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THE QUALITY OF CARE CERBERUS: PAYMENTS, PUBLIC REPORTING, AND ENFORCEMENT

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Introduction

Since the Institute of Medicine released its 1999 landmark report, *To Err is Human*, both the public and private sectors have focused a spotlight on quality and safety in the American health system.[1] The government has responded to this heightened attention by fundamentally changing its healthcare policies, intent on transforming its role from passive payor of healthcare services to active purchaser of only high-quality care. To achieve this transformation, the government has employed a three-pronged approach: (1) changing payment policy so payment is made only for high-quality care, not for merely rendering services; (2) making healthcare providers' quality transparent through public reporting; and (3) increasing enforcement of quality through criminal and civil actions under the False Claims Act ("FCA").[2]

In accordance with that paradigm shift, the Department of Health and Human Services' Office of Inspector General ("OIG") and the American Health Lawyers Association ("AHLA") issued a September 13, 2007 joint report, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors*.[3] The report urges boards of directors to take serious and immediate efforts to understand their healthcare organization's ability to monitor and provide high-quality care as a core fiduciary obligation. This urging mirrors the change in healthcare policy linking quality care with the right to receive payment. Presented with both a carrot and a stick, hospitals must act now to proactively manage their quality of care to receive full payments and incentives and minimize the serious enforcement risk associated with quality failures.

The Focus on Quality of Care

In the late 1990s, the increased attention on quality and safety of patient care gave rise to numerous studies identifying quality breakdowns and safety risks

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in the American healthcare system. *To Err is Human* identified medical mistakes as one of the leading causes of death in the country and estimated nearly 98,000 Americans die each year from substandard healthcare. The report immediately caught the attention of both the government and the healthcare community. Tales of egregious substandard medical care further raised awareness of healthcare safety risks.[4] In turn, these studies and stories birthed new initiatives to improve the safety, efficacy and transparency of healthcare, and fueled the current trend of quality of care enforcement.

Without question, substandard care is a financial burden for the federal government and contributes to rising national healthcare costs. Daniel Levinson, Inspector General of the Department of Health and Human Services ("HHS"), has commented that "fraudulent furnishing of medically unnecessary invasive procedures not only causes financial harm but puts patients at significant risk. The Office of Inspector General will vigorously investigate such cases and require appropriate corrective action to safeguard future patient care."[5] In June, 2007, the OIG reported that Medicare paid approximately $4.5 billion in 2004 for consecutive inpatient and skilled nursing facility stay sequences associated with quality of care problems and fragmentation of services.[6] With a variety of tools in its arsenal, including payment incentives, public reporting, and legal enforcement, the government is squarely focused on improving the ***quality*** of American healthcare.

Incentivizing Quality of Care Through Payment Reform

Historically, payments for healthcare services were made without regard to the quality of the services rendered, and hospital quality and peer review systems existed unrelated to the traditional billing and finance functions of a hospital. In response to the public's demand for increased safety and quality in healthcare, reimbursement policy is changing to align the right to receive payment with the quality of the care provided. Quality and billing are now inextricably tied.

The Deficit Reduction Act of 2005 authorized the Centers for Medicare and Medicaid Services ("CMS") to develop for Medicare a hospital pay-for-performance model (known as "Value-Based Purchasing").[7] CMS anticipates that Congress will authorize the initiation of the program in FY 2009 (commencing October, 2008). CMS and Congress both believe that linking quality with the right to receive payment will transform the healthcare industry.[8]

Under Value-Based Purchasing, hospitals that meet or exceed quality standards will receive full payment on claims, plus incentives. Hospitals that fail to deliver quality care will lose their right to incentive payments and may also find their claims denied. Already the private sector has begun to embrace the concept of paying for quality, and many private payors are adopting a pay for performance methodology. Hospitals and other healthcare providers should expect exponential growth in this area. The days of receiving payment solely for rendering the service may soon end.

Not only is CMS enacting Value-Based Purchasing to drive quality of care, it is also implementing payment policies to deny payment where poor quality exists. For example, Section 5001(c) of the Deficit Reduction Act requires hospitals to report certain secondary diagnoses that are present at the time a patient is admitted to the hospital.[9] Beginning October 1, 2008, cases with certain "hospital acquired conditions," sometimes referred to as "never events,"[10] (*e.g.*, catheter-induced urinary tract infections, falls, certain surgical infections, pressure ulcers, etc.) will not be assigned to a higher paying Diagnosis-Related Group ("DRG") unless it was reported that the patient had the condition at the time of admission to the hospital.[11] This is an evolving list, and CMS will expand the number of "never events."[12] In CMS' view, it will no longer pay for conditions it believes to be caused by poor quality of care.

Value-Based Purchasing and the refusal to pay for "never events" are just the beginning. Hospitals should expect more reimbursement changes in the future as the government and private payors address quality and safety problems through quality-based payment reform.[13] In light of these payment restrictions, the hospitals that will suffer the most are those which lack an effective program to link quality and safety with billing and compliance.

Driving Quality of Care Through Public Reporting

Recognizing the need to change healthcare behavior more broadly, the government's second prong is focused on driving quality by making it transparent through public reporting. The Hospital Quality Initiative and the Physician Quality Reporting Initiative seek to change healthcare delivery by publicizing providers' outcomes. The government has access to more information than ever before about quality of care in individual hospitals and healthcare providers across the country.

In its most recent Strategic Plan, CMS stated it is "expanding the use of electronic data to more efficiently detect improper payments and program vulnerabilities."[14] Data mining is a technology that facilitates the ability to sort through masses of information through database exploration, extract specific information in accordance with defined criteria, and then identify patterns of interest to its user.[15] Although some data is used for administrative purposes, such as determining eligibility for federal benefits, it also may be used to detect

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potential instances of fraud, waste, and abuse in federal health programs.[16]

Several sources of publicly reported information will be reviewed by CMS in its data mining efforts: (1) the Hospital Quality Initiative; (2) the Physician Quality Reporting Initiative; (3) the Performance Measurement and Reporting System; (4) the Program for Evaluating Payment Patterns Electronic Report; (5) Comprehensive Error Rate Testing; (6) Payment Error Rate Measurement; and (7) the Recovery Audit Contractor Program.

- The Hospital Quality Initiative ("HQI") The HQI was created to improve hospitals' quality of care by distributing objective, easy- to-understand data on hospital performance. Through the HQI, hospital quality data is reported and made available to the public using a website/web tool known as Hospital Compare. Data gathered under the HQI is based on a standardized set of hospital quality measures.
- The Physician Quality Reporting Initiative ("PQRI") The PQRI was created to improve quality of care by establishing financial incentives for healthcare professionals who participate in the quality reporting program. Professionals who successfully report a designated set of quality measures on claims may earn a bonus payment, subject to a cap, of 1.5% of total allowed charges for covered Medicare physician fee schedule services.
- Performance Measurement and Reporting System ("PMRS") PMRS is used to capture and aggregate information on an array of measures, linking outcomes and performance and allowing for comprehensive data mining. According to CMS, "PMRS will serve as a master system of records to assist in projects that provide transparency in health care on a broad scale, enabling consumers to compare the quality and price of health care services so that they can make informed choices among individual physicians, practitioners and providers of services."[17]
- Program for Evaluating Payment Patterns Electronic Report ("PEPPER") PEPPER is an electronic data report containing hospital-specific Medicare claims data and statistics for areas identified by CMS as high risk for payment errors.[18] PEPPER was developed as part of CMS' Hospital Payment Monitoring Program to assist inpatient acute care prospective payment system hospitals with identifying and preventing payment errors. The target areas include one-day stays, hospital readmissions and several DRGs that have historically been associated with payment errors.[19]
- Comprehensive Error Rate Testing ("CERT") The CERT Program measures the Medicare fee-for-service ("FFS") error rate for claims submitted to carriers, durable medical equipment regional carriers, and fiscal intermediaries.[20] CMS established the CERT Program to monitor and report the accuracy of Medicare FFS payments. CMS receives over two billion FFS claims per year. Of these claims, CERT randomly selects a statistical review sample to determine whether the claims were paid properly.
- Payment Error Rate Measurement ("PERM") CMS implemented the PERM program to measure improper payments in the Medicaid program and the State Children's Health Insurance Program ("SCHIP") and comply with the Improper Payments Information Act of 2002 ("IPIA").[21] The IPIA requires the heads of federal agencies to annually review programs susceptible to significant erroneous payments, estimate the amount of improper payments, report those estimates to the Congress, and submit a report on all agency actions to reduce erroneous expenditures.[22] The Office of Management and Budget identified Medicaid and SCHIP as two programs at risk for significant improper payments.
- The Recovery Audit Contractor Program ("RAC") Under the RAC program, recovery audit contractors review the Medicare claims of physicians, providers, and suppliers to identify overpayments or underpayments.[23] These contractors receive a percentage of all overpayments they identify. The RAC program started as a three-year demonstration project, mandated by Section 306 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[24] but has been made permanent pursuant to Section 302 of the Tax Relief and Health Care Act of 2006 ("TRHCA").[25] RAC audits are currently underway in Florida, California, and New York. The TRHCA extends the RAC program to all states by 2010.

From a compliance perspective, hospital data must be appropriately managed to ensure that appropriate data is being reported. By understanding the public reporting systems, a hospital can take comfort in knowing exactly what data is being reported to the government, how the data impacts payments, and that the reported data is accurate.

Intersection of Public Reporting and Data Mining

The government has been actively mining data of healthcare providers

and, given the data available to the government to identify poor performing providers, a hospital may find itself the subject of a quality of care enforcement action based on data mining. As James Sheehan, Esq., Medicaid Inspector General of New York, cautioned healthcare providers, "We are reviewing assorted sources of quality information on your facility to see what it says and if it is consistent. You should be doing the same."[26]

Voluntary and mandatory reporting has increased the government's response to quality of care concerns. These public reporting efforts complement the increased use of software to aggregate and analyze the reported information. This combination permits greater analysis than ever before about quality of care in individual hospitals nationwide. Such quality data is typically not subject to any privilege or discovery protection; it is reported directly to the government or government contractor and publicly posted.[27]

The government is quickly becoming adept at using statistical data in its quality of care enforcement efforts. This summer, a special Strike Force consisting of federal, state, and local investigators arrested approximately 38 people in Florida in connection with alleged schemes to defraud Medicare, including billing Medicare for unnecessary services.[28] The Strike Force identified the individuals through its real-time analysis of Medicare billing data.

Enforcing Quality of Care Through the False Claims Act

Imposing significant civil penalties for submitting fraudulent claims for payment under federal healthcare programs, the FCA is emerging as the government's most powerful tool to enforce quality of care.[29] The FCA can be imposed in the criminal context as well and the past few years have seen numerous civil and criminal enforcement actions, many resulting in multi-million dollar settlements, prison sentences, and exclusion from federal healthcare programs. Because the federal government recovers $15 for every $1 it invests prosecuting FCA cases, enforcement of quality of care is a profitable undertaking for the government and will only increase.

The government uses a variety of legal theories under the FCA to attack quality failures, but all follow the same principle: the government will not pay for medically unnecessary or substandard care.

Express False Certification

The FCA theory of express false certification is based on a healthcare provider's false certification that the care provided met the legal requirements for payment. Under this theory, fraudulent claims under the FCA arise when a healthcare provider falsely certifies compliance with statutes or regulations that are a precondition of government payment.[30] Each time a claim for payment is submitted, a hospital must certify the medical necessity and appropriateness of the care provided, and the government will not reimburse for care that is not medically necessary.[31] Thus, services found to be unnecessary or substandard allow the government to contend the certification was false, rendering the entire claim ineligible for payment and violative of the FCA. For example, the government has aggressively pursued cases of medical necessity fraud when it finds a pattern or high volume of lucrative, elective services.[32]

Not all courts have adopted the express false certification theory as a basis for FCA liability, and not all false certifications of compliance are sufficient to render a claim fraudulent. Generally, to trigger a FCA violation, the certification must have affected or coaxed the government's decision to pay. Although courts hesitate to use the FCA to police all regulatory violations, many hold that a certification on a claim for payment includes an allegation of compliance with the Anti-Kickback or Stark self-referral laws and is, therefore, a precondition for government payment.[33] Some courts have also limited a claim of medical necessity fraud under the FCA to apply only to the decision to provide care, and not to the quality of the treatment provided; if the *decision* to provide the treatment is appropriate, the fact that the treatment itself may have been substandard is (according to at least some courts) insufficient to render the certification false.[34]

Implied False Certification

Even if a hospital does not make an express certification of compliance with regulatory requirements, prosecutors have nevertheless used the FCA in enforcement actions under the theory of implied false certification. Under this theory, the alleged fraud is not based on a false statement contained in the claim itself, but rather on an *implied representation* that the underlying care provided to the patient complied with the regulations and statutes that define the conditions required to bill for the service.

Some courts have refused to adopt the implied certification theory generally, and instead limit it to cases where the provider knowingly submits a claim that violates a statute or regulation which "expressly condition[s] payment on compliance with its terms."[35] Other courts, however, have allowed the government to use the implied certification theory whenever the government would not have paid a claim had it known of the hospital's failure to comply with the regulation or statute.[36] In particular, the Sixth Circuit has adopted the implied false certification theory, and found a continuing duty to comply with regulations even after a claim is submitted.[37]

Worthless Services

If a provider actually renders medically necessary services, but those services were of such poor quality as to be considered worthless, FCA liability can attach.[38] The worthless services theory is unique because it focuses squarely on the quality of care provided, rather than on express or implied certifications of compliance with laws or regulations.

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"Worthless services" is a high standard. As one court described it, "the performance of the service [must be] so deficient that for all practical purposes it is the equivalent of no performance at all."[39] As with all theories of liability under the FCA, the scienter element must be satisfied; (*i.e.*, the defendant must know or act in reckless disregard or deliberate ignorance of the fact the service being billed to the government was worthless).

Criminal Enforcement

In particularly egregious cases, the government can, and has, criminally prosecuted individuals associated with quality of care violations. The criminal charges at the government's disposal include laws prohibiting healthcare fraud,[40] mail and wire fraud,[41] false statements,[42] and kickbacks.[43] These statutes have resulted in significant criminal penalties for hospitals and high-ranking individuals working at those hospitals and reflect the seriousness of the government's approach to quality of care violations.

That Won't Happen to Our Hospital … Right?

Enforcement actions to date generally have focused on six areas: (1) ordering medically unnecessary treatments or procedures;[44] (2) payment of kickbacks;[45] (3) special treatment for physicians who are big admitters;[46] (4) fraudulent documentation;[47] (5) lack or failure of appropriate internal review processes (*e.g.*, credentialing or peer review);[48] and (6) underlying regulatory violations.[49] Consider these recent enforcement actions:

- On July 27, 2007, California regulators imposed a $3 million fine on a California hospital system for failure to provide adequate oversight of quality assurance programs, including peer review and patient complaint management. The problems were discovered by analyzing randomly-selected charts following patient complaints.[50]
- A rural hospital in Northern California was accused of allowing physicians to perform unnecessary cardiac catheterizations, angioplasty, and open heart surgeries. As a result, and to avoid the hospital's exclusion from federal healthcare programs, the hospital's parent organization entered into a $54 million settlement with the Department of Justice and agreed to divest the hospital by selling it to an unrelated third party.[51]
- A FCA action against a Baton Rouge, Louisiana hospital for medically unnecessary surgeries resulted in a $3.8 million settlement.[52]
- A medical center in Chicago, Illinois was found to have paid physician kickbacks that resulted in medically unnecessary care. The hospital administrator and several physicians received prison sentences and were required to make restitution payments totaling over $26 million.[53]
- A hospital in Tampa, Florida paid over $900,000 to settle charges that it had permitted a neurosurgeon to perform unnecessary spine operations in violation of the FCA.[54]
- The CEO and members of the Medical Executive Committee at a Michigan hospital were indicted on charges of criminal conspiracy, mail fraud and wire fraud by billing for medically unnecessary pain procedures. The government's case centered on the hospital's allegedly deficient peer review procedures, which failed to curtail the unnecessary pain procedures. After the anesthesiologist who performed the procedures was convicted of mail fraud and sentenced to three years in prison, the hospital and other individual physician defendants pleaded guilty, serving over 1,000 hours community service and paying over $1,000,000 in fines.[55]
- A Louisiana cardiologist was indicted on multiple counts of healthcare fraud and one count of criminal forfeiture for performing unnecessary angiograms and angioplasties.[56]
- A Florida hospital and its current and former owners paid $15.4 million to settle a FCA lawsuit involving allegations that the hospital paid kickbacks to physicians in return for patient admissions that resulted in medically unnecessary treatments on elderly patients.[57]

"A Siloing of Responsibility"

Many hospitals are hampered in providing consistent quality of care and are simply unaware of their compliance vulnerabilities because they have not subjected their quality of care processes to the level of scrutiny they devote to other compliance concerns, such as billing and claims submission or physician financial relationships. Moreover, a hospital's compliance program traditionally is separate and distinct from its quality assurance and peer review programs. That type of structure does not permit the information exchange necessary to recognize and address the compliance risks that can arise from poor quality of care.

Lewis Morris, Chief Counsel to the Office of United States Inspector General of Health and Human Services, recognized that issue when he said, "When looking at some of these very large [healthcare] corporations, there is a siloing of responsibility, which has the effect of inadequate cross of information

between the peer review/quality people and the compliance people. The different components of a healthcare organization need to communicate and exchange information with each other and boards of directors can encourage this process."[58]

Next Steps for Hospitals and their Boards of Directors

Given the current enforcement environment, hospitals must evaluate whether they have sufficiently integrated quality of care review into their compliance programs. This is not a simple task, and requires a broad-based, coordinated approach among the governing body, the medical staff, the peer review and quality improvement committees, the quality assurance department, risk managers, the legal department, and the compliance officer.

Only by proactively addressing the reimbursement implications of a quality failure can a hospital avoid a potentially costly and public enforcement action. In this regard, it is important for an organization to structure the intersection of quality, compliance, and legal considerations to maintain, to the extent possible, the various state law privileges that often protect quality-related information.

In addition to reducing risk, a quality of care compliance program can offer increased financial rewards and streamlined organization efficiency. For example, it can reveal how a hospital can structure its operations to better ensure full payment of financial incentives once the pay-for-performance model goes into effect.

Establishing internal quality controls and identifying areas of potential quality breakdowns are two key areas a hospital should address to reduce the risk of an adverse government enforcement action.[59] An assessment can reveal to the board of directors and senior management the operational landscape of its healthcare organization, a necessary prerequisite to identifying and addressing the compliance implications of the quality of care provided by the hospital.

Conclusion

Addressing quality of care proactively, and integrating it with compliance, will place a hospital at a tremendous financial and operational advantage, not only because it will position the hospital on the cutting edge to meet pay-for-performance quality targets (maximizing reimbursement under the new model of payment) but also because it can prevent allegations of fraud based on poor quality of care. By understanding the legal connections between quality and compliance, hospitals can seek full reimbursement and other incentives under the new payment programs and decrease the likelihood of a government civil or criminal enforcement action.

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Endnotes

1 Committee on Quality of Health Care in America, Institute of Medicine, *To Err is Human: Building a Safer Health Care System* (Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson eds., National Academy Press, 1999).

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[2] False Claims Act, 31 U.S.C. §§ 3729-3733.

[3] Arianne N. Callender, et al., The Office of the Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association, *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors* (2007).

[4] For example, there was press coverage and public outrage over wrong body part surgeries. As a more recent example, Michael Moore highlighted the faults of the American healthcare system, including quality and safety, in his documentary, *Sicko*.

[5] August 17, 2006.

[6] Department of Health and Human Services Office of the Inspector General, *Consecutive Medicare Stays Involving Inpatient and Skilled Nursing Facilities* OEI-07-05-00340 3 (June 2007), available at http://www.oig.hhs.gov/oei/reports/oei-07-06-00340.pdf.

[7] Pub. L. 109-171.

[8] See Note 3, *supra*, at pages 6-7.

[9] 72 Fed. Reg. at 47201 (Aug. 22, 2007). The reporting requirement became effective October 1, 2007. According to a May 11, 2007 transmittal issued by CMS, if hospitals fail to report a valid present on admission ("POA") code for each diagnosis on a claim submitted after April 1, 2008, the claim will be returned to the hospital.

[10] According to the National Quality Forum, "never events" are errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients. Never events indicate a significant problem in the safety and credibility of a healthcare facility. http://www.cms.hhs.gov/apps/media/press/release.asp?counter=1863 (*see* Appendix 2 for a complete list of "never events."

[11] Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rules, 72 Fed. Reg. 47130, 47200 (Aug. 22, 2007).

[12] For example, CMS plans to add ventilator associated pneumonia, staphylococcus aureus septicemia, and deep vein thrombosis as non-reimbursable "hospital acquired conditions" for FY 2009. *See* 72 Fed. Reg. at 47218 for additional information and discussion.

[13] Some private companies have already announced that they will stop paying for "never events" and certain medical errors. These companies include members of the National Business Group on Health and the Leap Frog Group. *See* Jeremy Smerd, *Doctor's error, your expense: No minor mistake, Part 2*, Workforce Management, June 11, 2007 at 1.

Aetna's Chief Medical Director of National Accounts, Charles Cutler, M.D. has stated that Aetna is considering making non-payment for "never events" a standard part of the company's contracts. *See* Martin Sipkoff, *Hospitals Asked to Account for Errors on their Watch*, Managed Care, July 2007.

[14] Centers for Medicaid and Medicare Services, Achieving a Transformed and Modernized Health Care System for the 21st Century, CMS Strategic Plan 2006-2009. http://www.cms.hhs.gov/MissionVisionGoals/Downloads/CMSStrategicActionPlan06-09_061023a.pdf.

[15] Testimony of Mark Forman, Associate Director for E-Government and Information Technology, Office of Management and Budget Before the Subcommittee on Technology, Intergovernmental Relations, and the Census Committee on Government Reform, United States House of Representatives, March 25, 2003, *available at* http://www.whitehouse.gov/omb/legislative/testimony/forman032503.html.

[16] *Id.*

[17] Federal Register, Vol. 72, No. 176 (September 12, 2007).

[18] Journal of AHIMA, Seasoning Your Compliance Plan With PEPPER, by Lou Ann Wiedemann, Jan. 2007; PEPPER User's Guide available at: http://www.hpmpresources.org/LinkClick.aspx?fileticket=rmjMG7%2f7R0U%3d&tabid=1059&mid=105, April 2007.

[19] *E.g.*, DRG 143 (Chest Pain) and DRG 416 (Septicemia).

[20] Centers for Medicare & Medicaid Services, CERT Program, *available at* http://www.cms.hhs.gov/cert.

[21] To implement PERM, CMS published a proposed rule (FR/Vol. 69, No. 166/Friday, August 27, 2004), an interim final rule (FR/Vol. 70, No. 192/Wednesday, October 5, 2005), and a second interim final rule (FR/Vol 71, No. 166/Monday, August 28, 2006). CMS published the Final Rule on August 31, 2007. http://www.cms.hhs.gov/PERM/Downloads/PERM%20Final%20Reg.pdf.

[22] Improper Payments Information Act of 2002, Pub. L. 107-300, 116 Stat. 2350.

[23] Centers for Medicare & Medicaid Services, *Recovery Audit Contractor Overview, available at* http://www.cms.hhs.gov/RAC/01_Overview.asp.

[24] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, § 306, 117 Stat. 2066, 2256.

[25] Tax Relief and Health Care Act of 2006, Pub. L. 109-432, Division B, § 302, 120 Stat. 2922, 2991 (codified as amended at 42 U.S.C. § 1395ddd).

[26] February 6, 2007 AHLA presentation in Las Vegas, Nevada.

[27] Certain protections exist for healthcare quality information (*e.g.*, state laws protecting from discovery certain medical staff peer review information, privileged attorney-client communications, certain information reported to a Patient Safety Organization ("PSO") under the Patient Safety and Quality Improvement Act ("PSQIA")). However, the publicly-available quality data the government uses for data mining is not subject to those protections and can be a source for FCA liability.

[28] Press Release, U.S. Department of Health and Human Services, *Strike Force Formed to Target Fraudulent Billing of Medicare Program by Health Care Companies* (May 9, 2007), *available at* http://www.hhs.gov/news/press/2007pres/05/pr20070509c.html.

[29] Lewis Morris, counsel to the U.S. Department of Health and Human Services Office of Inspector General, Daniel Levinson, explained that the OIG is adamant in using the False Claims Act to combat quality of care violations in hospitals and nursing homes. *OIG's Morris Tells AHLA to Watch For Increase in False Claims Act Cases*, 10 BNA Health Care Fraud Report 524 (July 5, 2006).

[30] *See, e.g., United States ex. rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997).

[31] 42 C.F.R. § 402.3.

[32] *See, e.g.*, Press Release, Department of Justice, *Tenet Healthcare Corporation to Pay U.S. more than $900 million to resolve False Claims Act Allegations* (June 29, 2005), *available at* http://www.usdoj.gov/opa/pr/2006/June/06_civ_406.html.

[33] *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32 (D.D.C. 2003); *U.S. ex. rel. Thompson v. Columbia HCA Healthcare Corp.*, 20 F. Supp. 1017, 1047 (S.D. Tex. 1998) (on remand).

[34] *Mikes v. Straus*, 274 F.3d 687, 698 (2d Cir. 2001).

[35] *Id.* at 702; *see also United States ex. rel. Willard v. Humana Health Plan of Texas, Inc.*, 336 F.3d 375 (5th Cir. 2003).

[36] *See, e.g., United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F.Supp.2d 28, 31-33 (D.D.C. 2003).

[37] *United States ex. rel. Augustine v. Century Health Servs.*, 289 F.3d 409, 415 (6th Cir. 2002).

[38] *See, e.g., United States ex rel. Lee v. Smithkline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001).

[39] *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001).

[40] 18 U.S.C. § 1347.

[41] 18 U.S.C. § 1341 (Mail Fraud); 18 U.S.C. § 1343 (Wire Fraud).

[42] 42 U.S.C. § 1320a-7b(a); 42 U.S.C. § 1320a-7b(c); 18 U.S.C. § 1035.

[43] 42 U.S.C. § 1320a-7b(b).

[44] *See, e.g., Florida Hospital, Owners Pay $15 Million to Settle False Claims, Kickback Lawsuit*, 10 BNA Health Care Fraud Report 880 (December 6, 2006); *United States ex. rel. Thomas Gayeski v. Sebastian Hospital, Inc.*, (S.D. Fla. 2004) (No. 04-14349); *United States ex rel. Thomas Gayeski v. Linda Bland*, (S.D. Fla. 2007) (No. 04-14349).

[45] *See, e.g., Chicago Hospital's Former Owner to Pay $64 Million for Role in Health Care Fraud*, 10 BNA Health Care Fraud Report 743 (October 11, 2006).

[46] *See, e.g., Grand Jury in Michigan Indicts Physicians, Hospital for Conspiracy, Health Care Fraud*, 5 BNA Health Care Fraud Report 917 (December 12, 2001).

[47] *See, e.g., Court Denies Motion for Reconsideration By Health Care Providers Convicted of Fraud*, 10 BNA Health Care Fraud Report 382 (May 10, 2006).

[48] *See, e.g., Grand Jury in Michigan Indicts Physicians, Hospital for Conspiracy, Health Care Fraud*, 5 BNA Health Care Fraud Report 917 (December 12, 2001).

[49] *See, e.g., HealthSouth Agrees to Pay $325 Million to Resolve Medical Billing Allegations*, 9 BNA Health Care Fraud Report 29 (January 5, 2005).

[50] *State Fines Kaiser Again*, Los Angeles Times (July 26, 2007).

[51] *Tenet to Sell Redding Medical Center to End OIG Bid to Exclude It From Federal Programs*, 8 BNA Health Care Fraud Report 14 (January 7, 2004).

[52] *Louisiana Hospital Settles Federal Claims of Billing for Medically Unnecessary Services*, 10 BNA Health Care Fraud Report 679 (September 13, 2006).

[53] Press Release, U.S. Department of Justice, *Edgewater Medical Center Management Firms To Pay $2.9 Million In Resolving Related Criminal and Civil Health Care Fraud Cases* (January 15, 2003), *available at* http://www.usdoj.gov/usao/iln/pr/chicago/2003/pr011503_01.pdf.

[54] *Florida Neurosurgeon, Hospital to Pay $1.2 Million in Unnecessary Surgeries Suit*, 11 BNA Health Care Fraud Report 549 (August 1, 2007).

[55] *United States v. United Memorial Hospital*, 2002 WL 33001119 (D. Mich., 2002) (denying defendants' motion to dismiss).

[56] Press Release, U.S. Department of Justice, *Lafayette, Louisiana Cardiologist Indicted by Federal Grand Jury* (March 23, 2006), available at http://neworleans.fbi.gov/dojpressrel/2006/no032306.htm.

[57] *See, e.g., Florida Hospital, Owners Pay $15 Million to Settle False Claims, Kickback Lawsuit*, 10 BNA Health Care Fraud Report 880 (December 6, 2006); *United States ex. rel. Thomas Gayeski v. Sebastian Hospital, Inc.*, (S.D. Fla. 2004) (No. 04-14349); *United States ex rel. Thomas Gayeski v. Linda Bland*, (S.D. Fla. 2007) (No. 04-14349).

[58] September 25, 2007 AHLA/HCCA presentation in Baltimore, Maryland.

[59] In light of the government's quality of care initiative, these areas should be given equal oversight attention as areas of traditional concern (*e.g.*, billing and claims submission, physician financial relationships, etc.).