

PAY FOR PERFORMANCE, QUALITY OF CARE AND THE REVITALIZATION OF THE FALSE CLAIMS ACT

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I. INTRODUCTION

The Federal government is in the process of fundamentally changing the rules of engagement with the healthcare entities it regulates. Confronted with rising costs,¹ the Federal government is fomenting a quiet revolution in how doctors and hospitals are paid and regulated. At the forefront of this revolution are two trends, one punitive, and one incentive based, which will require healthcare providers to rethink the way they do business. Over the last ten years, the Federal government has dramatically increased its enforcement activities, both criminal and civil, in an effort to essentially force healthcare providers to improve the quality of care they provide. This trend is balanced by initiatives broadly known as “pay for performance,” which seek to improve the overall quality of medical care by giving healthcare providers a financial incentive to improve their services. The combination of these two trends is going to substantially alter the legal and risk environment for all healthcare providers.

Since at least 1997, the Federal government has used its expansive powers under the various Medicare and Medicaid enabling acts to become increasingly involved in dictating the quality of care that must be provided by healthcare professionals. In a series of high visibility

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¹ The statistics speak largely for themselves. Medicare spending has grown nearly 1200% in 17 years, from \$37 billion in 1980 to \$432 billion in 2007. MEDICARE PAYMENT ADVISORY COMM’N, A DATA BOOK: HEALTHCARE SPENDING AND THE MEDICARE PROGRAM 10 (2008), available at http://www.medpac.gov/documents/Jun08DataBook_Entire_report.pdf. The trustees of the Medicare program project that Medicare spending will grow from about 3 percent of gross domestic product today to 7.1 percent by 2036. *Id.* at 14. Of the \$1.76 trillion spent on health care in the United States in 2006, public programs—including Medicare, Medicaid, SCHIP, and other programs—accounted for 46 percent of health care spending. *Id.* at 5.

criminal and civil prosecutions, focused primarily on nursing homes, the Federal government has taken the position that it can use the various anti-fraud statutes directed at billing fraud as a tool to prosecute healthcare professionals and facilities for providing substandard care.

The primary tool being used by the government is the False Claims Act ("FCA"), a civil war era statute designed to eradicate fraudulent claims by government contractors. In essence, the government has transformed this "enforcement tool" directed at billing practices into a "regulatory tool" to force facilities to provide a higher quality of care. The government's enforcement activities have been supplemented by any number of "private attorney general" actions brought under the FCA's *qui tam* provisions. In doing so, the Federal government has begun to supplant the bodies that traditionally defined quality, such as state licensing boards and the tort system, with what is in essence a federally dictated standard of care.

The use of fraud statutes to impose a federal standard of care is well entrenched. The second trend, known in the popular vernacular as "pay for performance," is less well defined. As part of the Medicare Modernization Act of 2003, the Center for Medicare and Medicaid Services ("CMS")² was directed by Congress to explore options for aligning performance with payment in the Medicare Program.³ This dictate has resulted in a flurry of experimental programs, primarily in the hospital setting, to tie reimbursement levels directly to the quality of care being provided. All indications suggest that these initiatives will be migrating to other segments of the healthcare market, including nursing homes, home healthcare providers and individual physicians.

At first glance, these two trends appear distinct. That appearance is deceiving. Both trends rely on a baseline of "quality" or "standard of care" to determine (1) what facilities will get paid for their services, and (2) more ominously, what facilities will get prosecuted or sued for failing to meet that baseline. In both cases, the Federal government is essentially using its enforcement powers and "power of the purse" to dictate the quality of care that must be provided by healthcare professionals.

The use of quality indicators to drive both reimbursement decisions and enforcement actions is going to fundamentally change the legal risk environment for healthcare facilities and require them to undergo a reassessment of the structures they have put into place to

² Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

³ *Id.* at §238.

respond to legal risks. As a legal matter, this convergence will likely lead to an even greater reliance by federal and state regulators on federal fraud statutes as a tool to establish quality of care standards. Over the last several years, courts around the nation have become increasingly skeptical of suits brought under the FCA that raise substantive quality issues. Contrary to the position taken by the Federal government, most courts have rejected the view that entities can be held liable under the FCA for falsely certifying that they are in compliance with federal quality standards. Courts adopting this view have uniformly rejected “quality” based FCA claims because compliance with federal quality standards is not currently seen as a precondition to receiving payment. These theories of liability, known as the “express” and “implied” false certification theories, will be revitalized by the pay for performance movement.

The federalization of quality standards also presents a formidable challenge to the organizational structure of most healthcare entities. Most healthcare facilities have historically observed a formal distinction between their “risk” and “compliance” functions, a distinction that was largely driven by the discrete regulatory roles played by states and the Federal government. Historically, the states, in conjunction with private accreditation organizations, were primarily responsible for regulating the quality of care provided by healthcare facilities. The states generally met this responsibility through a combination of licensing statutes and through application of common law malpractice standards.⁴ Systems such as peer review committees, quality and utilization committees and risk managers were developed to manage this risk.

The Federal government, in turn, was primarily responsible for regulating payment standards and preventing billing fraud.⁵ This risk was managed by most healthcare facilities by compliance committees and compliance officers. Under the new regime, this distinction loses meaning as “quality” and “compliance” essentially merge.

Facilities that fail to adjust to this changing environment risk being swept away by these cross-currents.

⁴ For an insightful criticism of this decentralized form of quality regulation, see COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn, Janet M. Corrigan & Molla S. Donaldson eds., 2000).

⁵ See, e.g., Michael J. Astrue, *Health Care Reform and the Constitutional Limits on Private Accreditation as an Alternative to Direct Government Regulation*, *LAW & CONTEMP. PROBS.*, Autumn 1994, at 75, 77. (“[Health Care Financing Administration] has attempted to minimize its role as regulator through liberal use of private contractors and private accrediting agencies.”).

II. THE HISTORIC MODEL OF HEALTHCARE REGULATION

To fully appreciate how the trend towards pay for performance and the federalization of quality will ultimately effect the legal environment for healthcare providers, one must first understand how the current system has resulted in a formal separation between the quality and compliance functions. Most healthcare entities have organized themselves in a fashion that reflects the differing roles historically played by state regulators (who were primarily responsible for “quality” issues) and federal regulators (who were historically responsible for regulating compliance with payment requirements). The quality of care provided by healthcare professionals has historically been defined by state licensing agencies and, to a lesser extent, common law tort and malpractice standards.⁶ Most facilities managed this risk through a combination of risk officers, peer review committees and quality and utilization committees.⁷ Quality improvements, in turn, were largely driven by needs identified by quality surveys performed either by the state or private credentialing entities, or, to a lesser extent, in response to claims made in litigation.⁸

“Compliance,” in contrast, refers to a separate category of risk involving reimbursement and billing issues. In its role as the largest healthcare payor in the nation, the Federal government has traditionally taken the lead in investigating and prosecuting healthcare providers who illegally obtain payment from the various federally funded healthcare programs. The purpose of the compliance function, as described by the Federal government, is to insure that facilities are in compliance with the various billing and reimbursement requirements intended to prevent such fraudulent billing.⁹

⁶ See, e.g., *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985) (“[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern.”).

⁷ As required by federal law, utilization committees are responsible for “review[ing] professional services provided, to determine medical necessity. . . .” 42 C.F.R. § 482.30(f) (2007).

⁸ For a criticism of the traditional decentralized model of quality regulation, see Alexander D. Eremia, *When Self-Regulation, Market Forces and Private Legal Actions Fail: Appropriate Government Regulation and Oversight is Necessary to Ensure Minimum Standards of Quality on Long-Term Health Care*, 11 ANNALS HEALTHL. 93 (2002).

⁹ See, e.g., Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 20,680 (Apr. 16, 2008) (noting that the primary purpose of a compliance program is to “prevent[] the submission of erroneous claims and . . . combat[] fraud and abuse in the Federal health care programs . . .”).

The entire notion of a separate compliance function dates back to 1995 when then-President Clinton announced “Operation Restore Trust.”¹⁰ This initiative resulted in \$250 million in new federal funds designated towards “combat[ing] fraud, waste and abuse in Medicare and Medicaid programs.”¹¹ The program paid for new auditors, investigators, and prosecutors who were assigned the task of rooting out billing fraud.¹¹

Using new data-mining techniques, and the ever popular “whistle-blower,” Operation Restore Trust reported 74 criminal convictions, 218 exclusions, and over \$187 million in “fines, recoveries, settlements, audit disallowances and civil monetary penalties” in its first two years of existence.¹² Not surprisingly, the government has expanded its antifraud programs since Operation Restore Trust, most recently to combat Medicaid fraud.¹³

The need for a separate compliance function was made explicit in 1998 when the CMS published its “Compliance Program Guidance for Hospitals.” This Compliance Guidance was the first in a series of recommended compliance programs issued by CMS. Using the Federal Sentencing Guidelines as its model, CMS identified seven basic compliance elements that all Hospitals should implement. Among other things, the Guidelines emphasized the importance of designating a “high-level” compliance officer and creating a corporate compliance committee charged with the task of developing, operating and monitoring a comprehensive compliance program.¹² An additional eight compliance guidance programs have been subsequently issued, covering, *inter alia*, pharmaceutical manufacturers,¹³ nursing facilities¹⁴ and small physician offices.¹⁵

¹⁰ See OFFICE OF INSPECTOR GEN., DEP’T OF HEALTH & HUMAN SERVICES, OPERATION RESTORE TRUST ACTIVITIES (1995), available at <http://oig.hhs.gov/oei/reports/oei-12-96-00020.pdf>.

¹¹ *Id.* at 1.

¹¹ *Id.*

¹² Fact Sheet, Operation Restore Trust Accomplishments (May 20, 1997), <http://www.os.dhhs.gov/news/press/1997pres/970520d.html>.

¹³ The Deficit Reduction Act of 2005 created a new sub-agency within CMS, called the “Medicaid Integrity Program,” which was assigned the task of implementing the “first national strategy to detect and prevent Medicaid fraud and abuse in the program’s history.” MEDICAID INTEGRITY GROUP, CENTERS FOR MEDICARE & MEDICAID SERVICES, COMPREHENSIVE MEDICAID INTEGRITY PLAN OF THE MEDICAID INTEGRITY PROGRAM: FY 2006 – 2010 2, 4 (2006), available at <http://www.cms.hhs.gov/DeficitReductionAct/Downloads/CMIP%20Initial%20July%202006.pdf>.

¹² OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8993 (Feb. 23, 1998).

¹³ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68

A decade ago the distinction between the “quality” function and the “compliance” function was essentially static. A new malpractice case went to the Risk Department and, potentially, to the Peer Review Committee. Quality and utilization kept an eye on larger trends within the hospital that might suggest a “quality” problem in the way the hospital was providing particular services. Compliance, in turn, operated as “an internal control in the reimbursement and payment areas” to insure that the facility was operating in compliance with “Federal, State and private payor health care program requirements. . . .”¹⁶ Thus, a claim that procedures were being “upcod[ed]” or “unbundle[d]” in violation of federal law was routed to the Compliance Department.¹⁷ As a result of its limited role, compliance managers and committees were primarily responsible for managing the institution’s relationship with the Federal government.

This historic separation between the “quality” and “compliance” functions was reinforced by the economics of healthcare reimbursement. Most government reimbursement programs, like the “Inpatient” and “Outpatient” “Prospective Payment Systems” (“IPPS” and “OPPS”, respectively) focus exclusively on either the nature of the service being provided (OPPS), or on the presenting diagnosis (IPPS) as the sole basis for determining reimbursement levels.¹⁸ The underlying *quality* of the service being provided—traditionally a state concern—was irrelevant to the reimbursement decision. Thus, the leading cardiac surgeon in the nation would be paid the exact same amount as the worst cardiac surgeon for placement of a stent, even if the latter was under trained and had a high failure rate.

The same is true in the payment structure for Skilled Nursing Facilities, which are paid “per diem” based on patient count irrespective of the level of services provided.¹⁹ Thus, the nursing facility that serves gruel to its patients is paid the same amount as one that specializes in the finest French Cuisine. These kinds of payment systems,

Fed. Reg. 23,731 (May 5, 2003).

¹⁴ OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,289 (Mar. 16, 2000).

¹⁵ OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59,434, 59,434 (Oct. 5, 2000).

¹⁶ OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. at 8988.

¹⁷ “Upcoding” occurs when a facility submits a bill for a higher reimbursing service than what was actually provided. *Id.* at 8990 n.15. “‘Unbundling’ is the practice of submitting bills piecemeal . . . to maximize the reimbursement for various tests or procedures that are required to be billed together. . . .” *Id.* at 8990 n.20.

¹⁸ The IPPS is codified at 42 U.S.C. § 1395ww (2000 & Supp. V 2005). The statutory basis for the OPPS is located at 42 U.S.C. § 1395l(t)(9).

¹⁹ 42 U.S.C. § 1395yy(e)(1)-(12).

which focus exclusively on objective criteria (i.e. the number of patients or the nature of the service) create a disincentive to provide the highest (and potentially most expensive) level of care.

Under this system, there is little incentive to integrate the compliance and quality functions. Compliance departments needed only to focus on fraudulent billing claims, irrespective of the quality of care being provided. Thus, the vast majority of fraud cases historically brought under either the False Claims Act or the various federal fraud statutes²⁰ involved either “upcoding,” “unbundling,” or “fictitious patients or procedures.”²¹ What all three of these have in common is the absence of any subjective inquiry into the quality of the service provided. Either all five digits of a hand were replaced by a hand surgeon, or they weren’t. Either the patient received a level “3” evaluation and management, or he didn’t. The question of the underlying quality of the service being provided was simply not the compliance department’s concern.

A compliance department during this milieu had little reason to trouble itself with the activities of its risk, quality or utilization departments. Revenue departments were also outside of this loop, until such a time that the compliance department determined that reimbursement was necessary. Conversely, the quality, utilization and peer review departments had no particular reason to keep the compliance staff informed about investigations into doctors who were providing inadequate care. Quality was “care,” compliance was “billing,” and never the twain shall meet.

III. CHALLENGE ONE TO THE HISTORIC MODEL: THE USE OF FEDERAL FRAUD STATUTES TO IMPOSE QUALITY STANDARDS

The traditional model of healthcare regulation—and the organizational structures it engendered—is under attack. The Federal government has increasingly tried to leverage its control over the monies paid to healthcare providers to essentially supplant the states and impose a federal standard for quality of care. This control has both a regulatory aspect, in terms of the rules that must be followed in order

²⁰ See 18 U.S.C. § 1343 (2000) (wire, radio, or television fraud), and 18 U.S.C. § 1347 (2000) (health care fraud).

²¹ *United States v. Krizek*, 111 F.3d 934, 936 (D.C. Cir. 1997) (referencing an “up-coding” claim); see also *OIG Compliance Program Guidance for Hospitals*, 63 Fed. Reg. at 8990 (identifying “upcoding,” “unbundling” and “DRG creep,” *inter alia*, as the most common forms of health care fraud).

to participate in the program, and is reflected in how the government has exercised its civil and criminal enforcement authority.

A. The Tools of Federal Enforcement

The government has a variety of tools in its arsenal to pursue claims of false billing. The Medicare and Medicaid fraud statute is the most obviously applicable, if not the most utilized, criminal provision available to federal prosecutors. Under this statute, the Federal government may prosecute anyone who “knowingly and willfully” makes or causes to be made a false *material* statement to Medicare, Medicaid, or a state healthcare program, as part of a claim for payment.²²

Although the Medicare Fraud statute applies specifically to healthcare providers, the Federal government is not precluded from using other fraud statutes when prosecuting a person for making false statements in order to obtain payments from a healthcare program.²³ Other criminal statutes commonly used by the government to combat healthcare fraud include:

1. Submitting False Claims: 18 U.S.C. § 287.
 - (a) Making or presenting a claim that is false, fictitious, or fraudulent;
 - (b) To a department or agency of the United States; and
 - (c) Knowing that it is false, fictitious, or fraudulent.
2. False Statements: 18 U.S.C. § 1001.
 - (a) Knowingly and willfully;
 - (b) Making a false, material statement or concealing a material fact or using a writing or document that is false in a material matter; and
 - (c) In any manner within the jurisdiction of any department or agency of the United States.
3. Mail Fraud: 18 U.S.C. § 1341.
 - (a) Devising a scheme or artifice to defraud or for obtaining money or property by means of false or fraudulent pretenses; and
 - (b) Use of the mails in furtherance of the scheme.

The Federal government also has expansive civil enforcement tools. The Civil False Claims Act,²⁴ which was originally enacted during the Civil War to prevent widespread fraud in defense procure-

²² 42 U.S.C. § 1320a-7b(a)(1).

²³ See, e.g., *United States v. Simon*, 510 F. Supp. 232, 236-37 (E.D. Pa. 1981).

²⁴ 31 U.S.C. §§ 3729-3733 (2000).

ment contracts, has metamorphosed into a major weapon in the government's fight against Medicare/Medicaid fraud. To prevail, the government must establish that the healthcare provider:

- (a) Presented, or caused another to present, a "claim for payment" or "to get" payment from the United States;
- (b) The claim was "false or fraudulent"; and
- (c) The healthcare provider must act "knowing" that the claim was false.²⁵

The statute also encompasses preparation of false records to support a payment. The Act provides for a monetary fine of up to \$10,000 per false claim *plus* treble damages for the amount of the claim.²⁶

Perhaps more troubling, the FCA has a "private attorney general" provision that allows anyone to prosecute a violation. In practical terms, this means that disgruntled former employees, unhappy patients, or anyone with access to a lawyer can file suit on behalf of the government to collect the foregoing damages. A successful plaintiff in this kind of suit, known as a *qui tam* action, is normally awarded between 25-30% of any recovery. If the government intervenes in the action, the bounty goes down to 15-25%, but the *qui tam* relator (that is, the person who started the suit) is then freed from the burden of prosecuting the action.²⁷ The *qui tam* procedure provides an enormous incentive for disgruntled patients or employees to inform on healthcare providers.

The number of successful *qui tam* actions has escalated dramatically in the last several years. Once again, the government and third party payers have aggressively encouraged disgruntled current employees and/or former employees to file *qui tam* actions. The success of these efforts is evident from the numbers. The Office of the Inspector General recently reported that in the first six months of 2008 it had participated in 141 civil and administrative False Claim Act cases. Total expected recoveries from these cases exceeded \$1 billion.²⁸

The Civil Monetary Penalties Law creates an administrative procedure that can be pursued by the government in lieu of a criminal

²⁵ 31 U.S.C. § 3729(a)(1)-(2).

²⁶ 31 U.S.C. § 3729(a).

²⁷ 31 U.S.C. § 3730(c)(1), (d)(1).

²⁸ OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVICES, SEMIANNUAL REPORT TO CONGRESS: OCTOBER 1, 2007-MARCH 31, 2008, at 26 (2008), available at http://www.oig.hhs.gov/publications/docs/semiannual/2008/semiannual_spring2008.pdf.

or civil action.²⁹ Like the Civil False Claims Act, the Monetary Penalties Law provides for penalties of up to \$10,000 per false claim, plus an assessment of up to three times the amount falsely collected. The primary difference between this and a civil or criminal prosecution is that the matter is heard by an administrative law judge and the defendant loses his or her right to a jury trial.

The trigger for any of these enforcement tools is essentially submission of a claim for reimbursement for an item or service that was either medically unnecessary or simply not provided. Prior to 1997, the vast majority of fraudulent billing cases involved a claim for a service that was either (1) not provided, (2) not necessary, or (3) had been “upcoded” to bill for a higher level of service than was actually provided.³⁰ Traditionally, the underlying quality of the service being provided was irrelevant to the reimbursement. So long as the service was actually provided—no matter how deficient in its execution—the government had no basis under the various billing fraud statutes to bring an enforcement action.

B. Liability for Providing “Worthless Services”

The formal separation between the “quality” and “compliance” functions began to blur in 1996, when the Federal government first began to use the FCA as a vehicle to enforce quality of care standards. There are essentially three closely related theories of liability *related to the quality of services being provided* that have been asserted under the FCA: “Worthless service,” “Express certification” and “Implied Certification,” each of which will be discussed in turn. The first, “worthless service” is based on the notion that some services can be so deficient in quality as to rise to the level of “no service” at all. Since billing for a service that was not rendered is the epitome of a FCA violation, the theory posits, liability can also attach when the service is so deficient that it equates to “no service.”

The “worthless service” theory was brought to life by the U.S. Attorneys for the Eastern District of Pennsylvania in a series of widely reported enforcement actions commencing in 1996. In 1994, an elderly gentleman was transported from a local nursing home, “Tucker House,” to a local emergency room. The patient was suffering from 26 ulcers, a gangrenous leg and a series of other serious compli-

²⁹ 42 U.S.C. § 1320a-7a (2000).

³⁰ OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8990 (Feb. 23, 1998) (identifying an additional 18 areas of “special concern,” including “DRG creep,” “duplicate billing,” “unbundling” and self-referrals). See 31 U.S.C. § 3729-3733 (2000).

cations. The hospital contacted the state's long term care ombudsmen who, in turn, contacted federal officials. Typical of the enforcement milieu of the day, the Pennsylvania Department of Health surveyed the facility and found numerous deficiencies in the services that were being provided.³¹

After reviewing the case, the Federal government concluded that the facility was providing inadequate dietary and wound care for its residents. The U.S. Attorneys developed the then-novel theory that the actions of the nursing home, in addition to violating state elder care laws, also constituted a violation of the FCA. In February of 1996, the U.S. Attorneys' office for Philadelphia filed a civil complaint against the facility and its management consultant, alleging that the defendants had violated the FCA by submitting claims for "medically inadequate" services.³² The case was unique because the government did not assert that the billed services were not provided, were medically unnecessary, or even upcoded. Rather, the government's theory was that the FCA covered the provision of medically necessary services in a grossly negligent manner. In essence, the government reasoned that providing "bad" service was the functional equivalent of providing "no" service.

In early 1998, the government employed the same theory in a second case, *United States v. Chester Care Ctr.*, against three Pennsylvania area nursing homes.³³ Ultimately this case was settled, at the cost of a \$500,000 fine.³⁴ Both cases also resulted in consent orders that required the defendants to implement detailed and intrusive quality care standards.³⁵

The principal established in these cases—that antifraud statutes could be used to regulate quality of care issues—has been seized upon by any number of state and federal enforcement agencies in a thinly veiled effort to impose a "federal" standard of care on health care

³¹ David R. Hoffman, *The Federal False Claims Act as a Remedy to Poor Care*, 45 UNITED STATES ATTORNEYS' BULLETIN 54, 56-57 (1997), available at http://www.usdoj.gov/usao/eousa/foia_reading_room/usab4502.pdf.

³² Compl., *United States v. GMS Management-Tucker, Inc.*, No. 96-1271 (E.D. Pa. Feb. 21, 1996); available at <http://clearinghouse.wustl.edu/chDocs/public/NH-PA-0001-0001.pdf>. The case was ultimately resolved pursuant to a consent decree. See Consent Order, *United States v. Tucker House II*, No. 96-1271 (March 6, 1996), <http://www.usdoj.gov/usao/pae/nursing/tucker.pdf>.

³³ Consent Order and Judgment, *United States v. Chester Care Center*, No. 98-CV-138 (E.D. Pa. 1998).

³⁴ *Id.* at 3.

³⁵ Consent Order, *United States v. Tucker House II, Inc.*, *supra* note 32; Press Release, U.S. Dep't of Justice (Jan. 13, 1998) (on file with author).

providers.³⁶ According to the Office of Inspector General for Health and Human Services, between 1996 and 2003, more than 20 cases involving quality of care issues were settled against nursing homes based on alleged violations of the FCA.³⁷

What started out as creative but flawed theory of billing fraud has now been officially adopted as CMS policy. On April 16, 2008, the Office of Inspector General formally adopted the theory first advanced by the U.S. Attorneys of the Eastern District of Pennsylvania:

In cases that involve failure of care on a systematic and widespread basis, the nursing facility may be liable for submitting false claims for reimbursement to the Government under the Federal False Claims Act, the Civil Monetary Penalties Law (CMPL), or other authorities that address false and fraudulent claims or statements made to the Government. Thus, compliance with applicable quality of care standards and regulations is essential for the lawful behavior and success of nursing facilities.³⁸

The distinction between “systematic and widespread malpractice,” which, in the view of the government, gives rise to a claim for billing fraud, and “simple malpractice,” which would presumably not, is difficult to discern. In *United States v. NHC Healthcare Corp.*,³⁹ the court ruled that a legitimate dispute over the “proper standard of care” would not give rise to a liability under the FCA. Or, as stated by the court in *Mikes v. Straus*, “the performance of the service [must be] so deficient that for all practical purposes it is the equivalent of no

³⁶ See *United States v. United Mem'l Hosp.*, No. 1:01CR238, 2002 WL 33001119 (W.D. Mich. 2002); *United States ex rel. Moczulski v. Kidspeace Corp.*, No. 02-1846 (E.D. Pa. 2004) (agreeing to repay between \$1.8 and \$1.9 million to settle false claim action for failure to comply with state and federal regulations relating to staffing, coding and billing issues); *United States v. Tenet Healthcare Corp.*, CV-03-206 (C.D. Cal. 2003); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000) (denying declaratory judgment on claim that a nursing home's low staffing ratio resulted in inadequate care, in violation of the Federal Claims Act).

³⁷ *Statement of Dara Corrigan Before the S. Finance Comm.*, (2003) (statement of Dara Corrigan, Acting Principal Deputy Inspector General, U.S. Department of Health and Human Services), available at <http://www.oig.hhs.gov/testimony/docs/2003/071703fin.pdf>.

³⁸ Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 20,680, 20,683-84 (Apr. 16, 2008).

³⁹ 115 F. Supp. 2d 1149, 1155 (W.D. Mo. 2000).

performance at all.”⁴⁰ Other commentators have suggested that the standard lies somewhere between gross neglect and perfect care.⁴¹ In the earliest cases, *Tucker* and its progeny, the government suggested that liability was premised on the notion that the standard of care was so low as to essentially equate with “no service” being provided at all.

All healthcare providers are at risk under the “worthless service” theory. The very nature of nursing home reimbursement, however, places such facilities at a particular risk of being targeted for tort, civil enforcement and criminal cases under the various billing fraud statutes. Unlike most “pay for service” schemes, Medicare and Medicaid pay nursing homes a “per diem” for providing a “basket” of services. This basket, in turn, is defined by Medicare regulations with both generality and specificity. As to the former, to qualify for Medicare funding, the SNF must “care for its residents in such a manner and in such an environment that will promote . . . the quality of life of each resident” and provide services of sufficient quality to “attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.”⁴²

These general conditions of participation, in turn, are supplemented and expanded by several dozen pages of regulations, which, among other things, codify each resident’s legal right to have “dignified existence”;⁴³ to be free from “physical or chemical restraints”⁴⁴ and to engage in therapeutic recreational activities.⁴⁵ Other regulations are more specific. Thus, as a condition of participation, the facility must maintain a “Quality Assessment and Assurance Committee” and prepare a written “plan of care” for each of its residents based on a “comprehensive, accurate, standardized” resident assessment.⁴⁶

The nature of the reimbursement scheme places nursing homes at a disadvantage in both avoiding and defending against fraudulent quality claims. For most medical practitioners, *identifying* (if not defining) the appropriate standard of care is relatively straightforward.

⁴⁰ 274 F.3d 687, 703 (2d Cir. 2001).

⁴¹ See James E. Utterback, *Substituting an Iron Fist for the Invisible Hand: The False Claims Act and Nursing Home Quality of Care – A Legal and Economic Perspective*, 10 QUINNIAC HEALTH L.J. 113 (2007) (suggesting a standard of gross negligence); Accord Constantin I. Miskis & William F. Sutton, Jr., *Enforcing Quality Standards in Long-Term Care: The False Claims Act and Other Remedies*, FLA. B. J., June 1999, at 108, 110.

⁴² 42 U.S.C. § 1395i-3(b)(1)(A), (4)(A)(i) (2000).

⁴³ 42 C.F.R. § 483.10 (2007).

⁴⁴ 42 C.F.R. § 483.13(a).

⁴⁵ See 42 C.F.R. § 483.15(f).

⁴⁶ 42 C.F.R. §§ (b)(1)(B) and (b)(2-3).

Consider this example. In the case *United States v. Askanazi*,⁴⁷ the defendant, a pain doctor, was prosecuted under the wire and mail fraud statutes for, among other things management, submitting claims for pain management services that were either medically unnecessary or deficiently rendered.⁴⁸ For the unnecessary service claims, the jury had to answer the relatively straightforward question of whether a particular patient really needed a particular pain treatment. The quality-of-care claims required an analysis of how the profession traditionally administers the single form of treatment (called the “Racz procedure”) being litigated and whether the doctor met that standard. Ultimately, the jury concluded that Dr. Askanazi had both billed for unnecessary services and provided those services in a grossly negligent matter, finding him guilty on 33 counts of billing fraud.⁴⁹

In the Askanazi case and others like it that involve distinct procedures, the quality of care issue can be defined narrowly. But when reimbursement is based on a bundle of services, defined, *inter alia*, as those generally necessary to “attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident,”⁵⁰ the potential theories of liability and risk in general rise exponentially.

The message from *NHC Healthcare, Tucker* and their progeny is that healthcare facilities which consistently fail to meet whatever standard of care the Federal government currently considers appropriate, are at risk of both malpractice claims (the traditional ambit of the risk and quality departments) and of being charged with either civil or criminal billing fraud.⁵¹

⁴⁷ *United States v. Askanazi*, Case No. 98-CR130 (W.D. Mich. July 12, 2001).

⁴⁸ Brief for Appellant at 30-31, *United States v. Askanazi*, 2001 WL 814940 (6th Cir. 2001).

⁴⁹ *See id.* The author was tangentially involved in the Askanazi case; serving as special counsel for the hospital where a majority of Dr. Askanazi’s services were performed. Materials related to the Askanazi prosecution are on file with the author.

⁵⁰ 42 U.S.C. § 1395i-3(b)(1)(A), (4)(A)(i) (2000).

⁵¹ As is too often the case where government uses its enforcement powers in ways they were never envisioned, the law of unintended consequences applies. According to the National Association of Board of Examiners, the number of potential nursing home administrators sitting for licensure has declined by as much as 40% between 2000 and 2006. THE AMERICAN ASSOCIATION OF HOMES AND SERVICES FOR THE AGING, CMS ANNUAL LEADERSHIP SUMMIT (April 24, 2006). The American Association of Homes and Services for the Aging has cited the expansion of LTC enforcement initiatives as one of the primary causes of what it terms as an “exodus” of healthcare professionals from the field. *Id.* This exodus occurs at a time when the percentage of individuals over 65 who potentially will need nursing home care is expected to double by 2026. *Id.*

C. The “Express” and “Implied” False Certification Theories

The government and private litigants have relied upon two additional theories, known as the “express” and “implied” false certification, to impose liability under the FCA for providing inadequate service. These two theories are distinguished by the nature of the federal regulation that has allegedly been violated. Federal regulations involving quality of care fall roughly into two categories. Some rules, such as the requirement that any procedure for which reimbursement is sought be medically necessary,⁵² are a “condition of payment.” Thus, seeking payment for unnecessary procedures (and certifying falsely that they were in fact necessary) violates the FCA. Other requirements, such as the requirement that the care provided by physicians “be of a quality which meets professionally recognized standards”⁵³ must be met as a condition to participate in the first instance in the Medicare program.

The “express” certification theory is predicated on the fact that every claim for reimbursement submitted by healthcare facilities includes a certification that the services for which reimbursement is sought were “medically indicated and necessary for the health of the patient.”⁵⁴ Private litigants, as well as the Federal government, have argued that this condition of payment is “expressly” violated anytime a facility submits a request for reimbursement for substandard care, on the theory that the term “medically necessary” imposes a “quality obligation” on the submitting facility. In essence, the “express” certification theory equates “medical necessity” with “medical quality.”

The “implied” theory of false certification, in contrast, is premised on the fact that facilities are required to be in “substantial” compliance with all federal and state laws as a condition to participate in government payment programs. To cite one of many examples, section 1156(a)(2) of the Social Security Act requires participants to insure that all services they provide “will be of a quality which meets professionally recognized standards of health care.”⁵⁵ Nursing homes are required as a condition of participation to “[b]e in compliance with the applicable conditions or long-term care requirements” set forth in

⁵² See e.g., CMS Form 1500, available at <http://www.cms.hhs.gov/cmsforms/downloads/CMS1500805.pdf>.

⁵³ 42 U.S.C. § 1320c-5(a)(2) (2000).

⁵⁴ CMS Form 1500, *supra* note 52; see also § 1395y(a)(1)(A) (imposing the requirement that all services paid for by Medicare be “reasonable and necessary for the diagnosis or treatment of illness or injury”).

⁵⁵ 42 U.S.C. § 1320c-5(a)(2).

subchapter IV of the Social Security regulations.⁵⁶ The implied false certification theory is based on the notion that anytime a healthcare provider falsely certifies that it has met all of the conditions of participation, it has by definition also “impliedly” certified that it is in “compliance with governing federal rules that are a precondition to payment.”⁵⁷

Both theories met with initial success, gaining recognition in a troika of cases, *United States ex rel. Aranda v. Cmty. Psychiatric Centers of Okla., Inc.*,⁵⁸ *United States ex rel Thompson v. Columbia/HCA Healthcare Corp.*⁵⁹ and *United States v. NHC Healthcare Corp.*⁶⁰ In the leading case, *United States ex rel. Thompson v. Columbia/HCA Healthcare*, the *qui tam* relator asserted that the defendant had violated the FCA by falsely certifying in its annual cost report that it was in compliance with all “laws and regulations” regarding the provision of health care services.⁶¹ The Plaintiff asserted that this certification was both “expressly” and “impliedly” false because the defendant had entered into a series of Byzantine financial relationships with referring physicians that violated the Stark anti-referral and anti-kickback statutes.⁶² The defendant, a large integrated health system, responded that the allegedly false statements were immaterial because they related only to the systems’ conditions of participation, and not conditions of payment.

In rejecting the defendant’s argument, the court relied extensively on an affidavit submitted by the then acting Chief of HHS Health Care Financing Administration, David Goldberg. In this affidavit, Mr.

⁵⁶ 42 C.F.R. § 488.3(a)(2) (2007).

⁵⁷ *Mikes v. Straus*, 274 F.3d 687, 699 (2d Cir. 2001).

⁵⁸ 945 F. Supp. 1485 (W.D. Okla. 1996).

⁵⁹ 20 F. Supp. 2d 1017 (S.D. Tex. 1998), *on remand from* 125 F.3d 899 (5th Cir. 1997).

⁶⁰ In *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149, 1151 (W.D. Mo. 2000) the government brought a FCA claim against a long term care facility based on the complaints of two residents, who the government alleged had developed pressure sores, incurred unusual weight loss and had experienced unnecessary pain as a result of the facilities’ “woefully low staff numbers.” In addition to bringing a “worthless service” claim, the government alleged an express certification claim. *Id.* The gravamen of the government’s complaint was that the facility illegally billed the per diem charge for these patients *knowing* that it had not provided sufficient services to “promote maintenance or enhancement of the quality of life.” *Id.* at 1153, 1155 (citation omitted). In terms of the certification claims, the court ruled that an “implied” certification claim could proceed in the very narrow situation where the standard of care is “at the heart” of the agreement between the provider and the government. *Id.* at 1155.

⁶¹ 20 F. Supp. 2d at 1020.

⁶² *Id.*

Goldberg asserted that *any* false statement to the Federal government gave rise to liability under the FCA, *irrespective* of whether the statement related to a condition of payment or a condition of participation.⁶³ The Goldberg affidavit essentially blurred the distinction between the two kinds of conditions by asserting that HCFA (now CMS) relied on all certifications to determine both eligibility for payment and eligibility for participation.

The momentum behind the two theories was short lived. In the case that led the counterrevolution, *Mikes v. Straus*, a disgruntled physician alleged that the defendants had violated the FCA by performing and billing for tests performed with equipment that the defendants knew was not properly calibrated.⁶⁴ The alleged failure to properly calibrate the equipment, the plaintiff argued, rendered the tests so unreliable as to essentially make them worthless.⁶⁵ As with any claim submitted for payment for the government, the defendants had expressly certified when they sought payment for the tests that the underlying services were “medically necessary.” This express certification, the plaintiff asserted, was false and therefore violated the FCA.⁶⁶

The Court rejected the express certification theory, reasoning that the term “medical necessity” as used in the certification did not translate to a quality guarantee:

The term “medical necessity” does not impart a qualitative element mandating a particular standard of medical care. . . . Medical necessity ordinarily indicates the level—not the quality—of the service.⁶⁷

According to the Court, the only thing being expressly certified by the defendant was that (1) a procedure reimbursable by Medicare was performed, and (2) that the procedure was medically necessary. The fact that the “quality” of the tests might not have met the applicable standard of care, the court reasoned, was irrelevant under the FCA.

The court in *Mikes* also rejected the implied false certification theory. Contrary to the position taken by CMS in *Columbia Healthcare*, the court found the distinction between conditions of participation and conditions of payment to be critical. The court relied heavily on the plain language of the FCA in creating a bright line between the

⁶³ *Id.* at 1042.

⁶⁴ 274 F.3d 687, 693 (2d. Cir. 2001).

⁶⁵ *Id.* at 694-95.

⁶⁶ *Id.* at 693.

⁶⁷ *Id.* at 698.

two kinds of conditions. The Act only prohibits false claims “for payment”⁶⁸ or “to get” payment.⁶⁹ Thus, submitting a “false statement” to the government that is unrelated to payment; i.e. not necessary “to get” payment, is not a violation of the act. As explained by the court:

[T]he False Claims Act was not designed for use 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. . . . [I]mplied 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.⁷⁰

This distinction is logical in light of fundamental differences between the “payment” and “participation” requirements. Payment requirements, in a sense, are absolute. If the facility provides a medically necessary service, it gets paid. Conditions of participation, however, are both more ambiguous and, concomitantly, more flexible. Hence, a facility needs only to certify that it is in “substantial compliance” with applicable regulations to participate in the program.⁷¹

CMS also has discretion to choose sanctions and remedies for facilities that fall out of substantial compliance with the conditions of participation. Under the Social Security Act, HHS has the authority to impose a number of penalties short of outright exclusion for noncompliant facilities, including civil monetary penalties, denial of payment, and appointment of temporary management and temporary suspension of payment.⁷² Allowing a False Claims suit to essentially bootstrap the conditions of participation would inappropriately turn the FCA into a “federal malpractice statute,”⁷³ and interfere with CMS’s discretion to respond in a measured fashion to facilities that provide

⁶⁸ 31 U.S.C. § 3729(a)(1).

⁶⁹ 31 U.S.C. § 3729(a)(2).

⁷⁰ 274 F.3d at 699-700. The requirement that the certification be a condition of payment has also been described in terms of “materiality.” *See e.g.*, *United States ex rel. Sharp v. Oklahoma Orthopedic Ctr.*, No. 05-CV-572-TCK-TLW, 2009 WL 499375 (N.D. Okla. Feb. 27, 2009) (holding certification must be “material” to the government’s payment decision).

⁷¹ 42 C.F.R. § 488.330(b)(1) (2007).

⁷² 42 U.S.C. § 1395i-3(h)(2)(B) (2000).

⁷³ *United States ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005) (citation omitted).

substandard care.⁷⁴ Widespread adoption of the implied false certification theory would supplant the regulatory discretion granted to CMS under the Social Security Act.

Most courts that have been presented with a false certification claim since *Mikes* have essentially adopted its reasoning.⁷⁵ Notwithstanding the courts' skepticism, however, the government continues to bring cases based upon the false certification theories. In September of 2007, to cite one example, the U.S. Department of Justice filed a complaint in the Southern District of Florida against an attorney who was responsible for signing annual reports submitted on behalf of the Tenet Healthcare Corporation that were required by a Corporate Integrity Agreement. The government alleges that in 1997 and 1998, the attorney signed annual reports in which she certified that the company was in "material" compliance with all applicable federal laws. In fact, according to the government, Tenet was aware that certain physician contracts one of its Florida hospitals had entered into violated the so-called Stark self-referral laws. The government is seeking repayment of approximately \$18,000,000 for claims that were paid during the period the company falsely certified that it was in compliance.⁷⁶

D. Quality Through Direct Regulation—CMS and Program Guidance

The strongest evidence of the Federal government's intent to "federalize"—and criminalize—quality of care standards can be found in the Compliance Program Guidance documents most recently issued by the OIG. Beginning in 1998, CMS has periodically published Guidance documents for various industry sectors designed to assist facilities in developing "effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State and private health plans."⁷⁷ The first Guidance document, for hospitals, focused almost exclusively on

⁷⁴ See, e.g., *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1222 (E.D. Cal. 2002).

⁷⁵ See *id.* at 1221-22; *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005); *United States ex rel. Cooper v. Gentiva Health Services, Inc.*, No 2:01 CV00508, 2003 WL 22495607 (W.D. Pa. 2003).

⁷⁶ Complaint at 37, *United States v. Sulzbach*, No. 07-61329, 2007 WL 5078620 (S.D. Fla. Sept. 18, 2007). For a general discussion of the potential impact of the *Sulzbach* case, see S. Sandra Park & Katie C. Pawlitz, *False Claims Act and False Certifications – An Old Dog with a New Trick*, J. HEALTH CARE COMPLIANCE, May-June 2008, at 47.

⁷⁷ OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8987 (Feb. 23, 1998).

“compliance” in its traditional sense of insuring the proper billing, coding and collection of government healthcare dollars. Hence, the Program Guidance for hospitals instructed healthcare providers to implement “internal control in the reimbursement and payment areas, where claims and billing operations are often the source of fraud and abuse. . . .”⁷⁸ Hospitals were directed to provide education and perform audits directed at preventing “[b]illing for items or services not actually rendered”; “[u]pcoding”; “DRG creep”; “[d]uplicate billing”; and “[f]alse cost reports.”⁷⁹ The initial Guidance directives maintained the distinction between “quality issues”—historically a state licensing issue—and “billing compliance.” “Quality” issues were largely an afterthought, raised largely in the context of any facilities obligation to insure that all services being provided are medically necessary.⁸⁰

The original Compliance Guidance for Nursing Facilities and its recent supplement, however, evidence the Federal government’s new found interest in expanding its power to regulate quality. Unlike the earlier compliance documents, the 2000 Nursing Home Compliance Guidance identifies improving “Quality of Care”—not billing compliance—as the primary goal of any active compliance plan:

The OIG believes that a nursing facility’s compliance policies should start with a statement that affirms the facility’s commitment to providing the care and services necessary to attain or maintain the resident’s “highest practicable physical, mental and psychosocial well being.” To achieve the goal of providing quality care, nursing facilities should continually measure their performance against comprehensive standards that . . . must include Medicare requirements.⁸¹

The 2008 Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities goes even further, stating that facilities which do not meet the Federal government’s view of “quality” “risk becoming the target of governmental investigations.”⁸² The areas of particular concern listed by the OIG focus almost exclusively on quality of care issues, such as the need for “comprehensive [resident] care

⁷⁸ *Id.* at 8988.

⁷⁹ *Id.* at 8990.

⁸⁰ *Id.* In essence, the OIG devoted a single sentence in the Compliance Program Guidance for Hospitals to quality issues by identifying the provision of medically unnecessary services as one of 18 areas “of special concern.”

⁸¹ OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289, 14,293 (Mar. 16, 2000) (footnotes omitted).

⁸² 73 Fed. Reg. 20,680, 20,684 (Apr. 16, 2008).

plans,” “sufficient staffing,” “medication management” and “resident safety.”⁸³ Failure to meet these requirements, the Guidance highlights, exposes the facility to prosecution for civil or criminal billing fraud. The need to submit “accurate claims,” in contrast, is relegated to three paragraphs in a 17 page document.

The government has had mixed success in its efforts to federalize quality of care standards using federal fraud statutes. On one hand, the “worthless service” theory has been validated by courts, but the standard it imposes, i.e., the services must be so deficient as to equate with “no service,” protects all but the most deficient of healthcare providers. On the other hand, providers can take solace in the fact that the “express” and “implied” false certification theories appear to have been largely discredited. The current stasis, however, may be the proverbial calm before the storm. The pay for performance movement promises to fundamentally change the way in which healthcare providers are reimbursed. More ominously for healthcare providers, pay for performance as currently envisioned will most likely have the unintended consequence of revitalizing both the FCA and dramatically expanding the Federal government’s power to impose national standards of care.

IV. THE FEDERALIZATION OF QUALITY PART TWO: PAY FOR PERFORMANCE

The principal that the Federal government can use its authority under the FCA and related fraud statutes to “regulate” quality of care is now well-established. Less certain is how the burgeoning pay for performance trend, also known as “Value Based Purchasing” will affect the risk environment for healthcare providers. Although pay for performance is in its infancy, it has all the hallmarks of a trend that is likely to grow to the point that a sizable portion of future reimbursements will likely be tied directly to quality measurements.⁸⁴

⁸³ *Id.*

⁸⁴ See The National Committee for Quality Health Care, *Hospital CEO Guide to Pay for Performance*, available at http://www.leapfroggroup.org/for_hospitals/CEO_Guide_For_P4P (according to the National Committee for Quality Healthcare, there are already over ninety pay for performance projects being sponsored nationwide by private payors). The Centers for Medicare & Medicaid Services (“CMS”) has announced 5 Value Based Purchasing demonstration projects. See Centers for Medicare & Medicaid Services, Medicare Demonstrations, <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/> (last visited Jan. 7, 2009). First, CMS created a project covering hospitals, known as the “Premier Hospital Quality Incentive Demonstration.” *Id.* See also *infra* note 87 and accompanying text. Additionally, CMS created the following projects: Large Physician groups (“Medi-

Pay for performance is based on the commonsense notion that giving providers more money for providing excellent care will result in an overall improvement in the quality of care being given.⁸⁵ The philosophy behind pay for performance was described in detail in three reports prepared by the Institute of Medicine at the National Academies (“IOM”), which had been retained by CMS to perform a study to explore the weaknesses in the current Medicare program.⁸⁶ The third of these reports, entitled “Rewarding Provider Performance: Aligning Incentives in Medicare” (the “IOM Report”), discussed in detail the need to institute programs that wedded reimbursement rates to the quality of healthcare services being provided.⁸⁷ In essence, pay for performance is a strategy designed to create incentives for providers to deliver higher quality of care as measured by selected objective and subjective standards.

The IOM Report identified two steps in creating an effective pay for performance program. First, there needs to be enough data collected and available to define the quality criteria upon which reimbursement will ultimately be based. Second, that data must be normalized in a fashion that allows for logical distinctions in payment levels among competing facilities. The government is well along the path of establishing and measuring quality criteria, at least in the hospital industry. Two hospital based programs, the “Reporting Hospital Quality Data for Annual Payment Update” (“RHQDAPU”) and the “Hospital Consumer Assessment of Healthcare Providers and

care Physician Group Practice Demonstration”); Small to medium physician offices (“Medicare Care Management Performance Demonstration”); Nursing Homes (“Nursing Home Value-Based Purchasing”); and Home Health Agencies (“Home Health Pay for Performance Demonstration”). Centers for Medicare & Medicaid Services, *supra*.

⁸⁵ Proponents of the pay for performance movement argue that it will both improve quality and result in substantial savings. *E.g.*, PREMIER, EXPLORING THE NEXUS OF QUALITY AND COST: METHODOLOGY AND PRELIMINARY FINDINGS *passim* (2006), available at <http://www.premierinc.com/p4p/press/quality-cost-methods-paper3.pdf>. INSTITUTE OF MEDICINE, RE-WARDING PROVIDER PERFORMANCE: ALIGNING INCENTIVES IN MEDICARE, Sept. 21, 2006, at 7, available at http://www.nap.edu/catalog.php?record_id=11723 (hereinafter REWARDING PROVIDER PERFORMANCE) (noting that the “reward pool” might require the investment of substantial government funds to create a sufficient financial incentive).

⁸⁶ See INSTITUTE OF MEDICINE, REWARDING PROVIDER PERFORMANCE, *supra* note 85. See also Institute of Medicine, MEDICARE’S QUALITY IMPROVEMENT ORGANIZATION PROGRAM: MAXIMIZING POTENTIAL, Mar. 9, 2006, available at http://www.nap.edu/catalog.php?record_id=11604, see INSTITUTE OF MEDICINE, PERFORMANCE MEASUREMENT: ACCELERATING IMPROVEMENT, Dec. 1, 2005, available at http://www.nap.edu/catalog.php?record_id=11517.

⁸⁷ INSTITUTE OF MEDICINE, REWARDING PROVIDER PERFORMANCE, *supra* note 85.

Systems” (“HCAHPS”), have given us a glimpse of the future of pay for performance. The RHQDAPU, adopted as part of the 2003 Medicare Modernization Act, “encourages hospitals” to submit data on a series of specific quality measures, including myocardial infarction, heart failure, surgical care, and pneumonia. Hospitals that do not participate in the program receive a 2.0% reduction in their annual Medicare payments. This data, in turn, is made available to the public through the internet.⁸⁸

Similar data is also being collected for Skilled Nursing Facilities through the so-called Nursing Home Quality Initiative (“NHQI”). The purpose of the NHQI, according to the Center for Medicare and Medicaid Services, is to provide consumers with enough information to make informed choices regarding nursing home services.⁸⁹ The NHQI relies on data collected by nursing homes as part of their quarterly obligation to assess patients. The program currently uses 19 measurements, known as the “Minimum Data Set,” to measure quality. This information, along with staffing levels and the results of recent state surveys, is then made available for review by patients and families on the Department of Health and Human Services “Nursing Home Compare” website.⁹⁰

The RHQDAPU and NHQI rely on “objective” data as a measure of quality. The recently expanded HCAHPS program, in contrast, is the government’s first foray into using subjective criteria as a measure of quality.⁹¹ The HCAHPS program, initially launched in October of 2006, “encourages” hospitals to survey patients on 18 items that encompass virtually every aspect of their hospitalization.⁹² The subjective nature of the survey is evident from the questions it asks. Patients are asked, for example, “How often did nurses treat you with courtesy and respect?” and directed to rate their experience at the hospital on a “1 to 10” scale.⁹³

⁸⁸ Centers for Medicare & Medicaid Services, Reporting Hospital Quality Data for Annual Payment Update, http://www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp (last visited Jan. 6, 2009).

⁸⁹ See Centers for Medicare & Medicaid Services, Nursing Home Quality Initiatives: Overview, <http://www.cms.hhs.gov/NursingHomeQualityInits/> (last visited Jan. 6, 2009).

⁹⁰ HHS.gov, Nursing Home Compare, <http://www.medicare.gov/NHCompare/Home.asp> (last visited Feb. 1, 2009).

⁹¹ The HCHAPS program is described in detail at http://www.cms.hhs.gov/hospitalqualityinits/30_hospitalhcahps.asp.

⁹² CAHPS Hospital Survey Instrument (2007), available at [http://www.hcahpsonline.org/Files/Appendix%20D%20-%20CAHPS%20Hospital%20Survey%20\(English\).pdf](http://www.hcahpsonline.org/Files/Appendix%20D%20-%20CAHPS%20Hospital%20Survey%20(English).pdf).

⁹³ *Id.* at 1.

Training on the program took place in January of 2008. Hospitals that choose to not participate will have their “Average Patient Unit” (“APU”), a measurement used in establishing reimbursement rates, cut by 2%. Like the RHQDAPU and the NHQI, CMS intends to post the results once a statistically significant amount of data is collected.⁹⁴

How the data will ultimately be used to drive payment determinations is still an open question, but a potential preview can be derived from the ongoing Premier/Hospital Quality Improvement Demonstration Program (“HQID”).⁹⁵ This project, which was first launched in 2003 by CMS, currently involves more than 260 hospitals. Initially, the program merely collected and reported quality data on a series of nationally recognized quality indicators. In late 2005, however, CMS allocated \$8.85 million in “incentive payments” for the top performing hospitals. Last year, hospitals in the top 10% of quality indicators received a 2% bonus payment, while those in the second decile received a 1% increase.⁹⁶

The impact of the Premier project in its first two years was rather benign. Hospitals that reported lower quality were not punished. Starting this year, however, hospitals in the lower 20% will receive a payment penalty that matches the incentive payment given to the highest performing facilities.⁹⁷

The sponsors of the HQID program have essentially declared victory. According to January 31, 2008 report issued by Premier, the median hospital cost per patient among participating hospitals

⁹⁴ Centers for Medicare & Medicaid Services, HCAHPS: Patients’ Perspectives of Care Survey, http://www.cms.hhs.gov/hospitalqualityinits/30_hospitalhcahps.asp (last visited Jan. 6, 2009).

⁹⁵ CMS recently completed a related test pay-for performance program for Physicians, known as the “Physician Group Practice Demonstration Project.” MICHAEL O. LEAVITT, HEALTH & HUMAN SERVICES, REPORT TO CONGRESS: PHYSICIAN GROUP PRACTICE DEMONSTRATION FIRST EVALUATION REPORT (2006), http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PGP_Final_Congress.pdf. Ten large physician groups, representing 5,000 physicians and 220,000 Medicare patients, participate in the project. *Id.* at 1. Using a complicated formula, CMS paid a bonus “performance payment” to groups that successfully improved patient quality while holding down program costs. *Id.* at 1-2. Thirty-two objective quality measurements were chosen for the pilot study. *Id.* at 4. A final report on the study has not yet been published.

⁹⁶ PREMIER, INC., CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) / PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION PROJECT: PROJECT OVERVIEW AND FINDINGS FROM YEAR ONE 4 (2006), available at <http://www.premierinc.com/quality-safety/tools-services/p4p/hqi/hqi-whitepaper041306.pdf>.

⁹⁷ Premier, Inc., Overview of CMS Hospital Quality Incentive Demonstration Project Payment Method, <http://www.premierinc.com/quality-safety/tools-services/p4p/hqi/payment/project-payment-year5.jsp> (last visited Jan. 12, 2009).

declined over \$1,000, while the median mortality rate decreased by 1.87%. Premier claims that expanding the program nationwide will result in over 70,000 fewer fatalities and aggregate cost savings in excess of \$4.5 billion.⁹⁸ As a result, in June of 2008 the Center for Medicare Services reported that it was going to extend the program by an additional three years.⁹⁹

The purported success of the Premier Demonstration Project makes its expansion almost a foregone conclusion.¹⁰⁰ In the very near future, quality reporting requirements are going to increase. Perhaps more ominously, payment decisions are going to be increasingly based on the data being reported. As stated by the American Medical Association in a 2004 report, “pay for performance is a Tsunami building offshore in a sea of stakeholder unrest, threatening those who are not prepared.”¹⁰¹

The purported success of the HQID program has not gone unnoticed in other segments of the industry. In June of 2006, to cite one example, a CMS sponsored study prepared by ABT Associates entitled *Quality Monitoring for Medicare Global Payment Demonstrations: Nursing Home Quality Based Purchasing Demonstration* described in detail the steps CMS could take to implement a nursing home pay for performance system.¹⁰² First, the report recommended that four measurements be used to establish a baseline upon which reimbursement could be based:

- (1) Nursing home staffing (staffing level and nursing staff turnover);

⁹⁸ Press Release, Premier, Inc., Hospital Quality Improving, Cost, Mortality Rate Trends Declining for Participants in Medicare Pay-for-Performance Project (Jan. 31, 2008), available at <http://premierinc.com/about/news/08-jan/performance-pays-2.jsp>.

⁹⁹ Premier, Inc., Premier Hospital Quality Incentive Demonstration: Rewarding Superior Quality Care (June 2008), available at <http://www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalPremierFactSheet200806.pdf>.

¹⁰⁰ A study comparing hospitals that participated in the HQID and those that merely reported quality data, published in the *New England Journal of Medicine*, reported that pay for performance only resulted in “modest[]” improvement and recommended that additional research be performed before pay for performance is more broadly implemented. Peter K Lindenauer et al., *Public Reporting and Pay for Performance in Hospital Quality Improvement*, 356 *NEW ENG. J. MED.* 486, 495 (2007).

¹⁰¹ AMERICAN MEDICAL ASSOCIATION, *PAY FOR PERFORMANCE: A PHYSICIAN’S GUIDE TO EVALUATING INCENTIVE PLANS* (2004).

¹⁰² ALAN WHITE ET AL., ABT ASSOCIATES INC., *QUALITY MONITORING FOR MEDICARE GLOBAL PAYMENT DEMONSTRATIONS: NURSING HOME QUALITY-BASED PURCHASING DEMONSTRATION* (2006), http://www.cms.hhs.gov/DemoProjects/EvalRpts/downloads/NHP4P_FinalReport.pdf.

- (2) Rate of potentially avoidable hospitalizations;
- (3) MDS-based resident outcome measures; and
- (4) Outcomes from state survey inspections.¹⁰³

The proposal to use “potentially avoidable hospitalizations” and the “MDS-based resident outcome measures,” if implemented, would greatly expand the government’s ability to “federalize” quality of care standards. As to the former, the report identifies “congestive heart failure, chronic obstructive pulmonary disease . . . and urinary tract infection” as three conditions that are “largely avoidable with appropriate outpatient care.”¹⁰⁴ In terms of the MDS measurements, the report concludes that the level of payment to nursing homes should turn, in part, on their ability to control “pressure sores,” the use of catheters, physical restraints and bladder incontinence.¹⁰⁵ In essence, adoption of the ABT report would result in the creation of a national standard upon which payment would be made based on these and other related quality measurements. The difference between a “high quality” nursing home and a “negligent” nursing home would no longer be measured exclusively by state survey results, but rather on how well the facility was able to keep people out of the hospital.

Having established a baseline “quality of care,” the report goes on to suggest that nursing home rankings in the top 20% of the quality measures should qualify for a performance payment, as well as the 20% of nursing homes who best improve their performance over a years time.¹⁰⁶ Although the proposal does not call for a reimbursement cut for lower performing facilities, the experience from the HQID demonstration project suggests that such a “penalty” will ultimately become part of the program.

There is a great deal of momentum to implement these kinds of pay for performance programs. As stated by CMS’s then Acting Administrator, Kerry Weems:

Posting the poor performing nursing homes on our website was not an isolated activity, but just one milestone in a year-long, special effort to move nursing homes forward on quality. It includes a pay-for-performance initiative for nursing homes, a pilot demonstrating a comprehensive system of criminal and other background checks for prospective new-

¹⁰³ *Id.* at i.

¹⁰⁴ *Id.* at ii.

¹⁰⁵ *Id.* at iii.

¹⁰⁶ *Id.* at v.

hires in nursing homes, and strengthened surveillance of infection control and nutrition in nursing homes.¹⁰⁷

The signs could not be clearer: The Federal government is going to increasingly define for nursing homes, hospitals and physicians the quality of care they must provide in order to receive full payment. Perhaps more importantly, facilities and physicians that fail to meet those standards are going to be increasingly exposed to malpractice claims, civil billing fraud claims and even criminal “fraud” prosecutions.¹⁰⁸

V. THE MARRIAGE OF COMPLIANCE AND QUALITY WILL HAVE FAR REACHING LEGAL IMPLICATIONS FOR THE HEALTHCARE INDUSTRY

The trends identified above present serious legal and organizational challenges for healthcare providers. In terms of the former, the combination of pay for performance and the federalization of quality standards will likely have the effect of revitalizing the FCA as a tool to impose a uniform, federally created standard of care. This, in turn, will greatly expand the Federal government’s ability to prosecute enti-

¹⁰⁷ Kerry Weems, Acting Adm’r, Centers for Medicare & Medicaid Services, Speech to JP Morgan Health Care Conference: The CMS Forecast for 2008 (Jan. 9, 2008), available at <http://www.cms.hhs.gov/apps/media/press/speech.asp>.

¹⁰⁸ CMS’s efforts to federalize quality standards is also evidenced by the fact that CMS is considering imposing specific credentialing requirements for reimbursement of certain highly technical procedures. In the area of artificial hearts, to cite one example, CMS has imposed a rule requiring, as a condition of payment, that “at least one member of the [ventricular assist device] team . . . [have] experience implanting at least 10 [devices] . . . over the course of the previous 36 months. . . .” CENTERS FOR MEDICARE & MEDICAID SERVICES, MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL: CHAPTER 1, PART 1 (SECTIONS 10 – 80.12): COVERAGE DETERMINATIONS (2008), available at http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part1.pdf. The rule further requires the facility to be a member of the “Interagency Registry for Mechanically Assisted Circulatory Support” group and be credentialed by the Joint Commission. *Id.* Imposing direct credentialing requirements as a condition of payment further blurs the lines between risk, compliance, and quality. As common sense would suggest, having unqualified doctors perform services raises obvious risk (i.e. litigation) and quality issues. Under the new regime, however, it also potentially implicates serious compliance concerns if services provided by “under-credentialed” doctors are billed. Even if a facility deems a physician to be qualified to provide a particular service, billing that service is illegal if the physician does not meet the differing standards imposed by the federal government. If this trend continues, a single, “one size fits all” federal standard, will increasingly supplant the role of states and private credentialing bodies.

ties that fail to meet whatever standard of a care is ultimately imposed.

A. The Revitalization of the FCA as a Tool
to Impose Quality Standards.

Under the current regime, the potential for criminal or even civil exposure for reporting false data is limited. In terms of the FCA, the current weight of authority does not allow for imposition of liability for submitting false quality data that is not directly related to payment. This much is evident from the plain language of the Act. The first section of the Act prohibits only a “false claim” *for reimbursement*. Reporting false quality data *unrelated* to a “claim” for reimbursement simply does not violate the act.¹⁰⁹ The second section of the Act forbids the submission or creation of a false record or statement *to get* a false or fraudulent payment from the Federal government. Again, when “quality” and “payment” are divorced, reporting quality data has nothing to do with “*getting*” a government payment.¹¹⁰

But tying payment to the data being reported dramatically increases both the incentive to falsely report and the danger in doing so. The former is obvious. When payment is directly tied to the data being reported, facilities have an additional incentive to misrepresent that data in a fashion that will lead to higher reimbursement. This was in many ways the lesson of the corporate scandals of the early 2000’s, where numerous companies reported higher than actual earnings because the compensation paid to management was often tied directly to what was reported.¹¹¹

Pay for performance will breathe new life into both the express and implied theories of liability to the point that they will merge into a single viable theory of recovery. In terms of the former, CMS has every reason as part of any pay for performance system to amend the certification requirements to make explicit that the “condition(s) of

¹⁰⁹ See, e.g., *United States ex rel. Bonin v. Cmty. Care Ctr. of St. Martinville, LLC*, No. 05-1005, 2008 WL 2113055, at *11-15 (W.D. La. May 16, 2008) (holding a facility was not liable for a “false certification claim” under the False Claims Act for false information contained in Minimum Data Sheets because payment is not conditioned on the data).

¹¹⁰ See e.g., *Allison Engine Co. v. United States*, 128 S. Ct. 2123, 2126 (2008) (submitting false quality data by subcontractor to government contractor is not a false claim because the purpose of submission is not “to get” payment directly from the government).

¹¹¹ See MARIANNE M. JENNINGS, *THE SEVEN SIGNS OF ETHICAL COLLAPSE: HOW TO SPOT MORAL MELTDOWNS IN COMPANIES . . . BEFORE IT’S TOO LATE* (2006) (summarizing how the relationship between financial reporting and economic incentives resulted in widespread corporate fraud).

payment” include an express requirement that the underlying quality data upon which payment is premised is accurate. Indeed, the current CMS draft of the MDS 3.0 reporting tool already contains such a certification:

I certify that the accompanying information accurately reflects resident assessment information for this resident and that I collected or coordinated collection of this information on the dates specified. . . . I understand that this information is used as a basis for ensuring that residents receive appropriate and quality care, and as a basis for payment from federal funds.¹¹²

The inclusion of this language in the reporting tool is essentially an effort by the government to codify the position it took in *United States ex rel. Thompson v Columbia/HCA Healthcare*; a position that was subsequently rejected in *Mike ex rel. Strauss*. As of today, this language alone should not be enough to impose liability under the express certification because it is simply not true.¹¹³ With the exception of hospitals participating in the HQID project, quality data and the quality of services being provided simply do not currently play any role in reimbursement decisions.¹¹⁴

Under a pay for performance system, in contrast, quality data also becomes highly relevant to reimbursement decisions. By definition, facilities will be required to submit quality data to the government to qualify for higher—or to avoid lower—levels of reimbursement. Thus, the quality data becomes a “false record” necessary “to get” a “claim paid” under the second provision of the FCA.¹¹⁵ A similar analysis applies to the “materiality” requirement imposed by most other federal fraud statutes. Under pay for performance, quality data is not only “material” to the government’s reimbursement decision, it is in many ways the most critical element of any claim made for reimbursement. Direct liability under the FCA for reporting false quality

¹¹² DEBRA SALIBA & JOAN BUCHANAN, RAND HEALTH CORP., DEVELOPMENT & VALIDATION OF A REVISED NURSING HOME ASSESSMENT TOOL: MDS 3.0, at 10 (2008), available at <http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf> (emphasis added).

¹¹³ See e.g., *Bonin*, 2008 WL 2113055 (dismissing a false certification claim where defendants allegedly forged MDS’s; but allowing other theories under the False Claims Act to proceed). Cf. *United States v. Morrison*, 529 U.S. 598, 601-02, 627 (2000) (explaining that Congress’s assertion of authority in a given area is not proof that Congress possesses actual authority, derived from the Constitution).

¹¹⁴ See *supra* Part III.C.

¹¹⁵ 31 U.S.C. § 3729(a)(2) (2000).

data arises from the fact that the data is now relevant to both “getting” a payment from the Government and becomes an integral part of a false claim *for reimbursement*.

Pay for performance could also lead to the reinvigoration of the currently discredited “implied” certification theory. Quality data serves two functions under a pay for performance regime. It continues to serve the traditional role of assuring that the facility meets its conditions of participation. But the data also (arguably) becomes the “deciding factor” in making reimbursement decisions. To paraphrase, a facility submitting data under the current system is essentially making the statement: “For purposes of determining whether this facility should be allowed to participate in the Medicare system we hereby certify that we achieved the following quality standards.” When reimbursement is based on the level of quality, this changes to the “implied” statement: “The government should pay us ‘X’ dollars because we achieved the following quality standards.”

Quality data is only relevant today to the government’s determination of whether a particular facility is “substantially” in compliance with the conditions of participation. Pay for performance requires quality data to be accurate so the government can make the “correct” reimbursement decision on every claim submitted by a facility. Tying payment decisions directly to the quality of care being provided will have the unintended consequence of giving the Federal government a powerful tool under the FCA and Medicare Fraud statute to impose national quality of care standards.

The revitalization of federal fraud statutes, combined with pay for performance, will also result in a diminished role for the states and private credentialing agencies. Reimbursement under all pay for performance schemes currently envisioned is determined in relationship to the quality of care provided by other similarly situated entities. Thus, under the Premier/HQID program, additional payment is given to the top 20% of participating facilities *as measured against* the other facilities participating in the program.¹¹⁶ A facility operating under such a scheme has every economic incentive to pour its limited resources into improving its quality in the areas selected by the Federal government that will result in higher payments, instead of dedicating resources towards meeting the more objective standards set by state licensing agencies or private credentialing agencies.

This focus, in turn, will give the Federal government a reason to constantly expand the list of quality measures it considers important for the purpose of establishing reimbursement levels. This expansion

¹¹⁶ See PREMIER, *supra* note 85.

has already occurred in the RHQDAPU program. In 2005, the program started with 10 quality measures. This grew to 21 measured parameters in 2007. The Center for Medicare and Medicaid Services initially proposed a total of 30 measurements for 2009, ballooning to 72 measurements in 2010. After strong criticism, CMS compromised by imposing “only” 42 measurements for 2010, but the trend is unmistakable.¹¹⁷ As pay for performance grows, so too will the Federal government’s role in defining quality of care.

B. The Organizational Impact of “Pay for Performance” and the Federalization of Quality

Few healthcare facilities are prepared for the federalization of quality.¹¹⁸ As discussed in detail above, the organizational structure of most large healthcare entities continues to reflect the limited role historically played by the Federal government in regulating quality of care. Under the historic model, billing and quality issues could be easily and logically categorized. A malpractice claim, governed by state law, was the responsibility of the risk manager and/or quality assessment committee. A claim of improper billing, governed by federal law, was the responsibility of the compliance officer. But in a world where the failure to provide adequate care affects both the amount of money the facility is paid and potentially raises criminal billing fraud concerns, the two functions essentially are merged.

This “merger” is perhaps best illustrated by example. Posit a mythical non-profit integrated health system, “Enormous Healthcare, Inc.” (“Enormous”).

Enormous operates a main hospital campus, a separate Long Term Care Facility, a half dozen urgent care centers, a “CORF,” a rehabilitation facility, and a home health agency. Like most healthcare organizations, Enormous has a comprehensive compliance plan, codes of conduct, and a mission statement. And, like most health care organizations, Enormous has divided the risk, quality, revenue and compliance functions among a series of independent departments, including:

¹¹⁷ IOWA FOUND. FOR MED. CARE, QUALITY IMPROVEMENT ORG. SUPPORT CTR. FOR THE HOSP. REPORTING PROGRAM, REPORTING HOSPITAL QUALITY DATA FOR ANNUAL PAYMENT UPDATE, RHQDAPU MEASURES FOR FY 2010.

¹¹⁸ Portions of the following material are adapted from Devin S. Schindler, *Quality of Care Initiatives: Malpractice and Pay for Performance*, 9 COMPLIANCE TODAY MAGAZINE 4, November 2007.

- 1) A Compliance Department, which is responsible for preventing the submission of erroneous claims for payment and unlawful or noncompliant conduct involving federal and state healthcare programs.
- 2) A Risk Manager and associated Risk Department which are primarily concerned with managing and preventing malpractice claims.
- 3) A Finance Department managed by the Chief Financial Officer, which is primarily concerned with revenue generation and cost-control.
- 4) A Medical Director who chairs the Peer Review Committee. Like most peer review committees, Enormous' committee is the body with primary responsibility for credentialing and disciplining the medical staff.
- 5) The Quality and Utilization Department. As required by federal law, Enormous' utilization committee is responsible for "review(ing) professional services provided, to determine medical necessity".¹¹⁹ The "quality" side of the department is responsible for analyzing overall trends in the hospital that could affect patient mortality or morbidity.

Historically, there was little reason for the "compliance" and "revenue" functions to interact with the "risk" and "quality" functions. The results of annual surveys or quality of care investigations would be cycled to the Quality Committee. Malpractice claims were under the jurisdiction of the risk manager and, in well managed facilities, the Peer Review Committee. Compliance with billing and reimbursement issues was monitored by the compliance manager. Under the historic model of healthcare regulation, there was no reason or incentive for "compliance" and "finance" to become actively involved in quality issues.

The merger of "reimbursement" and quality, both through the use of FCA as a basis for enforcement actions against entities that provide low quality care and the pay for performance initiatives, fundamentally changes this historic model. Consider the following hypothetical example:

The year is 2012 and Enormous is struggling. The (fictional) CMS pay for performance heart stenting rules provide for a 5% payment reduction if a facility falls below certain quality standards. A review by Enormous' Revenue Department

¹¹⁹ 42 C.F.R. § 482.30(f) (2007).

suggests that the facility is close to triggering the payment cut. The quality standards upon which payment is based have a strong subjective element related to the patient's perceived recovery. The Revenue Department's review suggests that part of the problem may result from an unwritten policy of the "Big Heart" cardiology group, which thinks that the solution to all heart problems is stenting. As a result, this group arguably "over prescribes" the procedure, which, in turn, has the effect of lowering the overall quality measurements as a result of complications and a substantial number of patients who do not report any relief following the procedure.

An unrelated review by the Quality Department reveals that several of the physicians employed by "Big Heart" have not received the training required under the government's new (fictional) coverage requirements. This combination of factors has also resulted in a higher than expected number of malpractice complaints, which is noted by the Risk Department. The Peer Review Committee has reviewed and approved Big Heart's practice pattern, citing a report by the manufacturer of stents used by the practice.

The Revenue Department is concerned about the potential reimbursement cut but does not want to alienate "Big Heart" because the practice is a major revenue source for the hospital. It instructs the Quality Department to err on the side of reporting a "favorable" outcome anytime the subjective criteria could arguably justify such a finding. As a result, the 2011 and 2012 quality reports are dramatically better than the 2010 report, where more stringent internal standards were utilized for determining a "favorable" outcome. Enormous is ultimately paid the full rate by Medicare for these procedures.

Who is responsible for solving this problem? Certainly, the Quality Department has a role. Patient quality is potentially suffering and the trends need to be analyzed. Risk Management has a role in defending the malpractice suits; as does Peer Review. The most important player, however, is the Compliance Department. Under the new system, the Company faces substantial civil and even criminal exposure. Knowingly reporting false data to the government under the new regime gives rise to both criminal and civil liability.¹²⁰ The

¹²⁰ See 18 U.S.C. § 1001 (2000); 18 U.S.C. § 1035 (2000).

Revenue Department would argue, of course, that it did not “knowingly” report false data because its interpretation of the regulations allowed it to give the hospital the “benefit of the doubt” when a quality indicator fell within a gray area.

So who really is responsible for handling this problem? One risk is that the various departments respond without careful deliberation and coordination. This increases the risk of enforcement activity because the “solution” implemented by management to solve the revenue issue may be contrary to the wishes of the Quality Committee and the steps being taken by the Compliance Department to keep the facility in compliance with the reimbursement statutes. Before long, a prosecutor’s case is made for him as the various departments point fingers.

VI. DEFENDING HEALTHCARE PROVIDERS IN THE NEW MILLENNIUM

The entities that will prosper under the new regime are those that best integrate the risk, revenue, quality and compliance functions. There is no single “right” solution because healthcare facilities have differing goals, culture, and competitive pressures. Still, facilities could benefit from performing a comprehensive review of how well they respond to risk, quality and compliance issues that cut across institutional lines. The adage “an ounce of prevention is worth a pound of cure” applies equally to medicine and law. Among the issues that can (and should) be considered include:

A. Revitalize the Existing Compliance Committee or Create a Multidisciplinary Team to Foster Change

Most healthcare facilities have implemented the various antifraud measures recommended by the Program Compliance Guidance documents promulgated by CMS, including creation of compliance committees, implementing educational programs and designating a compliance officer. A properly structured compliance committee that has been given a modicum of discretion can be an extremely useful tool to implement comprehensive strategies for responding to potential risk, quality, and compliance issues. The effectiveness of any committee turns on several variables. First, a committee that is not staffed with *active*, high level representatives of each department will be ineffective. The convergence of pay for performance and the criminalization of malpractice are going to require substantive changes in organizations that wish to prosper. A committee whose membership does not include the facilities’ actual decision makers will be unable to execute the policies that need to be implemented.

An effective compliance committee will need the authority and tools necessary to implement structural change. In simple terms, to be effective the committee needs to be able to make policy and require individual departments to comply with those policies. The compliance committee (or its equivalent) should evolve from its historic advisory role to a fully empowered legislative body with the authority to make policy and punish transgressors.

B. Share Information

Data that might formerly concern only one department under the historic model now has relevancy to all departments involved in the risk, quality and compliance functions. A disproportionate number of rejected claims received by the revenue department might be the sign of a serious underlying quality or compliance problem. A healthcare provider experiencing an excessive number of malpractice claims, or patient complaints, likely raises risk, quality and compliance issues. In the world of pay for performance, “compliance problems” often-times masquerade as “revenue” or “quality” problems. Without an active sharing of information across the facility, the compliance department may not discover the problem until the government has already instituted enforcement activities.

Databases tracking malpractice claims, payment trends and quality measurements should be made available across departmental lines. Compliance and risk teams should be active participants in the day-to-day operations of the revenue team. Most importantly, each department head should be sensitized to the fact that an issue that may have historically “belonged” to their department might in fact need to be shared with others.

C. Start Planning Today

More so than many of the other initiatives that have washed over the healthcare field over the last twenty years, the federalization of quality standards and pay for performance cannot be handled in a vacuum. All aspects of management—from revenue to compliance to quality—are implicated. And, to be successful, all must be actively involved in the planning process. Facilities should begin today to reconsider how they both insure *and document* the quality of the services they provide.

VII. CONCLUSION

The government and other third party payors are incrementally changing the rules of engagement with the facilities that depend on its

money to survive. Too many facilities will respond by trying to compartmentalize their response to a subset of the departments involved in risk, quality, and compliance issues. Facilities should start evolving now, or risk finding themselves extinct.