WHAT HEALTH CARE EXECUTIVES
NEED TO KNOW ABOUT
QUALITY OF CARE

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The Government’s Three-Prong Approach to Quality of Care

Cerberus, William Blake (1757-1827)
The Government’s Three-Prong Approach To Quality of Care

1. Incentivizing Quality Care Through Payment Reform
2. Driving Quality of Care Through Public Reporting
3. Enforcing Quality of Care Through the False Claims Act

Prong 1: Incentivizing Quality of Care Through Payment Reform

- The new paradigm for reimbursement.
- CMS is transforming payment policy from passive payor of services to active purchaser of high value health care.
- Private payors also are changing payment policies to pay for quality.

“I strongly support linking provider payment to quality care as a way to make Medicare a better purchaser of health care services. Today, Medicare rewards poor quality care. That is just plain wrong and we need to address this problem.”

Sen. Chuck Grassley,
Budget Hearing with Michael Leavitt
February 7, 2007
Incentivizing Quality of Care Through Payment Reform

“The current sector is all about volume. The future is about value.”
Michael Leavitt, U.S. Health & Human Services Secretary
March 29, 2008

Pay for Performance

Financial incentives for:
- Adhering to recommended tasks or processes.
- Adopting desired tools or infrastructure.
- Meeting or improving measured outcomes.

Gainsharing

The number of private P4P programs is increasing exponentially.

Medicare Value Based Purchase Plan

Hospitals are reporting quality data to CMS under RHQDAPU program.
CMS issued final report to Congress on November 21, 2007.
VBP will build on the RHQDAPU program.
As required by the DRA, CMS has been developing a Value Based Purchasing plan.
## Incentivizing Quality of Care Through Payment Reform

### Quality FIRST Act (H.R. 7067)
- Introduced in the House Sept 25, 2008. The most substantive VBP bill to date.
- VBP proposals were included in physician-based payment bills S. 3101, and S. 3118.
- The Act would reward hospitals for their performance on process measures for the four specified conditions currently reported to CMS:
  - acute myocardial infarction;
  - heart failure;
  - pneumonia; and
  - surgical care improvement/surgical infection prevention.

### Under the Quality FIRST Act
- A four-year, phased-in transition of Medicare payment bonuses would start with 0.5% for FY 2011, 1% for FY 2012, 1.5% for FY 2013, and 2% for FY 2014.
- Hospitals would have the opportunity to earn up to 2% of their reimbursement payments by meeting certain performance quality benchmarks. Bonus payments would be made to high-performing hospitals from the pool of funds made available by payment reductions to hospitals that do not meet the full-incentive benchmark level.

### Medicare VBP Demonstration Project
- 270 participating hospitals could receive financial rewards for better outcomes.
- Measured 34 processes of care and outcomes for 5 common clinical conditions.
- 15 hospitals moved from the bottom to the top 5th in rankings in one or more clinical areas, improving by an average 32.6% in quality scores.
- Last year, the top-performing hospitals earned $7 million in incentive payments.
- CMS awarded more than $24.5 million over the first three years of the project.
Incentivizing Quality of Care Through Payment Reform

Medicare Physician Group Practices Demonstration Project

- Began April 1, 2005.
- Ten participating physician groups.
- July 11, 2007 CMS Press Release – All achieved benchmark performance on at least seven of ten diabetes clinical quality measures, and two met all ten.
- “...all participating physician groups improved the clinical management of diabetes patients in the first year...”
- Earned $7.3 Million of the $9.5 Million in savings to the Medicare program.

Medicare Acute Care Episode (ACE) Demonstration Project

- Provide global payments for acute care episodes within Medicare FFS.
- Focus on select orthopedic and cardiovascular inpatient procedures.
- Goals:
  - improve quality for FFS Medicare beneficiaries
  - produce savings for providers, beneficiaries, and Medicare using market-based mechanisms
  - improve price and quality transparency for improved decision making
  - increase collaboration among providers

No Payment for Poor Quality

- Hospitals will not be paid for 11 Hospital Acquired Conditions (HAC) unless present on admission (POA).
  - Object left in during surgery
  - Air embolism
  - Catheter associated UTI
  - Pressure ulcers
  - Vascular catheter associated infection
  - Surgical site infection following CABG
  - Falls
  - Surgical site infections following certain elective procedures, including certain orthopedic surgeries, and bariatric surgery for obesity;
  - certain manifestations of poor control of blood sugar levels; and
  - deep vein thrombosis or pulmonary embolism following total knee replacement and hip replacement procedures.
Evolving system

- CMS is considering ways to make HAC more precise, including risk-adjusting for a condition's prevalence and assessing rates of a condition's occurrence over time.

- CMS is also looking into expanding the policy to other payment settings, including outpatient hospitals, ambulatory surgery centers, physicians' offices, home health agencies, and skilled nursing facilities.

**Prong 2: Driving Quality of Care Through Public Reporting**

**Sources of Data**
- Hospital Quality Initiative
- PERM
- CERT
- PQRI
- Adverse event reporting
- Medical malpractice litigation
- Qui tam relators
Driving Quality of Care Through Public Reporting

“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.”

James G. Sheehan, Medicaid Inspector General, New York
February 6, 2007

The Hospital Quality Initiative

- The measures currently reported through the Initiative are:
  - Heart attack (MI) – 8 measures
  - Heart failure (HF) – 4 measures
  - Pneumonia (PN) – 7 measures
  - Surgical Care Improvement Project (SCIP) – 5 measures
  - Pediatric Asthma – 2 measures
  - Mortality – 2 measures
  - Experience of Care (HCAHPs survey)
  - Outpatient – 7 measures
  - Hospital Compare publicly reports the data (www.hospitalcompare.hhs.gov), payment and volume info added in Spring, 2008

Hospital Compare

[Diagram showing hospital comparison]
Driving Quality of Care Through Public Reporting

Physician Quality Reporting Initiative

What is PQRI?

- Voluntary program of financial incentives to physicians who successfully report quality data to CMS.
- Eligible professionals who satisfactorily submit quality data will earn an incentive payment of 1.5% of their total allowed charges for Physician Fee Schedule covered professional services furnished during that same period.

Data Generated by Physicians Through PQRI

- 2008 PQRI consists of 119 quality measures, including 2 structural measures. One structural measure conveys whether a professional has and uses electronic health records and the other concerns electronic prescribing.
- Reporting only applies to measures applicable to the services rendered to Medicare beneficiaries.
Driving Quality of Care Through Public Reporting

Performance Measurement Reporting System

- Proposed new master system of records
- Public reporting of price/quality transparency in health care (physicians & hospitals).
- Pools and analyzes information about quality, performance and cost, down to individual physician level.
- Uses both public and private payor data.

Information disclosed to:
- Consumers
- CMS contractors
- Other agencies (state & federal)
- Chartered Value Exchanges and data aggregators, who will generate single or multi-payor performance measurement
- Providers/physicians
- Quality Improvement Organizations
- Law enforcement

PMRS will be a springboard for data mining and government enforcement actions.

Other Public Reporting Initiatives

Chartered Value Exchanges

- As of September, 2008, CMS has identified 25 Charter Value Exchanges (“CVE”) to allow providers, consumers, employers and insurers to work together to achieve quality and price transparency
- CVE’s have access to Medicare data on quality/price and can combine the data with private sector data to produce and publish all-payor performance results
Driving Quality of Care Through Public Reporting

- Consumer-Purchaser Disclosure Project

Data Mining

- Defined: 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.
- Goals
  - Correct inappropriate behavior
  - Identify overpayments
  - Deny payment

Florida Data Mining Technology

- Florida uses HWT’s iQSuite data mining package. It offers: data warehousing, iQSafeguard, iQAI, and iQBudget.
- Florida employs all modern data mining technology, including data warehousing; data mining; data matching/modeling; smart technology; and the Medi-Medi program.
Prong 3: Enforcing Quality of Care Through the False Claims Act

- The FCA is emerging as the government’s most powerful tool to enforce quality of care.
- Physicians, executives, and board members face real risks for poor quality of care.

Enforcing Quality of Care Through the False Claims Act

- “You will see more and more physicians going to jail.”
  - Kirk Ogrosky, Deputy Chief for Health Care Fraud, Department of Justice, Criminal Division (Dec. 4, 2007)
- “We’re holding those individuals accountable.” “You may not go to jail ... but we will take your money.”

Enforcing Quality of Care Through the False Claims Act

- Six themes present in cases:
  - Unnecessary treatment/procedures
  - Kickbacks
  - Big admitters receiving special treatment
  - Fraudulent documentation
  - Poorly structured, or failure to follow, internal process
  - Underlying regulatory violations
Enforcing Quality of Care Through the False Claims Act

**Elements of a False Claim**
- Submit or cause to be submitted, a claim for payment;
- Claim is false or fraudulent (false statement); and
- Scienter: “Knew or should have known” or “reckless disregard” for the truth or falsity of the claim.
  - No specific intent needed

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.

**Traditional Theories**
- Claims for services not rendered
- Unbundling
- Claims for services not covered (e.g., wound care kits, urinary incontinence devices)
- Duplicate payments

**Quality of Care Theories**
- Express False Certification
- Implied False Certification
- Worthless Services
- Criminal Statutes
Enforcing Quality of Care Through the False Claims Act

- In 2002, 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.

- In 2002, the FBI raided a California hospital resulting in a payment of over $55 million to settle a FCA lawsuit alleging the hospital billed for medically unnecessary open heart surgery. The parent company was required to divest the hospital to avoid termination from the Medicare program. The publicity from the case led to a flurry of malpractice cases ultimately costing over $500 million to defend.

- New legal/compliance risks to consider:
  - Knowledge arising from data reporting.
  - Work force whistleblower education per DRA.
  - Processes and structures are not effective in identifying quality failures.

- May lead to:
  - False Claims Act liability
  - Corporate liability
  - Liability of board members, owners and high-ranking officers and physicians.

Practical Tips

- **Improve Board Education and Oversight**
  - Board must recognize quality/safety as a core fiduciary obligation
  - Health care quality is a key component of corporate mission and a core fiduciary obligation for the board
  - Elevate quality to the same level of fiduciary obligation that financial viability and regulatory compliance currently constitute
Practical Tips (cont’d)

- Board and medical staff need to frame an agenda for quality – IHI campaign, Joint Commission, quality measures
- Governance responsibility for quality – measures and goals
- Board needs to receive regular reports (errors, outcomes)
- Increasing board education on quality – part of orientation
- Recruiting one or more board members with expertise on quality
- Government/Industry Roundtable to be held on November 10, 2008

Assessment to Enhance Quality and Compliance

- Subject quality processes to same compliance scrutiny as billing/coding or physician financial relationship
- Close gaps in processes
- Know fraud and abuse risks
- Assess for 2009 OIG Work Plan risks
- Is there an auditable trail for quality data?

Practical Tips (cont’d)

Mine Your Own Data

- Need to know the data mining techniques used by federal government and your state
- Can you replicate reports?

“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.”

James G. Sheehan
Medicaid Inspector General, New York
February 6, 2007
Practical Tips (cont’d)
Integrate Quality and Compliance
- Policies and education to address compliance risks associated with quality
- Need to investigate compliance implications of quality failures. Reporting procedures need to be established. Be careful to maintain the privilege

Practical Tips (cont’d)
Revamp Medical Staff
- Standardization of care drives Quality and Safety under the new Paradigm
- Only Qualified and Aligned Physicians on Staff (voting vs. non-voting status)
- Consider:
  - Multi-disciplinary Peer Review
  - Cross-discipline departments
  - Competency based credentialing
  - Appoint only excellent physicians
  - Set and communicate expectations
  - Measure performance (case review, outcomes data (rate indicators), compliance with quality targets (rule indicators))
  - Proctoring
  - Manage poor performance

Practical Tips (cont’d)
Improve Hospital/Physician Collaboration
- Existing structures that meet current legal requirements:
  - Employment (different from employment wave of 1990s)
  - Co-management
  - Provision of mid-level support to physicians
  - Ancillary/whole hospital joint ventures
- Limitations of existing structures
OIG Advisory Opinion 08-16

Goals of New Structure
- Integrate physician and hospital clinical practice to meet safety/quality goals.
- Establish structure to provide quality across the continuum.
- Standardize clinical practice.
- Eliminate waste and reduce cost (may include gainsharing).
- Financially align physician/hospital incentives, but keep physicians/hospitals focused on their respective core business.

Rationale for New Structure
- National mandates for safety/quality and price transparency are difficult to meet without physician/hospital collaboration.
- “Carrot vs. Stick” approach.
- Pay for Performance ties reimbursement to achievement of quality outcomes.
- Manage legal risk arising from quality of care (liability for failing to comply with evidence-based guidelines, corporate liability, false claims liability for poor quality or unnecessary care, negligent credentialing).

Elements of New Structure
- Hospitals pay Physicians to meet quality targets.
  Includes a broad array of services necessary to achieve compliance.
- Pay for Performance dollars may provide funding source.
- Payments made based on achievement of targets (CMS quality indicators) set annually.
- Preamble to new proposed Stark exception recognizes benefits to be achieved through quality incentive program.
OIG Advisory Opinion 08-16

How is “Pay for Quality” Structured

- A new legal entity is created to which all physicians who have been on the active medical staff in relevant departments for at least one year can join.
- Each physician who joins pays an equal capital contribution to provide for the entity’s working capital.
- The physicians joining the entity commit to practice in compliance with certain quality targets established by CMS that form the basis for pay for performance awards under contracts with private insurers (and CMS in the future when Value Based Purchasing is implemented).

- The entity contracts with the hospital to provide a variety of tasks and services to improve quality.
- Payment to the entity is based on a percentage of pay for performance dollars earned by the hospital (up to 50%) and then distributed to the physicians on a per capita basis.

Certain protections in the structure that must be met to address the anti-kickback and Civil Money Penalty law implications of the structure.

- Only physicians who have been members of the hospital’s active medical staff for at least one year are eligible to become owners.
- The physician owners of the physician entity receive distributions on a per capita basis; there are no payments made to induce patient referrals to the hospital.
- The payments by the hospital to the physician entity are capped based upon historical activity levels of the payer(s) at the hospital.
- The hospital will provide written disclosure of its arrangement with the entity to its patients.
OIG Advisory Opinion 08-16

- The hospital will monitor both the quality of care provided and the volume and case mix of its patients to ensure that the financial rewards of the program do not reduce quality or inappropriately change referral patterns of the physician participants.
- The quality targets that can be incentivized under the program are limited to those listed by the Centers for Medicare & Medicaid Services and Joint Commission in the Specifications Manual for National Hospital Quality Measures.
- Year to year changes must consider initiatives where activity is necessary – not just paying to maintain improvements already obtained.

### Proposed Structure to Reward Physicians for Quality

![Proposed Structure Diagram]

- Measurable Quality Improvement
- X% of PAP Incentive
- (Active & Aligned Physicians)

Questions?

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Quality of care and compliance: Existing challenges and first steps for hospitals

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Compliance officers, in-house counsel, and other health care professionals should by now be aware that the government has made quality of care a top priority. The government’s three-prong approach seeks to:

- incentivize quality of care through payment reform,
- drive quality of care transparency through public reporting, and
- enforce quality of care through the False Claims Act and other federal and state mechanisms.

Many of these professionals understand that quality of care poses significant compliance risks to hospitals, including potential individual liability for the high-ranking executives, board members, physicians, and owners. Despite their awareness, these same professionals are struggling to figure out how to address quality of care and minimize its attendant compliance risks.

Foley & Lardner LLP is providing Compliance Today with an ongoing series of articles designed to address these questions. This article, the first in the series, highlights the challenges hospitals face when managing quality-of-care compliance. It also discusses the first steps a hospital should take to address the compliance implications of quality-of-care failures, including education and a quality of care/legal risks audit. Several topics are broadly discussed, including Recovery Audit Contractor (RAC) audits, all of which will be addressed in greater depth as this series of articles unfolds. Forthcoming articles will include: (1) tools and mechanics of a quality of care/legal risks audit; (2) quality of care enforcement; (3) quality-based payments and reimbursement; (4) quality of care compliance and the medical staff; (5) public reporting and quality of care; and (6) quality of care, data mining, and RAC audits.

Awareness and education challenges

Before a hospital can address the compliance implications of quality of care, its leadership must understand the connections between quality and compliance. Executives, board members, key leadership, and physicians need, at a minimum, a general understanding of the government’s quality-of-care efforts regarding payments, public reporting, and enforcement. Educating these key leaders on quality-of-care compliance is an essential first step in the process.

The lack of board education and oversight on quality issues is troubling. A Joint Commission research effort conducted interviews with CEOs and Board Chairs at 30 hospitals in 14 states, and revealed that “the level of knowledge of landmark Institute of Medicine (IOM) quality reports among CEOs and board chairs was remarkably low” and that there were significant differences between the CEOs’ perception of the knowledge of board chairs and the board chairs’ self-perception.

This disconnect has not been lost on the Office of Inspector General (OIG), that is beginning to look to boards to ensure fiscal integrity and oversight.

One approach to education would divide key personnel into categories (e.g., executives, board members, physicians, and care staff) and provide tailored education to each group. Certain quality-of-care issues are more appropriate for the board, whereas other issues would resonate better with physicians. Use education modules (again tailored to each group) for the training. This approach can help standardize the education process, collect feedback from the trainees, and create a documented record of the hospital’s quality-of-care education efforts.

The order in which personnel are trained is also an important aspect to consider. Certain key executive positions (e.g., CEO, general counsel, director of quality) will be the champions for a compliance officer who is seeking resources for quality of care efforts, and therefore, it is important for those individuals
to hear the message first. Educating the board is the next step and there is already an excellent resource available for board education: Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors. This resource, issued jointly by the OIG and the American Health Lawyers Association (AHLA), should be required reading for boards, senior management, and compliance officers. According to the report, a “new era of focus on quality and patient safety [is] rapidly emerging, and oversight of quality also is becoming more clearly recognized as a core fiduciary responsibility of health care organization directors.”

Boards must provide an appropriate level of oversight of health care services to satisfy their core fiduciary duties to the hospital. Board members who breach these duties may be exposed to personal liability. Board members owe a duty of care, requiring them to exercise appropriate care in their decision-making process. Generally, the duty of care is satisfied when directors act in good faith, with the care that an ordinarily prudent person would exercise in similar circumstances, and in a manner they reasonably believe to be in the best interests of the hospital.

Because the duty of care has been interpreted to require that directors actively inquire into the hospital’s operations, educational materials should be designed to help board members ask knowledgeable and appropriate questions related to quality and quality reporting requirements, as well as the metrics employed. Education and active involvement will help board members establish, and affirmatively demonstrate, that they have followed a reasonable process for quality oversight.

Boards need not approach these issues alone. Once the board is “on board” with the compliance officer’s quality-of-care efforts, the board should seek periodic updates from executive staff on hospital quality-of-care initiatives and how the hospital intends to address legal issues associated with those initiatives. When quality shortcomings are identified, the board should allocate appropriate resources to address the gaps including, for example, enlisting the help of outside attorneys and consultants to evaluate quality risk areas within the hospital.

Organizational challenges

Hospitals are large, complex organizations created (like many other large businesses) in a bureaucratic structure with specialized departments and groups, each focusing on a different aspect of the hospital. This structure is useful for efficiency and specialization, but has limited capabilities to readily share information across and between departments. This problem is known as “siloing.” Lewis Morris, Chief Counsel to the Department of Health and Human Services (HHS) OIG, recognized the issue when he said,

“When looking at some of these very large [health care] corporations, there is a siloing of responsibility, which has the effect of inadequate cross[ing] of information between the peer review/quality people and the 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.”

Compliance, Quality, and Peer Review departments each deal, to a certain degree, with quality-of-care issues, and there is an overlap of subject matter. Yet, 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. Hospitals need to develop structures that can transcend the department silos and exchange quality-of-care information, at least among the three departments for which this exchange has become critical.

Challenges in the peer review process

Critics of the medical staff peer-review process claim it has proven itself an ineffective tool to resolve quality and safety issues, both from the physician and the hospital perspective. They contend that the current peer review process is subject to bias and political motive and cannot adequately help a hospital meet government-imposed mandates on quality of care. Of course, the peer review process offers certain benefits. It enables physicians to speak frankly, at a peer-to-peer level, on quality issues and care processes. They are sometimes more persuasive and receptive when dealing with each other and often show greater respect to the clinical judgment of trained, experienced peers.

The most significant limitation in the traditional peer review process, and the one which poses the greatest compliance risk, is that the process is largely retrospective and based on isolated, past incidents. Constantly looking backward, rather than identifying patterns of care failures, the process is always reactive, not proactive. The hearings are often lengthy and can suffer significant delay caused by the subject physician or simply the unavailability of the hearing panel. These delays can permit a pattern of poor quality or unnecessary care to persist before the peer review process is able to react.

Hospitals must consider new approaches to integrate into the peer review process. Consider real-time chart audits based on daily monitoring of key quality indicators. If a

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pattern emerges, the hospital can take action. Also consider a greater emphasis on patterns (and projected patterns) of care. Physicians should be permitted a degree of freedom in their treatment style, but certain care approaches pose a higher risk than others. Treatments and medications constantly evolve, and the hospital should identify and address physicians who use outdated, high-risk processes before bad outcomes are manifested. Because nearly half of physicians do not report medical incompetence by their peers, the hospital cannot rely on physicians to police themselves.

Challenges in the traditional medical staff structure
As physician roles continue to change, the traditional medical staff structure finds itself ill-equipped to adapt to emerging compliance and quality-of-care challenges. There are an increasing number of hospital-based physicians, including hospitalists, intensivists, obstetrical hospitalists, and pediatric hospitalists. Specialty lines have begun to blur with cross-credentialed physicians playing multiple roles on the care team (e.g., interventional radiology/cardiology/neurology). The growing number of outpatient-based physicians has complicated the credentialing process and led to reduced collegiality with the specialists and hospital-based physicians.

As hospitals adapt to these physician-driven changes, regulators mandate further change, such as competency-based credentialing, standardization of care processes, and increased medical staff oversight of quality.

Another key change is the increased public reporting of quality data, both on the hospital level and the individual physician level. Hospitals must crunch their own data and understand it, not wait for the government to do so first. Additional transparency by the medical staff, who share quality data, is essential and can be achieved with a better medical staff infrastructure, improved design, and aligned incentives to address national patient safety and quality mandates.

Need for effective incentive strategies
Many would argue that a lack of effective hospital-physician collaboration strategies exist to provide incentives based on quality of care. In this respect, hospitals and physicians are co-dependent and should collaborate on new structures. Hospitals must enlist physician support to meet quality targets and earn pay-for-performance incentives. Similarly, physicians must enlist hospitals to offer systems that drive quality across the continuum of care.

Current, traditional equity joint-ventures often fail to align physician and hospital interests in improving quality of care. Consumer-driven health care and increased access to quality data will eventually lead to greater patient choice and create consumers who are better informed and more discerning about the hospital and physician they choose. Hospitals need to develop viable, compliant incentive structures to connect physicians and reward desirable behavior patterns and quality-of-care efforts. New structures need to focus on quality, reducing waste, and promoting transparency to assist the hospital’s own data mining efforts. These new joint ventures should also account for coordinating the care delivered by providers outside the venture.

Quality of care/legal risks audit
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. This requires a broad-based, coordinated approach among the administration, the medical staff, physicians, nursing staff, risk managers, utilization review, Quality department, Compliance department and legal counsel.

A quality-of-care/legal risks audit is an important step in addressing quality of care and compliance. Such an audit identifies areas of potential quality breakdowns and helps establish internal quality controls, two key areas a hospital should immediately address to reduce the risk of an adverse government-enforcement action. A quality-of-care/legal risks audit, ideally performed by objective outside health care counsel under the attorney-client privilege, can reveal the true operational landscape of a hospital. Because of siloing and the various structural and operational challenges discussed above, it is difficult to imagine a hospital adequately addressing its quality-of-care compliance risks without this broad-based approach.

Patient care is the heart of a hospital’s enterprise, and some key personnel may hesitate to scrutinize their hospital’s quality of care. They might fear an audit will reveal a slew of previously unknown problems, which the hospital would then need to remedy. They might also believe (with regard to liability) that ignorance is bliss, and would rather not know of existing problems. Such attitudes are understandable but misguided.

In light of the OIG/AHLA guidance, board members have an affirmative duty to understand their hospital’s quality-of-care risks. Affirmatively choosing not to conduct a quality-of-care compliance audit, simply because the hospital fears the results, could constitute willful ignorance or reckless disregard of the failures, if the problems later become known in a government investigation.
A responsible, less-invasive alternative to the audit process would be to perform a risk assessment based on key quality-of-care and compliance factors. The underlying concepts would be the same as those in the quality-of-care/legal risks audit, but the investigation would not run as deep as an audit. This process would give the compliance officer a general understanding of the hospital’s risks. The results would highlight and prioritize key risk areas, which the compliance officer can then report to the board. A quality-of-care/legal risks audit could then be performed on selected, priority risk areas.

Quality of care and RAC audits

As the RAC programs start again, hospitals should be particularly concerned about quality-of-care compliance risks. In the time since the RAC audits were temporarily suspended, the government has announced a significant number of quality-of-care initiatives regarding reimbursement methodology. Commencing October 1, 2008, Medicare will no longer reimburse for certain hospital-acquired conditions unless the condition was present on admission. Where previously, hospitals were required to report only certain quality indicators, Medicare’s impending Value-Based Purchasing plan will deny payment altogether. State Medicaid programs, including Massachusetts, Minnesota, and New York, have announced plans to deny payment for medical errors and/or certain hospital-acquired conditions. These are just a few of the quality-of-care payment changes, to say nothing of the growing enforcement focus on quality-of-care failures.

RAC auditors are aware that hospitals have invested significant resources to address and reduce traditional billing errors. They are also aware that many of these same hospitals have not invested the resources to address and reduce quality-of-care errors. It should be no surprise when RAC auditors focus their data mining efforts on quality-of-care issues. The RAC audits might reveal patterns of substandard care or medically unnecessary surgeries, all submitted for reimbursement. Hospitals must ready themselves to address and defend against quality-of-care issues brought by RAC auditors.

Conclusion

Quality of care, with its attendant impact on payments, public reporting, and enforcement, should be a major concern for hospitals. Traditional structures and business models are not designed to best respond to the government’s mandates on quality of care and compliance. Hospitals will need to work with the compliance officer, the Quality department, and legal counsel, who are experienced in these quality of care issues, to implement new models and incentives to promote quality of care.

The first step in the process is to educate key personnel and board members. After enlisting their support, the hospital should consider undergoing a quality-of-care/legal risks audit or, at least, a risk assessment based on those same factors.

Addressing quality of care proactively, and integrating it with compliance, will give a hospital a financial and operational advantage. Those same investments in quality-of-care compliance can provide additional returns by minimizing litigation exposure and enforcement actions based on poor quality. Hospitals that refuse to recognize and address quality-of-care risks and failures should not be surprised to find themselves subjected to whistleblower suits, RAC audits on quality of care, or (worse yet) excluded from federal programs.

4. See footnote No. 3
5. Lewis Morris, Chief Counsel to the Office of United States Inspector General of Health and Human Services, on September 25, 2007
8. The Deficit Reduction Act of 2005 authorized CMS to develop for Medicare a hospital pay for performance model (known as Value-Based Purchasing). Pub. L. 110-191
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. 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”).

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.* 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
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. 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.” 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. 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”). 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.

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. Beginning October 1, 2008, cases with certain “hospital acquired conditions,” sometimes referred to as “never events,” (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. This is an evolving list, and CMS will expand the number of “never events.” 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. 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.” 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. 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.”

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.” 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, mail and wire fraud, false statements, and kickbacks. 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; (2) payment of kickbacks; (3) special treatment for physicians who are big offenders; (4) fraudulent documentation; (5) lack or failure of appropriate internal review processes (e.g., credentialing or peer review); and (6) underlying regulatory violations. 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.
- 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.
- A FCA action against a Baton Rouge, Louisiana hospital for medically unnecessary surgeries resulted in a $3.8 million settlement.
- 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.
- 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.
- 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.
- A Louisiana cardiologist was indicted on multiple counts of healthcare fraud and one count of criminal forfeiture for performing unnecessary angiograms and angioplasties.
- 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.

**“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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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, SICK.
5 August 17, 2006.
8 See Note 3, supra, at pages 6-7.
9 72 Fed. Reg. at 47218 for
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.”
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.
16 Id.
17 Federal Register, Vol. 72, No. 176 (September 12, 2007).
19 E.g., DRG 143 (Chest Pain) and DRG 416 (Septicemia).
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. h t t p : / / w w w . c m s . h h s . g o v / P E R M / Downloads/PERM%20Final%20Reg.pdf.
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.
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.
34 Miles 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).
38 See, e.g., United States ex rel. Lee v. Smithkline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001).
39 Miles v. Straus, 274 F.3d 687, 703 (2d Cir. 2001).
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).
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).
86 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).

87 See, e.g., State Fines Kaiser Again, Los Angeles Times (July 26, 2007).

88 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).


91 September 25, 2007 AHLA/HCCA presentation in Baltimore, Maryland.

92 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.).
Florida Expands Quality of Care Reporting Efforts: AHCA Publicizes Hospital Readmissions Data

On June 26, 2008, Florida’s Agency for Health Care Administration (AHCA) announced Florida will become the first state in the nation to publish data on potentially preventable hospital readmissions. The data, publicly available at [www.FloridaHealthFinder.gov](http://www.FloridaHealthFinder.gov), is a powerful tool for consumers to consider when choosing a hospital. Because increased public access to quality of care data will lead to greater patient choice and better-informed consumers, hospitals are advised to improve their quality of care oversight. Hospitals should consider developing greater internal quality controls and increase information sharing between the quality and compliance departments, with particular attention to the data used for public reporting.

Floridahealthfinder.gov calculates a hospital’s readmission rate based on the number of patients readmitted to the same hospital or another short-term acute care hospital within 15 days of the original admission, for the same or a related condition. Between March 31, 2006 and March 31, 2007, AHCA tracked 54 conditions and procedures in 2.2 million adult hospital admissions. A total of 877,228 cases had one or more of the tracked conditions and procedures. Of those cases, AHCA identified 60,707 readmissions as potentially preventable. The data is valuable for patients interested in quality health care and for hospitals seeking to improve their discharge procedures.

AHCA’s effort is supported by the Florida Hospital Association (FHA), which issued a press release announcing a joint collaboration with AHCA to reduce readmission rates. “Hospital readmissions are often avoidable and always costly; by sharing this data we will help hospitals, providers and especially patients improve the discharge process and the delivery of health care,” stated AHCA Secretary Holly Benson in a press release. AHCA also announced it will develop tools for patients and providers to ensure quality care after a patient is discharged.

Florida’s effort is an important step toward improving quality of care and reflects a national trend toward greater transparency of quality through public reporting. Reporting quality of care data such as preventable readmission rates, will eventually lead to greater patient choice and create consumers who are better informed and more discerning about the hospital they choose. For this reason, hospitals must develop viable incentive structures to engage physicians and reward quality of care efforts. These new arrangements need to focus on quality, reducing waste, and promoting transparency and information sharing within the hospital to assist the hospital’s own data-mining efforts. By mining its own quality data, a hospital can become more aware of its quality indicators, and thus address problems before the data is reported to the public.


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Tina E. Dunsford...................................................................................................... 5
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Janice A. Anderson is a partner in Foley’s Health Care Industry Team with 25 years’ experience focusing on health regulatory and compliance issues and over 30 years’ experience working in the health care industry. Ms. Anderson is a participating member of Foley’s Business & Transactions, Payments, Compliance & Government Programs, Regulatory & Strategic Counseling and Medical Devices Focus Groups as well as a participant in a working group dealing with Medicare Reimbursement. She serves on the governing council of the Health Law Section of the State Bar of Michigan; is a member of the Michigan Health & Hospital Association’s Quality, Compliance & Patient Safety Committee; and is a member of the American Bar Association as well as the American Health Lawyers Association (AHLA). She is admitted to practice in both Illinois and Michigan. Ms. Anderson’s practice focuses on:

- Legal and regulatory compliance, including:
  - The development and implementation of corporate compliance programs
  - Legal/compliance risks, including enforcement risks arising from quality of care and patient safety issues
  - Stark, anti-kickback, HIPAA, EMTALA, False Claims Act, reimbursement, and civil money penalty laws

- Corporate health care and transactional law, including:
  - Mergers and acquisitions
  - Hospital/physician and other joint ventures
  - Physician relationships and contracting
  - Development of health care business structures to achieve strategic goals
  - Legal/regulatory issues arising in health care transactions such as certificate of need, licensure, tax-exempt status, reimbursement, etc.

- Medical staff issues, including:
- Legal advice and counsel on medical staff and peer review structures
- Development of medical staff bylaws and policy and procedures
- Medical staff disciplinary procedures
  - Clinical research
  - Advising nonprofit governing boards on a wide range of issues, including those related to the proper discharge of their fiduciary obligations

Prior to joining Foley, Ms. Anderson was the general counsel, vice president and corporate compliance officer for Borgess Health, a regional health system comprised of eight owned or affiliated hospitals, where she also provided administrative oversight to several facilities and corporate service departments. In that position, she developed the first in-house legal department, led numerous merger and acquisition transaction teams, and created and implemented the Borgess Health Corporate Compliance program.

Articles/Publications/Presentations:

- Co-authored “High Quality, Efficient Care for Medicare Beneficiaries - But at What Cost?” *HCCA Compliance Today* (November 2007)
- Co-authored "Healthcare Compliance Professional's Guide to the False Claims Act" (October 2007)
- Presented "Grappling with the Reimbursement Implications Associated with Off-Label Medical Devices" at the American Conference Institute’s (ACI) Medical Device Pricing & Reimbursement in Chicago, Illinois (June 2007)
• Presented "The Quality Revolution, Government Enforcement, and Compliance" at the Health Care Compliance Association (HCCA) Upper North Central Annual Conference in Detroit, Michigan (June 2007)

• Authored "The Board’s Fiduciary Role: Legal Responsibilities of Health Care Governing Boards" monograph published for the Center for Healthcare Governance (December 2006)

Ms. Anderson received her law degree, *summa cum laude*, from Michigan State University College of Law (1984) and earned a bachelor’s degree, *summa cum laude*, from the University of Detroit/Mercy in nursing (1973).
TINA E. DUNS福德

Tina Dunsford is senior counsel with Foley & Lardner. She is a member of the firm's Health Care Industry Team. Ms. Dunsford advises clients on managed care contracting, medical staff issues, compliance, fraud and abuse matters and physician contracting arrangements, and advises health care clients with specialized litigation including regulatory, fraud and abuse, and qui tam matters.

Prior to joining Foley, Ms. Dunsford was a shareholder at Dunsford & Associates, PA. She has also held in-house general counsel and legal counsel positions at health care entities where she advised senior management on structuring joint ventures and acquisitions; supervised federal and state health care programs; acted as company liaison at meetings and conferences with federal agencies, state agencies, political subdivisions, and advisory groups; and managed legal, compliance and litigation for 36 hospitals in 12 states.

Ms. Dunsford earned both her law degree (J.D., 1994) and her master of laws in taxation (LL.M., 1995) from Emory University School of Law. While attending law school, she was a Sol Golden Scholar. She graduated from Kennesaw State University with a bachelor’s degree in business administration (1989, summa cum laude).

Ms. Dunsford is a member of the Florida State Bar and the Georgia State Bar.
Nathaniel (Nate) Lacktman is an associate with Foley & Lardner and a Certified Compliance & Ethics Professional (CCEP). He is a member of the firm’s Health Care Industry Team and the Corporate Compliance & Enforcement Practice.

Mr. Lacktman practices health care litigation and has focused experience in matters involving enforcement actions by state and federal regulators, medical staff peer review, *qui tam* actions and the False Claims Act, external investigations and long-term care. He also has experience in general business litigation, particularly for health care providers, and has represented clients in state, federal and appellate courts, administrative hearings, mediations and arbitrations.

Outside the litigation context, Mr. Lacktman advises health care clients on business and regulatory issues, including fraud and abuse compliance, confidentiality and information sharing, Medicare and Medicaid, codes of conduct, medical staff credentialing, admission agreements, arbitration agreements, health care facility policies and procedures, hospital bylaws, plans of correction, patient transfer/discharge, informed consent, and mandatory reporting requirements.

Prior to joining Foley & Lardner, Mr. Lacktman was a judicial extern for the Honorable Ronald S.W. Lew of the United States District Court for the Central District of California. In 2004, he received the Excellence in Preparation for Trial Practice Award from the American Board of Trial Advocates. He was one of 12 attorneys selected as Outstanding Healthcare Litigators of 2007 by Nightingale’s Healthcare News.

Education

Mr. Lacktman received his law degree from the University of Southern California School of Law, where he was an
editor for the *Hale Moot Court Honors Program* and president of the Animal Legal Protection Society. Mr. Lacktman is a graduate of the University of Florida (B.A., *with honors*), where he was a University of Florida Scholar, member of Golden Key National Honor Society, Sigma Phi Epsilon fraternity, and recipient of Boston College’s John D. Donovan Award.

**Admissions and Professional Memberships**

Mr. Lacktman is admitted to practice in Florida and California. He is a member of the American Health Lawyers Association, the Health Care Compliance Association, the American Bar Association’s Health Law Litigation Committee, and the California Society for Healthcare Attorneys.

**Publications**

- "Quality of Care and Compliance: Existing Challenges and First Steps for Hospitals," *HCCA Compliance Today* (October, 2008)


"Florida Expands Quality of Care Reporting Efforts: AHCA Publicizes Hospital Readmissions Data," *Legal News: Health Care* (July 1, 2008)


"Florida Peer Review After Amendment 7: What Protections Are Left?" *Florida Medical Business* (June 10-23, 2008)

"New York Medicaid Program Ceases Hospital Payments for Never Events: Parallels Other State and Federal Efforts to Promote Quality of Care," *Legal News: Health Care* (June 6, 2008)


"CMS’ Special Focus Facility Initiative and Nursing Home Compare," *HCCA Compliance Today* (February, 2008)

"The Quality of Care Cerberus: Payments, Public
Reporting, and Enforcement," ABA The Health Lawyer (December, 2007)


- "Compliance and the Quality of Care Revolution: Fitting the Pieces Together in the Government’s New Enforcement Landscape," AHLA Health Lawyers News (September 2007)


- "Another Blow to Medical Staff Peer Review Privilege," Health Law360 (July 2, 2007)

- "Medical Staff Peer Review Privilege Is Dealt Yet Another Blow," Health Law e-Alert (June 20, 2007)


- "Topical Reports," California Health Law News (Spring 2007)


- "What's In Your Wallet? OIG Advisory Opinion Approves Credit Cards Rewards Program at Nursing Home," Legal News: Senior Living & Long-Term Care (Spring 2007)

- "States Address Evolving Long-Term Care Needs with Regulatory Changes and New Licensure Categories," Legal News: Senior Living & Long-Term Care (Spring 2007)

- "New Laws Require Carbon Monoxide Detectors in Long-Term Care Facilities," Legal News: Senior Living & Long-Term Care (Spring 2007)


"As Many Seniors Choose Alternatives to Traditional Long-Term Care, Demand for Nursing Homes Declines," *Legal News: Senior Living & Long-Term Care* (Winter 2007)


"Arbitration Agreements for Health Care Providers: Recent Legal Changes and Strategies to Consider," *ABA Health Law Litigation* (Fall 2006)

"CMS to Increase Payments for Skilled Nursing Facilities Under the Prospective Payment System by 3.1%," *Legal News: Senior Living & Long-Term Care* (Summer 2006)


"OIG Issues Report Regarding Access of Medicare Beneficiaries to Skilled Nursing Facilities Under Prospective Payment System," *Legal News: Senior Living & Long-Term Care* (Summer 2006)


Mr. Lacktman has also been published in the *Entertainment Industry Litigation Reporter*, the *E-Business Law Bulletin*, and the *Software Law Bulletin*

**Presentations**

"Enhancing Quality and Compliance," Poster Board Presentation at Quality Colloquium, Harvard University (August 19, 2008)

"The Amendment 7 Challenge: Is a PSO Hype or Hope?" Foley & Lardner LLP, Orlando (April 29, 2008)
"Quality of Care: Important Changes to Reimbursement and Enforcement," Foley & Lardner Health Care Friday Focus Web Conference (March 28, 2008)


"Quality of Care: Transforming Health Care Through Payment Reform, Public Reporting and Enforcement," Healthcare Financial Management Association and Nebraska Hospital Association (November 1, 2007)

"Recent Developments in Medical Staff Law: The Patient Safety and Quality Improvement Act: A New Opportunity to Protect Peer Review Information," California Association of Medical Staff Services, Long Beach Chapter (October 27, 2006)

"Advance Health Care Directives," Beverly Hills Bar Association (March 25, 2006)