Highlights of the CMS Final Rule: The Impact on Compliance

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– 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/outpatient 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
  - 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

Implementation Timeline

<table>
<thead>
<tr>
<th>Implementation Date</th>
<th>Type of Change</th>
<th>Details of Change</th>
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<tbody>
<tr>
<td>Phase 1: November 2016</td>
<td>Effective date of new LTC Requirements for Participation</td>
<td>New Regulatory Language under current F Tags</td>
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| Phase 2: November 2017 | • Appendix PP of State Operations Manual  
  • Implement new survey process | • New F Tag numbers  
  • Interpretive Guidance (IG) Changes  
  • Begin surveying with the new survey process |
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, intimidation, 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.
Freedom From Abuse, Neglect & Exploitation (§483.12)

- Use of “willful” in the definition means the individual must have acted deliberately, not that they must have intended to inflict injury or harm.

- 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

• Final Rules published October 4, 2016.
  – Phase I regulations effective November 28, 2016
  – Phase II regulations effective November 28, 2017
  – Phase III regulations effective November 28, 2019
Compliance & Ethics

- 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.

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Compliance & Ethics

- 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.**
Minimum Components of Program

- 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

Minimum Components of Program

- 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