The False Claim Act's broad-reach to substandard healthcare: Recommendations to organizations

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ABSTRACT

This article reviews the application of the False Claims Act (FCA) to substandard care cases in the healthcare setting. The efforts by the government to bring FCA suits against institutions for substandard care have broadened the traditional notions of "fraud." This expanded application of the FCA suggests that healthcare providers that submit claims for reimbursement for substandard care are liable for fraud against the government. This relatively new breed of substandard care FCA suit defies the original intent of the FCA and is not an appropriate tool for enforcement quality of care issues in healthcare settings. This paper briefly presents the history and elements of the FCA and identifies the legal theories the government has used to pursue substandard healthcare quality cases. Alleged substandard care cases are then reviewed to substantiate the extent and significance of the application of the FCA to substandard care. Finally, presented are recommendations for healthcare organizations to mitigate FCA violations as it pertains to substandard care.

Key Words: False Claim Act, substandard care, healthcare organizations, healthcare compliance, healthcare quality

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Introduction

A number of False Claims Act (FCA) (31 U.S.C. § 3729-3733) healthcare cases continue to revolve around the traditional fraudulent activities such as billing for goods or services not rendered, upcoding,[1] violations of Anti-Kickback Statute (42 U.S.C. §1320[a]-[7b])[2], Physician Self-Referral or Stark Regulations (42 U.S.C.S. §1395nn; 42 C.F.R. §411.350-411.389).[3] A growing trend exists where the FCA is used to enforce penalties for substandard quality of care in healthcare institutions. Over the past decade, the government's use of the FCA in these cases has broadened the concept of "fraud" to include within its purview various quality of care violations as a relatively new kind of fraudulent activity (Hoffman, Geroux, & Schwartz, 2010). The birth of this new fraud allegation is, in part, a result of the last decade's focus on quality of care as a major issue in reforming delivery of health care.

This trend of the federal government's application of the FCA to substandard care continues into 2014. A recent Office of Inspector General (OIG) publication listed several quality of care related issues among its priority recommendations (Office of Inspector General, 2014a). These recommendations according to the OIG would best protect the integrity of Department of Health and Human Service programs, if implemented (Office of Inspector General, 2014a). Examples of Medicare quality and safety issues identified in this publication are: addressing adverse events in hospital settings, improving care and discharge planning for beneficiaries in nursing homes, addressing harm to patients, reviewing questionable resident hospitalizations, and inappropriate drug use in nursing homes (Office of Inspector General, 2014a).

The underlying basic argument in favor of the expanded reach of FCA is that the government, the largest buyer of health care, should not be paying for services that are so substandard as to be essentially worthless. The significant monetary losses to the Federal Treasury (U.S. Department of Health & Human Services and Department of Justice, 2013), coupled with a growing disapproval of substandard care in healthcare institutions (Leape, 2005), creates a compelling incentive for the government to broaden the concept of FCA fraud to include quality of care issues.

This paper will present the history and elements of FCA, discuss the legal theories that allow FCA's application to this area. Data related to the government's use of the FCA to combat alleged substandard healthcare cases for the fiscal years from 1996 to 2012 are reviewed to substantiate the government's focus in this area. Recommendations are then provided for healthcare organizations to mitigate exposure through board involvement, departmental restructuring, education, and compliance measures targeted toward healthcare quality.

History of the False Claims Act

[1] Upcoding is a "fraudulent practice in which provider services are billed for higher CPT (current procedural terminology) procedure codes than were actually performed, resulting in a higher payment by Medicare or 3rd-party payors." http://medical-dictionary.thefreedictionary.com/upcoding (accessed on April 30, 2014)

[2] The Federal Anti-Kickback Statute prohibits the payment or receipt of any "remuneration" that is intended to induce the purchasing, leasing or ordering of any item or service that may be reimbursed, in whole or in part, under a Federal Health Care Program, such as Medicare or Medicaid. It also prohibits the payment or receipt of any remuneration that is intended to induce the recommendation of the purchasing, leasing or ordering of any such item or service.

[3] The Stark Regulation prohibits a physician from referring a patient to a medical facility in which he has a financial interest.

The False Claims Act (U.S.C. 31 § 3729-3733) was enacted in 1863 to combat the "rampant fraud"—such as "broken rifles, lame horses, and useless ammunition"— that Civil War defense contractors perpetrated on the federal government (Cong. Globe). This Federal act passed under the administration of President Abraham Lincoln carries both civil and criminal penalties for anyone who knowingly presents, or causes to be presented, to the U.S. government a false or fictitious claim for payment (Steiner, 2014). The FCA's authority encompasses more than just healthcare claims. It applies equally to all others who make claims for payment from government funds to the government. Currently, the FCA extends to any fraudulent activities involving government funds—violators of the FCA may face a civil fine of $5,000 to $11,000 per fraudulent claim, plus treble damages of the amount wrongly paid out (U.S.C. 31 § 3729 [a]). Adjustments to Penalties (28 C.F.R. § 85.3[a][9]) allow the government to increase penalties by 10 percent due to inflation).

What makes the FCA especially powerful is that it contains a "qui tam" provision. The "qui tam" provision permits any person to bring an action on behalf of the government and to retain a portion of the damages (U.S.C. 3, § 3730 [d]). The "qui tam" provision encourages private parties, known as "relators," to police the healthcare market. The qui tam provisions of the FCA provide a wide breath of those who can report fraud against the government and can include a healthcare organization's employees, vendors, and patients. Relators stand to gain at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of a claim, depending upon the extent to which the person substantially contributed to the prosecution of the action (U.S.C. 31, § 3730[d]).

The federal government has a major incentive to police providers submitting false claims for reimbursement. The government is the largest buyer of health care services, funding the Medicare program and contributing through grants about half of the state Medicaid program. Medicare contributions totaled $297 billion in 2004 and are estimated at $708 billion by 2014 (Congressional Budget Office, 2005). The Centers for Medicare and Medicaid Services (CMS) projects that Medicaid benefits spending will increase to $674 billion by 2017 (Center for Medicare and Medicaid Services, 2008).

Due to the hundreds of billions of dollars spent yearly in the health care arena, the government, through the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (P.L 104-191), established the Health Care Fraud and Abuse Control Program (HCFAC) to coordinate Federal, State and local law enforcement activities concerning healthcare fraud and abuse (The DHHS and DOJ, 2008). According to the *HCFAC Annual Report for 2007*, the Federal government won or negotiated approximately $1.8 billion in judgments and settlements in 2007. As a result of these efforts, the Medicare Trust Fund received transfers of approximately $797 million during this period, in addition to $266 million in Federal Medicaid money similarly transferred separately to the Treasury (The DHHS and DOJ, 2008). The HCFAC account has returned over $11.2 billion to the Medicare Trust Fund since the inception of the Program in 1997 (The DHHS and DOJ, 2008).

Elements of the FCA

Liability under the FCA is brought under section 3729(a)(1) of the FCA, which provides that "any person who knowingly presents, or causes to be presented, to … the United States Government … a false or fraudulent claim for payment or approval … is liable to the United States Government (U.S.C. 31 § 3729[a][1])." The courts have found that the government has

the burden to establish the following elements: (1) that the provider submitted a claim to the U.S. Government, (2) that was false or fraudulent, (3) with "sufficient knowledge" of the falsity of the claim, and (4) that had a negative and direct effect on the federal treasury" (United States ex rel. Mikes v. Straus, 2001). The FCA does not provide a definition of "false." Several courts, however, have found that falsity in the healthcare context exists when the provider fails to comply with statutes and regulations and that failure is at the core of the agreement between the provider and the government (U.S. v. NHC Healthcare Corp., 2000; U.S. ex rel. Mikes v. Straus, 1999). The NHC Healthcare Corp. case illustrates the problem that "knowingly submitting claims against the United States for Medicare and Medicaid services not actually performed clearly violates the FCA." In Mikes v. Straus case, the court mentioned that implied false certification exists only if statutory compliance is "at the core" of the agreement between the contractor and the government, and that the government would have refused to pay had it been aware of the noncompliance. "Knowledge" under the FCA can be satisfied by actual knowledge, deliberate ignorance of the truth, and reckless disregard of the truth (31 U.S.C. § 3729[b]). The government does not have to show that the provider specifically intended to defraud the government in submitting its claim (U.S. v. Krizek, 1997). When the provider submits a claim for reimbursement, it is assumed that the provider is aware of the rules and regulations associated with making a claim (Mikes v. Straus, 2001).

Theories of FCA Liability for Violations of Substandard Care

Clearly, a provider that submits a claim for reimbursement by the government for services not rendered is liable under section 3729(a) for submitting a false claim. With respect to the expanded reach of the FCA to substandard care FCA cases, however, the government expands the concept of falsity to include the provision of "worthless" services (Hoffman, Geroux, and Schwartz, 2010). In order to bring a substandard care FCA case, the government takes a two pronged approach: it must show that 1) the provider failed to provide the requisite standard of care to its Medicare and Medicaid patients; and 2) the provider is certifying that it has complied with the requisite standard of care when it submits a claim for reimbursement (Fabrikant & Solomon, 1999). In other words, the government must show that the provider submitted a false claim because the care provided was substandard and, therefore, not equivalent to the amount billed to the government.

It is important to note that in the past, the government has used such sanctions as civil monetary penalties, Corporate Integrity Agreements (CIAs), payment withhold, and exclusions to address poor performance and inadequate quality of care (Hoffman, Geroux, & Schwartz, 2010). However, in recent years, the government added the FCA to address those cases involving care that is so bad that traditional remedies were insufficient. There are two major theories under which the government attempts to impose FCA liability on healthcare facilities: certification (expressed or implied) and worthless services (Hoffman, Geroux, & Schwartz, 2010). The two prevailing theories that have been employed by the Department of Justice under the FCA concern claims for medically unnecessary goods or services and services that are so substandard as to render them "worthless," so that any claim submitted for payment is false.

Worthless services theory.

Under this worthless services theory, the government attempts to show that the provider violated the FCA by knowingly submitting a claim for services so substandard as to be "worthless" (Hoffman, Geroux, & Schwartz, 2010). The presumption is that the federal government would not have reimbursed the provider for a claim had it known that the services failed to meet acceptable standards. In order to bring such a claim, the government must prove that the quality of care fell so far below the norm as to be grossly negligent or reckless in conduct.

In United States v. NHC Healthcare Corp, the government alleged that the defendants had provided inadequate care to two nursing home patients that did not satisfy Medicare and Medicaid standards (163 F.Supp.2d, 1051, 2001). The government argued that NHC had such low staff levels that NHC knew it could not provide all of the services for which it billed Medicare and Medicaid (*Id.* at 1055). While the government brought the suit under the implied certification theory, the court found that no certification, whether express or implied, is necessary "when the liability stems from the Defendants' activities of billing for procedures which they did not perform" (*Id.*). The court applied the worthless services theory, and held that FCA liability exists where a facility files claims for payment for services not rendered to residents. While the court struggled to define the exact point at which substandard care becomes fraud, it found that if a facility "fail[s] to perform the necessary care activities required to promote the patient's quality of life," and still submits reimbursement claims, "the provider has simply committed fraud against the United States" (*Id.* at 1055-56). The court emphasized that FCA did not require specific intent, and found that NHC operated its facility in deliberate indifference to its staffing shortages. NHC should have known that such a staffing shortage might lead to substandard care (*Id.* at 1058). The government has also attempted to broaden the reach of the FCA using express and implied certification theories.

Certification theory: Express or implied.

Express certification.

An FCA case premised on express false certification involves a provider's express statement that it has complied with the laws and regulations required for Medicare and Medicaid participation and is, therefore, properly entitled to government reimbursement (Stimson, 2008). For example, a provider must submit form CMS-1500 Health Insurance Claim Form, which requires providers to attest to certain certifications including healthcare quality metrics. This provider certification is a precondition to Medicare reimbursement.

A notable case in this area is United States ex rel. Mikes v. Straus (2001). Here, the physician-plaintiff in United States ex rel. Mikes v. Straus alleged that the defendant failed to comply with American Thoracic Society (ATS) standards for performing spirometry tests by using improperly calibrated instruments and inadequately trained staff (*Id*. at 694). The plaintiff alleged that the defendant had made false explicit statements that it provided quality medical services. The court found that defendants' submission of form CMS-1500 was an express certification that the services provided were *medically necessary* (*Id.* at 698), and that compliance with healthcare quality requirements on the form was a "precondition of government payment" (Id.). The court, however, distinguished medically necessity from quality of care and focused its analysis on whether the test was necessary, not whether the test was accurate. The Court found that submission of CMS-1500 addressed only the express certification of the medical necessity. The plaintiff did not support her allegations that the defendant-ordered

spirometry tests were medically unnecessary. In this instance, the plaintiff's allegation under the express certification theory failed. The government does have the option of pursuing substandard FCA cases under this theory.

Implied certification.

The government can also bring an FCA case premised on an implied false certification theory, whereby the mere act of submitting a claim implies that the provider complied with necessary laws and regulations as a precondition to government reimbursement. In United States ex. rel Aranda v. Community Psychiatric Centers of Oklahoma (1996), the government argued that the Community Psychiatric Centers (CPC) violated the FCA by filing claims for reimbursement despite failing to provide its Medicaid patients with "appropriate quality of care and a safe and secure environment (*Id.* at 1487)." The government introduced evidence that understaffing, absence of monitoring equipment, and inappropriate housing assignments led to instances of physical injury and abuse to CPC patients (United States ex. rel Aranda v. Community Psychiatric Centers of Oklahoma, 1996, p.1487-88). The government alleged that this amounted to a violation of the FCA because CPC "implicitly certified that it was abiding by applicable statutes, rules and regulations" regarding required quality of care and environment standards, but knew that it was not providing medical services to its patients that complied with those standards *(Id.* at 1487-88). The court found that the Medicaid program imposed the duty on providers to assure that medical care "will be of a quality which meets professionally recognized standards of health care" and that compliance with these standards was a condition of government payment (*Id.* quoting 42 U.S.C. § 1320c-5).

The *Straus* court's interpretation of implied certification departed drastically from that of the *Aranda* court. The *Straus* court (2001) found that implied certification theory is applicable only where the pertinent statute or regulation expressly provides that compliance is a precondition to payment. The *Straus* court ultimately concluded that the Medicare statute did not require that spirometry tests comply with ATS standards in order for providers to submit for their reimbursement (42 U.S.C. § 1395y[a][1][A]). The court (United States ex rel. Mikes v. Straus, 2001) noted that the FCA "was not designed for use as a blunt instrument to enforce compliance with all medical regulations" (*Id.* at 699) and that quality of care issues should be addressed at the state and local regulatory levels rather than in courtrooms (*Id.*700).

Examples of Alleged Substandard Care Cases

Eradicating healthcare fraud and abuse such as kickbacks (42 U.S.C. §1320[a]-[7b]) and self-referrals (42 U.S.C.S. §1395nn; 42 C.F.R. §411.350-§411.389) has long been a priority of the government. As the government expanded the concept of "fraud" to include quality of care violations, the number of FCA alleged substandard care cases and associated recovered amounts continues to rise steadily over the years. Based on the OIG's statement of priorities (Office of Inspector General, 2014a) and the significant monetary recoveries associated with the FCAs application to substandard care, this trend would appear to continue. Providers will need to take steps to effectively mitigate their exposure. Example alleged substandard care data were reviewed to substantiate the significance of this trend. It appears, by a review of the data, that the federal government does not concur with the *Straus* court (United States ex rel. Mikes v. Straus, , 2001) that the FCA was not designed to enforce compliance with medical regulations (*Id*. 699).

Data Collection

Alleged substandard care cases are those FCA settlements that meet either "worthless" theory or certification theories (express or implied certification). According to our review of the data, common risk areas for healthcare providers involving substandard care are areas such as: inappropriate or insufficient treatment and services to address patients' clinical condition; inadequate staffing levels or ineffectively supervising staff to provide medical, nursing and related services; and, failure to properly prescribe, administer and monitor prescription drug usage.

Our source of secondary data comes from several locations. FCA alleged substandard care cases from 1996 to 2012 were identified from the following websites: Department of Justice Press Release (www.doj.gov) of settled FCA cases, Office of Inspector General (oig.hhs.gov/fraud) for recovered cases, Taxpayers Against Fraud Education Fund (www.taf.org) for top FCA cases from 2004 to 2012, and James F. Segroves' "Survey of Federal False Claims Act settlements involving allegations of substandard care in health care facilities (1996-2009)" (Segroves, 2010). Substandard cases were reviewed for resulting financial penalties against individuals and organizations.

Results

A summary of the settled alleged FCA substandard cases can be found in Table 1. Ten out of 136 substandard cases exceeded ten million dollars. It should be noted that the table is not a complete listing of all federal False Claims Act settlements between the Federal Government and healthcare organizations involving allegations of substandard care for the time period reviewed. Currently, the Department of Justice only discloses FCA settlement statistics that are general in nature (Segroves, 2010). FCA allegations often remain under seal making and are not always publicized by the Department of Justice (DOJ). Usually, DOJ reports to the press for alleged substandard care cases are limited to those with multi-million dollar recoveries (Segroves, 2010). United States Attorney's offices also vary widely in the amount of information they provide to the public related to FCA substandard settlements (Segroves, 2010). It is not uncommon for private lawyers to keep settlements secret; also, as part of their settlements, government attorneys agree not to publicize the case (Gaul, 2005a). For example, the U.S. Attorney's Office for the Eastern District of Virginia only placed such settlements on its website after an article in the *Washington Post* criticized the secrecy given such settlements (Gaul, 2005b).

Even with the limitations of this data set, it is observed that the average number of alleged substandard of care FCA cases increased steadily in the study period (Figure 1). The first wave of cases reaches a peak between 2004 and 2005, followed by a somewhat faster decline from 2005 to 2006. The second wave of cases began immediately after 2006. The average dollar amount of settlements (Figure 2) followed a similar trend as the average number of cases per year. It reaches the first peak in 2005; a second peak in 2011. Additionally, examining the data in two equal time periods (1996-2003 and 2004-2011, excluding the cases that exceeded $100 million) for the period 1996-2003 the average dollar amount was $345,463, while the average for 2004-2011 was $5,636,972. The number and dollar amounts of these cases indicate, healthcare

organizations must proactively and consistently address quality of care issues within their organizations to avoid the expanded reach of the FCA.

Insert Table 1
Insert Figure 1
Insert Figure 2

What Can a Healthcare Organization Do: Recommendations for Mitigating Exposure

A review of alleged FCA substandard care settlements indicates that the FCA has emerged as major tool for the federal government to enforce quality of care. The Office of Inspector General (OIG) working collaboratively with The Department of Justice (DOJ) continues to actively pursue substandard care cases (Office of Inspector General, 2014a). Healthcare organizations found to have substandard care, under the FCA application, can be subjected to civil and criminal liability accompanied by significant monetary penalties (31 U.S.C. § 3729A [1][g]), Corporate Integrity Agreements (CIAs), and risk possible exclusion from Medicare programs (Social Security Act 42 USC §1128, §1156). Providers must, therefore, take steps to mitigate potential litigation under the FCA for allegations of substandard care.

Involve and Educate the Board

Board involvement and education is one method of mitigating these issues. Board involvement is crucial to creating an organizational cultural that supports patient safety and quality thus mitigating the potential application of the false claims act to quality of care issues. The Board's responsibility for quality is not new. A 1965 case, Darling v. Charlston Community Hospital (Darling v. Charleston Community Memorial Hospital, 1965*)* articulated the board's responsibility for healthcare quality. Outlined in this case was a healthcare organization's board fiduciary responsibility for oversight of healthcare quality. What is relatively new is the government's broad application of the FCA to quality of care issues.

Recognizing the need for board education as it pertains to healthcare quality and compliance, the Office of Inspector General (OIG) and American Health Lawyers Association (AHLA) co-sponsored a series of documents: *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Board of Directors* (n.d.a), *An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Board of Directors* (2004), and *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (n.d.b). These documents provide resources specifically for healthcare boards of directors. One such document *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (n.d.b) calls attention to the "new era of focus on quality and patient safety". This new focus has raised the importance of healthcare organizations directors' core fiduciary duty for healthcare quality.

Some recommendations for boards to achieve the required oversight and fiduciary responsibility as it relates to healthcare quality are:

1. *Conduct regular and on-going management reporting to the Board on these issues.* Quality and patient safety issues and concerns should have a place on each board agenda. There should be a collaborative discussion between compliance and healthcare quality departments

identifying the quality and compliance related issues. A dashboard that tracks significant issues should be available at each board meeting.

2. *Provide board education on quality and compliance issues.*

Boards should be actively involved in oversight of quality and compliance issues, sufficiently educated on these issues, and actively pursue their legal duty of inquiry (Caremark International Inc. Derivative Litigation, 1996*).* Several documents are available to assist boards in understanding their duties in these areas. Many have specifically outline a set of questions boards should ask management regarding the scope and operation of quality and compliance initiatives. These questions encompass such areas as the organization's goals for quality improvement program; how the organization measures and improves the quality of care; and, how the organization's quality assessment and improvement processes are integrated and coordinated with its corporate compliance program (Office of Inspector General and American Health Lawyers Association, 2004; Office of Inspector General and American Health Lawyers Association, (n.d.a); Office of Inspector General and American Health Lawyers Association, (n.d. b)).

3. *Establish quality/patient safety as a strategic priority.*

Boards should include the continuous improvement of healthcare quality and patient safety as part of their strategic priorities. Healthcare organizations should incorporate this directive in their mission statements and include a discussion as part of any strategic planning process. Consideration should be given to how healthcare quality/patient safety will be measured and how opportunities for improvement once identified will be improved.

4. *Allocate resources to quality/patient safety.*

One measure of an organization's actual commitment to quality/patient safety will be the amount of resources allocated to these activities. Operating budgets and staffing levels should be adequate to reflect the organization's commitment to quality and patient safety.

5. *Elect board members who have expertise in quality/patient safety.*

Hospital boards' nomination committees should actively seek and appoint those individuals who have expertise in healthcare quality and patient safety. Traditionally, hospital boards have sought those individuals with financial and management expertise from the community. Careful attention and planning should be given to balance the board with community leaders who bring a depth and understanding of healthcare systems, clinical processes, and accreditation requirements.

Board education and involvement in healthcare quality, patient safety and compliance issues should be an ongoing and regular part of a healthcare organization's board activities. A provider's board should be aware of the elements of the FCA, the intersection of compliance and quality issues, and the theories of liability for substandard care under the FCA.

Restructure Organizational Areas: Quality and Compliance Areas

Restructuring of traditional health care provider organizational structures needs to occur to assure departmental collaboration and minimize duplication of efforts. Lewis Morris, Former Chief Counsel of the Office of Inspector General (OIG), stated:

> "When looking at some of these very large [health care] corporations, there is a siloing of responsibility which has the effect of inadequate cross of information between the peer review/quality people and compliance people. The different components of a health care organization need to communicate and exchange information with each other and boards

of directors can encourage this process (L. Morris, Chief Counsel, OIG, personal communication, January 12, 2009)."

Health care organizations can no longer view quality of care and compliance initiatives as separate and distinct directives. Organizational structures should allow for close coordination among compliance, legal, medical, peer review, billing and risk management staffs, departments and committees.

Insert Figure 3

This can be implemented through a number of avenues. First, a reporting structure can be established that facilitates collaboration between Quality/Patient Safety and Compliance Areas. Reporting up to one Vice-President might encourage a collaborative culture and diminishing of silos. Second, joint board reporting (quality and compliance) should occur on a regular basis. Third, senior leadership should support a collaborative rather than a silo culture. Finally, the OIG recommends that the organization's compliance officer have direct access to the board (Office of Inspector General, 2000; Office of Inspector General, 2005). The organization's healthcare quality department should also have a reporting relationship that allows for direct access to the board. Compliance and quality departments afforded this board access may assure that quality/compliance issues receive full board attention without the possibility of navigating any potential conflict of interest that may be present with senior management. Any collaboration between a healthcare quality department and compliance department within a healthcare organization will require a leadership team that fosters such a culture.

Align Compliance and Quality Goals

Compliance and quality goals should be closely aligned. Providers should implement an effective compliance program that incorporates the organization's quality of care goals. Quality of care-compliance audits should be developed and implemented with the same focus as financial audits. Key quality indicators should be concurrently monitored for compliance. Risk areas should be prioritized and action plans developed for improvements. The board should receive regular reports of these audits. Special emphasis should be placed on risk areas the OIG has outlined in its guidance documents (Office of Inspector General, 2000). These areas include staffing, care plans, medication management, use of chemical and physical restraints and resident safety, as examples.

Review and Periodically Audit Potential Legal Implications of Gain Sharing and Performance Based Incentives

Centers for Medicare & Medicaid Services (CMS) and others have sought methods to incentivize improved quality in healthcare organization through various gain sharing programs and pay-for-performance (P4P) measures (Centers for Medicare and Medicaid Services ,n.d.a). Recent gain sharing demonstration projects have sought to identify how physicians and hospitals can financially share in gains from improving quality and efficiency of care provided to Medicare beneficiaries (Centers for Medicare and Medicaid Services, 2011). In other words, gain sharing programs seek to share cost savings between the hospital and physician generated by physicians'

efforts in controlling costs of providing care. Related are P4P incentive programs designed to provide financial reward for improved patient outcomes. One such program is the Medicare Shared Savings program where physician practices will be allowed to form Accountable Care Organizations (ACOs) and receive 50-60% of cost savings generated by the practice for Medicare beneficiaries. The important caveat to this program is ACO must achieve their quality reporting and performance metrics to benefit from the cost savings (Centers for Medicare and Medicaid Services, n.d.a).

The proliferation of these incentivized quality of care arrangements may make healthcare organizations vulnerable to compliance and legal issues, if improperly administered, implemented or designed. Programs should be evaluated to assure violations of relevant laws such as the Civil Money Penalty Law (CMPL) (Social Security Act §1128A [b][1]-[2]; 42 CFR Part 1003), Anti-Kickback Statute (42 U.S.C. §1320[a]-[7b]), and Physician Self-Referral Law (42 U.S.C.S. §1395nn; 42 C.F.R. §411.350-411.389) do not occur. For example, a CMPL trigger could occur for gain sharing and P4P programs that pay incentives to physicians for meeting quality targets for Medicare or Medicaid fee-for-service beneficiaries. The potential violation exists if the incentives could induce the physician to reduce or limit services to these beneficiaries.

As such, healthcare quality departments should work closely with the compliance and legal departments prior to implementing programs that seek to incentivize quality. These programs should also be periodically audited to assure compliance with OIG advisory opinions and potential legal issues.

Conclusion

The use of the FCA by the federal government as a tool to improve healthcare quality is a step back in creating an environment for real improvements in the healthcare delivery system. The original intent of the FCA was to reimburse the government for claims for payments for good and services that were not provided (S. Rep. No. 99-345, 1986). The Act's legislative history suggests that it was intended to cover "each and every claim submitted under a contract, a loan guarantee, or other agreement which was originally obtained by means of false statements of other corrupt fraudulent conduct, or in violation of any statute or applicable regulation…." (S. Rep. No. 99-345, p.9, 1986). These are objective issues; quality of care, however, is largely subjective. Since neither prosecutors nor courts are proper evaluators and determinants of quality, the FCA should not be used as a tool to enforce subjective standards of quality. There is a wealth of various state and federal agencies such as CMS, the States' Departments of Health, and the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") that are far better equipped to determine and monitor whether healthcare organizations are in compliance with quality of care standards.

There are, however, many incentives for the government to embrace the FCA as a tool in substandard care cases. The government may recover treble damages (31 U.S.C. § 3729 A[1][g]) if it successfully brings a substandard care FCA case and, since liability under the FCA does not require specific intent, the government need only show reckless disregard, a relatively low burden of proof. Many recent multi-million dollar settlements have allowed the government to recover enormous amounts of money (U.S. Department of Health & Human Services, February 11, 2013). The damages in this type of suit serve to replenish the Federal Treasury; they do not, however, remedy the harm suffered by the recipient of the substandard care or encourage a non-punitive culture necessary to make substantive improvements in health care quality.

The impetus for quality improvement in healthcare institutions should not grow from fear of courtroom prosecution or coercive multi-million dollar settlements. In order for the government to initiate an effective strategy to improve and maintain quality of care issues in the healthcare setting, it must disarm itself of the FCA as a tool to enforce quality. Rather, the movement for quality improvement in healthcare should focus on the development and implementation of effective processes, programs, and a culture that encourages open discussion of opportunities for improvement supported by data to identify those areas. Furthermore, individual healthcare institutions should promote and enforce quality with a comprehensive quality improvement program requiring stricter quality oversight, developmental targeted training processes, third-party quality monitoring, and the establishment of a corporate compliance program. Each institution should align its billing, quality and risk management departments and complete routine audits to ensure accuracy and compliance in its billing procedures. The board should be actively involved in designing a strategic imperative for the organization that focuses on healthcare quality and patient safety and regularly monitors progress toward goals. These comprehensive quality improvement programs will not only serve to avoid costly FCA litigation, but will improve the overall quality conditions in healthcare settings.

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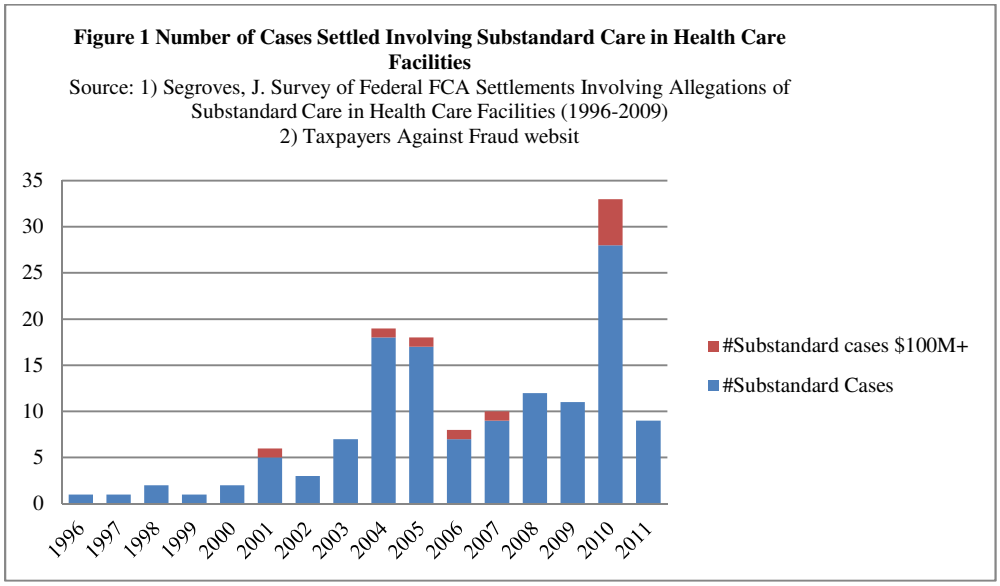
Table 1
FCA Substandard Cases, 1996-2011

Year	# Cases	# Cases Exceeded $100 Million	Average $ Included Cases Exceeded $100 Million	Average $ Excluded Cases Exceeded $100 Million	Minimum Settlement $	Maximum Settlement $
1996	1	0		$600,000	$600,000	$600,000
1997	1	0		$750,000	$750,000	$750,000
1998	2	0		$282,500	$65,000	$500,000
1999	1	0		$195,000	$195,000	$195,000
2000	2	0		$160,000	$160,000	$160,000
2001	5	1	$21,064,430	$205,537	$100,000	$104,500,000
2002	3	0		$131,667	$45,000	$275,000
2003	7	0		$439,000	$50,000	$870,000
2004	18	1	$21,272,733	$3,406,424	$50,000	$325,000,000
2005	17	1	$25,711,059	$7,005,500	$126,000	$325,500,000
2006	7	1	$24,068,571	$2,246,667	$510,000	$155,000,000
2007	9	1	$18,429,333	$3,170,500	$45,000	$140,500,000
2008	12	0		$4,675,634	$36,000	$10,500,000
2009	11	0		$3,746,910	$82,256	$23,963,100
2010	28	5	$76,323,584	$6,432,664	$92,000	$600,000,000
2011	9	0		$14,411,474	$369,744	$68,500,000

Source:
1) Segroves, James. Survey of Federal FCA Settlements Involving Allegations of Substandard Care in Health Care Facilities (1996-2009)
2) Taxpayers Against Fraud website (2004-2012)



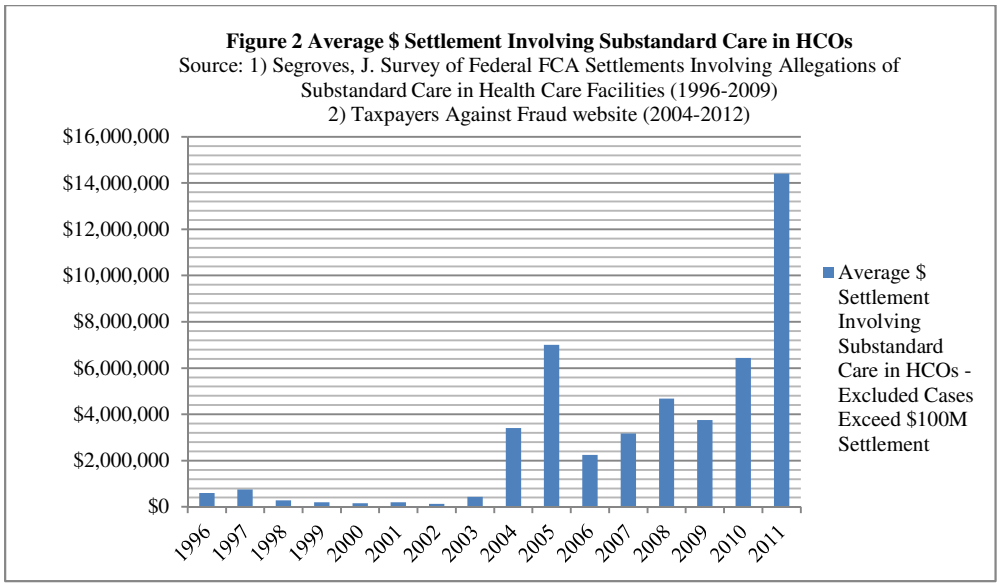


Figure 3
Organizational Chart