The Mega Rule: Reform of Requirements for Long-Term Care Facilities

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Disclosures
- I have no conflicts of interest relating to the material covered in this presentation.
- I do not serve on any speaker bureaus.
- I do not have any personal grants concerning the area of discussion today.

Objectives
- Distinguish between CMS conditions for participation ("The Mega Rule") and guidance to surveyors ("F tags")
- Examine those provisions of The Mega Rule that may have the greatest impact on long-term care facilities and clinicians
- Propose potential strategies that facilities may adopt to comply with regulatory mandates
The Mega Rule vs. “F Tags”
Compare and Contrast

Mega Rule vs. F Tags

Reform of Requirements for LTCF (Mega Rule)
- Specific mandates that a nursing home must meet to receive Medicare/Medicaid funding
- The Mega Rule will be the first change since 1991 in the requirements for facilities to participate in the Medicaid/Program
- Incorporates elements of the IMPACT Act and the Affordable Care Act
- Extensive update (700+ pages)

Guidance to Surveyors (F Tags)
- Provides advice to surveyors regarding interpretation of the rules for participation
- Also known as the State Operations Manual
- F Tags are revised on regular basis
- Each F Tag in length and complexity
The “Mega Rule”
Review Key Provisions

Background

- Mega Rule draft released July 2015 for comment
- Mega Rule final version released October 2016
- Effective Date: November 28, 2016
- Staggered Implementation Dates:
  - Phase 1 implementation on November 28, 2016
  - Phase 2 implementation on November 28, 2017
  - Phase 3 implementation on November 28, 2018

Transitions of Care

- Requires communication of the following at time of transfer between two post-acute facilities:
  - History of present illness
  - Past medical/surgical history
  - Reason for transfer
- Only applies to non-hospital transfers
- No specific methodology or form, specified
- Potential role for EHR interoperability can be achieved
- Effective November 2017
Person-Centered Care & Planning

- Development of care plan
  - Within 48 hours of admission
  - Effective November 2017
  - Focus on person-centered care (note similarities to F309)
  - New required care plan team members
    - Nursing assistant
    - Dietary/Food Services staff member
  - Requires participation of resident or representative
  - Facility must document rationale in the medical record if participation of resident or representative is not practical

Care Planning & Discharge Summaries

- Care Plan must include Discharge Planning (per IMPACT Act)
  - Goals for admission
  - Potential for future discharge
- Discharge Summary must include medication reconciliation
  - Prescription drugs
  - Over-the-counter products
- Discharge Summary must include:
  - Summary of arrangements made for post-discharge care
  - Description of post-discharge medical and non-medical services

Quality of Care and Quality of Life

- Special Needs: Pain Management
  - Facilities must ensure that residents receive necessary and appropriate pain management (note similarity with F309)
- Potential Barriers . . . Particularly with opioid use:
  - DEA’s refusal to accept LTCF chart orders
  - DEA’s narrow interpretation of the LTCF “agent of the prescriber”
  - CDC Guidelines may discourage use of opioids
  - Various state regulatory and law enforcement efforts may discourage the prescribing of opioids
- Effective November 2016
Physician Services

- Require an in-person evaluation of a resident to plan physical, occupational, speech, and other needed transfers.
- Rural facilities with few providers?
- Overnight coverage?
- Delays in emergency situations?

- Allow physicians to delegate dietary orders to dietitians and therapy orders to therapists.

Effective November 2016

Nursing Services

- Sufficient Staffing Requirement
  - Competency requirements for determining sufficient staff based on:
    - Number of residents
    - Resident acuity
    - Range of diagnoses
    - Content of care plans
    - Formula undetermined
    - CMS may review payroll-based journal reporting data in the future

Effective November 2017
Pharmacy Services

- Pharmacist review of the resident’s chart:
  - At least every six months
  - On admission or readmission
  - During the monthly medication regimen review if resident receives:
    - Antipsychotic
    - Antibiotic
    - Antidepressant
    - Anxiolytic
    - Sedative
    - Pain management
  - Final rule requires medical record review during each MRR
  - Effective November 2017

Psychotropic Drugs

- Existing requirements for antipsychotics will apply to psychotropic drugs
  - Non-drug or behavioral interventions
  - Gradual dosage reduction attempts
  - Psychotropic drug includes:
    - Antipsychotics
    - Antidepressants
    - Anxiolytics
    - Sedative-hypnotics
  - Opioids (Removed from final rule)
  - Any drugs that affect brain activities associated with mental processes and behavior
  - Effective November 2017

Psychotropic Drugs

- PRN Psychotropic Orders
  - Duration limited to 14 days unless:
    - PCP evaluates the ongoing need and documents the rationale for continued use in the medical record
    - This exception does not apply to PRN antipsychotic medications (a new order must be written every 14 days to continue a PRN antipsychotic)
  - Effective November 2017
Medication Regimen Review (MRR)

- Pharmacist to report "irregularities" to:
  - Director of Nursing
  - Attending Physician
  - Medical Director (not previously specified in the Requirements for Participation)
- If no changes are to be made in response to the recommendation, then the physician must document the rationale in the medical record (also already required by F428)
- Action must be timely
- Effective November 2017

Medication Regimen Review

Define timely response to pharmacy recommendations?

Perhaps it is a matter of perspective . . .

Facilities must create their own standards

Timely response to pharmacy recommendations

- A time frame for the physician to respond to the pharmacist is not specified in either the "Mega Rule" or the "F-Tags."
- CMS has proposed that timely identification and response to potential drug irregularities be adopted as a future quality measure to help determine a nursing home's Star Rating
- That proposal would designate a timely response as a response received by the facility with orders implemented by midnight following the day of the medication irregularity identification
- Proposed data collection to begin 10/1/18
Infection Prevention and Control Program (IPCP)

- Facility to establish an Infection Prevention and Control Program (IPCP) as part of the QAPI process (effective November 2017)
- Must follow national standards
- Goal: Prevent, identify, report, investigate, and control, infectious diseases for all residents, staff, visitors, and contractors
- Designation of an Infection Prevention and Control (IPC) Officer who has received specialized training in infection prevention and control beyond that required for his/her initial degree (Effective November 2019)
- Development of written policies and procedures for the IPCP
- Education and training programs related to infection control

https://federalregister.gov/d/2016-23503

Ethics Program

- Establish written compliance ethics standards, policies, and procedures
- Avoid administrative, civil, and criminal violations
- Program updated annually
- Formalize the disciplinary process for violations of the facility’s ethics policy
- Create methods to report potential ethics violations without retaliation
- “Chain” facilities (five or more communities)
  - Not subordinate to General Counsel, CFO, or COO
  - Have a Compliance Liaison in each facility
  - Conduct annual compliance training

https://federalregister.gov/d/2016-23503
Training Programs

- Each facility must develop, implement, and maintain a training program for new and existing staff.
- Topics include, but are not limited to:
  - Communication
  - Residents’ Rights
  - Abuse, Neglect, and Exploitation
  - QAPI
  - Infection Control
  - Compliance & Ethics

https://federalregister.gov/d/2016-23503

Training Program

- Nursing Aides must have at least 12 hours of training per year.
  - Dementia Management Training
  - Resident Abuse Prevention Training
  - Areas of weakness based on performance review and facility assessment
  - Needs of the Cognitively Impaired (if working with that population)
- Effective November 2016

https://federalregister.gov/d/2016-23503

Arbitration

- Facilities are now prohibited from entering into an agreement for binding arbitration until after a dispute arises between the facility and resident.
- CMS expressed concern that a resident should not be forced to surrender right of legal recourse as a condition of admission (common practice in many facilities)
- Nursing home providers have expressed concern about the potential for increased costs resulting from increased litigation

https://federalregister.gov/d/2016-23503
Physical Environment

- Newly constructed, re-constructed, or newly certified facilities must have no more than two residents per room.
- Each room must have at least one sink.
- Each room must have at least one commode.
- Potential to impose significant costs on existing facilities that wish to make minor physical plant improvements.

Projected Implementation Costs

- Implementation Costs
  - Year 1: $831,000,000
  - Subsequent Years: $736,000,000
- Implementation Costs per Facility
  - Year 1: $62,900
  - Subsequent Years: $55,000
- Additional funding provided to facilities
  - ZERO

Strategies

Consider potential responses
Initiate QAPI discussions with your facilities (the sooner, the better)

Transitions & Templates

- Written template of needed information
  - With transfer to or from another post-acute care facility
  - With transfer to or from the hospital
  - With discharge to home
  - For medication reconciliation
    - Proposed required at discharge
    - Would be helpful if done on admission
    - When contacting medical (or pharmacy) team

Care Planning - Questions to Consider

- How is the baseline care plan established now?
- Does that process change for late day, weekend, or holiday admissions?
- How can facility staff move towards completing the baseline care plan within 48 hours?
- Which staff members currently participate in the process?
- How will the staff members involved change going forward?
- For facilities with low rates of employee retention how might that impact availability of staff to complete the baseline care plan promptly?
Psychotropic Drugs

- What non-drug interventions are consistently implemented (and documented) before a PRN psychotropic is prescribed?
- Are there procedures in place for the IDT to re-evaluate resident status following initiation of a PRN psychotropic medication?
- Can unintended consequences be avoided?
  - Will there be a temptation to request/order more scheduled psychotropic medications in response to the restrictions on PRN psychotropic drug?

Medication Regimen Review

- Does the facility have specific policies for how and when MRR will be conducted?
- Are responses obtained in a timely manner?
- What are the best systems to communicate recommendations to promote timely review?
- Is the Medical Director involved in reviewing the entire medication regimen review report (not just the recommendations for resident s/he provides care)?

Leadership