The Intersection of Compliance and Quality

Health Care Compliance Association
North Central Regional Annual Conference
October 1, 2010

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What We Will Cover:

I. Health care quality initiatives – what they are and why they developed
II. Primary legal risks and enforcement
III. Action steps to minimize risks
Background and Description of Health Care Quality Initiatives
Impetus for Quality

- Isn’t quality in medicine a “no brainer?”
- A perfect storm
  - IOM’s To "Err is Human" and "Crossing the Quality Chasm"
  - Voluntary reporting programs
  - Dramatic advancements in IT
  - Depletion of Medicare Trust Fund/Increasing costs to Medicare program
  - Physician Compensation Models
Health Care Quality Initiatives

- Federal and State initiatives to promote high quality, efficient care:
  - Payment Incentives (P4R and P4P)
  - Withholding or decreasing payments for preventable injury (HACs and NCDs)
  - Transparency through public reporting
  - Patient Safety Organizations
- Health reform
- Physician contracting
Payment Incentives: Pay for Reporting (P4R)

- Began as voluntary initiative in 2003 with 10 quality measures
- Now mandatory and involves even more quality measures
- Reductions in Medicare payment for failure to report
- Data is on the web at [www.hospitalcompare.hhs.gov](http://www.hospitalcompare.hhs.gov) (2.5 million visits per month).
Payment Incentives: Pay for Performance (P4P)

- Goal to move from passive payer to active purchaser
- Not implemented yet by CMS
- Already embraced by private sector—more than 50% of commercial payors have implemented a P4P plan (physician and hospital providers)
Serious Adverse Events

- National Quality Forum (NQF) definition of serious adverse events:
  
  *Errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility.*

- Sometimes known as "never events"

- NQF identified 28 serious adverse events resulting from care management deficiencies and failure to follow standard of care of institutional practices and policies.
Importance of Serious Adverse Events

- At least 25 states require reporting of some or all of the NQF events.
- AHA is implementing no-charge policy for serious adverse events.
- CMS has used NQF's list as basis for its treatment of POA/HACs and NCDs.
- Insurers like Wellpoint and Aetna are following CMS' lead.
Payment Disincentives: Hospital-Acquired Conditions (HACs)

- Deficit Reduction Act of 2005 required CMS to select conditions that meet the following criteria:
  - High-cost, high-volume, or both
  - Assigned to a higher paying DRG when present as a secondary diagnosis
  - "Reasonably preventable" through application of evidence-based guidelines
Payment Disincentives: POA/HAC

- Since October 1, 2007, hospitals required to report specified HACs; and
- Since October 1, 2008, hospitals are not paid the higher rate for the reportable condition unless it was documented as present on admission (POA).
- Affects only payments to hospitals for inpatient stays
Serious Adverse Events and National Coverage Determinations

- Certain Serious Adverse Events identified by NQF not covered by POA/HACs
  
  "We are not selecting wrong surgery because it is not an event for which Medicare should pay less; it is an event for which Medicare should pay nothing at all."  August 1, 2007, 72 F.R. 47214

- CMS decided to use NCDs to address them
- Wrong surgery, wrong site, wrong patient
Payment Disincentives

- CMS is looking to expand to other settings, including outpatient, ESRD facilities and physician practices
- Urging state Medicaid programs to consider similar programs
  - FSSA recently announced its intent to promulgate rules regarding payment for "specified hospital-acquired conditions not present on admission"
  - Expected to mirror CMS policy
Health Reform

- Patient Protection and Affordable Care Act
  - Key Titles:
    - Quality Affordable HC for All Americans
    - Improving the Quality & Efficiency of HC
    - Prevention of Chronic Disease & Improving Public Health
    - Transparency & Program Integrity
    - Revenue Provisions
    - Strengthening Quality, Affordable HC for All Americans
Health Reform (cont.)

- PPACA (cont.)
  - Key Provisions:
    - It requires most U.S. citizens and legal residents to have health insurance.
    - It creates state-based Health Benefit Exchanges through which individuals and small businesses can purchase coverage.
    - It imposes new regulations on health plans in the Exchanges and in the individual and small group markets.
    - It expands Medicaid to 133% of the federal poverty level.
Health Reform (cont.)

- PPACA (cont.)
  - Access and cost aside, much of the ACA is about payment and delivery system reform in order to drive down cost through better quality and greater cost-efficiency.
  - Quality-related concerns include:
    - Constraints on future reimbursement in the shadow of ever-increasing hospital costs
    - Significantly increased fraud and abuse enforcement
    - Infectiveness of current quality assurance activities
    - Recruiting PCPs
Health Reform (cont.)

- PPACA (cont.)
  - With the introduction of the various reporting and HAC payment initiatives, Medicare/Medicaid is becoming a value-based purchaser.
  - Value-based purchasing/P4P is the future of reimbursement – and in a big way.
  - Once Medicare speaks, commercial payers listen.
  - Development of the CMS Innovation Center to further explore changes to quality-based payment structures
Health Reform (cont.)

- PPACA (cont.)
  - Value-based purchasing initiatives target improving quality of care and containing costs by:
    - Connecting reimbursement to measured quality outcomes and efficiency
    - Promoting coordination of care among providers
    - Emphasizing primary care and home-based/pre-acute care
    - Reducing hospital admission and readmissions
    - Expanding the use of HIT
Quality-Based Financial Incentives for Physicians

- P4P rewards *hospitals* for quality care given by *physicians*.
- How can incentives of hospitals and physicians be aligned without violating fraud and abuse laws?
- Becoming more and more common to reward physicians financially for achieving quality incentives.
Gainsharing

- Regulators have approved hospital programs in which P4P financial benefits from third-party payors are shared with physicians.
- This type of program is referred to as "gainsharing"
Benefits of Physician Quality Incentives

- Provides physicians incentive to maintain high levels of compliance with specific quality standards
- Encourages physicians to take lead in developing methods to measure quality
- Incentivizes physicians to engage in encouraging recommended medical practice to others, and meaningful peer review
Primary Legal Risks and Enforcement
Quality vs. Compliance

- Quality of care and patient safety are emerging as enforcement areas for OIG and other regulators

- So why do we care??
You look lousy in orange!
Anti-Kickback Statute

42 U.S.C. § 1320a-7b(b)

- Designed to prevent certain payments in connection with the furnishing of services reimbursable under the Medicare and Medicaid programs as well as other governmental health care initiatives.

- Prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other government health care program.
Anti-Kickback Statute (Cont.)

- Violation is a felony, punishable by fines up to $25,000 and up to 5 years imprisonment. Violation can also result in imposition of civil monetary penalties and/or exclusion from such government health care programs.

- Safeguards:
  - It is imperative that any arrangement not be pursued for the purpose to induce referrals.
  - It is always possible that a trier of fact, such as a judge or jury, could misconstrue the facts and find differently.
  - Intent and structure of an arrangement are vital!
The Stark Law

When a physician (or physician's immediate family member) has a financial relationship with an entity (*unless an exception applies), the federal Stark Law (42 U.S.C. 1395nn) provides that:

- Physician may not make referrals to the entity for "designated health services"; and
- Entity may not present a claim or bill to the government, patient or any other party for designated health services furnished pursuant to a prohibited referral.

*If Stark is implicated, an exception must be found.
The Stark Law (cont.)

- Stark prohibits providers from submitting claims to Medicare or Medicaid as well as bills to any other third party payor, including the patient, for services furnished pursuant to a prohibited referral.

- If a patient is eligible to receive payment under these government health care programs and receives care, they are patients who may be subject to the law.
The Stark Law (cont.)

- The OIG may impose a civil money penalty of up to $15,000 against any person who:
  - Has presented or cause to be presented a claim for a payment that such person knows, or should know, may not be made under Medicare or Medicaid,
  - Or against any person whom it determines has not refunded on a timely basis (within 60 days) amounts collected as a result of billing an individual, third party payor or other entity for a designated health service that was provided in accordance with a prohibited referral under Stark.
  - In addition, Stark sanctions include exclusion from Medicare and Medicaid and fines of up to $100,000 for circumvention schemes.
Civil Monetary Penalties Law

- A Hospital is prohibited from making payment to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care.
- Payment doesn't have to be tied to an actual diminution of care, just the likelihood that the payment will influence a reduction!
- Penalties include $10,000 for each item or service plus 3 times the amount claimed for each such item or service, and even debarment.
False Statements relating to Health Care Matters

- It is a criminal violation under 18 U.S.C. Section 1035 to “knowingly and willfully...make any materially false, fictitious or fraudulent statements...in connection with the delivery of or payment for health benefits...”
- Criminal penalties and imprisonment for up to 5 years.
- Due to higher burden of proof for criminal cases, false claims actions are more frequently pursued as civil actions.
Civil False Claims Act ("FCA")
31 U.S.C. § 3729

- Liability for Certain Act-Any person who:
  - Knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;
  - Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.
Knowing and knowingly means:
- Has actual knowledge of the information;
- Acts in deliberate ignorance of the truth or falsity of the information;
- Act in deliberate or reckless disregard of the truth or falsity of the information.
- Does NOT require specific intent to defraud.

Sanctions
- Up to $10,000 per claim (treble also)
- Potential exclusion from federal healthcare programs (Medicare, Medicaid, etc.)
Qui Tam Provisions of the FCA

- Case brought by a private individual (a "whistleblower") in the name of and on behalf of the US government
- Filed under seal and in camera while DOJ investigates merits for civil or criminal prosecution and considers whether to intervene
- If gov't intervenes, qui tam relator receives 15-25% of settlement (25-30% when gov't doesn't intervene)
- Relator is protected from employer retaliation
FCA Liability

- 3 primary theories of liability, predominantly triggered under the False Claims Act by claims for reimbursement:
  - Provision of medically unnecessary services
  - Provision of care so deficient that it amounts to no care at all, such that the claims are essentially for services not rendered
  - Implied/false certification
- Hospitals have been penalized for conduct such as chronic understaffing, reckless imposition of budgetary constraints that impaired patient care, and reckless submission of claims.
- May also implicate federal Stark or Anti-Kickback laws (or state law corollaries).
Potential Provider Fraud Related to Federal Health Care Quality Initiatives

- Billing for services not provided
- Upcoding - billing for a higher level of service than was provided, or billing for services that did not meet the P4P or P4R incentive payment conditions
- Billing the higher DRG for a hospital acquired condition not present upon admission
- Failure to provide appropriate care
- Unnecessary and incorrectly performed procedures
- Billing for an serious adverse health event in violation of a prohibition to do so
- Poor quality – intentional low quality care to save money.
- Evidence of pervasive billing and coding compliance issues
- Remember, under the FCA, the *knowingly* standard can be satisfied if the hospital is reckless as to its submissions!
Action Steps for Addressing Quality of Care Issues and Minimizing Legal Risks
Improve Quality Compliance Oversight

- Need to elevate quality to the same level that financial and regulatory compliance currently occupy.

- Need to understand relevant patient safety and quality issues, and establish a system of performance goals and monitoring elements to ensure compliance.

- Involve individuals knowledgeable in quality matters in compliance activities.
Engage Leadership

- Engage Leadership in discussing the following questions:
  - What processes are in place to promote the reporting of quality concerns and medical errors and to protect those who ask questions and report problems?
  - Are human and other resources adequate to support patient safety and clinical quality?
  - How are proposed changes in resource allocation evaluated from the perspective of clinical quality and patient care?
  - Are systems in place to provide adequate resources to account for differences in patient acuity and care needs?
Engage Leadership (cont.)

- **Questions (cont.)**
  - Do the Hospital's competency assessment and training, credentialing, and peer review processes adequately recognize the necessary focus on clinical quality and patient safety issues?
  - How are “adverse patient events” and other medical errors identified, analyzed, reported, and incorporated into the organization’s performance improvement activities?
  - How do we address quality deficiencies without unnecessarily increasing the Hospital’s liability exposure?
Employ Education Strategies

- Standardize and evaluate education efforts.
- Keep records of quality-of-care education and attendance.
- Provide tailored education to categories of key personnel, including:
  - Executives;
  - Board members;
  - Physicians;
  - Care staff
Be Accountable

- Transparency and accountability are here to stay.
- Make accountability part of the fabric of your organization.
- Shift attitudes from avoiding risk to maximizing quality
- Patience is a virtue!