Highlights of the CMS Final Rule: The Impact on Compliance

21st Annual Compliance Institute

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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/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.

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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

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Overview of Requirements of Participation

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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

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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

Implementation Date	Type of Change	Details of Change
Phase 1: November 2016	Effective date of new LTC Requirements for Participation	New Regulatory Language under current F Tags
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

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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;

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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.

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
- 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**.

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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

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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"

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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?

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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?

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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

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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

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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 "deterring, reducing and detecting" FCA violations
  - Improve performance in promoting quality of care

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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

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Questions

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