

# FEDERAL ENFORCEMENT OF MINIMUM QUALITY STANDARDS

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James G. Sheehan

Associate United States Attorney

215-861-8301

[Jim.Sheehan@usdoj.gov](mailto:Jim.Sheehan@usdoj.gov)

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# WHAT KIND OF QUALITY ISSUES LEND THEMSELVES TO CIVIL AND CRIMINAL FRAUD ENFORCEMENT

# Institutions knowingly did not knowingly respect patient's autonomy and right to decide on own care

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- Restraints
- Hartford Courant series, 1998-142 deaths among juvenile patients in previous decade involving use of restraints. See Children's Health Act of 2000 – established restrictions on restraints for residential facilities for children 42 U.S.C. 290-jj
- Bancroft Neurohealth, Haddonfield, NJ (state penalty and consent agreement July 2003)
- Medication (chemical restraints), Kino Hospital, Tucson (July 2003)

# Institutions knowingly did not knowingly respect patient's autonomy and right to decide on own care (cont.)

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- Physical abuse of juvenile patients by staff, Lipman Training and Education Center, Newark Star-Ledger 5/18/03
- Research without consent
- Confinement
- Mandated services as condition of care
- Withholding needed treatment
- False statements about treatment options
- “Standing orders” based revenue needs, not medical necessity

# Institutions knowingly failed to provide minimum standards needed to maintain life and health

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- Since 1996, more than 20 nursing home cases have been settled based on False Claims Act allegations. See testimony of Dara Corrigan, Acting Principal Deputy Inspector General to Senate Finance Committee, July 17, 2003.
- Repeated medication errors
- Bedsores – prevention and treatment
- Lack of nutrition/hydration

# Institutions knowingly failed to provide minimum standards needed to maintain life and health (cont.)

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- Failure to treat delirium in elderly patients
  - Present in significant percentage on admission; increases during stay
  - Most common in hip fracture patients
  - Related to other quality issues
  - Physical restraints
  - Malnutrition
  - 3 or more medications added during hospital stay
  - Use of bladder catheter
  - Turn off alarms, buzzers

# Institutions knowingly failed to provide minimum standards needed to maintain life and health (cont.)

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- Unlicensed or non-credentialed staff; how effective are credentials checks?
- Lack of staff (see Hichman, et al. AHRQ study – Impact below med/surg. 6 patients/RN; ICU 2 patients/RN)
- Dangerous physicians allowed to continue practice on staff (or refer for outpatient services) United States v. United Memorial Hospital indictment (WD Mich, 2001) – indictment of hospital and two physicians (former Chief of Staff and Chair of Professional Activities Committee) for allowing physician to remain on staff and perform unnecessary pain management procedures, and obstructing investigation (hospital pled guilty to wire fraud; physicians pled guilty to misdemeanors)

# Institutions knowingly failed to provide minimum standards needed to maintain life and health (cont.)

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- Persons on HHS/OIG “list of excluded persons/entities” (Medicare/Medicaid)
- State licensing board sanctions
- No valid DEA number
- NPDB reported clinical privilege actions
- Substance abuser monitoring/controls
- FDA clinical research sanctions

# Institutions knowingly prepared false records or reports, or failed to make reports connected to quality

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- Charting parties (records creations)
- False reports of physician presence of involvement in procedure
- False reports, failure to make required reports of medical errors required by a least 15 states (Hartford Courant, April 29, 2002)
  - e.g. Pa.Act 13 of 2002, the Medical Care Availability and Reduction of Error Act; Minnesota Adverse Health Care Events Reporting Law signed May 2003 (using National Quality Forum's 27 event system)

# Institutions knowingly prepared false records or reports, or failed to make reports connected to quality (cont.)

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- False records to hide errors
- False/non-existent quality assurance or utilization review
- Destruction of records
- False reports to state/federal agencies
- Urea clearance rate
- NPDB – reportable events
- JCAHO required reports on unanticipated outcomes to patients (deemed status by reason of accreditation – 42 U.S.C. 1395bb)

# Institution knowingly provided worthless services

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- Lab reports based on bad samples
- Cutting off wrong leg
- Uncalibrated equipment
- Talk therapy for demented patients
- Standing order testing

# Off label use of FDA approved drugs on a systemwide basis

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- Neurontin
- Risperdal
- Wellbutrin
- Topamax

# Institutions denied access to services

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- Utilization review prior to admission
- Early discharge
- EMTALA

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Institution retaliated against employees and staff physicians who raise concerns about quality of care