

Direct Supply Clinical Leadership Conference 2014

A New Era of Accountability and Transparency
For Long Term Care Professionals
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A Perfect Storm?

- Industry Under DOJ and Whistleblower Scrutiny.
- Quality of Care
- Billing
- ACA Mandates
- Changing Care Models
- Congressional interest
- Consumer/Patient interest
- Media interest.
- Transparency Initiatives





ACA MANDATES AND CLINICAL LEADERSHIP

- ACA theme of transparency and accountability extends to clinical operations of long term care facilities.
- Compliance and Ethics Program for nursing homes focused on reducing deficiencies in surveys and improving quality.
- Nursing Home Compare tracks staffing, surveys, complaints and personnel.
- Cost Report Re-Design and Public Availability focused on transparency in direct care staff, indirect staff, capital assets and administrative costs.
- Reporting Staffing Data: ensuring accountability for adequate staffing.
- National Independent Monitor Demonstration Project.
- Improving Staff training-dementia services
- Direct Patient Access Caregiver Background Checks.



DOJ Initiatives

- Task Force and Coordination Approach. Criminal and civil fraud liability. Feds and State AG's.
- Investigation criteria for quality of care allegations under False Claims Act. Long term and post acute care. Hospitals too. Assisted Living Facilities too.
- Qui tam whistleblower role in identifying viable investigation issues.
- Role of CMS in DOJ quality of care initiatives.
- Role of State surveyors and survey process.
- Use of outside experts in DOJ quality of care investigations.
- Data mining-what is it and how does it work in DOJ quality of care investigations?
- Who is on the hot seat for quality of care violations?



Trends in Asserted Liability

- Inadequate Staffing. Failure to have measurable acuity based process.
- Quality Metrics Substandard (Falls, Nutrition, Wound Care, Geri-Psyche services, Medication Errors).
- Quality of life issues: activities, social services.
- Poor Survey Performance.
- Unqualified or Incompetent Managers and Health Care Professionals.
- Medical Director Issues.
- Demonstrable Patient Harm.
- Falsification of Medical Records.
- MARS/TARS RECORD Deficiencies
- Arrangements with Service Providers (Therapy, Hospice, Pharmacy) for anti-kickback and billing compliance.
- Credentialing and Background Checks
- Overpayments



Spotlight: Staffing

- Enforcement focus is on staffing. All care failures are staffing failures.
- What level and type of staffing is adequate to provide for resident needs? Are industry standards good clinical practice standards?
- Is staffing determined by census or acuity or is that the same thing?
- Is there an objective measurable acuity based staffing protocol or does the DON “wing it” daily?
- Too much agency?
- Too much pressure to meet budget instead of staffing needs?
- Recruitment issues? Are wages competitive?
- Effective clinical and care training?



Spotlight: Therapy Services

- Therapy Services provided to Medicare and Medicaid patients under Medicare Part A and Medicare Part B.
- Medical necessity issues
- Business practices to increase therapy services
- Clinical initiatives and presumptions for Medicare Part A therapy services and impact on RUG levels.
- LifeCare Litigation Proceeding (M.D. Tenn.).
- Therapy Settlements.



Spotlight: Pharmacy Services

- Medication Administration Reviews.
- Pharmacy Audits-Controlled Substance Logs.
- Clinical Review of Chemical Restraints.
- Switching Practices for anti-depressant and other medications.
- Off-label usage.
- Purchase Arrangements (discounts, bundled services, invoice reconciliation).
- DEA Compliance.



DOJ/OIG Quality of Care Enforcement

- Momence Meadows Nursing Center (**Ongoing Litigation**) 2013/2014
 - **District:** N.D. Illinois
 - Allegations of inadequate care and falsification of records.
 - Two former nurses alleged that the nursing home failed to provide adequate staffing and neglected patients (*e.g.*, permitted patients to lie in urine and feces, failed to deliver prescribed medications, failed to deliver meals, failed to provide a sanitary environment, and failed to take appropriate skin precautions) and then forged and destroyed medical documents, logs, etc. to conceal the failures in care.
 - \$28 million dollar jury verdict against the nursing home and its former owner. *The \$28 million dollar verdict was subsequently reduced to \$9 million, after the Court ruled that the other \$19 million in penalties levied by the jury were excessive under the 8th Amendment.*
 - The matter is on appeal.



DOJ/OIG Quality of Care Enforcement

- **Villaspring Health Care Center** (February 2013)
 - **District:** Eastern District of Kentucky
 - **FCA Settlement Amount:** \$350,000
 - **Corporate Integrity Agreement:** As part of the agreement, Villaspring and Carespring agreed to retain an independent compliance consultant, subject to the approval of the USAO, for a period of 3 years.
 - Settlement agreement resolved allegations that defendants provided inadequate care to patients resulting in the deaths of five residents and actual harm to additional residents. The investigation appears to have been initiated after poor survey performance.



DOJ/OIG Quality of Care Enforcement

- **MonPointe Continuing Care Center** (March 2012)
 - **District:** Northern District of West Virginia
 - **FCA Settlement Amount:** \$2.25 million
 - **Corporate Integrity Agreement:** None
 - Settlement agreement resolved allegations that MonPointe submitted fraudulent claims to Medicare and Medicaid for substandard care of skilled nursing facility patients provided as a result of inadequate staffing. The federal investigation leading to the settlement was initiated after state inspectors closed the facility.



DOJ/OIG Quality of Care Enforcement

- **Golden Living** (December 2012)
 - **District:** Northern District of Georgia
 - **FCA Settlement Amount:** \$613,300
 - **Corporate Integrity Agreement:** Golden Living entered into a 5-year CIA covering 6 facilities in the greater Atlanta region.
 - *Qui tam.* Settlement agreement resolved allegations that Golden Living provided inadequate and worthless wound care services at 2 of its Atlanta area nursing homes.



DOJ/OIG Quality of Care Enforcement

- **Maxim Healthcare** (September 2011)
 - **District:** District of New Jersey
 - **FCA Settlement Amount:** \$130 million
 - **Corporate Integrity Agreement:** Maxim entered into a 5-year Corporate Integrity Agreement.
 - Maxim Healthcare, a home health services provider based in Columbia, Maryland, agreed to pay a \$20 million criminal fine and \$130 million to resolve civil False Claims Act allegations.
 - Resolved allegations that Maxim emphasized sales goals at the expense of clinical and compliance responsibilities; billed federal for services not documented or not actually rendered; falsification of time sheets, training records, and caregiver qualifications.
 - Note: Nine individuals pleaded guilty in connection with the allegations.



DOJ/OIG Quality of Care Enforcement

- **Cathedral Rock** (January 2010)
 - **District:** Eastern District of Missouri
 - **FCA Settlement Amount:** \$628,000
 - **Corporate Integrity Agreement:** Cathedral Rock also entered into a 5-year CIA
 - Cathedral Rock Nursing Homes entered into a deferred prosecution agreement for a period of 2 years.
 - the company's 5 nursing homes and majority owner agreed to jointly pay \$1 million in criminal fines and penalties.
 - Cathedral Rock agreed to pay \$628,000 to resolve civil FCA allegations. In the plea agreement, Cathedral Rock admitted to (1) providing inadequate staffing, resulting in inadequate care; (2) failing to provide wound care; (3) failing to deliver medications as prescribed; (4) falsifying medical records related to medication administration



DOJ/OIG Quality of Care Enforcement

- **Willowcrest Nursing Home** (August 2009)
 - **District:** Eastern District of Pennsylvania
 - **FCA Settlement Amount:** \$305,072. resolved allegations that Willowcrest provided sub-standard pressure ulcer treatment and prevention, incontinence care, pain management, nutrition, weight monitoring, infection control, and diabetic care.
 - **Corporate Integrity Agreement** required Willowcrest:
 - to hire a full-time physician assistant or nurse practitioner to be responsible for care of residents on a full-time basis, at a minimal annual cost of \$120,000, in order to supplement monthly physician's visits required under federal regulations.
 - to retain an independent monitor, approved by the government, to assess the effectiveness, reliability, and thoroughness of Willowcrest's quality control systems, training programs, and monitoring and corrective action.
 - to implement an enhanced corporate compliance program, appoint an internal Compliance Officer, create a Quality Assurance Committee, and provide annual training to employees on compliance with federal and state health care regulations, directives, and guidelines.



DOJ/OIG Quality of Care Enforcement

- Pleasant Care (March 2006)
 - **District:** State of California
 - **FCA Settlement Amount:** \$1.3 million (CA state FCA).
 - to resolve allegations that the company failed to meet **professionally recognized standards of care** with respect to (1) patient care planning and assessments; (2) nurses' signal systems; (3) medications and treatments; (4) prescription drug orders; (5) skin care protocols; (6) resident supervision; (7) resident hygiene; (8) monitoring of medical conditions; and (9) required staffing levels under state law.
 - The allegations, stemmed from 2 patient deaths in one of Pleasant Care's 30 nursing homes in California.



DOJ/OIG Quality of Care Enforcement

- **Life Care Centers of Laurenceville** (December 2005)
 - **District:** Northern District of Georgia
 - **FCA Settlement Amount:** \$2.5 million
 - **Corporate Integrity Agreement:** Life Care was required to enter into a 5-year CIA.
 - *Qui tam.* Settlement agreement resolved allegations that LifeCare billed for services that either were not provided or were worthless.
 - alleged severe understaffing, inadequate staff training, high staff turnover, an ineffective medical director, poor nursing documentation, and insufficient budgetary allowances, which resulted in a systemic failure to provide adequate care to residents.



DOJ/OIG Quality of Care Enforcement

- **American HealthCare Management (October 2005)**
 - **District:** Eastern District of Missouri
 - **FCA Settlement Amount:** \$1.25 million
 - American Health Management and three of its facilities were permanently excluded.
 - numerous residents of the three homes suffered dehydration and malnutrition, went long periods without cleaning or bathing, and contracted preventable pressure sores.
 - insufficient staff to meet the residents' needs and submitted false claims for payment when the facilities failed to provide the federally-required standard of care.



Compliance Challenges

- Management acknowledgement that regulatory enforcement focus is assuring resident quality of care on metrics known to clinical staff.
- Empowering **Clinical leadership** is key determinant in successful compliance program.
- Meeting professionally recognized standards of care.
- How is compliance to manage enforcement risk different than Quality Assurance Activities?
- Are QAPI Models sufficient for today's risk?
- How is Compliance and QAPI best coordinated?
- Are clinical leaders provided sufficient training, information and resources to manage risk?
- Are clinical managers at risk for licensure or other enforcement?

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