

USING HEALTHCARE FRAUD ENFORCEMENT TOOLS- ADDRESSING QUALITY ISSUES

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THE QUALITY COLLOQUIUM AT HARVARD

SPEAKER

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Disclaimers

- My opinions – but not official policy of Department of Justice
- Complaint or indictment contains allegations – defendant has right to put the government to its proof at trial
- Discussion of pending cases limited to public record information-news reports, filed documents

CORE QUESTION: WHY (AND WHEN) FRAUD ENFORCEMENT?

- KNOWING CONDUCT BY INSTITUTION/GROSS AND SYSTEMIC LEADERSHIP FAILURES
(Notice, warning, failure to act)
- INTENTIONAL ACTS BY INDIVIDUALS
- FALSE REPORTING, FAILURE TO REPORT
- APPALLING OUTCOMES
- WHAT WILL BE CONSEQUENCES OF OUR INVOLVEMENT?

HANDLING ALLEGATIONS OF SYSTEMIC LEADERSHIP FAILURES

- UNITED METHODIST HOSPITAL-MICHIGAN-DEFERRED PROSECUTION
- REDDING HOSPITAL-CALIFORNIA-SALE OF HOSPITAL
- PUTNAM HOSPITAL-WEST VIRGINIA
- EDGEWATER HOSPITAL-ILLINOIS-CONVICTION OF MANAGEMENT COMPANY
- CENTRAL MONTGOMERY HOSPITAL- Pa.-SETTLEMENT AGREEMENT FOR OVERSIGHT CHANGES

UNITED METHODIST HOSPITAL

- Dr. Jeffrey Askanazi-anesthesia and pain management
 - Nurse complaints (pace of practice, lack of sterile techniques, treatment of patients w/no observable improvement)
 - Physician complaints (medical necessity, repeated procedures with no benefit)
 - Patient complaints (doctor admitted doing procedure solely for reimbursement)

UNITED METHODIST HOSPITAL-RESPONSE

- CEO to complaining physician-your complaints are not welcome
- CFO to Board after referral of doctor to Profession Activities Committee-Askanazi generates one-third of hospital income-hospital would not want to hurt him
- Medical expert to PAC-cannot do medical necessity review-lack of documentation-Askanazi counseled to improve paperwork

United Methodist Hospital-2003

- UMH, Dr. Seward (UMH chief of staff), and Dr. DeWys (chief of Emergency Medicine) indicted (Seward and DeWys) had a joint venture with Askanazi, but sat on medical staff committees reviewing his practices
- 2003-hospital agrees to deferred prosecution agreement

REDDING HOSPITAL- CALIFORNIA(Tenet)

- From 1999 to 2002, Redding doctors billed Medicare for unnecessary heart surgeries-”medically unnecessary and failed to meet professional standards of care” according to Inspector General.
- Dr. Chae Hyun Moon, director of cardiology and Dr. Fidel Realyvasquez, chief of cardiac surgery alleged in civil suits of performing unnecessary surgeries.
- November, 2005-Moon and Realyvasquez agree to civil resolution-never bill Medicare again, resolve pending suits.
- No criminal charges were brought; US Attorney states that there was little chance of convincing a jury of a physicians’ criminal intent beyond a reasonable doubt.

REDDING HOSPITAL-2005

- Physicians were major revenue sources
- Thirteen prior lawsuits-1988-2002 (relevant?)
- Moon's privileges restricted at competing Redding hospital (lack of availability)
- Tenet spokesman states to New York Times, "we don't have an independent means of judging medical necessity." (November 2002)
- November, 2002-Tenet hires Mercer national medical audit practice to review medical necessity after whistleblower suit, FBI search warrant, state medical board action.

PUTNAM HOSPITAL(HCA)

- Dr. John King-orthopedic physician, hired 11/02-6/03
- 100 malpractice suits
- Peer reviewer, brought in by hospital –Dr. King is a “snake-oil salesman” “not competent to practice medicine.” (Wall Street Journal, 9/21/05 citing federal court suit.)
- Issue-failure of credentialing to discover prior malpractice suits, history of drop-out in residency programs, prior suspension .(JCAHO found Putnam’s credentialing deficient in 2002, before King was hired)
- Problem- need for additional orthopedic surgeon –what should hospital have done?
- Mark Foust,HCA: neither HCA nor Putnam responsible for any harm to patients (per WSJ)-once issues identified by consultant, privileges suspended

EDGEWATER MEDICAL CENTER

- MANAGEMENT COMPANIES PLEAD GUILTY TO HEALTH CARE FRAUD-2003
 - Physicians falsely stated need for hospitalization to patients
 - Physicians performed unnecessary angioplasties and cardiac catheterizations
 - Kickbacks to physicians for patient recruitment

CENTRAL MONTGOMERY MEDICAL CENTER-2005

- USE OF PATIENT RESTRAINTS WITHOUT APPROPRIATE ORDERS
- NEED FOR SYSTEMIC SOLUTION IN COMPLIANCE WITH CONDITIONS OF PARTICIPATION

Medical Errors and Care Failures Since “To Err Is Human”

- “The Long Road to Patient Safety: A Status Report on Patient Safety Systems” Daniel Longo, et al. 294 JAMA No. 22 (December 14,2005)
 - “Data are consistent with recent reports that patient safety system progress is slow and is a cause for great concern. . .” the current status of patient safety system progress is not close to meeting IOM recommendations. . .” (based on 2002 and 2004 study of Missouri and Utah hospitals)
- At what point does the failure to have an effective safety system result in False Claims Act or other fraud liability?

Medical Errors

Longo Measures

- Computerized physician order entry systems
- Computerized test results, and assessment of adverse events
- Specific patient safety policies
- Use of data in patient safety policies
- Drug storage, administration, and safety procedures
- Manner of handling adverse event/error reporting
- Prevention policies
- Root cause analysis

Section 501(b) 10 Quality Measures (RHQDAPU)

- Acute myocardial infraction
- Heart failure
- Pneumonia
- These are same measures collected by JCAHO for use in their certification program

SECTION 501 Reporting-and payment

- CMS FAQ RESPONSE:
- “Data from selected charts for each hospital that submits data will be audited; a successful audit is not required for the FY 2005 annual payment update. Additional requirements for data accuracy will likely be added for fiscal years 2006 and 2007.”

Multiple Sources and Reports

- RHQDAPU (reporting hospital quality data for annual payment update)
- JCAHO
- State reporting
- Mandated reports-errors, near misses
- Mandated apologies
- Quality improvement organizations
- Whistleblowers

Compliance and Medical Errors Issues

- Section 501(b) of Medicare Modernization Act of 2003 – 0.4% reduction in reimbursement for each fiscal year (2005 and after) if the hospital fails to submit quality data on 10 quality measures
- During FY 2006, “approximately 96% of all eligible hospitals received their full annual payment. . .”

Example of one hospital system's program

- Ensuring patient safety
- Facilitating physician excellence
- Building best in class quality reporting
- Improving the practice, resources and leadership of nursing
- Facilitating patient flow through care delivery
- Maximizing effective use of perioperative supplies

501(c) + RHQDAPU x Knowing Falsity =

- False claim?
- False statement in support of claim?
- False statement in order to avoid repayment to government?

Express False Certifications

- Services were in fact provided as claimed
 - Phantom services
 - Different (unqualified) provider
- Services were medically necessary
- Services were supervised as required for payment

Implied False Certification

- Many courts have premised False Claims Act liability on an implied certification of compliance with a statute or regulation that creates a precondition to payment
 - *US ex rel. Lee* (9th Cir.)
 - *US ex rel Mikes* (2d Cir.)
 - *US ex rel Quinn* (3d Cir.) (suggesting *in dicta* that precondition need not be express as long as compliance is not irrelevant to payment decision)

Conditions of Participation

- Some courts have concluded that conditions of participation are not necessarily the same as conditions of payment
 - US ex rel. Mikes
 - US ex rel. Swan (E.D. Cal)
 - US ex rel. Cooper (W.D. Pa.)
- But a fraudulent representation or promise to comply with conditions of participation could make subsequent claims false
 - US ex rel. Swan
 - US ex rel. Curtis (M.D. Fla.)
 - A fraudulent representation of compliance is a false claim

Conditions of Participation Issues

HCFA Form 2552-96

- Patients' Rights – 64 FR 36069 (1999) (includes right to freedom from physical and chemical restraint, with limited exceptions.) Deaths related to restraint must be reported by hospital 42 CFR 480.13(f)
- Quality Assessment/Performance Improvement – 68 FR 3435 (2003)
- Authentication of Verbal Orders – 42 CFR 482.24(c)(1) – dated, timed, authenticated
- Renal Dialysis Facilities – proposed 70 FR 6184-6254 (2005) – extensive changes to 42 CFR 494

Medical Errors and Care Failures Move to Criminal Cases

- USA v. Martha Bell and Atrium I (W.D. Pa. 2005)
Bell(nursing home administrator) convicted of health fraud and Atrium convicted of making false statements arising out of false records of care
- USA v. American Healthcare Management (W.D. Mo. November, 2005) – indictment charging violation of 18 U.S.C. § 1035 (False Statements concerning Health Care) because “the Defendants knew, at the time the claim was submitted, that the services were so inadequate, deficient and substandard as to constitute worthless services.”
- [Http://www.usdoj.gov/usao/moe](http://www.usdoj.gov/usao/moe)

Medical Errors and Failures to Report – Exclusion

- American Healthcare Management v. Inspector General (www.hhs.gov/dab/decisionsCR1278) (February 15, 2005)
- Misdemeanor conviction of parent company of a snf for failure to report elder abuse is a conviction which relates to “neglect or abuse of patients in connection with delivery of a healthcare item or service.”
- 5 year exclusion upheld

Reporting Requirements For Hospitals (PA, IL, NY, RI)

- Act 13 of 2002, 40 P.S.A. 1303. – requires mandatory reporting to the Patient Safety Authority and the Department of Health by hospitals of “serious events” and “incidents” starting June 2004
- Requires designation of patient safety officer and patient safety committee, patient safety plan, reporting scheme
- Prohibits retaliation against employee for reporting serious event or incident
- Requires written notice to patients of certain events

Physical and Chemical Restraints in Care Facilities

- *USA v. Kinspeace* E.D. Pa. – Settlement in excess of \$1.8 million with Consent Decree – restraints (child psychiatric facility)
- Mercer County Geriatric Center (restraints, nutrition and hydration) – D-NJ (Civil Rights case)
- A. Holly Patterson, E.D. NY – restraints, nutrition, inadequate care (Civil Rights case)
- Hospital restraints, Medicare condition of participation, 42 C.F.R. 482.13
- *USA v. Central Montgomery Hospital*, July 25, 2005 – \$200,000 settlement and consultant required to review restraint usage at the hospital, US Attorney Office, E.D. Pa.

Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. 299c-21)

- “A provider may not take an adverse employment action. . .against an individual. . . Based upon good faith reported information. . . To the provider. . . Or to a patient safety organization.”
- “Adverse employment action” includes credentialing and certification
- Equitable relief authorized “for any aggrieved individual” to enjoin any violation or for reinstatement and back pay

Future of Health Fraud Prosecutions

- Quality/Safety/Dignity issues
- Financial loss to government and beneficiaries
- Whistleblower information and referrals
- Part D exposures from new program

Compliance Safeguards

501(c) + RHQDAPU =

- Significant role for audit and compliance in assuring the accuracy and reliability of data, data collection, and data reporting
- “Chart audit validation process”
- “Publishable data”

Compliance Safeguards Hospital Boards in Quality and Patient Safety

- “Getting the Board on Board: Engaging Patient Boards in Quality and Patient Safety” in 32 Joint Commission Journal on Quality and Patient Safety 179-187 (April 2006)
- Interviews conducted with CEOs and Board Chairs at 30 hospitals in 14 states
- “The level of knowledge of landmark IOM quality reports among CEOs and board chairs was remarkably low. . . There were significant differences between the CEOs’ perception of the knowledge of board chairs and the board chairs’ self-perception”

Compliance Safeguards Hospital Boards in Quality and Patient Safety

- Increasing education on quality
- Frame an agenda for quality
- Quality planning, focus from board level
- Governance responsibility for quality
- Greater focus on patients

Compliance Safeguards

Red Flags

- “The Buzz” – employees talking about problems in the organization
- Complaints – patient or employee complaints or complaints by others including physician complaints
- Administration not taking appropriate or timely action
- Medical staff not taking appropriate or timely action

Compliance Processes and Safeguards

- Upfront processes – commitments to quality and other preventative measures
- Compliance officer/patient safety officer role
- Utilization programs
 - Plans
 - Policies
 - Training
 - Monitoring of utilization processes
- Peer review processes/conflicts
- Quality of care as an element of a compliance program

COMPLIANCE PROCESS AND SAFEGUARDS

- 42 U.S.C. 1395x(k), 42 CFR 482.30- utilization review requirements for hospitals
- Review of durations of stay
- Review of medical necessity of services, drugs
- Every outlier case; sampling of other cases

Deficit Reduction Act Impact

- Quality Demonstration Project –ultimate goal- induce and reward quality
- 2005 Deficit Reduction Act requirement effective (1/07) – advise employees of federal and state false claims acts and whistleblower statutes – likely to generate additional government enforcement activity

QUALITY AND ENFORCEMENT

- HAS THERE BEEN A SYSTEMIC FAILURE BY MANAGEMENT AND THE BOARD TO ADDRESS QUALITY ISSUES?
- HAS THE ORGANIZATION MADE FALSE REPORTS ABOUT QUALITY, OR FAILED TO MAKE MANDATED REPORTS?
- HAS THE ORGANIZATION PROFITED FROM IGNORING POOR QUALITY, OR IGNORING PROVIDERS OF POOR QUALITY?
- HAVE PATIENTS BEEN HARMED BY POOR QUALITY , OR GIVEN FALSE INFORMATION?

QUALITY AND ENFORCEMENT

- PROSECUTION SHOULD BE LIMITED TO EGREGIOUS CASES, SYSTEMIC FAILURES TO RESPOND
- REGULATORS AND PROSECUTORS SHOULD SUPPORT VOLUNTARY EFFORTS, WHISTLEBLOWERS INTERNAL REMEDIES
- PEER REVIEW PROCESS SHOULD RECEIVE NEEDED LEGAL PROTECTION-(Patient Safety Act, Kibler v. Northern Inyo County Hospital)

Useful Web Sites

- www.cms.hhs.gov/HospitalQualityInits
(qualifying for Annual Payment Update)
- www.hospitalcompare.hhs.gov
(what reports from your hospital are shown to consumers)