke the implied certification theory in a quality of care action. In doing so, the court suggested that quality of care violations may form the basis of FCA liability only when government payments are *expressly* conditioned on compliance with a particular standard. The Second Circuit Court of Appeals affirmed in a case that is widely cited for distinguishing between quality of care conditions of payment versus conditions of participation.

The plaintiff in *Straus* alleged that the defendant violated the FCA by knowingly submitting claims for Medicare reimbursement for spirometry tests[33] that did not comply with the American Thoracic Society's ("ATS") guidelines for administering such tests.[34] Because the tests did

27 945 F. Supp. 1485 (W.D. Okla. 1996).
28 *Id.* at 1488.
29 *Id.*
30 *Id.*
31 *Id.*
32 84 F. Supp. 2d 427 (S.D.N.Y. 1999), *aff'd* 274 F. 3d 687 (2d Cir. 2001).
33 Spirometry is a pulmonary function test used by doctors to detect both obstructive (*e.g.*, asthma and emphysema) and restrictive (*e.g.*, pulmonary fibrosis) lung diseases. *See Straus*, 274 F. 3d at 694.
34 84 F. Supp. 2d at 433.

not comport with ATS guidelines, the plaintiff alleged that the providers knowingly submitted claims for reimbursement for services that violated their obligation to assure Medicare beneficiaries receive services "of a quality which meets professionally recognized standards of health care. . . ."[35]

The district court dismissed the complaint on summary judgment and held that "[s]ubmitting a claim to the Government for a service that was not provided in accordance with the relevant standard of care, . . . without more, does not render that claim false or fraudulent . . . ."[36] Instead, FCA liability under the implied certification theory "is to be found only in those exceptional circumstances where the claimant's adherence to the relevant statutory or regulatory mandate lies at the core of its agreement with the Government, or, in more practical terms, where the Government would have refused to pay had it been aware of the claimant's non-compliance."[37]

The Second Circuit affirmed on appeal, and it emphasized the difference between conditions of payment and conditions of participation under government health care programs.[38] Specifically, the court explained that a provider may be subject to FCA liability based on a quality of care violation only if compliance with the underlying standard is an express condition of payment.[39] In contrast, FCA liability may not be based on the violation of a standard that is a general condition of participation in a government health care program, particularly when the violation of a standard would result in sanctions only when dereliction occurs in a substantial number of cases.[40]

The Second Circuit supported its conclusions with two policy considerations. First, the court stated that permitting FCA actions based on quality of care violations would inappropriately promote the federalization of medical malpractice, with government or *qui tam* plaintiffs standing in the shoes of aggrieved patients.[41] Second, the court stated that state, local, and private medical agencies are better suited than the courts to resolve medical issues concerning levels and quality of care.[42]

C. *United States v. NHC Healthcare Corp.*[43]

In this quality of care action, the federal district court in the Western District of Missouri relied on *Aranada* and *Straus* and held that the government stated a claim upon which relief could be granted under the FCA. In *NHC*, the government alleged that a nursing home and skilled nursing facility submitted bills to Medicare and Medicaid for services that it could not possibly have administered to two patients because it was so severely understaffed. The patients allegedly died as a result of the substandard care. The government argued that the provider violated the FCA by submitting false claims for per diem reimbursements under Medicare and Medicaid and failing to "care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life."[44]

At the outset, the court recognized that the quality of care standard relied upon by the government is "[o]bviously . . . amorphous [and] in need of further clarification."[45] However, the court held that the government sufficiently pled a cause of action under the FCA by alleging that per diem payments to NHC were expressly conditioned on complete care of NHC's residents, and NHC breached its obligation by knowingly failing to perform all acts necessary to promote the overall maintenance and quality of life of its residents.[46] The court implied that it would not have permitted this case to go forward if it required the court to analyze "technical compliance" with quality of care regulations and standards.[47]

35 *Id.* at 433.
36 *Id.* at 433.
37 *Id.* at 435.
38 *See* 274 F. 3d at 700-02.
39 *Id.* at 700-01.
40 *Id.* at 701-02.
41 *Id.* at 700.
42 *Id.*
43 115 F. Supp. 2d 1149 (W.D. Mo. 2000).
44 *Id.* at 1153 (citing the Nursing Home Reform Act).
45 *Id.* at 1153.
46 *Id.* at 1155.
47 *Id.* at 1155.

D. *United States ex rel. Swan v. Covenant Care, Inc.*[48]

The plaintiff in this *qui tam* action alleged that Covenant Care, a skilled nursing facility, violated the FCA by failing to provide adequate care to its patients and falsifying records to justify claims for reimbursement under Medicare. The federal court in the Eastern District of California summarily dismissed the claim and questioned the rationale of cases like *Aranda* and *NHC* that give clout to the implied certification theory.

The court began by stating, like *Straus*, that "'regulatory violations do not give rise to a viable FCA action' unless government payment is expressly conditioned on a false certification of regulatory compliance."[49] Moreover, after summarizing the comprehensive regime through which the Department of Health and Human Services ("HHS") monitors and enforces the quality of care guidelines included in the Social Security Act, the court stated:

> To allow FCA suits to proceed where government payment of Medicare claims is not conditioned on perfect regulatory compliance — and where HHS may choose to waive administrative remedies, or impose a less drastic sanction than full denial of payment — would improperly permit *qui tam* plaintiffs to supplant the regulatory discretion granted to HHS under the Social Security Act. . . .[50]

This analysis should apply equally when federal or state prosecutors attempt to supplant the regulatory discretion afforded to HHS and other federal and state government agencies to enforce quality of care standards.

E. *United States ex rel. Landers v. Baptist Memorial Health Care Corp., et al.*[51]

In one of the most recent FCA quality of care actions, the federal district court in the Western District of Tennessee granted the defendant medical corporations' motion for summary judgment based primarily on the distinction between conditions of participation and conditions of payment. The *qui tam* plaintiff alleged that despite certifying their compliance quality of care standards in the Social Security Act and Medicare laws and regulations, the defendants failed to: (a) maintain adequate nursing staffing; (b) organize surgical services appropriate to the scope of services offered; (c) adopt policies governing surgical care aimed at maintaining high standards of care; and (d) provide a sanitary environment.[52]

The *Landers* court granted the defendants' motion for summary judgment after concluding that these standards of care were conditions of participation under Medicare, not express conditions of a particular payment to the defendants.[53] The court also explained that not every false or fraudulent statement that is tangentially related to a claim for payment from the Government will result in FCA liability. Instead, before FCA liability may attach, the court explained that the false statement must be material, or have a natural tendency to influence, the government's decision to pay.[54]

F. Chippenham Manor Nursing Home Settlement.

In August of 2005, the U.S. DOJ released the terms of a settlement it reached in January of 2002 with Chippenham Associates L.P. d/b/a Chippenham Manor Nursing Home and its management company, Richmond Management Associates L.L.C.[55] The government alleged that the defendants violated the FCA and Virginia's Medicaid statutes by failing to: (a) provide adequate wound care, nutrition, and nursing services in a timely manner in view of the clinical condition of their nursing home residents; (b) notify family and physicians of changes in the residents' conditions promptly; (c) obtain orders for and/or administer medications timely and accurately. The government

48 279 F. Supp. 2d 1212 (E.D. Cal. 2002).
49 *Id.* at 1221 (citations omitted).
50 *Id.* at 1222.
51 525 F. Supp. 2d 972 (W.D. Tenn. 2007).
52 *Id.* at 975-76.
53 *Id.* at 978-79.
54 *Id.* at 979.
55 A copy of the settlement agreement is *available at*: www.usdoj.gov/usao/vae/documents/ chippenhammanornursinghome.pdf.

also alleged that as a result of these failures, the defendants subjected nursing home residents to conditions that posed significant or potential risks to their health and well being.

Under the terms of the settlement, Chippenham and Richmond agreed to pay a total of $300,000 in penalties, and Chippenham further agreed to establish an escrow account of $300,000 to be used to pay expenses associated with "the federal monitor, quality of care improvements, approved capital expenditures, and other compliance requirements" set forth in the settlement. Those requirements included, among other things, that Chippenham would: (a) provide each resident with adequate skin care, nutrition, turning and positioning and other services to decrease the likelihood of skin breakdown and the development of pressure sores; (b) implement and/or maintain a nutritional monitoring program; (c) only provide enternal and paternal feedings to those residents who are unable to obtain adequate nutritional intake orally and whose clinical condition demonstrates that such feedings are unavoidable; (d) provide incontinence care in a timely fashion and ensure that reasonable personal hygiene measures are provided to all residents; (e) timely offer and administer effective pain management to residents in need; and (f) timely distribute medications consistent with contemporaneous professional standards.

G. Hillcrest Healthcare Settlement.

In May of 2005, the U.S. Attorney for the District of Connecticut and the Connecticut Attorney General announced a settlement with Hillcrest Healthcare, Inc. stemming from a joint investigation of quality of care problems at Hillcrest nursing homes.[56] The government alleged that quality of care problems at these nursing homes resulted in severe pressure sores and ulcers, dehydration, and weight loss in many patients and caused the death of one. The government also alleged that the nursing homes were inadequately staffed and failed to follow patient care plans.

Under the terms of the settlement, Hillcrest agreed to surrender its nursing home license and has been permanently excluded from the Medicare and Medicaid program. Hillcrest also agreed to pay a $750,000 in civil penalties.

V. CONCLUSION

The complexities of actually proving an FCA enforcement action against a health care provider based on the implied certification theory seem nearly insurmountable. However, the government is not likely to give up this basis for FCA liability anytime soon. Indeed, the threat of FCA liability is one of the government's biggest sticks, and the implied certification theory has the potential to significantly broaden the circumstances in which that stick may be used.

As is evident from the case law and settlements described above, the trends in implied certification theory cases are emerging primarily in the nursing home industry. In the coming years, that industry almost surely will experience an exploding demand for services as the largest generation of Americans — the Baby Boomers — approach nursing home age. As the demand for nursing home care increases, so too will government scrutiny of that care and the entities providing it. When providers step up to meet the increasing demand, they will be forced to find ways to continue providing high quality care even though the dollars available to pay for it are short.

Health care providers facing a threat of FCA liability will almost always want to avoid the negative headlines associated with a public enforcement proceeding. However, when they have been willing to fight, providers have successfully challenged the government's use of the implied certification theory by arguing that:

1. The FCA is not designed or intended to regulate health care quality, and courts are ill equipped to enforce subjective quality of care standards.

56 *See* Press Release, U.S. Attorney's Office District of Connecticut, Nursing Home Agrees to Pay $750,000 to Settle Allegations Under the False Claims Act (May 18, 2005) (*available at*: www.usdoj.gov/ usao/ct/Press2005/20050518.html).

2. The authority to enforce quality of care standards has been delegated to federal, state, and local government agencies through comprehensive enforcement provisions, and those provisions should preclude additional liability under the FCA.

3. FCA liability should attach only if adherence to the underlying quality of care standard lies at the core of the provider's agreement with the government and payment is expressly conditioned on the provider's compliance with that standard.

A provider's decision on whether to negotiate with the government or put it to its proof will likely depend on the facts and circumstances of each case, including the egregiousness of the alleged conduct and the relative acceptance of the implied certification theory in the relevant jurisdiction. As the case law continues to develop, however, it appears that health care providers are in a better position to put the government to its proof than might ordinarily be the case.