A discussion on Corporate Compliance & Ethics Week

See page 16

23
Compliance officer and the audit committee: Building an effective relationship
Steven Forman

28
Tax-exempt hospitals: Putting your hospital’s IRS exemption at risk
Gerald Griffith, James King, and Catherine E. Livingston

36
Physician-owned entity fraud alert: Hospital compliance officers take note
Tom Bulleit, Eliza Andonova, and Natalie D. Morris

40
Compliance and quality of care, Part 1: Laws and case studies
Michelle Moses Chaitt, Mark L. Mattioli, Richard E. Moses, and D. Scott Jones

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Compliance and quality of care, Part 1: Laws and case studies

» Understand the intersection of regulatory compliance, quality of care, and medical negligence or malpractice.
» Discuss the need for a functional, interdisciplinary approach in compliance.
» Review the quality-of-care implications of current laws and regulations, including understanding how laws and regulations mandate both compliance and quality.
» Examine the quality-of-care connections of the False Claims Act (FCA).
» Stress the need for communications and interdisciplinary efforts between billing, coding, compliance, medical malpractice, quality of care, and physicians.

Over the last decade, the connection between compliance and quality of care has become increasingly clear. Healthcare providers, compliance officers, and malpractice defense counsel must connect adherence to regulatory compliance, provision of high-quality care by clinicians, and the potential for medical malpractice actions as a result of failure to deliver quality.

Ignoring the quality-of-care aspects and professional medical liability or medical malpractice aspects of regulatory compliance is a fundamental error. In fact, this connection becomes increasingly important with the types of quality-focused compliance investigations taking place today. Quality issues, as well as billing and coding issues, lead to compliance investigations—and investigations lead to malpractice lawsuits against organizations and physicians. Compliance officers, billers, coders, medical providers, quality officers, and risk managers must recognize that their field of effort is involved in a multi-disciplinary endeavor known as “regulatory compliance.”

Compliance, quality, and malpractice: The intersection

The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) first made quality of care central to compliance in the landmark update to a Corporate Integrity Agreement (CIA) signed by Tenet Healthcare Corporation in 2006. More than one-third of the document’s 63 pages addressed or named quality...
issues. This was one of the first national CIAs that specifically required the development of Clinical Quality departments, clinical audits, evidence-based medicine programs, and standards of clinical excellence and quality metrics.\(^1\)

The OIG Work Plan Table of Contents for FY 2013 includes 17 section titles that address improving the quality of healthcare through vigorous enforcement of laws and regulations.\(^2\)

The Patient Protection and Affordable Care Act (PPACA) established a variety of quality reporting mechanisms. Analyzing PPACA on behalf of members of Congress who were concerned that the regulation might establish new standards of care in medical malpractice actions, the Government Accountability Office (GAO) stated:

Certainly, Medicare beneficiaries and others who receive healthcare from providers who adhere to the PPACA provisions, and the guidelines and standards developed under these provisions, may receive higher quality care because of the incentives that these provisions extend to providers to improve the quality of the care they provide. Conversely, those who receive care from providers who fail to do so may receive lower quality care.\(^3\)

The GAO quickly connected quality-of-care provisions under PPACA to improvements in overall quality and viewed a possible change in how courts might perceive the standard of care in medical malpractice lawsuits by postulating that “...it is possible that, if these standards and guidelines become accepted medical practice, they could impact the standard of care against which provider conduct is assessed in medical malpractice litigation.”\(^4\)

### Laws support compliance and quality

Historically, the sundry departments across a health system or hospital focused on regulations within their own purview and failed to cross communicate regarding common-ground regulations and compliance issues. This has been referred to as a “silo approach” with each department working within its own silo to comply with regulations and laws that might potentially affect the system. A champion of open communication and silo elimination across departments and throughout organizations has many allies in current and long-standing laws and regulations. Teaching administrative and clinical staff about these laws and regulations and their impact is a critically important function.

Authors Moses, Chaitt, and Jones summarized\(^5\) the key provisions of laws and regulations that should be familiar to all compliance officers, providers, and healthcare counsel:

- PPACA and the Healthcare and Education Reconciliation Act establish a broad range of quality and quality reporting measures.
- The federal False Claims Act (FCA) and the companion criminal law provisions (18 U.S.C. §287) establish civil and criminal penalties that cover any federally funded program or contract. The FCA establishes fines ranging from $5,500 to $11,000 per claim filed, plus three times the amount of damages sustained by the government.
- The Anti-Kickback Statute (AKS) provides that healthcare providers may not provide “kickbacks” to other providers, institutions, or patients in the form of fees or services. AKS provides criminal penalties for certain acts, as well as a penalty of up to $50,000 plus three times the total amount of remuneration involved, against those involved in remuneration schemes.
- The Physician Self Referral (Stark) Law prohibits physicians from referring patients to entities with which the physicians have a financial interest. The Stark Law creates certain “exceptions” for designated health services (DHS), and establishes penalties of
$15,000 per claim and civil penalties up to $100,000. A failure to meet Stark reporting requirements carries an additional $10,000 per day penalty.

In addition, under 42 C.F.R. §411.384, the Centers for Medicare & Medicaid Services (CMS) is required to issue advisory opinions under §1877(g) (6) of the Social Security Act. An advisory opinion provides guidance to providers on whether specific referrals or specified actions are prohibited. The opinion is specific to the case stated in the request for opinion. Advisory opinions are fact-specific and binding only on the requesting party and specific situation, but are an effective learning tool for healthcare professionals.

In addition, compliance officers, healthcare counsel, and healthcare providers must be aware of the quality provisions of the Medicare Conditions of Participation (CoP) that every provider that bills Medicare and Medicaid must incorporate into their compliance programs, including patient rights (64 FR 36069), quality assessment, performance improvement (68 FR 3435), and other issues.

Overview of False Claims Act and application to quality of care
Of all the statutes governing fraud and abuse, the federal False Claims Act (FCA) is probably the most potent weapon for combating fraud. The FCA imposes liability on persons or organizations that defraud government agencies by submitting false claims or by submitting false information in support of those claims. It applies to federally funded programs and contracts.

The birth of the FCA dates back to 1863. Its precursor Act, “An Act to Prevent and Punish Frauds upon the Government of the United States,” was designed to combat procurement fraud committed by government contractors during the Civil War. The Act contained a qui tam provision, which allowed private parties with knowledge of fraudulent acts to bring claims on behalf of the government. If the claim was successful, the party who brought the suit was entitled to half of the recovery, as well as costs awarded by the court. The original FCA contained both civil and criminal penalties, but these provisions were separated in 1872.

Several court decisions during the 1940s encouraged the filing of qui tam lawsuits that were duplicative of suits already filed by the Government. As a result, in 1943, Congress amended the FCA to require that a private individual filing under the FCA provide the government with new information in order to proceed with the claim. If the government already had the information, it could not be the basis for a qui tam action.

In 1986, the framework of the FCA was enacted when Congress expanded the Act to include Medicare and Medicaid. The definition of “knowingly” was broadened to include (1) individuals having actual knowledge that the information was false, (2) individuals acting in deliberate ignorance of the truth and (3) individuals acting in reckless disregard of the truth. Perpetrators no longer needed to possess specific intent to submit a false claim to fall under the purview of the Act. In addition, the 1986 amendments and subsequent amendments lessened the restrictions that had been placed on qui tam suits during the 1940s.

Today, the FCA is commonly used to combat healthcare fraud and permits the government to recover monetary damages from
physicians or providers who file false claims. Individual case settlements and verdicts easily total in the millions. The FCA provides that any person who knowingly presents or causes to be presented a false or fraudulent claim for payment or approval to the United States government is liable to the government for a civil penalty of not less than $5,500 and not more than $11,000, plus three times the amount of damages that the government sustains.

The FCA continues to authorize private citizens to assert claims on behalf of the United States and recover a portion of the damages (typically 15-30%) plus expenses and attorney fees depending on the circumstances. These whistleblower or qui tam actions are designed to encourage those with knowledge of fraud to report it. Whistleblowers come in the form of employees, former employees, business associates and present/former employees. In addition to the civil FCA, there is a criminal FCA that imposes criminal penalties, including imprisonment.

**Application of the FCA to quality of care**

In addition to claims for services not actually rendered, the FCA has become a vehicle by which the government can attempt to recover damages from healthcare providers who submit payment claims for services provided that fall below the acceptable standard of care. In these so-called “quality of care” cases, the government argues that notwithstanding the actual performance of the service, the quality of care that the patient received was insufficient; therefore, billing for that service amounts to a fraudulent claim under the FCA.

In *United States v. NHC Healthcare Corporation*, the government alleged that a nursing home in Missouri submitted false claims in connection with two residents, because the facility failed to provide the services for which it had billed. One resident suffered dehydration and pressure sores while in NHC’s care and the other suffered pressure sores and weight loss, and ultimately died. Evidence indicated that staffing shortages may have contributed to substandard care. The government alleged that the quality of the services provided was so poor that billing for them at all constituted a fraudulent claim under the FCA.

In denying NHC’s motion for summary judgment and allowing the government to proceed, the court noted that by billing Medicare on a per diem basis for the overall care of these patients, NHC agreed to provide a certain standard of care. The court agreed with the government that at a certain point, a healthcare provider “can cease to maintain this standard by failing to perform the minimum necessary care activities required to promote the patient’s quality of life. When the provider reaches that point, and still presents a claim for reimbursement to Medicare, the provider has simply committed fraud against the United States.”

More recently, in *United States ex rel., Sanchez v. AHS Tulsa Regional Medical Center*, several employees in Oklahoma filed a qui tam action against their employer alleging, among other things, that it had submitted numerous false claims for inpatient psychiatric services.11 Plaintiffs cited an Oklahoma regulation which mandated weekly minimum therapy requirements for adolescent patients. They claimed that in fact patients had been receiving brief “drive-by” sessions. Plaintiffs argued that the regulation mandated a quality of care that the patients failed to receive and that billing for a service that was less than the minimum requirement amounted to a false claim under the FCA. The Oklahoma District Court held that in order to survive summary judgment on a quality-of-care theory, a plaintiff must present facts amounting to (1) the provision of an entirely worthless service; or (2) at a minimum, the provision of grossly negligent services with regard to a particular standard of care or regulatory requirement.

The court accepted the “worthless services” standard announced in a 2001 Second Circuit case, *United States ex rel. Mikes v. Strauss*, in
which the court deemed that only claims for reimbursement for the performance of a service that is so deficient it is the equivalent of no performance at all will be fraudulent claims under the FCA. In granting the motion for summary judgment of AHS on the “quality of care” theory, the court found no evidence to support that the services being billed for amounted to a worthless service or that they were grossly negligent.

To date, there is very little case law to assist practitioners in understanding their obligations regarding application of the quality-of-care standard to the FCA. The two cases addressed above show examples of the threshold standard required to survive summary judgment and demonstrate that results are fact dependent.

Conclusion

Clearly, current and past regulations are now being interpreted from a platform based on quality of care as well as billing and coding aspects of regulatory compliance. Compliance officers, billers, coders, medical providers, quality officers, and risk managers must recognize that their field of effort is involved in a cross-disciplinary endeavor known as regulatory compliance. The case for multidisciplinary compliance has never been stronger, as healthcare organizations undergo massive changes and the entire system in the United States anticipates the looming near future impact of the Patient Protection and Affordable Care Act (PPACA).

Compliance officers must be in the forefront of efforts to break down silos and communication barriers between the offices working with billing, coding, compliance, medical malpractice, quality of care, and physicians.

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1. Corporate Integrity Agreement, Office of Inspector General (OIG) and Tenet Healthcare Corporation, Sept. 27, 2006. Available at http://1.usa.gov/1ailUXzw
3. GAO, Causes of Action under the Patient Protection and Accountable Care Act, March 23, 2010. Available at http://1.usa.gov/1eceqZn
4. Id.
8. “Hospital Liability” supra note 2, at 218-19.
12. 274 F.3d 687, 703 (2d Cir. 2001).