The Merged Vision of Quality and Compliance

HCCA Compliance Institute 2015

AGENDA

- From the “old” compliance paradigm to the “new” reality
  Diana Salinas, Senior VP & Chief Compliance Officer, Rideout Health

- A data driven approach to the quality compliance continuum
  Monica Arrowsmith, Vice President, Quality Management and Patient Safety, Rideout Health System

- Quality of care enforcement update
  David Hoffman, President, David Hoffman & Associates
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

▶ The Affordable Care Act raises the bar for:
  ▶ Compliance Programs
  ▶ Quality of Care
  ▶ Reimbursement

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Healthcare providers are struggling to withstand an era where quality and fiscal accountability at every level is no longer a goal, but a mandate.
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Will your Compliance Program survive this challenge?

How does your Compliance Program comply with this mandate?

What does this mean for your Compliance Program of the future?

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Will your Compliance Program survive this challenge?

- Is your compliance program restricted to a focus on liabilities related to false claims, upcoding, and other billing wrongdoings?

- Does your compliance program operate parallel but apart from the fundamental activities of your hospital or system?

- Does your compliance program contribute to clinical processes of care for the patients you serve?
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

DESIGNING THE REGULATORY COMPLIANCE COMMITTEE INFRASTRUCTURE

Key Institutional Partners:
- Chief Compliance Officer / Privacy Officer
- VP Quality and Patient Safety
- VP Revenue Cycle
- Corporate Director IT / IT Security
- Director HIM and Coding
- Director Patient Access
- System Risk Manager
- System Case Manager
- System Pharmacist
- System Pathology Lab
- Internal Audit
- Associate Chief Medical Officer
- Chief Nursing Officer
- Member of the Legal team
- System Hospital Education Lead
- System Credentialing Lead
- System Managed Care Lead
- Public Safety Lead
- Lead System Physician Resident
- Associate Chief Financial Officer

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

How does your Compliance Program comply with this mandate?

- More coding and billing audits?
- Step up compliance policing?
- Generate more policies to address the multiplying statutory, contractual, regulatory, mandated reported sentinel events, pay-for-performance, etc.?
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

What does this mean for your Compliance Program of the future?

- While a Compliance Program is regulatory driven, being compliant is quality dependent, and requires the implementation of a merged quality and compliance enforcement strategy by both the quality management sector and the compliance program of your organization that goes beyond the typical roles of quality assurance, quality control, and traditional compliance programs.

- It must include the development of an ethical culture that merges compliance, quality and patient safety in order to permeate the organization with a mindset of continuous quality improvement.

- The shift to this paradigm can help maintain the focus on the sustainability of high quality care in a compliant environment.

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Compliance-Quality connection is vital to the essential purpose of the health care enterprise:

- Overall goals of healthcare reform and the Affordable Care Act is to get us moving from a fragmented healthcare delivery system to a less cost and more efficient integrated model.

- Transcending silos MUST happen to help hospitals achieve coordinated delivery of care that will improve quality and overall efficiency of the institution.

- As health care gets more and more patient centric and quality driven this will increase in importance.

- Shared responsibility for building a continuously sustainable quality, compliance and ethical health care system environment

The stakes are high - every missed opportunity for improving health care results in unnecessary suffering.
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

TRANSCENDING SILOs:

- By breaking down silos between departments, hospitals can create collaborative teams that can effectively improve patient safety, especially during transitions of care, quality, compliance and protect reimbursement. The many intersections between Patient Access, Quality, Credentialing, HIM, Coding, Risk Management, Compliance and Revenue Cycle make them ideal departments to integrate, and staff from these departments can work together to reach common goals of efficiency, quality and compliance. This integrated model will be a key feature of hospitals on the cutting edge of care delivery as the healthcare industry moves toward a more coordinated system of care.

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Appreciating the relationship between quality, risk management, patient safety and compliance is not new:

- 1999 - To Err is Human: Building a Safer Health System
- 2001 - Crossing the Quality Chasm: A New Health System for the 21st Century
- 2012 - Best Care at Lower Cost - The Path to Continuously Learning Health Care in America
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

- Medical Staff is key to quality patient centric care - hospital Medical Staff should develop a “quality literacy” regarding patient safety, clinical care, compliance and healthcare outcomes.

THIS IS NOT AN EASY ASSIGNMENT FOR PHYSICIANS!

From the “old” compliance paradigm to the “new” reality

As Compliance Officers:

- How are you aligned with Quality, Risk Management and Medical Staff?
- Do you know how rigorously peer review is practiced in your hospital?
- What are the indications for external peer review?
- Are summary results presented to the Board?
- Are you assured of the fairness and consistency of the process?
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

The cautionary tales of the fraud and abuse cases such as Redding and St. Joseph Medical Center require hospitals operating in the current enforcement environment to ask questions including:

(1) How did the hospital’s process fail to address these quality and compliance issues?
(2) Why was there an apparent failure in communication between the peer review process and the compliance function? and
(3) What can be done to avoid ending up in similar circumstances?

COMPLIANCE OFFICERS - DON’T BE SCARED TO ASK NON-TRADITIONAL COMPLIANCE QUESTIONS!

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

- Board engagement
- Develop metrics and regular reporting to keep the Board informed about quality improvement activities and the relationship to compliance:
- Quality continues to emerge as an enforcement priority for health care regulators
- Conditions of Participation
- OIG, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors
Where’s the data?

Compliance can find itself isolated from the strategic and operational center of the organization.

FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Compliance should be knowledgeable about how data quality is controlled and monitored – best case scenario compliance officers/offices receive regular reporting on data quality.

Compliance should be active in data governance programs.
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

How can a compliance officer effectively integrate quality-oriented issues into workflow?

- **Teamwork**
  - Develop a strategy to work with the risk management and quality improvement departments to determine where compliance ought to be involved.
  - Participate in efforts to monitor how standardization of care along good clinical practice guidelines can facilitate meeting the new standards
- **Quality data needs to be a critical focus of attention.**
  - Become familiar with the quality metrics, report card, and transparency initiatives applicable to your enterprise.
  - Find out who is reporting what, to whom, and how often.
  - Develop effective techniques to monitor these reports over time for accuracy, completeness, and as sentinels or leading indicators of risk.
FROM THE “OLD” COMPLIANCE PARADIGM TO THE “NEW” REALITY

Questions

Comments

Opinions

It’s Not Easy!

• What is quality?
• How do you know if you have or have not experienced or received quality healthcare?
• What about this “quality” of care is significant from a compliance perspective?
QUALITY: THE HOLY GRAIL

- National Quality Agenda
- The Triple Aim: Better Health, Better Care, Lower Cost
- QIO's / LAN's; P4P / HEN
- NQF, AHRQ, IOM, IHI, etc.
- CMS Innovation Center
- HHS Incentive / Penalty Programs (MU, HQRPAU, VBP, Readmission Reduction, HAC)

HHS Goal: Better Care. Smarter Spending. Healthier People:
Paying Providers for Value, Not Volume

WHAT IS QUALITY?

IOM / WHO Dimensions
- Safe
- Effective
- Patient / Family Centered
- Timely
- Efficient
- Equal
- Accessible

Compliant Care
- Conditions of Participation
- Clinical Legal Operations
SAFE CARE & COMPLIANCE

- Risk Management & Patient Safety
  - Adverse Events & Reporting Requirements
  - Complaints & Grievances
  - Sentinel / Significant / PCE's
  - HAC's and HAI's

Spotlight: Patient Falls
- A 72 y/o male patient falls on 3M, breaks his hip, has surgery to repair it, due to the fragility of his elderly bones, a secondary fracture occurs during surgery (a known risk), prolonging his stay.
- Falls data shows a cluster of falls occurred on one unit during previous month; none caused harm, but one resulted in a grievance.

EFFECTIVE CARE & COMPLIANCE

- Traditional “Quality”
  - Where there is known care that has been proven effective for most patients.
  - “Core” Measures for Annual Payment Update (AMI, HF, Pneumonia, etc.)
  - Standard of Care in particular instances (blood transfusion for low H/H; antibiotic for bacterial infection)

Spotlight: Venous Thromboembolism (VTE)
- Patient was admitted for pneumonia; during stay patient condition worsened and ended up in ICU for a pulmonary embolism; on review, VTE prophylaxis had not been ordered.
- Further review of data shows historic underperformance (less than 50th percentile) of this metric
### EFFICIENT CARE & COMPLIANCE

**Process Improvement (Lean) & Utilization**
- PI / Lean focuses on eliminating waste – non-value-added components of healthcare
- The single, most expensive category of cost in healthcare is waiting.
- Utilization encompasses use of services.

**Spotlight: Cardiac Cath**
- Patient is hospitalized as observation (outpatient) for chest pain; On day 2 of stay, cardiologist decides to cath the patient, which is done on day 4 due to “scheduling conflicts.”
- Upon data review, the hospital’s clean coronary rate is noted to be 47%; national average is 18%.

### LEGAL CARE & COMPLIANCE

- Significant regulatory agency oversight of patient care operations
  - CMS – CoP’s and program requirements
  - DEA
  - DOJ
  - FDA
  - OCR
  - State Law Counterparts

**Spotlight: Cardiac Rehab Program**
- During routine internal “tracer,” quality staff discovered cardiac rehab program was not compliant with “immediately available” requirement and never had been; no safety events had occurred and patients had been well cared for.
GETTING YOUR ARMS AROUND IT

- Standing Quality – Compliance Meetings
  - Quality – Compliance Checklist

- Compliance participate on Key Groups
  - Quality Council / Oversight Committee
  - PI Oversight Team (EPIC)
  - Utilization Meeting

- Compliance and Quality co-lead RCC
  - Regulatory Compliance Monitoring Reports
  - Regulatory Activity Reports

QUALITY COMPLIANCE CHECKLIST

Quality-Compliance Connection Points

03/09/15

The following quality events are those that may be of significance from a corporate compliance perspective and, as such, will be shared with Compliance as incurred or during our periodic, regularly scheduled Quality-Compliance forums.

- Suspected Patient Abuse or Neglect
- State Reportable Adverse Events (as per Adverse Event Reporting Law)
- Unusual Events (under CDPH reporting requirement)
- Service Disruptions
- CoP Failure Trends (substantial & resistant non-compliance)
- Quality Failures
  - Hospital Acquired Condition (consistent with HAC / POA program)
  - Substandard Care (trends, PCE’s, risk event clusters, etc.)
  - Care Discrepancies
  - Errors resulting in RCA
REGULATORY COMPLIANCE REPORT

Patient Care Documentation Review: This audit consists of 11 questions, covering adequacy of care plan documentation, physician orders implemented, physical notification of missed medication/treatments, patient education, patient weights, pain assessment, and Activity of Daily Living (ADLs). Conducted across 10 patient care units, this audit uses chart review, with each response yielding a yes or no. Denominators reflect total responders and numerators reflect those with a yes response.

Analysis and Action Plan: Opportunities identified during the Patient Care Documentation Review include: medication issues not given as ordered, MD not notified if not given or held (20/85 = 23%), critical values reports (12/13 = 92%), height assessment and monitoring (24/86 = 28%), pain assessment/assessment (57/107 = 91%), and patient teaching (542/613 = 90%). Nurse managers worked with the staff involved in non-compliance, the physicians, and the patient education. These areas were discussed at monthly staff meetings. A daily report is now being sent to nurse managers, charge nurses, and clinical coordinators, listing patients that did not have admission weights documented for correction. All other indicators met at 95% or above.

REGULATORY ACTIVITY REPORT

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<th>Date of Visit</th>
<th>Surveyor(s) Name</th>
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THEORIES OF PROSECUTION
“QUALITY OF CARE/FAILURE OF CARE” CASES

▶ Express Certification Theory
▶ Implied Certification Theory
▶ Worthless Services Theory

FALSE CLAIMS ACT VIOLATIONS

When a defendant **knowingly** bills for health care (goods or services) that was:
▶ Not rendered,
▶ Medically worthless, or
▶ Violated a statutory, regulatory or contractual provision with a nexus to payment

▶ Nursing Homes---heavily regulated; ALFs—state-by-state regulatory framework
ARE “FAILURE OF CARE CASES” APPROPRIATE FOR FCA THEORIES?

- Civil War Era--Food that was rotten; guns that would not shoot based on poor quality gun powder; lame mules provided instead of horses

- Case law on “worthless or nonexistent” services
  An entity may not bill the government for nonexistent, worthless, or grossly substandard services

“WORTHLESS SERVICES”

- When does a “failure of care” equal a “worthless service”?

Parameters:
- Evidence of egregious care that rises to the level of actionable neglect;
- Systemic or widespread problems;
- Evidence of significant risk/actual harm to residents.
US EX REL. MIKES V. STRAUS
274 F.3D 687 (2D CIR. 2001)

- The Ninth Circuit’s recent decision in United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048 (9th Cir. 2001), is the leading case on worthless services claims in the health care arena. In Lee, the relator alleged that defendant, an operator of regional clinical laboratories, falsified laboratory test data when test results fell outside the acceptable standard of error. Id. at 1050. The Ninth Circuit held that the false certification theory addressed in Hopper, 91 F.3d 1261, was only one form of action under the Act, and that the district court should have considered the distinct and separate worthless services claim. Lee, 245 F.3d at 1053. As the Ninth Circuit explained, “[I]n an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729 [of the False Claims Act], regardless of any false certification conduct.” Id. We agree that a worthless services claim is a distinct claim under the Act. It is effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. See Fabrikant & Solomon, supra, at 111-12. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all.

EXAMPLES OF DEFICIENT CARE

- Residents with diabetes not having their blood glucose levels monitored on a regular basis and suffering adverse consequences
- Residents developing pressure ulcers based on a lack of a wound care program/treatment of wounds wholly inadequate and allows wounds to worsen
- Typically, NOT a one-time event
CASE LAW REVIEW

*United States v. Villaspring Healthcare Center*, the Court found:

Although it is true that a worthless services claim is not easy to establish in the context of nursing home services, the defendants' articulation of the situation is an exaggeration of what is required. It is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that “patients were not provided the quality of care” which meets the statutory standard. *United States v. NHC Healthcare Corp.*, 115.Supp.2d 1149, 1153 (W.D. 2000) (NHC Healthcare II ). A per diem billing arrangement presupposes that a nursing facility will agree to provide “the quality of care which promotes the maintenance and the enhancement of the quality of life.” 42 U.S.C. §1396r(b)(1)(A).

VILLASPRING/NHC

However,

- [a]t some very blurry point, a provider of care can cease to maintain this standard by failing to perform the minimum necessary care 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.

U.S. EX REL. ACADEMY HEALTH CENTER, INC. V. HYPERION FOUNDATION, INC.

- Southern District of Mississippi—2014
- Government intervened in qui tam case
- “[C]ourts have recognized that worthless services claims under the FCA are not, as a legal matter, limited to instances where no services at all are provided. A service can be worthless because of its deficient nature even if the service was provided.”

U.S. EX REL. ABSHER V. MOMENCE MEADOWS NURSING CENTER

- 7th Circuit—2014
- Allegations: Inadequate care and falsification of records
- 2 former nurses (one whose mother was in the facility) alleged that the facility failed to provide care on a routine basis, including failing to deliver medications, failing to provide a sanitary environment etc.…and then forged, concealed and destroyed medical records to subvert the survey process.
MOMENCE (CONT’D)

► Scabies outbreak---hid the logs from surveyors that evidenced when the outbreak started and who was affected
► Government declined to intervene
► Jury verdict---$28 million against nursing home and former owner
► Judge reduced the verdict to $9 million

MOMENCE (CONT’D)

► 7th Circuit reversed—judgment to be entered for Momence Meadows
► Flaws in relators’ case---No definitive damages model presented to jury---Need false claims in a FCA case
► No link of MDS forms with claims
► Plan of Correction misrepresentations
ORAL ARGUMENT

- Panel member: “No one wants to be in a nursing home”
- Noted that scabies occurs in nursing homes; BUT RESIDENTS KEPT GETTING THEM REPEATEDLY
- Disregarded the concealment of the logs from surveyors/MDS forms require check if resident have scabies—not done
- Wondered why if the facility was so bad, relator’s mother stayed in the nursing home

MOMENCE OPINION

- The Court did not address the validity of the worthless services theory but found that to succeed on a “worthless services” claim under the FCA, “the performance of the service [must be] so deficient that for all practical purposes it is the equivalent of no performance at all.” Momence at p. 18 (citations omitted).
- “It is not enough to offer evidence that the defendant provided services that are worth some amount less than the services paid for. That is, a ‘diminished value’ of services theory does not satisfy this standard. Services that are ‘worth less’ are not ‘worthless.’”
- The Court, however, offered no citations associated with this statement.
MOMENCE OPINION (CONT’D)

“any such claim [worthless services] would be absurd in light of the undisputed fact that Momence was allowed to continue operating and rendering services of some value despite regular visits by government surveyors. The surveyors would certainly have noticed if Momence was providing no or effectively no care to its residents.”

CRIMINAL CASES

U.S. v. Houser--11th Circuit 2014
Criminal worthless services case

“[M]edications were not available for residents because [Mr. Houser] had not paid the pharmacy bill. On some occasions, the nurses ‘borrowed’ the medications from one resident and gave those to another resident[]. . . . On other occasions, the residents never received the medications they were supposed to have.”

“Numerous witnesses testified that all three nursing homes frequently ran out of diapers, wound care supplies, and basic nursing supplies.” Laboratory services that had been ordered by a physician, including those for patients on dialysis, were not performed because the bills for such services went unpaid.”
CRIMINAL CASES

“The homes went without blood sugar testing devices and strips necessary to monitor diabetic patients. Patients went without dialysis because the transportation company refused to service the homes due to unpaid bills. Facilities also were without medical directors and physical therapy services for significant periods of time.

The administrators at the facilities informed Mr. Houser and Washington that failure to pay the bills for these services was placing the patients at risk and the homes in jeopardy of closure.”

HOUSER (CONT’D)

Resident care directly suffered as a result of staffing shortages. Residents and their beds were soaked with urine or caked in feces because diapers were not changed. “The short staffing problem became more severe on paydays, when employees raced to the bank or stood in line to cash their checks at the money van.”

Insufficient food was a significant problem because Mr. Houser failed to pay food vendors. Residents were given small, nutritionally inadequate meals and often little or no milk. “Residents with special dietary needs often did not receive protein shakes, other dietary supplements, or required therapeutic meals.” Residents regularly complained to both the staff and relatives that they were hungry.
SURVEY PROCESS-HOUSER

- During the relevant period, state officials conducted surveys on an annual basis and also in response to specific complaints. Mr. Houser appeared to have some advance notice of survey times, and he placed calls to facilities instructing them to increase services and staffing levels during those times.

- Ultimately regulators closed down the facilities but the Indictment charges the time from 2004-2007—3 years of criminal conduct.

HOUSER—DAMAGES THEORY

- Worthless services are those that are not provided or rendered, were deficient, inadequate, substandard, and did not promote the maintenance or enhancement of the quality of life of the residents and were of a quality that failed to meet professionally recognized standards of health care.

- The court arrived at this figure after concluding that approximately twenty to twenty-five percent of the services Mr. Houser provided under those programs were “worthless”.
U.S. V KLEIN ET AL.

- Western District of Virginia—June 2014
- RICO conspiracy, wire, mail and health care fraud, conspiracy to make false statements ("filling in the holes")
- The Indictment alleges that the defendants defrauded Medicare and Medicaid by causing: the SNF to operate with insufficient nursing aide staff and supplies; residents to subsist in unsanitary conditions; and residents to receive no or inadequate pressure ulcer treatment. The Indictment also details vendor fraud.
- The Indictment describes with particularity the care of five residents, which the government alleges was so substandard that the patients suffered bodily injury. The indictment also asserts that two defendants coached a witness scheduled to testify before a federal grand jury to say that the facility was not short staffed, and that "we did nothing wrong."

EXTENDICARE SETTLEMENT

FOR IMMEDIATE RELEASE
Friday, October 10, 2014

Extendicare Health Services Inc. Agrees to Pay $38 Million to Settle False Claims Act Allegations Relating to the Provision of Substandard Nursing Care and Medically Unnecessary Rehabilitation Therapy

- Extendicare Health Services Inc. (Extendicare) and its subsidiary Progressive Step Corporation (ProStep) have agreed to pay $38 million to the United States and eight states to resolve allegations that Extendicare billed Medicare and Medicaid for materially substandard nursing services that were so deficient that they were effectively worthless and billed Medicare for medically unreasonable and unnecessary rehabilitation therapy services, the Justice Department and the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) jointly announced today. This resolution is the largest failure of care settlement with a chain-wide skilled nursing facility in the department’s history.
- As part of this settlement, Extendicare has also been required to enter into a five year chain-wide Corporate Integrity Agreement with HHS-OIG. Extendicare is a Delaware corporation that, through its subsidiaries, operates 146 skilled nursing facilities in 11 states. ProStep provides physical, speech, and occupational rehabilitation services.
- $28 million =worthless services claims
THE FUTURE

- Active investigations into “failure of care” cases
- Theories of liability
  - MDS misrepresentations
  - POC/fraud in the inducement
- Challenges surrounding damages models
- Root of these cases grounded in improving care and protecting residents
- “Quality of Care Corporate Integrity Agreements”—improve resident care through systemic changes
- Do we need to fix the survey and certification process?
  - YES!