Quality Failures and the False Claims Act

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Overview

• Historical perspective
• Current government fraud theories based on quality
• Challenges presented to providers
• What can providers do?
Historical Perspective

- Development of FCA theories
  - Originally enacted to combat fraud on U.S. Treasury in procuring military equipment in the Civil War
  - Moved into health care fraud arena (billing for services not provided, upcoding)
  - NOW....

Quality Oversight: Past, Current and Future

- Medical negligence litigation, but tort reform?
- Professional and institutional licensure
- Private accreditation and certification bodies
- Transparency of data and results initiatives
- OVERALL: Increased attention on quality combined with increased attention on health care fraud
  - IOM Report: *To Err is Human*
  - OIG and AHLA White Paper: *Corporate Responsibility and Health Care Quality: A Resource for Health Care Board of Directors*
Current Environment

- National debate over healthcare delivery & financing
  - Projected Medicare insolvency
  - Changing structure of healthcare organizations
  - Complexity of healthcare delivery
- Climate of uncertainty, frustration and distrust
- Increasing incidence of fraud and abuse?
  - $100 billion?
  - Declining reimbursement
- Constant Congressional action and new OIG initiatives
- Whistleblower actions

Current Enforcement Environment

- Criminal enforcement risks
- Regulatory enforcement risks
- Whistleblowers
- Stakeholders
  - Employees, unions, shareholders
- Civil claims and punitive damages
- Federal and state enforcement
- Media and public scrutiny
- Risks from trying to do right
The Beginning of FCA Actions Based on Quality Failures

• Nursing home cases
  – Between 1996 and 2003 more than 20 nursing home quality-based FCA cases were settled.
  – The power of the consent decree: GMS-Management Tucker, Inc., Chester Care, Northern Health Facilities

Current Government Fraud Theories Based on Quality of Care

• Express False Certification
  – Provider’s false certification that the care provided met the legal requirements for payment
  – Services are unnecessary or substandard
Current Government Fraud Theories Based On Quality of Care

• Implied False Certification
  – Fraud based on underlying representation that the care provided complied with the conditions to bill for the care
  – Some courts have adopted this theory, but in varying degrees

• Worthless Services
  – Such poor quality to be considered worthless

  “In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.”

  • United States ex rel. Mikes v. Straus, 274 F.2d 703 (S.D.N.Y. 2001), following United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048 (9th Cir. 2001)
Conditions-of-Payment vs. Conditions-of-Participation

• Conditions-of-Payment
  – Most jurisdictions follow
    • Typically only for express conditions
  – Examples: medically unnecessary, experimental, duplicative services

• Conditions-of-Participation
  – Very detailed
  – Aranda and NHC
  – 7th and 9th Circuits: Education funding cases

Quality Based FCA Actions in the Hospital Context

• Redding Medical Center - $54 million settlement
• O’Hara Regional Center for Rehabilitation- $1.9 million settlement
• Our Lady of Lourdes Medical Center - $3.8 million settlement
Challenges Presented to Providers

- How far will Aranda and NHC go?
  - Conditions-of-Participation cases
- Increased quality focus in the nursing home industry
  - 2008 OIG Work Plan
  - List of poorly performing nursing homes
  - This will only bring more attention to quality concerns in all settings

Challenges Presented to Providers

- Increased focus on quality in the media
  - Might “inspire” qui tam relators
  - Gets the government's attention
- Corporate Integrity Agreements
  - Outside quality of care monitor
  - Systemic quality controls
  - Quality improvement process
Challenges Presented to Providers

*Increased data mining efforts*

- Government monitoring
  - The Hospital Quality Initiative
  - PERM
  - PEPPER reports
  - CERT Testing
  - Recovery Audit Contractors (RACs)
  - People’s Health Network investigation

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Challenges Presented to Providers

- FCA Amendments
- Deficit Reduction Act of 2005 and State FCAs
- Dissatisfied or angry patients as *qui tam* relators
Challenges Presented to Providers

- Quality messages in other areas:
  - Pay For Performance
  - CMS Physician Group Practice (PGP) Demonstration
  - Do-not-pay list (some voluntary state programs)
  - Union messages – nurse ratios
  - Leapfrog Group
  - 2008 Physician Quality Reporting Initiative
  - Overall: Debate about how to improve quality

Both Sides of the Coin

**Pros**
- Fines, money, and exclusion are the best forms of deterrence
- Qui tam suits when people will not listen to quality concerns

**Cons**
- Better ways to promote quality
- “Federalization of medical malpractice”
- Quality is too subjective—should courts establish clinical care norms?
- Other groups and agencies already monitor quality
- Federal administrative discretion
What Can Providers Do?

• Quality as part of the compliance program
  – Screen providers
  – Education
  – Safe reporting environment

• Quality monitoring
  – Develop quality monitoring tools and use them
  – Understand your own data

• Quality benchmarking
  – Comparative reports to identify risk areas

What Can Providers Do?

• Be aware of internal data monitoring, typically performed by:
  – IT Department
  – Risk Management
  – Compliance Department
  – Case Managers/Utilization Review
  – Peer Review Process
  – Quality Improvement Committees
What Can Providers Do?

• Broaden Quality-Oriented Committees
  – Multidisciplinary
  – Really look at the issues
  – Take action and monitor corrective action
  – Respond to all concerns
  – “Compliance goggles”

What Can Providers Do?

• Be aware of issues specific to quality based FCA actions
  – Fact-specific inquiries
  – Differences with this action vs. medical negligence action
• Quality discussions at all levels in the organization
• Quality discussions at the Board level
  – OIG and AHLA White Paper: Corporate Responsibility and Health Care Quality: A Resource for Health Care Board of Directors
  – OIG – HCCA Roundtable Report
THANK YOU

Questions?