

**THE FALSE CLAIMS ACT:  
A PROPER TOOL FOR ENFORCING  
HEALTH CARE QUALITY STANDARDS?**

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# TABLE OF CONTENTS

ABOUT WLF’S LEGAL STUDIES DIVISION .....	ii
ABOUT THE AUTHOR .....	iii
INTRODUCTION .....	1
I. THE FEDERAL FALSE CLAIMS ACT .....	2
II. THEORIES OF LIABILITY UNDER THE FCA .....	3
A. “Facially” False Claim Theory .....	3
B. Express False Certification Doctrine .....	4
C. Worthless Services Theory.....	5
D. Implied False Certification Doctrine.....	6
1. Most jurisdictions follow the condition-of-payment view .....	7
2. Few jurisdictions follow the condition-of-participation view.....	10
3. Policy critiques of the minority condition-of-participation view .....	16
a. The condition-of-participation view encroaches on the exercise of federal administrative discretion.....	16
b. The condition-of-participation view federalizes state malpractice law .....	17
III. FCA HEALTH CARE QUALITY ENFORCEMENT .....	17
CONCLUSION .....	24

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# **THE FALSE CLAIMS ACT: A PROPER TOOL FOR ENFORCING HEALTH CARE QUALITY STANDARDS?**

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## **INTRODUCTION**

Congress enacted the federal False Claims Act (“FCA”), 31 U.S.C. §§ 3729 – 3733, in 1863 to combat fraud on the U.S. Treasury in procuring military equipment for the Civil War. Federal prosecutors used the FCA sparingly until 1986, when amendments strengthened the FCA in favor of private plaintiffs called *qui tam* relators. Prosecutors and relators have since used the FCA to fight almost every kind of health care fraud — from billing for procedures that were not performed, to billing for non-reimbursable costs, to “upcoding” for higher reimbursement.

Increasingly, prosecutors are using the FCA as a tool for enforcing compliance with federal health care quality standards. These health care quality investigations and actions have relied on several theories of liability, some of which are legally controversial. This WORKING PAPER surveys these theories, with particular emphasis on the implied false certification theory, and also examines the federal government’s FCA health care quality enforcement activities and priorities.

## I. THE FEDERAL FALSE CLAIMS ACT

The FCA makes submitting a false claim for payment to the federal government actionable and subjects the submitter to a range of onerous penalties. 31 U.S.C.A. § 3729(a)(1). To impose liability, the government or the relator must show that the defendant (1) made a claim, (2) to the U.S. Government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury. *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001).

A “claim” is defined broadly to include any request or demand that is made to a contractor or recipient if the government provides any portion of the money requested, or if the government will reimburse the contractor or recipient for any portion of the money requested. 31 U.S.C.A. § 3729(c). The FCA reaches claims, including Medicare cost reports, which health care providers submit to Medicare payment intermediaries. *Peterson v. Weinberger*, 508 F.2d 45 (5<sup>th</sup> Cir. 1975), *cert. denied*, 423 U.S. 830 (1975); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1034-35 (S.D. Tex. 1998).

The government or a private whistleblower plaintiff called a *qui tam* relator may bring a FCA claim. A *qui tam* relator must first serve a copy of the complaint, and substantially all material evidence on the federal government. 31 U.S.C.A. § 3730 (b)(2). The complaint then remains under seal for at least 60 days, and is not served until the court orders. *Id.* This gives the government an opportunity to investigate the claim and make an intervention decision. The government may intervene within the 60 days, unless the time to intervene is

extended (as occurs frequently). *See Id.* The government must notify the court within the 60 days if it declines to intervene, and then permit the *qui tam* relator to proceed. 31 U.S.C.A. § 3730 (b)(4)(A)-(B). The defendant has 20 days to answer from the date on which the complaint is unsealed and served. 31 U.S.C.A. § 3730 (b)(3). If the government intervenes and is successful, the relator may receive a bounty — usually between 15 and 25 percent of any proceeds or settlement, plus reasonable expenses, attorneys’ fees, and costs from the defendant. 31 U.S.C.A. § 3730(d)(1). If the government declines to intervene, the relator may proceed independently and, if successful, may be awarded a “reasonable amount,” usually 25 to 30 percent of any proceeds or settlement, plus reasonable expenses, attorney’s fees, and costs from the defendant. *Id.*

A defendant’s exposure under the FCA includes (1) civil penalties of between \$5,500 and \$11,000 per false claim, plus (2) three times the amount of the damages the government sustains because of the violation. 31 U.S.C.A. § 3729(a).

## **II. THEORIES OF LIABILITY UNDER THE FCA**

### **A. “Facially” False Claim Theory**

In a typical FCA action, a private company overcharges for a government contract and the claim for payment is itself literally false or fraudulent. *United States ex rel. Woodruff v. Haw. Pac. Health*, Civil No. 05-000521 JMS/LEK, 2007 WL 1500275, at \*4, (D. Haw. May 21, 2007). The defendant, on the face of its claim for payment, bills for services that it never provided, or bills for more services than it actually provided, or bills inflated amounts for services that it

provided. All jurisdictions recognize this most basic form of FCA liability, which is sometimes called the “facially” false claims theory.

## **B. Express False Certification Doctrine**

A claimant can expose itself to FCA liability without making a facially false statement about the amount of services that it has provided by making a “legally false” statement. Under the express false certification doctrine, the claimant’s false statements about its legal status or compliance in providing the services (or the legal status or compliance of the services themselves) are just as actionable as facially false statements.

The touchstone for applying this doctrine is the claimant’s expressly and falsely certifying in its claim that it has complied with a particular statute, regulation, or contractual term, where compliance is a prerequisite for obtaining payment.

For example, in *United States ex rel. Riley v. St. Luke’s Episcopal Hospital*, 355 F.3d 370, 376-78 (5<sup>th</sup> Cir. 2004), a nurse brought a *qui tam* action against a hospital, alleging that it filed or helped file claims falsely certifying that patient hospitalizations and upgrades to the intensive care unit care were medically necessary. The hospital had submitted Medicare claim forms stating: “[T]he services shown on this form were medically indicated and necessary for the health of the patient.” *Id.* at 376 n.6. This language tracked and invoked federal laws stipulating that medical necessity is a condition for payment for billed services. *See Id.* (citing 42 U.S.C. § 13957(a)(1)(A), 42 C.F.R. § 424.32(b)). The U.S. Court of Appeals for the Fifth Circuit held that the plaintiff had stated an

FCA claim by alleging that the hospital had executed the claim forms knowing that its certifications concerning medical necessity were false, and not merely scientifically debatable or erroneous. *Id.* at 376.

All jurisdictions recognize some species of the express false certification doctrine.

### **C. Worthless Services Theory**

The so-called “worthless services” theory of FCA liability is a strain of the facially false claim theory in which the relator alleges that the defendant did not provide what it billed the government for, because what it ultimately provided had no value.

The U.S. Court of Appeals for the Ninth Circuit recognized this theory in *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051 (9<sup>th</sup> Cir. 2001), where the relator alleged that a laboratory falsified medical test results and billed Medicare for the tests. The relator tried to couch his FCA action as one for express false certification of compliance with federal testing regulations. *Id.* at 1052-53. But the district court dismissed his complaint, reasoning that regulatory violations cannot support an FCA action. *Id.*

The Ninth Circuit reversed and granted the relator leave to amend his complaint to allege that the laboratory billed for worthless services. The Ninth Circuit did so because:

In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct ... Neither false certification nor a showing of government reliance on false certification for payment

need be proven if the fraud claim asserts *fraud in the provision of goods and services*.

*Id.* at 1053 (emphasis added). The Ninth Circuit thus reasoned that providing worthless services knowingly, or with deliberate ignorance, is tantamount to submitting a facially fraudulent claim. *See Id.* at 1053-54.

The few federal jurisdictions that have entertained the worthless services theory have adopted the theory. *See, e.g., United States ex rel. Landers v. Baptist Mem'l Health Care Corp.*, No. 2:99-cv-2097, 2007 WL 4380006, at \*5, (W.D. Tenn. Dec. 17, 2007) (accepting worthless services theory as viable but nonetheless granting summary judgment).

#### **D. Implied False Certification Doctrine**

Increasingly, the courts are pushing the limits of FCA liability beyond express statements made in health care claim forms by implying certifications of legal compliance from the mere act of submitting a claim. Under this implied false certification doctrine, implied misrepresentations of statutory, regulatory, and contractual compliance are as actionable as express falsehoods.

Support for this sweeping doctrine can be found in Congress's stated purpose that the FCA encompass at least some kinds of legally false claims, *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (citing S. REP. NO. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274), and the Supreme Court's admonition that the FCA intends to reach all types of fraud that might cause financial loss to the government, *id.* (citing *United States v. Neirfert-White Co.*, 390 U.S. 228 (1968)).

The concept of implied false certification is straightforward: a claimant should know the requirements for obtaining payment when it submits a claim, and is therefore deemed to certify compliance with those requirements. The courts, however, maintain starkly different views on what certifications may be imputed to claimants based on the mere act of submitting a claim. Most courts only imply certifications of compliance with health care quality provisions that expressly demand compliance as a condition for payment. Other courts apply the implied false certification doctrine broadly, and impute certifications of compliance with the myriad provisions establishing health care quality minimums for participating in Medicare and Medicaid.

**1. Most jurisdictions follow the condition-of-payment view**

Most jurisdictions favor the more measured view that a person submitting a claim for payment to Medicare or Medicaid only impliedly certifies that it has complied with statutory and regulatory health care quality requirements that are conditions for payment. *Mikes*, 274 F.3d at 700; *Landers*, 2007 WL 4380006, at \*3-\*5, *United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 459 F. Supp. 2d 1081, 1086-87 (D. Kan. 2006); *Sweeney v. ManorCare Health Servs., Inc.*, Civ. Action No. C03-5320RJB, 2005 WL 4030950, at \*4-\*5 (W.D.Wash. Mar. 4, 2005); *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1221-22 (E.D. Cal. 2002); *United States ex rel. Swafford v. Borgess Med. Ctr.*, 98 F. Supp. 2d 822, 827-28 (W.D. Mich. 2000), *aff'd*, 24 F. App'x 491 (6<sup>th</sup> Cir. 2001). These jurisdictions usually only impute a certification of compliance if the health care quality provision upon which the relator relies expressly states that the

person seeking payment must comply with the provision to obtain payment. *See Conner*, 459 F. Supp. 2d at 1086-87. This express-language rule limits the scope of defendants’ potential FCA liability for billing for substandard health care because so few health care quality provisions contain express condition-of-payment language.

In addition, those courts that have actually found condition-of-payment language in the Medicare and Medicaid provisions have construed that language narrowly. For example, in *Mikes v. Straus*, the relator argued that physicians’ claims to Medicare for payment for certain medical tests were false because the physicians impliedly certified compliance with medical standards of care for the testing, which they did not meet. 274 F.3d at 700-01. In other words, the relator argued that the claims were false because the physicians performed the tests in an unreasonable, medically negligent manner. *See id.*

The relator based her argument on 42 U.S.C. § 1395y(a)(1)(A), a Medicare statute entitled “Exclusions from states and Medicare as Secondary Payer – Items or Services Specifically Excluded,” which provides that:

- (a) Items or services specifically excluded  
... *no payment may be made* under part A or part B of this subchapter for any expenses incurred for items or services—
  - (1) (A) which, except for items and services described in a succeeding subparagraph, *are not reasonable and necessary* for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member ... .

(emphasis added).

The U.S. Court of Appeals for the Second Circuit held that the requirement that services be “reasonable and necessary” pertained to the physicians’ selection of

the tests, and not their clinical performance. *Mikes*, 274 F.3d at 701. The Second Circuit further held that the medical acceptance and effectiveness of the tests impacted the reasonableness and necessity of selecting the tests, but complying with the qualitative standard of care in administering the tests did not. *Id.* Because medical science accepted the tests, the physicians' certifications were not false. *Id.*

The Second Circuit noted that an unreasonable and unnecessary service under § 1395y(a)(1)(A) will typically be one that is deleterious, performed solely for profit, unproven, or experimental. *See id.* at 698. That is to say, billing for a medically-accepted and effective service may be actionable if the person providing the service knows that the patient does not have medical indications for receiving the service. The medical community's general acceptance of a particular service will not completely immunize providers who administer the service unnecessarily.

The U.S. District Court for Massachusetts interpreted a similar Medicare statute in *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 42-43 (D. Mass. 2000), where a laboratory allegedly billed Medicare for two blood tests that it split from a single test in order to increase its reimbursement. The statute, 42 U.S.C. § 1320c-5(a)(1), entitled "Obligations of health care practitioners and providers of health care services," states:

*It shall be the obligation of any health care practitioner and any other person . . . who provides health care services for which payment may be made . . . to assure, to the extent of his authority that services or items ordered or provided . . . to beneficiaries and recipients under this chapter—(1) will be provided*

*economically and only when, and to the extent, medically necessary.*

The district court concluded that the “provided economically” language of the statute creates a condition of payment. *Kneepkins*, 115 F. Supp. 2d at 42-43; *but see Mikes*, 274 F.3d at 701-03 (declining to find condition of payment). It then denied the defendant’s motion to dismiss, reasoning that the government sufficiently pled an implied false certification claim by alleging that the laboratory performed the tests in an “intentionally wasteful manner.” *Id.*

*Kneepkins* takes the principle of *Mikes* a step further and shows that billing for medically-accepted and effective services that are *also medically necessary* may nonetheless violate the FCA if the services are administered in a manner intended to increase reimbursement.

In sum, most jurisdictions follow the condition-of-payment view and only recognize potential FCA liability for violating express conditions of payment. As a result, exposure under the implied false certification doctrine for providing substandard health care usually only arises if a provider has billed for medically unnecessary, duplicative, or experimental services.

## **2. Few jurisdictions follow the condition-of-participation view**

The U.S. District Court for the Western Districts of Oklahoma and Missouri have long been the only courts espousing the view that a person submitting a claim for payment to Medicare or Medicaid impliedly certifies compliance with all express preconditions for payment, plus all health care quality requirements for participating in the program. *United States ex rel.*

*Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, 945 F. Supp. 1485, 1488-89 (W.D. Okla. 1996); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1152-56 (W.D. Mo. 2000).

In *Aranda*, the government alleged that in-patient psychiatric hospitals impliedly certified compliance with provisions requiring that Medicaid beneficiaries receive an “appropriate quality of care and a safe and secure environment.” 945 F. Supp. at 1487. The government accused the hospitals of violating the provisions by failing to provide their patients with “a reasonably safe environment.” *Id.* The hospitals argued that the regulations did not impose a billing requirement on them, much less an objective standard of safety or quality. *Id.* The district court rejected these arguments and denied the hospitals’ motion to dismiss, reasoning that: “[A] problem of measurement should not pose a bar to pursuing an FCA claim against a provider of substandard health care services ...” *Id.* at 1488.

The facts of *NHC Healthcare* were strikingly similar. The government alleged that a nursing home failed to provide two of its residents with the quality of care that Medicare and Medicaid regulations required. 115 F. Supp. 2d at 1151. The government also alleged that the nursing home billed Medicare and Medicaid despite knowing that it was not satisfying the regulations. *Id.* The nursing home, relying on *Mikes*, moved to dismiss on the theory that its claims were not false because the regulations purported to establish a subjective, qualitative standard of care, which the nursing home had satisfied. *See id.* at 1152-53.

The district court distinguished *Mikes* by characterizing the nursing home's substandard care as a complete failure to provide at least some items from the menu of health care services that the nursing home billed for on a capitated, "per diem" basis. *Id.* In denying the nursing home's motion, the court explained that: "As with the *Aranda* case, the [provider] [allegedly] failed to adhere to the relevant standard of care ... and, therefore, billed the United States for care it did not actually perform. Knowingly submitting claims ... for Medicare and Medicaid services not actually performed clearly violates the FCA." *Id.* at 1156 (emphasis added).

The common thread binding *Aranda* and *NHC Healthcare* is the long-term, inpatient-care, capitated-payment setting. In each case, the government alleged a systemic failure to meet subjective, regulatory health care quality standards, which equated to alleging a complete failure to provide at least some capitated services.

Tellingly, no courts have applied *Aranda* or *NHC Healthcare* outside of the long-term, inpatient-care, capitated-payment setting. For example, no courts have applied *Aranda* or *NHC Healthcare* to substandard care provided by an outpatient specialty clinic, acute care hospital, or other provider that bills on an itemized, fee-for-service basis.

The U.S. Courts of Appeals for the Seventh and Ninth Circuits, however, recently adopted the condition-of-participation view in the area of education funding. These decisions could pave the way for expanding the application of the condition-of-participation view beyond the long-term, inpatient-care, capitated-payment setting.

In *United States ex rel. Main v. Oakland City University*, 426 F.3d 914, 916 (7<sup>th</sup> Cir. 2005), the issue was whether Oakland University's claims for federal education funds could be false if it made false statements about its admissions department's incentive compensation plan when it first applied to become eligible for funding. The Seventh Circuit held that the claims could be false if the university's statements during the application process were false because the university's initial fraud could have tainted the entire process. *Id.* The court explained: "If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork." *Id.*

The Ninth Circuit entertained the identical issue in *United States ex rel. Hendow v. University of Phoenix*, 461 F.3d 1166, 1168-69 (9<sup>th</sup> Cir. 2006), *cert. denied*, 127 S. Ct. 2099 (2007), where the University of Phoenix supposedly made false statements about its admissions department's incentive compensation plan when it first applied to become eligible for federal funds. Persuaded by Seventh Circuit, the Ninth Circuit held that the university's claims for federal funds could be fraudulent because a federal statute expressly conditioned (1) payment of the claims on eligibility, and (2) eligibility on compliance with an incentive compensation ban. *Id.* at 1173-76. The university argued that the ban was merely a condition of participation, but the Ninth Circuit rejected the argument as semantics, concluding: "[I]f we held that conditions of participation were not conditions of payment, there would be no conditions of payment at all." *Id.* at 1176.

The U.S. District Court for the Northern District of Illinois recently extended the Ninth Circuit's reasoning to capitated Medicaid payments made to health plans. In *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 725 (N.D. Ill. 2007), the relators proved that certain health plans induced the State of Illinois to sign a Medicaid HMO agreement with the plans by promising not to discriminate against Medicaid beneficiaries, even though the plans had no intention of keeping the promise. *Id.* at 723-24. The relators also proved that the beneficiary enrollment applications that the plans submitted to obtain the payments were false claims because Illinois made capitated payments under the agreement. *Id.* The plans argued that the enrollment submissions were not false because neither the submissions nor the underlying HMO agreement conditioned payment on the plans' complying with the nondiscrimination promise. *Id.* at 726-27. The district court found this argument feeble and followed the rule that "a condition to participation is a condition to payment." *Id.*

Two months after *Tyson*, the U.S. District Court for Hawaii considered whether *Hendow* supports extending the condition-of-participation view to regulatory health care quality standards for acute care hospitals. The *qui tam* relator in *United States ex rel. Woodruff v. Hawai'i Pacific Health*, 2007 WL 1500275 at \*1, alleged that an acute care hospital fraudulently billed Medicaid for charges for services incident to certain medical procedures because the hospital (1) impliedly certified compliance with regulations that required using both licensed nurses and physicians, and (2) the professionals performing the procedures were unlicensed. The hospital, relying partly on *Mikes*, argued that

the relator failed to state a claim because she only alleged violations of the terms of the hospital's Medicaid provider agreement and other conditions of participation. 2007 WL 1500275 at \*1-\*2.

The district court declined the relator's invitation to extend the condition-of-participation view to acute care hospitals, stating:

The ... court has not found any case holding that violations of conditions of participation are sufficient to state a claim under the FCA based on false certification of Medicare or Medicaid claims. The Court agrees that *Hendow* does not purport to create a sweeping new rule that all conditions of participation give rise to liability under the FCA.

*Id.* at \*7.

The district court noted that in *Hendow*, the Ninth Circuit made a point of distinguishing *Mikes* on the grounds that it applies only to Medicare and Medicaid provisions. *See id.* at \*6-\*7. The district court also found that *Mikes* better serves the policy goal of enabling regulators—not *qui tam* relators—to manage Medicare and Medicaid consistent with the complex regulatory framework underlying those programs. *Id.*

Whether *Main* and *Hendow* will impact the implied false certification doctrine and FCA health care quality enforcement remains to be seen. For now, at least, the case law only supports applying the condition-of-participation view in actions involving nursing homes and other long-term inpatient care facilities that bill for services on a capitated basis.

### **3. Policy critiques of the minority condition-of-participation view**

Majority jurisdictions have typically relied on two policy critiques in adopting the condition-of-payment view instead of the conditions-of-participation view. First, the condition-of-participation view frustrates the administration of Medicare and Medicaid. Second, it federalizes state medical malpractice law.

*a. The condition-of-participation view encroaches on the exercise of federal administrative discretion*

Congress has enacted an immense statutory regime to govern the private delivery of federally-funded medical and nursing home care, under which the Department of Health and Human Services (“HHS”) has promulgated a vast set of regulations and rules. 42 U.S.C. §§ 1301-1320d-8, 1381-1383, 1395-1395ggg, 1396-1396v, 1397aa-1397kk; 42 C.F.R. §§ 430-1008. Congress intended for this massive body of law, and the public and private entities that administer it, to control the cost and improve the quality of health care.

For example, Congress has commanded HHS to contract with private peer review organizations to promote “the effective, efficient, and economical delivery of health care services.” 42 U.S.C. § 1395y(g). These organizations’ statutory duties include reviewing providers’ care for reasonableness, medical necessity, and quality. 42 U.S.C. § 1320c-3. To enforce the standards that the organizations apply, Congress has empowered HHS to sanction and expel providers from Medicare in the instance the organizations identify substandard care. 42 U.S.C. § 1320c-5.

FCA actions targeting alleged violations of regulatory health care quality standards frustrate this colossal and expensive framework by enabling federal courts to seize the money that a provider receives from Medicare, even where the agencies and other entities charged with enforcement would not do so. *Conner*, 459 F. Supp. 2d at 1088; *Swan*, 279 F. Supp. 2d at 1222. Public policy does not support usurping the agencies' discretion, particularly when Congress granted the agencies enforcement powers with the aim of improving health care quality.

*b. The condition-of-participation view federalizes state malpractice law*

FCA health care quality actions inherently conflict with federalism principles because regulating health and safety is historically the province of the states. By empowering *qui tam* relators to recover damages from providers that administer substandard care, the FCA substitutes (1) relators, the FCA, and federal courts, for (2) private plaintiffs, state medical malpractice law, and state courts, without compensating the persons who sustain injuries from the substandard care. *See Mikes*, 274 F.3d at 700. The condition-of-participation view is especially repugnant to the states' regulation of health and safety because it enables whistleblowers to sue providers based on a vast array of federal health care quality rules, and thus makes it easier for them to displace private plaintiffs trying to recover compensation from the same sources.

### **III. FCA HEALTH CARE QUALITY ENFORCEMENT**

Federal prosecutors, relying on the condition-of-participation view of implied false certification, have aggressively enforced federal health care quality

requirements since 1996, when the Western District of Oklahoma published *Aranda*.

The most aggressive enforcer to date has been the Office of the U.S. Attorney for the Eastern District of Pennsylvania, which has settled FCA quality investigations with at least fifteen nursing homes and one hospital. *Pennsylvania Hospital Settles Claims Arising from Restraints Used on Patients*, 9 BNA'S HEALTH CARE FRAUD REP. 623 (Aug. 3, 2005) (counting settlements). The Eastern District seems to have based almost all of its investigations on the condition-of-participation view of implied false certification. *Hospitals May See Fraudulent Billing Lawsuits over Medical Errors*, 7 BNA'S HEALTH CARE FRAUD REP. 568 (July 23, 2003) (identifying legal theory underlying cases).<sup>1</sup>

With the Eastern District of Pennsylvania pioneering the way, other districts have undertaken similar enforcement efforts. Altogether, the DOJ has initiated FCA health care quality matters in at least eight states — Connecticut, Delaware, Florida, Georgia, Illinois, Louisiana, Michigan, and Missouri — that have netted at least \$16.6 million in restitution and settlements.<sup>2</sup> Not

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<sup>1</sup>In approximately half of the cases, prosecutors never filed legal complaints against the settling defendants. See, e.g., *Quality of Care: Pennsylvania Nursing Home Settles DOJ Allegations of Inadequate Care*, 8 BNA'S HEALTH CARE FRAUD REP. 573 (July 7, 2004); *Nursing Homes: Nursing Home Settles Allegations Related to Care of Patients with Diabetes*, 8 BNA'S HEALTH CARE FRAUD REP. 413 (May 12, 2004). Pleadings are not available for the balance of the cases.

<sup>2</sup>Press Release, U.S. Attorney's Office for the Southern District of Florida, Florida Doctor Sentenced to 18 Months in Prison for Medicare Fraud (Oct. 2, 2007) (physician prescribing medically unnecessary and potentially harmful HIV infusion therapies ordered to pay \$5,116,366 in restitution for causing the submission of approximately \$7 million in false claims) (on file with author); *Nursing Homes: Michigan Nursing Home Company Settles Allegations About Care Quality, Billings*, 11 BNA'S HEALTH CARE FRAUD REP. 640 (Sept. 12, 2007) (Michigan-based operator of 30 nursing homes settles quality of care allegations for \$1.25 million); *Nursing Homes: DOJ Intervenes in*

surprisingly, these matters have usually involved nursing homes and allegations of inadequate care or abuse or neglect.

These kinds of health care quality enforcement activities will likely increase in 2008 in response to aggressive cost-cutting in the nursing home industry. Private equity firms are now acquiring nursing homes, reducing expenses and increasing profits, and reselling the facilities for gains. Charles Duhigg, *At Many Homes, More Profit and Less Nursing*, N.Y. TIMES, Sept. 23, 2007, at 1. In analyzing and reporting on this trend, *The New York Times* performed a statistical analysis of data collected by the Centers for Medicare & Medicaid Services (“CMS”) that supposedly shows that:

- Private-equity-owned nursing homes have tended to cut expenses and staff below minimum legal requirements;
- Residents of private-equity-owned nursing homes on average fare more poorly than occupants of other homes in common problems like

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*Whistleblower Lawsuit Against Five St. Louis-Area Nursing Homes*, 11 BNA’s HEALTH CARE FRAUD REP. 474 (July 4, 2007) (DOJ intervenes in FCA suit charging parent company of five nursing homes of providing worthless care); *Louisiana: State Judge OKs \$7.4 Million Settlement of Claims of Unnecessary Cardiac Surgery*, 11 BNA’s Health Care Fraud Rep. 366 (May 23, 2007) (discussing \$3.8 million settlement of FCA suit for medically unnecessary cardiac procedures); Press Release, U.S. Attorney’s Office for the Eastern District of Missouri, *American Healthcare Management, its CEO & Three Local Nursing Homes Plead Guilty to Conspiracy Charges Involving Failure of Care at Nursing Facilities* (Oct. 10, 2006) (on file with author); Taxpayers Against Fraud, FY 2006 False Claims Act Settlements, <http://www.taf.org/total2006.htm> (reflecting \$1.5 million settlement of FCA claims with defendants discussed in preceding authority) (last visited Jan. 8, 2007); Press Release, U.S. Attorney’s Office for the Northern District of Georgia, *Lawrenceville Nursing Home to Pay \$2.5 Million to Settle Allegations of Gross Neglect of Residents* (Dec. 22, 2005) (on file with author); Press Release, U.S. Attorney’s Office for the District of Delaware, *Harbor Healthcare Settlement Reached* (Nov. 10, 2005) (\$150,000 settlement of quality of care allegations against provider of healthcare to disabled and vegetative children) (on file with author); Press Release, U.S. Attorney’s Office for the District of Connecticut, *Nursing Home Agrees to pay \$750,000 to Settle Allegations Under the False Claims Act* (May 18, 2005) (quality of care allegations against Hillcrest Healthcare, Inc.) (on file with author); David Mendell, *Nursing Home Lawsuit Settled: Whistle-Blowers Alleged Fraud, Patient Abuse*, CHI. TRIB., Nov. 23, 2004, at C1 (\$1.6 million settlement with defendant Chicago-area nursing home) (on file with author).

depression, loss of mobility and loss of the ability to bathe and dress;  
and

- Private-equity-owned nursing homes usually score worse than national rates in 12 of 14 indicators for tracking problems such as bedsores, preventable infections, and improperly using restraints.

*Id.*

The newspaper's analysis — if correct — suggests that the kinds of problems that spurred the DOJ's past investigations are increasing at an alarming rate.

This purported trend has caught the attention of Congress. The U.S. House of Representatives' Ways and Means Committee's Health Subcommittee held a hearing on November 15, 2007, at which union and academic researchers testified that private equity is diverting Medicare and Medicaid resources away from residents and to the benefit of investors, typically by reducing staffing levels. *Nursing Homes: Quality of Care at Nursing Homes Suffers After Recent Buyouts, House Panel Told*, 11 BNA'S HEALTH CARE FRAUD REP. 856 (Nov. 21, 2007). Private equity firms issued statements following the hearing that disputed the participants' assertion that key quality-of-care metrics are decreasing under the private equity firms' watch. *Id.*

Regardless of private equity's true impact on the nursing home industry, the Department of Health and Human Services Office of Inspector General ("HHS-OIG"), which partners with the DOJ to bring FCA suits for quality of care violations, plans to expand its health care quality enforcement efforts. Speaking at an April 2007 health care conference, HHS Inspector General Daniel Levinson said that his agency's focus will broaden to include residential treatment facilities, intermediate care facilities, institutes for mental disease, and hospices.

*Enforcement: OIG Says Quality of Care Issues Remain Top Enforcement Priority*, 11 BNA'S HEALTH CARE FRAUD REP. 318 (May 9, 2007). The HHS-OIG Work Plan for Fiscal Year 2008, which HHS-OIG issued on October 1, 2007, echoes Levinson's comments, stating: "OIG will continue to examine quality-of-care issues for beneficiaries residing in nursing facilities ... We will expand our focus on these issues to additional institutions and community-based settings." (U.S. Dept. of Health & Human Servs., Office of Inspector Gen., Work Plan: Fiscal Year 2008 61, [http://www.oig.hhs.gov/publications/docs/workplan/2008/Work\\_Plan\\_FY\\_2008.pdf](http://www.oig.hhs.gov/publications/docs/workplan/2008/Work_Plan_FY_2008.pdf) (hereinafter HHS-OIG Work Plan)).

More recently, HHS-OIG Chief Counsel Lewis Morris announced that HHS-OIG is putting a high priority on quality of care cases, particularly in long-term care settings where individual executives make high-level decisions affecting resident care. *Enforcement: Law Enforcers Continue Growing Focus on Individuals in Health Care Investigations*, 11 BNA'S HEALTH CARE FRAUD REP. 895 (Dec. 5, 2007). Morris said that HHS-OIG will hold nursing home leaders *personally responsible* for quality of care **outcomes** for residents, with particular focus on multi-state abuses by large, national nursing home chains. *Id.* (emphasis added).

Executives of poorly-performing nursing homes will be increasingly easy to identify because CMS recently released its first national list of poorly-performing nursing homes. *Quality: CMS Makes Public National List of Poor-Performing Nursing Homes*, 11 BNA'S HEALTH CARE FRAUD REP. 895 (Dec. 5, 2007). This list consists of so-called "special focus facilities" that were consistently providing poor quality care, yet were periodically instituting enough

improvements to avoid repeatedly failing inspections. *Id.* These are exactly the types of facilities that the DOJ and HHS-OIG have made clear they will prosecute.

Beyond the nursing homes, there are indications that FCA health care quality actions involving home health agencies, physicians' offices, acute care hospitals, and health plans will increase. James Sheehan, New York's Medicaid Inspector General, and a former Assistant U.S. Attorney for the Eastern District of Pennsylvania, has predicted that the DOJ will begin bringing enforcement actions based on "data-mining" conducted by HHS-OIG and CMS. *Enforcement: Increase in Quality of Care Data Helps Feds Target Provider Failure, Sheehan Tells AHLA*, 11 BNA'S HEALTH CARE FRAUD REP. 120 (Feb. 14, 2007). Data-mining amounts to aggregating health plan data and conducting statistical analyses of the data to identify quality deficiencies or other trends.

The DOJ has already conducted at least one data-mining investigation of a health plan using the plan's quality data. Specifically, it investigated the People's Health Network ("PHN"), an entity in which Tenet Healthcare Corporation had an interest, for allegedly failing to ensure that Medicare enrollees received various services for which Medicare made capitated payments. *See Tenet Healthcare Corporation Settlement* (on file with author). The DOJ also investigated whether the services provided were inconsistent with statutory and regulatory quality standards. *Id.* During the PHN investigation, the DOJ sought data for patient admissions under various ICD-9 codes in order to identify deficiencies and select specific patient records for review. Tenet ultimately

settled the PHN investigation as part of its \$725 million global health care fraud settlement with the DOJ in June 2006. *See Id.*

HHS-OIG has made clear that in 2008 it intends to review Medicare Part B claims for staff services furnished “incident to” physicians’ professional services in order to examine the qualifications of the staff performing the services, as well as the medical necessity *and* quality of the staff services. HHS-OIG Work Plan at 10. This, incidentally, is the same type of data on which the *qui tam* relator in the *Woodruff* case based her FCA claims. HHS-OIG will conduct similar reviews of (1) home health agencies’ survey and certification deficiency data, (2) payment data for physical and occupational therapy services, and (3) capitated rate data for school-based services. *Id.* at 10, 47.

With “data-mining” on the rise, Mr. Sheehan has predicted that the DOJ will also begin bringing FCA actions against hospitals for failing to comply with mandatory quality reporting requirements. *Health Care Quality: Quality of Care at Hospitals May Become Bigger Focus for Prosecutors, Sheehan Says*, 10 BNA’S HEALTH CARE FRAUD REP. 579 (Aug. 2, 2006).

Mr. Sheehan’s prediction should concern hospitals and health plans alike, because reporting health care quality data may be a condition of payment under *Mikes v. Straus*. This is because regulations authorize private-sector quality improvement organizations (“QIOs”) to review the services furnished by physicians and hospitals for medical necessity and quality. 42 C.F.R. §§ 476.70-71. One of these regulations expressly directs providers submitting Medicare claims to furnish health care quality data to QIOs:

Health care providers *that submit Medicare claims must cooperate in the assumption and conduct of QIO. Providers must – ... (2) Provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations.*

42 C.F.R. § 476.78(b) (emphasis added).

The language of this provision is less forceful than the statutory language that the Second Circuit deemed a condition of payment in *Mikes v. Straus*. But in a sympathetic jurisdiction, it might support a FCA action for impliedly falsely certifying the accuracy of quality data.

In short, the DOJ and HHS-OIG will probably aggressively increase their FCA health care quality enforcement in the nursing home industry, while at the same time expanding their efforts to new classes of providers. This enforcement promises to accelerate as the government increasingly engages in data-mining of quality information.

## **CONCLUSION**

Notwithstanding the limited support in the case law for FCA actions targeting violations of quality standards that are merely requirements for participating in Medicare and Medicaid, the number of FCA health care quality actions against providers of all types should multiply in 2008 and 2009. These increases may result from the intersecting of the purported downward quality trends in the long-term care industry with the government's escalating enforcement activities. It is also possible that under the *Main* and *Hendow* appellate decisions, the courts will embrace the more expansive condition-of-participation view in new health care quality cases.

For these reasons, providers should be increasingly mindful of the FCA, applicable health care quality standards, and their own billing practices.

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