Highlights of the CMS Final Rule: The Impact on Compliance

21st Annual Compliance Institute
March 27, 2017
Presenters: Kris D’Ann Maples and Lyn Bentley

Kris D’Ann Maples, Esq.

- 19 years in Healthcare field
- Currently In-House Counsel and Compliance Officer at Hillcrest Health Services. Hillcrest is a mid-size, aging service provider in eastern Nebraska and western Iowa providing independent living, assisted living, memory support, skilled nursing, post-acute/patient rehab, home care and hospice services. Operates the first CCRC in the region.
- Prior to joining Hillcrest, served as general counsel at multi-state, multi-national intellectual disability services provider.
- Also worked as the VP Risk Management/Compliance Officer and VP of Human Resources at large multi-state human, social and aging services providers.

Lyn Bentley, MSW
Vice President, Quality & Regulatory Affairs
AHCA

- 28 years focused on Aging Policy/Long Term Care
- Assisted Living Specialist, FL Dept. of HRS; Aging Policy Specialist in Florida Senate; Director of Government Affairs, Marriott Senior Living Services
- Since 2001, AHCA/NCAL: Senior Policy Director, NCAL; Senior Director Regulatory Services, AHCA; VP, Quality & Regulatory Affairs
Overview of Requirements of Participation

Themes of the Rule

• Person-Centered Care
• Facility-Based Responsibility
  • Assessment/Staffing, Competency-Based Approach
    • Know Your Center, Know Your Patients, Know Your Staff
• Quality of Care & Quality of Life
• New/changed evidence-based practice
• Care Planning
  • Patient goals
  • Patient as the locus of control

Themes of the Rule

• Changing Patient Population
• Acuity
• Behavioral Health
• Reflects dramatic cultural & technology changes over three decades
Alignment with HHS Priorities

Advancing Cross-Cutting priorities:

• Reducing unnecessary hospitalizations
• Reducing the incidences of healthcare acquired infections/adverse events
• Improving behavioral healthcare

Alignment with HHS Priorities

Advancing Cross-Cutting priorities:

• Safeguarding nursing home residents from the use of unnecessary psychotropic (antipsychotic) medications
• Care Planning
• Quality Assurance & Performance Improvement
• Health Information Technology/IT Interoperability

Impact of New RoPs on Survey Process

• CMS developing a new survey process
• Merges QIS with traditional survey
• Incorporates new RoPs
• Goes into effect in Nov 2017
Added New Definitions

- “abuse”
- “adverse event”
- “exploitation”
- “misappropriation of resident property”
- “mistreatment”
- “neglect”
- “person-centered care”
- “resident representative”
- “sexual abuse”

Resident/Patient Rights (§483.10)

- Grievances, inform how to file and who may be contacted to file
- Identify a grievance official responsible for the process, including:
  - Receiving & tracking;
  - Leading investigations;
  - Maintaining confidentiality;
  - Issuing official decisions to the resident;
Resident/Patient Rights
(§483.10)
(Grievance Official responsibilities)
• Coordinating with State and Federal agencies;
• Preventing further violations while investigations are taking place;
• Documentation requirements; and
• Meeting all applicable State and Federal, laws and regulations.
• Facility must establish a grievance policy

Freedom From Abuse, Neglect & Exploitation
(§483.12)
• Formerly “Resident Behavior & Facility Practices”
• Definition of abuse: actions such as the willful
infliction of injury, unreasonable confinement,
imimidation, or punishment with resulting physical
harm, pain or mental anguish.
• Includes verbal, sexual, physical, and mental
abuse including abuse facilitated or enabled
through the use of technology.

• Use of “willful” in the definition means the
individual must have acted deliberately, not that
they must have intended to inflict injury or harm.
Freedom From Abuse, Neglect & Exploitation (§483.12)

- Report violations to State Agency and Adult Protective Services (per state law) immediately/not later than 2 hours if allegation of abuse or if serious bodily injury—24 hours, if no abuse and does not result in bodily injury.
- Expands employment ban to professional who has current disciplinary action against their license.
- Phase 2: Establish policies and procedures to ensure the reporting of crimes in accordance with section 1150 B of the act, with associated penalties for failure to act (Elder Justice Act).

Notifications (in Resident Rights (§483.10)

- Must send a copy of all notices of transfer or discharge to LTCO including reasons for the move
- Notification 60 days prior to increase in any charges not paid by Medicare or Medicaid
- At time of admission, and periodically during resident’s stay, services available in the facility and any associated charges

Regulatory Timing

- Proposed Rules were published July 16, 2015
  - Phase I regulations effective November 28, 2016
  - Phase II regulations effective November 28, 2017
  - Phase III regulations effective November 28, 2019
• There is now a new section in the Rules of Participation for SNFs entitled “Compliance and Ethics Program” - §483.85.

• Note: With the change in the administration and plan to abolish ACA, be on alert to changes in the regulations prior to the implementation dates for each phase.

• Past OIG Guidance for nursing centers was published in 2000 and 2008 have now been codified and compliance will be part of survey process.

• The operating organization for each facility must have a compliance and ethics program that meets the requirements outlined in §483.85 (a) & (c) by November 28, 2017. However, the entire Compliance and Ethics section [presumably that includes §483.85 (d) and (e) as well as (a) and (c)] must be implemented by November 28, 2019.

• Written compliance and ethics standards, policies and procedures that are “reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the act and promote quality of care”

• Corrective/Disciplinary standards that outline consequences of committing violations
  - Which are enforced consistently for all of the operation’s staff, contractors, and volunteers
  - Includes consequences for failure to detect or report a violation.
Minimum Components of Program
- Designate “appropriate” compliance and ethics program contact
  - Can report suspected violations
  - Means to report anonymously without fear of retaliation
- Designated contact reports to “high level” individual in organization who oversees compliance and ethics program for the organization.
  - CEO
  - Board
  - Director “of major division”

Minimum Components of Program
- Devote “Sufficient resources and authority” to the designated contact and designated high level overseer to “reasonably assure” program standards, policies and procedures are being met.
  - Level in organization and authority granted that individual?
  - Time devoted to compliance and ethics program?
  - Budget?

Minimum Components of Program
- Take “due care” to not delegate discretionary authority to individuals in the organization who the organization knew or should have known had a propensity to engage in potential civil or criminal violations under the FCA.
  - Background checks?
  - Past behavior?
Minimum Components of Program

- Take steps to “effectively” communicate standards, policies and procedures “in a practical manner”
  - Mandatory one time training for all new and existing staff, contractors and volunteers
  - Mandatory annual training if organization operates 5 or more facilities

Response taken after a violation:
- All “reasonable steps” to respond “appropriately” to prevents future similar violations
- Includes tweaking monitoring and auditing practices to detect violations

Annual Review of Program

By Phase III effective date:
- Annual review of program to make changes to:
  - Reflect any changes in applicable laws and regulations
  - Improve performance in “detering, reducing and detecting” FCA violations
  - Improve performance in promoting quality of care
**Additional Requirements**

By Phase III effective date:

- Additional requirements if have 5 or more facilities:
  - Annual compliance training for all staff members outlined in §483.95(f)
  - Designated compliance officer whose “major responsibility” in operating the organization’s compliance program.
  - Must report directly to organization’s “governing body”
  - CANNOT report to General Counsel, CFO or COO
  - “Compliance Liaisons” at each facility

---

**Questions**