IASC
CMS Final Rule: Requirements for Participation (RoP): The Good, the Bad and the Ugly

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February 8, 2017
Phase I is Here
CMS Goals

- Person-centered case/resident rights
- Staffing & Competency
- Quality of Life/ Quality of Care (including care goals and discharge planning)
- Facility Assessment
- Adverse Events

Note: This presentation is not intended to be all-inclusive but highlights just some of the many changes mandated by the 105-page Federal regulation (81 Fed. Reg. 68848, October 4, 2016).
Overview

- Final Rule Published October 4, 2016, Federal Register
- Almost 10,000 comments to Proposed Rule (July 2016)
- Most sweeping change in LTC since 1991

- Phase-In:
  - Phase 1 November 28, 2016
  - Phase 2 November 28, 2017
  - Phase 3 November 28, 2019

- Cost (according to CMS):
  - $62,900 first year
  - $55,000 each successive year
Prohibition on Pre-dispute Arbitration Agreements – Most Legally Controversial Aspect of Final Rule

- Final Rule prohibits pre-dispute arbitration agreements
- AHCA (others) sued CMS seeking to enforce rights, including the right to enter into pre-dispute arbitration agreements in accord with the FAA.
- District Court issues injunction
- Case currently on appeal
“We are taking this step to stop what is a clear overreach by CMS. Federal Law plainly prohibits CMS from issuing this type of regulation.” – Mark Parkinson, CEO, AHCA

“It appears to this court that the Rule enacted by CMS in this case crosses the line.

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Congress did not enact the Rule in this case; a federal agency did, and therein lies the rub.”

– Judge Michael P. Mills, U.S. District Court, Northern District of Mississippi (November 7, 2016)
Phase 1- November 28, 2017

Abuse, Neglect, Exploitation, and Misappropriation of Property
Admissions
Visitation Rights
Grievance Policy/Grievance Officer Appointment
Advance Directives
Room Change
Notification of Clinician
Bed Hold and Return
Transfer Process
Discharge Summary
PASARR
CPR
Bed Rail Assessment
Checklist/Process to Ensure Monitoring Variances in Resident’s Mood and Behavior
Drug Regimen Policy
Use and Storage of Food/Beverages Brought by Family and Others
Bed Inspection Policy

Source: LeadingAge, CMS Final Rule Update, January 3, 2017,
Definitions
42 CFR 483.5

- CMS has added definitions to the following terms: “abuse,” “adverse event,” “exploitation,” “misappropriation of resident property,” “mistreatment,” “neglect,” “person-centered care,” “resident representative,” and “sexual abuse.”

- CMS notes that regarding the definition of “abuse,” “willful’ means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.”

- CMS further defines “abuse” as including mental abuse “facilitated or enabled through the use of technology.” Thus, inappropriate use of social media could constitute abuse.

- Tip: Consider Drafting/Revising Appropriate Social Media Policies & Procedures. (See NLRB Decisions, Guidance)
In addition to documenting the reasons for a transfer or discharge in a resident’s medical record, facilities must also document and exchange specific information with the receiving facility.

The provisions for involuntary discharge remain the same (e.g., the health of individuals within facility is endangered; the resident no longer needs skilled nursing care; transfer is necessary for the resident’s welfare and the resident’s needs cannot be met; the resident has failed “after reasonable and appropriate notice, to pay for [or to have paid under Medicare or Medicaid] for a stay at the facility;” or the facility ceases to operate.)
Facility Assessment

- Beginning in Phase 2 (November 2017), SNFs must maintain a detailed, written facility assessment that provides the basis for determining compliance in key areas, such as whether nurse staffing is sufficient, staff in-service training, QAPI activities, compliance programs, and emergency preparedness.
- SNFs must undertake a “facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies.”
- The assessment includes both a facility-based and a community-based risk assessment (different from person-centered approach to care)
Facility Assessment –
Effective November 2017

- Each facility assessment must consider and address the following:
  - Resident population (including number of residents, types of care required, diagnoses, overall acuity, cognitive functioning, etc.);
  - Staff competencies required to meet the needs of the resident population;
  - Physical environment, equipment, and services needed to provide care;
  - Ethnic, cultural, or religious factors; Facility resources, including buildings, vehicles, and equipment;
  - Services provided by the facility, including therapies and medications;
  - Personnel and their education and training;
  - Contracts and other third-party agreements for services and/or equipment; and Health information technology resources.
- Facilities will need to review and update the assessment at least annually and “when they believe it is appropriate.”
- Nursing facilities should anticipate that the facility assessment will be a focus for surveyors.
- The Final Rule includes only minimal information on expectations for the assessment’s content and level of detail, expect to see future guidance in the SOM.
Facility Assessment –
Effective November 2017

- No one-size fits all approach
- Facilities should allow for diversity in their populations
- Focus should be (as already required) that each resident achieves their “highest practicable physical, mental and psychosocial well-being.” 42 CFR 483.25, F309
Facilities must develop and implement “a baseline care plan” for all new residents within 48 hours of admission with a focus on “effective and person-centered care that meets professional standards of quality care.” Additionally, a member of the food and nutrition services and a nurse aide must be part of the interdisciplinary team that develops the comprehensive care plan.
Attending physicians may delegate responsibility for writing therapy orders to qualified therapists in accord with their state’s scope of practice. Likewise, physicians may delegate responsibility to licensed dieticians and other qualified nutritional professionals to write dietary orders.

CMS expects this to provide greater responsiveness to resident needs since these folks interface with residents more often than docs.

CMS emphasizes that this does not relieve the attending physician for overseeing the care of the resident.
CMS added a competency requirement under nursing services. Essentially, the “sufficiency” of the nursing staff must be based on a facility assessment which incorporates factors such as, but not limited to, the number of residents, their acuity levels and scope of diagnoses as well as their needs as noted in their care plans.
A new section will require facilities to provide residents with necessary behavioral services in accord with their comprehensive assessment and plan of care.
“Facilities must have sufficient staff to provide direct services to residents with the appropriate competencies and skill sets…” These competencies and skill sets include:

- Caring for residents with psychological and mental disorders as well as residents with a history of trauma and PTSD
- Implementing non-pharmacological interventions
- Residents with dementia must receive “appropriate treatment and services to attain his or her highest practicable physical, mental, and psychosocial well-being.” Query: who defines “appropriate”? 
Pharmacy Services
42 CFR 483.45

- Monthly Drug Regimen Review (DRR) is already required. The Final Rule expands this to require the pharmacist to review the medical records of each resident concurrently with the monthly DRR and to report irregularities, in writing to the medical director in addition to the DON and attending physician – “and these reports must be acted upon.” This will be phased in in Phase 2.

- Also, in Phase 2 targeting of unnecessary use of psychotropic drugs.
Pharmacy Services
42 CFR 483.45

- The requirements for “antipsychotic drugs” will be changed to “psychotropic drugs.”

- CMS is requiring that psychotropic drugs be eliminated or reduced if not clinically contraindicated. Such a requirement is consistent with good medical practice and the regulations’ current requirement to reduce and/or eliminate unnecessary medications. F329 – unnecessary drugs

- So, what is a “psychotropic drug?”
According to CMS, “A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior.” 42 CFR 483.45

Psychotropic drugs include, but are not limited to:
- Antipsychotics
- Antidepressants
- Anti-anxiety
- Hypnotics
Pharmacy Services
Psychotropic Drug Requirements

- If resident has not used psychotropic drugs, they cannot be given “unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record”

- If a resident has used psychotropic drugs, the facility should attempt gradual dose reductions and behavioral interventions, unless clinically contraindicated.

- Some exceptions apply to PRN orders (e.g., they must be necessary to treat a diagnosed condition as documented in the clinical record and cannot exceed 14 days unless the attending physician or prescriber documents the rationale – “and indicates the duration of the PRN order.”
Laboratory, Radiology & Other Diagnostic Services

42 CFR 483.50 – This is a new regulation

- A licensed nurse practitioner, physician assistant or clinical nurse specialist will be permitted to order laboratory, radiology and other diagnostic services so long as within the scope of practice in their respective states.
Quality Assurance and Performance Improvement
42 CFR 483.75

- CMS is requiring facilities to “develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care and quality of life.”

- The new requirements regarding QAPI are extensive and facilities are advised to become thoroughly familiar with those requirements.

- *Required by Section 6102(c) of the ACA*
Quality Assurance and Performance Improvement
42 CFR 483.75(a)

- The facility must:
  - Maintain documentation and demonstrate compliance with requirements of 483.75
  - Present its QAPI plan to State survey agencies within one year of the regulation
  - Present its QAPI plan to State survey agency or Federal surveyors at each annual recertification survey and “any other survey”
  - Present “documentation and evidence of its ongoing QAPI program’s implementation and the facility’s compliance with requirements to a State survey agency, Federal surveyor or CMS upon request.”
Quality Assurance and Performance Improvement
42 CFR 483.75(b) – Program Design and Scope

- Design of QAPI must be comprehensive and ongoing, addressing all systems of care and management practices
- Must include clinical care, quality of life and resident choices
- Must define and measure quality indicators and facility goals
- Must “reflect the complexities, unique care, and services that the facility provides”
- Facilities “Must establish and implement written policies and procedures for feedback, data collection systems and monitoring, including adverse event monitoring.” (Specific elements required.)
Infection Control
42 CFR 483.80

- Facilities must create an infection prevention and control program (IPCP) that incorporates an “Antibiotic Stewardship” (e.g., monitoring and protocols for antibiotics).
- Facilities must also designate at least one Infection Preventionist (IP). The IP must be qualified by education, certification, training or experience (e.g., epidemiology, medical technology, microbiology, nursing, or other related field) and have completed specialized training in infection prevention and control.
- The IPCP must be implemented in Phase 1 but the Infection Preventionist will not be required until Phase 3 (November 28, 2019).
- The IP responsible for the IPCP is required to be a member of and report to the QAPI committee on a regular basis.
Compliance & Ethics Programs

42 CFR 483.85 – This is a new regulation

- By November 28, 2017, the “operating organization” for each facility must have an operational compliance and ethics program with written policies, standards and procedures aimed at reducing the likelihood of criminal, civil and administrative violations. Facilities must:
  - establish written compliance and ethics standards, P & Ps
  - designate “specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization’s compliance and ethics program”
  - allocate sufficient resources and authority to allow the committee to reasonably ensure compliance with the standards, policies, and procedures developed.
  - exercise due care to avoid delegating substantial discretionary authority to individuals the organization knows or should know have “a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.”
Facilities must:

Effectively communicate the policies and procedures of the operating organization’s compliance and ethics program to all staff, contractors, and volunteers (consistent with volunteers’ roles)

Employ procedures designed to achieve and ensure compliance (e.g., self-auditing and monitoring systems and publicizing the organization’s anonymous reporting system).

Respond appropriately to any detected violation including modification to the program, if necessary, to prevent violations from occurring in the future.

Consistently enforce violation through appropriate disciplinary actions.

Review and revise the compliance and ethics program annually (more often, if necessary).
Compliance & Ethics Programs

42 CFR 483.85(d) – This is a new regulation

- Organizations with five or more facilities have additional requirements, such as:
  - Designating a compliance officer who reports directly to the organization’s governing body (not the CFO, COO or GC)
  - The Compliance Officer’s oversight of the program will be a “major responsibility”
  - Conducting annual mandatory training on the organization’s compliance and ethics program
  - Designate compliance liaisons at each of the organization’s facilities
  - Conducting annual reviews at each facility with revisions as necessary
    - Required by Section 6102(b) of the ACA
Facilities constructed, reconstructed or newly certified after November 28, 2016 may accommodate no more than two residents per room and must also have a bathroom with a commode and a sink in each room.

Policies regarding smoking, smoking safety and smoking areas must comply with all federal, state and local laws, regulations, codes and also consider non-smoking residents.

CMS has provided guidance regarding smoking, see, CMS S & C Memo, *Smoking Safety in Long Term Care Facilities*, 12-04-NH, (November 10, 2011)

Training Requirements
42 CFR 483.95 – this is a new regulation

- Facilities will be required to provide training regarding dementia management, resident abuse and care of cognitively impaired residents.

- Section 6121 of ACA
Training Requirements

The Final Rule requires that “all new and existing staff, individuals providing services under a contractual arrangement and volunteers, consistent with their expected roles” must be trained.

CMS defines “direct care staff” as “Individuals who, through interpersonal contact with residents or resident case management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental and psychosocial well-being.”

Tip: Expect surveyors to focus on this aspect of the Final Rule (after guidance in the SOM).
Cost of Noncompliance

- CMS is now authorized to impose a CMP of up to $20,628 per day (CMP Inflation Adjustment Act) and amount will increase annually
- Be proactive
- Educate staff
- Read SOM, Appendix PP
- Track CMS Survey & Certification Memos
“Implementation of broad regulations that impose unrealistic timeframes, fail to recognize the negative impact in a challenging workforce environment, and for which guidance and resources have not yet been thoroughly considered or shared with the very providers who will be expected to comply, can only set up providers for failure. This will negatively impact patients and communities for years to come.”


(LeadingAge requested the Senate Finance Committee to address serious concerns as it considers the nominations of Rep. Tom Price for Secretary of HHS and Seema Verma for Administrator of CMS.)
Challenges Posed By Final Rule

- Cost of achieving “substantial compliance” (CMS estimate of $62,900 the first year and $55,000 for successive years may be underinflated)

- Training staff (expensive, resource-intensive)

- Hiring new staff (expensive, may be difficult in rural communities)

- Phase-in periods (are they realistic?)

- Lack of guidance (SOM, S & C Memos, etc.)

- Guidance exceeding regulations’ limits (SOM is sub-regulatory guidance and cannot, by itself be a basis for a deficiency).

- Does the Final Rule present “impossible burdens” for many providers?
Resources/Training

- Final Rule to Reform the Requirements for Long-Term Care Facilities by CMS (October 27, 2016)
- QAPI (CMS QAPI Website)
“A RoP Item Overview including the changes from the former rule to final rule as well as highlights for leadership awareness.

A Policy and Procedure Checklist indicating elements and/or language that needs to be included in the new policy.

A generic Sample Policy and Procedure.

A training template with speakers’ notes for operational implementation.

We will post these individual policy and procedure templates as they are completed, beginning in early January.”

The training contains information regarding Phase 1 of the New Nursing Home Regulations that will be effective starting November 28, 2016. This information addresses the new language included in the New Nursing Home Regulations, and how Phase 1 will be implemented via the State Operations Manual, F-Tags, and survey process.

This training prepares surveyors to implement Phase 1 requirements. Around this same time, CMS will be releasing a revised version of Appendix PP which retains existing tags and guidance, but incorporates the newly effective regulatory language. We will be releasing a job aid that identifies the F-Tags that have new regulatory language added. This training also address how the survey process will be used to address the regulatory requirements.

Resources

- IASC
- AMDA
- AHCA
- LeadingAge
- QIO
- CMS
Questions & Answers?
This presentation is intended to provide general information on various regulatory and legal issues. It is NOT intended to serve as legal advice or counsel on any particular situation or circumstance.