

When Poor Quality Care Becomes Fraud

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Session Overview

- This session will provide an overview of the extensive federal and state laws that govern the quality of care and the program guidance that has been issued to help navigate it. The session also will address the range of 1) administrative sanctions - including increased oversight to monetary penalties - and 2) government enforcement actions - such as monetary penalties, exclusion or incarceration - that may be imposed against providers that fail to provide quality care. Recent enforcement actions will be provided as case studies to generate discussion among the audience. Finally, steps and practical tools will be shared to demonstrate how to integrate quality into compliance.



Objectives

- Understand the relationship between the Medicare and Medicaid Conditions of Participation, the OIG/AHLA guidance for Boards of Directors on Compliance and Quality, the revised guidance for long-term care facilities, and the False Claims Act
- Discuss recent enforcement actions
- Take home practical tools and steps to integrate quality into compliance
- Understand emerging issues



Agenda

- I. Determining the Standard
- II. Legal Implications
- III. Example Enforcement Actions
- IV. What Compliance Officers Can Do to Integrate Quality into Compliance
- V. Conclusion and Emerging Issues



Determining the Standard

- Unlike some other types of health care fraud, quality of care cases can often be driven by subjective determinations rather than objective standards.
 - In the case of quality, is a picture worth a thousand words?
 - Do you know it when you see it?
 - Expert witnesses versus fact witnesses.
- When poor quality is identified and quantified –
 - Is once enough to warrant fraud and abuse enforcement action ?, or
 - must cases involve failure of care on a systemic and widespread basis?
 - If systemic, must the underlying failures be similar?
 - Must there be evidence of warning and notice?
- When fraud and abuse enforcement is considered, who should be targeted?
 - Frontline staff?
 - Local leadership?
 - Corporate leadership?
 - Others with a controlling interest?



Determining the Standard (cont.)

- Quality (or Poor Quality) According to Who?
 - United States Department of Justice
 - United States Attorneys
 - Federal Bureau of Investigation, Drug Enforcement Administration, etc.
 - United State Department of Health and Human Services
 - Centers for Medicare and Medicaid Services
 - Federal Certification Standards, (i.e.) Conditions of Participation
 - Office of Inspector General
 - Applicable Compliance Program Guidance
 - State Inspector General/State Survey Agency
 - Complaint or Standard Surveys (Federal Certification and State Licensure Standards)
 - State Attorney General
 - M.F.C.U



Determining the Standard (cont.)

- Social Services Agency
 - Adult and Child Protective Services
 - Abuse, Neglect, and Exploitation
 - Ombudsman, Protection and Advocacy Agencies, etc.
- Accrediting Bodies and Associations
 - Performance and Ethical Standards
 - (i.e.) Joint Commission, American Medical Association, etc.
- State Boards of Professional Licensure
 - Licensure action
 - Statutory standards
- External Peer Review Organizations
 - Government contractors, ((i.e.) Quality Improvement Organization, etc.)



Determining the Standard (cont.)

- Internal Peer Review Committees
 - (i.e.) Trauma Peer Review, Medical Staff, Infection Control, Quality Improvement, etc.
- Private Watch Dogs
 - (i.e.) Taxpayers Against Fraud
- Private Plaintiffs
 - Medical Malpractice
 - Qui Tam Relators
- Federal and state legislature
 - Introduction of testimony, proposed legislation, and final legislation
- Data or Literature
 - (i.e.) High death rates, high use of restraints, high rates of decubitus ulcers, questionable financial status, medically unnecessary care.
- Media
 - Enforcement agencies read the paper too!



Legal Implications

- In general, "fraud" is:
 - Any act, omission, or concealment calculated to deceive.
 - "making false statements or representations of material facts in order to obtain some benefit or payment for which no entitlement would otherwise exist."
- In general, "abuse" is:
 - Any excessive, improper or harmful acts
 - "any practice that, either directly or indirectly, results in unnecessary costs."
- Bottom Line
 - Did the government get what it paid for?
 - Did the government pay too much?



Legal Implications

- Liability based on alleged substandard quality can be premised on various theories.
- For example:
 - Reimbursement (False Claims and/or Overpayments)
 - Gross and/or systemic failures or conditions
 - Notice, warning, failure to act/respond
 - Performing medically unnecessary services
 - Underlying falsifications in official documents
 - False certifications
 - False statements or reports
 - Failure to make mandated reports
 - Abuse, Neglect, or Exploitation
 - Obstruction



Legal Implications

- Federal law provides a wide array of criminal, civil, and administrative sanctions that can be applied to cases involving substandard quality.
- For example:
 - Federal False Claims Act 31 U.S.C. Section 3729 et. seq.
 - Submitting False Claims 18 U.S.C. Section 287.
 - False Statements 18 U.S.C. Section 1001.
 - Mail/Wire Fraud 18 U.S.C. Sections 1341 and 1343.
 - 18 U.S.C. Section 1346 – intangible right to honest services.



Legal Implications

- Criminal Penalties for Acts Involving Federal Health Care Programs
 - 42 U.S.C. Section 1320a-7b(a) – false statements/representations re: payment.
 - 42 U.S.C. Section 1320a-7b(c) – false statements/representation re: condition or operation of institutions.
- Civil Monetary Penalties Law 42 U.S.C. Section 1320a-7a
- Exclusion From Participation in Federal Health Care Programs 42 U.S.C. Section 1320a-7.
- Termination of Provider Agreement by OIG 42 U.S.C. Section 489.54(a)(i)



Examples of Enforcement Actions

- Tucker House, Philadelphia, Pennsylvania
 - 1996 case involving a 180-bed Nursing Facility alleged to have violated the FCA.
 - Investigation targeted inadequate nutrition and wound care related to three former residents.
 - Settlement included payment of \$600,000 and consent orders imposing rigorous quality standards.
- Central Montgomery Medical Center, Lansdale, Pennsylvania
 - Systemic abuse of chemical and physical restraints
 - Investigation by the DOJ triggered by patient death
 - 2005 settlement with DOJ included \$200,000 payment, requirement to institute new standards and submit to third party monitoring.



Examples of Enforcement Actions

- United Methodist Hospital, Greenville, Michigan.
 - Systemic quality of care and medical necessity issues related to a anesthesia and pain management physician.
 - Hospital failed to appropriately respond to repeated complaints raised by various credible sources about the physician.
 - 2003 the hospital enters into a deferred prosecution agreement
- Redding Medical Center, California
 - Criminal and civil investigation into alleged unnecessary cardiac procedures and surgeries – “medical necessity fraud”
 - 2003 settlement under the FCA for \$54,000,000 related to procedures that occurred between January 1997 and December 2002.
 - Settlement included twice yearly audits for three years performed by outside expert with report to the United States Attorney’s Office, specified training for three years on peer review and informed consent for all members of the medical staff, creation of full-time compliance position.



Example Enforcement Actions

- Vencor Inc./Ventas Inc., Louisville, Kentucky
 - Failure to provide adequate health care (including, inadequate staffing, improper wound care, not meeting dietary needs)
 - 2001 settlement with DOJ, HHS, and DOD under the FCA for 219 million (more than 20 million related to care issues)
 - Settlement including requirement that Vencor hire an independent monitor, who was required to report findings directly to HHS
 - Coordinated investigation included nearly two dozen state and federal enforcement entities
- Purdue Frederick – OxyContin Case
 - Demonstrates aggressive “Look-up” Enforcement
 - Increase Focus on Responsibility of Corporate Officers
 - 2007 COO, CSO, and General Counsel pleaded guilty as responsible corporate officers to one count of misdemeanor misbranding; Corporation pleaded guilty to felony misbranding.
 - 2009 ALJ Affirms 15 year Exclusion of all three corporate officers



JHSMH

- Jewish Hospital & St. Mary's HealthCare (JHSMH) is a regional health care network that includes more than 70 health care facilities and 1,900 patients beds in Kentucky and southern Indiana. The merger of Jewish Hospital HealthCare Services and CARITAS Health Services to form JHSMH combines the strength and honors the heritages of the two organizations to provide a complete array of health care services to this region and beyond, including: hospitals, outpatient care, cancer care, occupational health, home health, psychiatric care and rehab medicine. JHSMH employs a network of physician practices that provide both primary and specialty medical care. The organization employs more than 8,100 people.



Steps Compliance Officers Can Take

- Assemble Regulatory Response Team
- Integrate Quality/Compliance in Training and Education
- Monitor/Audit Quality Indicators from a Compliance Perspective
- Report Findings to the Board



Regulatory Response Team:

One System's Approach

- JHSMH Regulatory Response Team
 - Corporate Compliance Officer
 - Corporate Quality Director
 - Corporate Risk Manager
 - Corporate Patient Safety Director



Regulatory Response Team: One System's Approach

- Ad Hoc members
 - Corporate Director of Care Management – oversees medical necessity reviews, inpatient v. observation
 - Corporate Director of Informatics – data mining
 - Corporate Director of Health Information Management
 - Corporate Director of Patient Accounting
 - Legal Counsel
 - Chief Medical Officer
 - Other management as needed



Training and Education

- Annually establish competencies for all team members, management, medical staff, vendors and volunteers
 - Corporate Compliance overview and annual update
 - Patient Safety
 - Patient Grievances and Patient Rights
 - Abuse, Neglect and Exploitation
 - Infection Control
 - Etc.



Monitoring and Auditing

- Hotline calls
- POA indicators and HACs
- RAC focus areas – medical necessity and coding
- Risk management issues
- PEPPER reports
- Patient grievances
- Quality of care concerns reported to medical staff peer review
- OIG visits related to COPs such as board oversight, patient rights, etc.



Reporting

- Board Environment of Care Committee
- Board Legal and Compliance Committee
- Audit Committee



Conclusions and Emerging Issues

- Scrutiny of corporate leadership, executive compensation and so-called “wall street greed” in all sectors will continue to escalate “corporate responsibility” enforcement in the health care industry
- Difficult economic times mean more focus on fraud and abuse to help offset shortfalls in Medicare and Medicaid budgets
- New political leadership has indicated there will be more focus on fraud and abuse especially as it relates to quality of care
- Sen. Charles Grassley (R-Iowa) expected to strengthen FCA by filing the False Claims Correction Act
- FCA suits expected increase as a result of \$1+ billion Eli Lilly case



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<http://www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf>
- **OIG's New Resource Guide on Corporate Responsibility & Healthcare Quality (Sept. 13, 2007)**
<http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>
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<http://oig.hhs.gov/oei/reports/oei-06-08-00220.pdf>
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Questions?

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