Health Care Compliance Association
17th Annual Compliance Institute

Quality of Care:
Are You On the Bus or Under It?

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April 21, 2013

Swiss Cheese Model of System Failure
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DEPOSE Analysis
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• Design
• Equipment
• Procedures
• Operators
• Supplies and materials
• Environment

Quality and Compliance Investigations
“The Wheels on the Bus....”

• Incident Reporting Systems
“HOSPITALS INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM” OIG Report January 2012
• Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm. Of the events experienced by Medicare beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent. In the absence of clear event reporting requirements, administrators classified 86 percent of unreported events as either events that staff did not perceive as reportable (62 percent of all events) or that staff commonly reported but did not report in this case (25 percent).
• Nurses most often reported events, typically identified through the regular course of care; 28 of the 40 reported events led to investigations and 5 led to policy changes.
2013 OIG Work Plan

• 3 new initiatives (in addition to 5 carryovers) in the 2013 OIG Work Plan related to SNFs:

  (1) Deficiency correction by State agencies

  (2) Inappropriate use of antipsychotic meds

  (3) Increased scrutiny of MDS submissions

November 2012 OIG Report

• “Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than A Billion Dollars in 2009”

• 25% of claims billed in error=$1.5 billion

• Inaccurate RUGs in 23% of claims—therapy is the key issue

• Misreported information on MDS for 47% of claims
### MDS Categories with Misreported Information

- Therapy—PT, OT, Speech = 30%
- Special Care—IV meds, tracheostomy care = 17%
- Activities of Daily Living = 7%
- Oral/Nutritional Status (e.g. parenteral feeding) = 5%
- Skin Care—pressure ulcers, wound dressings = 2.4%

### Quality of Care Issues

1. Sufficient staffing
2. Comprehensive resident care plans
3. Medication management
4. Appropriate use of psychotropic meds
5. Resident safety
   - Promoting resident safety
   - Resident interactions
   - Staff screening
Psychotropic Medications

• What are the evidence-based standards for using psychotropic medications?

• Why is that relevant?

• Barriers to compliance
  – Physicians
  – Family

State Investigations

• Suppose state surveyors demand to see all QA material.

  -What should the compliance officer and/or counsel do?

  -What does the law require?

  -Are there differences in federal and state laws and regulations regarding QA material?
QA Material & Privilege

- A State or the Secretary may not require disclosure of the records of such committee [QA] except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.
- Good faith efforts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

42 C.F.R. § 483.75(o)

What Constitutes QA Material?

- Minutes of QA committee
- Working papers
- Internal memos
- Attendance records
- Agenda
- Incident reports?
Incident Reports are Not Privileged

- Facilities may not refuse to provide surveyors with incident reports.

- Incident reports are not QA documents subject to “privilege.”

Jewish Home of Eastern PA v. HHS, CMS

- ALJ
- Board
- 3rd Circuit
- Supreme Court (pet. denied)
Attorney General Kamala D. Harris Announces Nurse Sentenced to 3 Years in Prison for “Convenience Drugging” Elder Patients

Wednesday, January 9, 2013

BAKERSFIELD -- Attorney General Kamala D. Harris today announced the sentencing of the former Director of Nursing of a Kern Valley Healthcare District hospital with a skilled nursing facility, a rare case in which a medical professional has been criminally charged and sentenced under elder abuse laws for the illegal chemical restraint of patients.

Gwen D. Hughes, 59, the former Director of Nursing, was sentenced to three years in state prison Wednesday in Kern County Superior Court. Hughes pled no contest on October 11, 2012 to one felony count of elder abuse with a special allegation that the abuse contributed to the victim's death.

Hughes ordered the administration of psychotropic medications to 23 elderly residents of the skilled nursing facility not for therapeutic reasons, but instead to control and quiet them for the convenience of staff. The drugs were given to patients who were noisy, prone to wandering, who complained about conditions or were argumentative. The drugs hastened three patients' deaths, according to the investigation, and all 23 suffered some form of adverse physical reaction as a result. Many of the patients were under care for Alzheimer’s or dementia.

"Elder abuse in skilled nursing facilities is a particularly heinous crime because vulnerable victims and their families have placed their trust in the facilities to provide quality care, preserve their dignity and enjoy a better quality of life," Attorney General Harris said. “This defendant maliciously and dangerously drugged patients for her own personal convenience. This is clearly outrageous conduct that justifies a state prison sentence.”

Nurse and Medical Director Sentenced

The California Department of Public Health began an initial investigation in 2007, following complaints from an ombudsman that a patient in the skilled nursing facility had been held down and injected with psychotropic medicine by force. They found evidence of patient harm, and issued a Certificate of Immediate Jeopardy against the facility, before turning the case over to the Justice Department.

Evidence indicated that Hughes directed the hospital's director of pharmacy to write doctor's orders for the unnecessary psychotropic medications.

The orders were signed at a later time by the medical director. Pamela Ott, former chief executive officer of the Kern Valley Health District, pled no contest to one felony count of conspiracy to commit an act injurious to the public health based on her failure to adequately supervise the Director of Nursing. Ott was sentenced to three years formal probation, 300 hours of volunteer service, restitution pending conclusion of civil lawsuits. She is required to comply with all orders from the Registered Nursing Board, which is conducting its own investigation into the matter.

In July 2012, Dr. Hoshang Pormir, the Medical Director, was also sentenced to 300 hours of volunteer service, restitution pending conclusion of civil lawsuits, and a requirement to comply with all orders from the Medical Board. Pormir failed to conduct examinations of patients or monitor their reactions to medications.