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FEDERAL ENFORCEMENT OF MINIMUM QUALITY STANDARDS

WHAT KIND OF QUALITY ISSUES LEND THEMSELVES TO CIVIL & CRIMINAL FRAUD ENFORCEMENT?

1. Institutions knowingly did not respect patient's autonomy and right to decide own care

- 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)
- 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

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

- 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
- 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
 - unlicensed or non-credentialed staff

How effective are credentials checks?

- lack of staff(See Hickman 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)
- 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

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

- charting parties (records creations)
- false reports of physician presence or involvement in procedure
 - false reports, failure to make required reports

of medical errors required by at 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)

- 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)

4. Institution knowingly provided worthless services

- lab reports based on bad samples
- cutting off wrong leg
- uncalibrated equipment
- talk therapy for demented patients
- standing order testing

5. Off label use of FDA approved drugs

- Neurontin
- Risperdal
- Welbuterin
- Topamax

6. Institutions denied access to services

- utilization review prior to admission
- early discharge
- EMTALA

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

A SURVEY OF CURRENT LAW, CASES AND LAW REVIEW COMMENTARY ON THE APPLICATION OF THE FALSE CLAIMS ACT TO QUALITY OF CARE, WORTHLESS SERVICES, AND PROMOTION/USE OF DANGEROUS SERVICES OR TREATMENTS:

As methods of reimbursement changes, the fraud to obtain that reimbursement change as well.

United States ex rel Scott Barrett v. Columbia/HCA

(Case No 99-3304-Part of 01-MS-50(RCL) DC District of Columbia)(extensive briefing by United States, relator, and defendants on issues of implied certification/tainted claims-filed during 2002, no decision yet).

Nursing Home Compliance Guidance issued by OIG - "knowingly billing for nonexistent or substandard care, items, or services may be actionable under the False Claims Act." 65 FR 14289(2000)

United States v. NHC Health Care Corp., 163 F. Supp. 1051(WD Mo. 2001)(nursing home quality of care false claims)

"No certification, implied or otherwise, is necessary when the liability stems from the Defendant's activities of billing for procedures they did not perform. This would plainly constitute fraud. The difficulty in proving that defendants committed such fraud lies in the per diem billing system utilized under Medicare/Medicaid. Obviously, if NHC billed the Government for \$4 for turning resident 1 ob July 18,1998, but in fact no had actually performed the task, a clear cut case of fraudulent billing would be presented. However, we are not blessed with such pristine circumstances. NHC billed the Medicare/Medicaid programs on a per diem basis . . . in so doing, NHC agreed to provide "the quality of care which promotes the maintenance and enhancement of the quality of life." At some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary activities required to promote the patient's quality of life. When the provider reaches that point, and still presents claims for reimbursement to Medicare, the provider has simply committed fraud against the United States.(at 1057)

. . . at some point the care rendered to a patient can be so lacking that the provider has simply failed to adhere to the standards it agreed to abide by and has thus committed a fraud. .
. (If) the Government has presented sufficient evidence to show

that NHC's conduct might have fallen to fraud . . . It would then be the jury's function to determine which side NHC's conduct falls. . .(at 1057)

In sum, a reasonable jury could conclude . . . that the Defendant did not have enough staff to properly care for Residents 1 and 2 as they promised to do pursuant to the terms of their Medicare/Medicaid agreements. This inference can be drawn from the evidence of staffing shortages, overall neglect of the facility and residents, and the direct evidence of neglect of Residents 1 and 2.(at 1058)

"Finally, the Court holds that an entity who is charging the Government for a minimum amount of care provided to its residents should question whether understaffing might lead to undercare (at 1058) (whether the submission of the fraudulent claim was knowing).

United States ex rel Franklin v. Parke-Davis, 147 F. Supp. 2d 39(D. Mass. 2001) (marketing of off-label uses for Neurontin; false statements to physicians using contrived data, falsified leaks from criminal trials, and scientifically flawed reports)

"The False Claims Act can be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit. . . . In this case, when all reasonable inferences are drawn in favor of the relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.(at 53)

United States ex rel. Insoon Lee v. Smithkline Beecham, 245 F. 3d 1048(9th Cir. 2002) "In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under Section 3729, regardless of any false certification conduct."(at 1053)

Powell, Daniel J. *"Using the Civil False Claims Act As A basis for Institutional Review Board Liability"* 69 University of Chicago L. Rev. 1399(Summer 2002)

Stockham, Michael *"This Might Sting a Bit; Policing Skin Care In Nursing Facilities By Litigating Fraud"* 87 Cornell Law Review

1041(May 2002) ("litigating under the False Claims Act is an efficient, effective, and arguably necessary tool for policing skin care and preventing bedsores in nursing facilities.")

This article provides a thorough summary and analysis of the quality of care settlements as well as the litigated cases)

Krause, Joan "*Promises to Keep: Health Care Providers and The False Claims Act*" 23 Cardozo Law Review 1363(March, 2002) (University of Houston professor previously a False Claims Act defense lawyer questions quality/failure of care cases but concedes the power of their theory and facts.)

Krause, Joan "*Health Care Providers And The Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*" 36 Georgia Law Review 121(Fall 2001) (author suggests that bringing False Claims Act cases based upon seriously deficient quality of care might alienate the health care industry.)

Krause, Joan "*Medical Error as a False Claim*" 27 American Journal of Law and Medicine 181(2001)

Matthew, Dayna Bowen "*Tainted Prosecution of Tainted Claims: The Law, Economics, And Ethics Of Fighting Medical Fraud Under The Civil False Claims Act*" 76 Indiana Law Journal 525(Summer 2001) (discusses merits of Thompson theory of tainted claims in kickback and self-referral cases)

AREAS OF SPECIFIC FUTURE INTEREST:

1. Residential Facilities

There are over 1.5 million residents.

1995 Consumer Reports study:

-40% of all facilities certified by HCFA have multiple, repeated violations of HCFA standards, according to inspection surveys.

-45% of all facilities have deficiency for failing to respect patients' dignity.

-25% of nursing homes cited for allowing decubitus

ulcers to develop.

-many facilities restrain patients without proper orders.

Nursing Home Outcome Measures mandated by OBRA 1987, P.L. 100-203
- Regulations effective 1992, 42 C.F.R. 483.

Nursing home minimum data set, includes:

- cognitive status
- communication and vision
- mood and behavior
- mobility
- decubitus ulcers
- nutritional status

Survey and certification process, using state and federal inspectors.

- structure and outcome indicators
- interview and evaluate case - mix stratified sample of patients
- review medical records
- extremely detailed, cookbook review

2. Behavioral Health

The behavioral health area lends itself to managed care approaches because of its history, its rapid growth in cost, and because of rapid changes in techniques and theory of care. At the same time, managed behavioral health techniques impose unique burdens on patients and providers, and public and judicial suspicion of managed care is highest when its intrusiveness into uniquely private and personal issues is greatest. In this area, quality measures and denial of care issues will be substantially more concerned with process - does it protect individual autonomy and dignity? Does it support the therapeutic effort? Does it discourage patients from seeking medically necessary care?

Any system of utilization review in behavioral health creates numerous problems for both the provider and the patient seeking care. First, unlike indemnity insurance plans, benefits

in a managed care system are not predictable or reliable from the perspective of that patient, that patient's family, and the patient's treating provider because, although the managed care plan may say that it covers all "medically necessary" care up to specified contractual limits, the patient's and the utilization review's definition of "medically necessary" care may be very different. Increasingly, HMO and managed care plans have expressly abandoned their contractual commitment to "medically necessary" behavioral health care to provide only such case as will provide significant improvement in functioning in a reasonable period of time, modeling their benefit package after the basic services required by the HMO Act. Providers and patients never know at any point during therapy how many sessions will be granted by the utilization review company and throughout treatment are constantly afraid of sessions being cut off. In addition, they can not rely on being granted other therapeutic options believed necessary for successful treatment.

Second, reviews of treatment by behavioral health firms, which include extensive analysis of the interaction between the patient and the therapist, may make it difficult or impossible for the therapist to be effective. See United States v. Redmond, 116 S.Ct. 1923, 1928 (1996).

3. Managed Care/Utilization Review

One solution to denial of care is to regulate utilization review by requiring that the clinical review criteria used be objective and based on realistic treatment timelines reflecting well-know and highly predictable patterns of health services and health care service delivery and utilization. At least states have attempted to enact legislation to regulate companies which provide review of service utilization. The stated purpose for this regulation is to "promote the delivery of quality health care in a cost-effective manner," make sure that "utilization review agents adhere to reasonable standards for conduction utilization review," improve communications between all parties involved, protect patients, business, and providers by making sure the utilization review agents are "qualified to perform utilization review activities and to make informed decisions on the appropriateness of medical care," and to "ensure that utilization review agents maintain the confidentiality of medical records in accordance with applicable [state and federal] laws."

Utilization review is defined in most of these statutes as "a system for reviewing the appropriate and efficient allocation or charges of hospital, outpatient, medical, or other health care services given or proposed to be given to a patient or group of patients for the purpose of advising the claim administrator who determines whether such services or the charges therefor should be covered, provided, or reimbursed by a payor according to the benefits plan." Generally, the utilization review legislation requires that the utilization review company become certified before it can operate in the state. To apply for a certificate, the agent is required to submit a utilization review plan. This plan generally includes: specific criteria and standards to be used in utilization review; a description of the procedures for appeals of adverse decisions; the qualifications of the personnel working for the utilization review company; the procedures that ensure a representative of the company is reasonably accessible to patients and providers; a description of the policies and procedures in place to ensure applicable state and federal confidentiality laws are complied with; and a copy of the material used to inform patients and providers of the requirements of the utilization plan. Some states additionally require the company to submit a list of the health care providers who come up with the reviewing standards used by the company, certification that the criteria and standards it comes up with are "objective, clinically valid, compatible with established principles of health care, and flexible enough to allow deviations from the norms when justified on a case by case basis," and a list of the third party payers for which the review company performs its utilization review services. These certification requirements are in addition to the application, the application fee, and the required signatures. The entire application is then reviewed by the Director/Commissioner of Insurance for the state, who has the authority to grant or deny certification.

Although the extent of regulation by some states is the certification process, some states additionally require certain minimum standards to be used by utilization review companies. Certain states, such as Maryland, limit these minimum standards to review of services for treatment of alcoholism, drug abuse, and mental illness. Some of these standards include: mandating particular appeal procedures from adverse decisions with set time limits for notification; requiring that at least one board certified physician be involved in the making of an adverse

decision; requiring that notification of denial include the "principal reason(s) for the determination and the procedures to initiate an appeal of the determination; mandating that the utilization review company make staff available by toll-free telephone at least during business hours, forty hours a week, and requiring them to have a system in place to take incoming calls at times other than normal business hours with the understanding that these calls must be responded to within two days; requiring an expedited appeals process (two days) for emergency or life threatening situations; requiring that the health professionals making the decisions have current licenses; requiring that the practitioner who review the appeal be a specialist in the area of the treatment under review; forbidding a fee to be charged for appeal of an adverse decision; and finally, requiring that no employee of such a company receive any "financial incentive based on the number of denials of certification made by such employee."

Although this type of state regulation is a useful check on the discretionary decisions made by utilization review companies, it can be less effective in practice than might be expected. The majority of the states that have enacted legislation do not require the utilization and review company to identify the health care providers who develop the reviewing standards, to demonstrate from peer reviewed literature the medical basis for the standards, or even to certify that the standards they use are compatible with established principles of care. Even those states that have these requirements in place can not assure that these are the same requirements that are actually being used by the reviewers. Many of the states that have adopted this type of legislation allow the requirements to be waived for the utilization review company if the Insurance Commissioner finds that the company "adheres to standards which are substantially similar to the standards" set forth in the statute, or if the utilization review company has been accredited by a utilization review accreditation organization.

*The opinion expressed herein is personal to the author's and not an official statement of the United States Department of Justice.