The Centers for Medicare and Medicaid (“CMS”) this week released its long-awaited nursing facility “Mega-Rule,” the most comprehensive revision of CMS’s requirements for nursing homes since 1991. CMS said that the new requirements are the result of significant changes in the delivery of care since the early 1990s, including the increasing acuity level of nursing facility patients, a new emphasis on reducing hospital readmissions, the development of healthcare information technology, and an emphasis upon resident behavioral health. The final rule – consisting of 109 pages of revised regulations and another 604 pages of CMS commentary – will go into effect over three years, with Phase 1 beginning November 28, 2016. CMS estimates that compliance with the new rule will cost an average of $62,900 in the first year per certified nursing home, and then $55,000 per facility per year. The largest expected costs are centered on infection control, resident rights, compliance and ethics programs, and quality assurance programs.

The Requirements of Participation, or RoPs, are CMS’s requirements for nursing homes that are certified for participation in the Medicare or Medicaid programs. Many aspects of the new rule will require their own deep review in the coming days, but key requirements are highlighted here.

**Prohibition on “Pre-Dispute” Binding Arbitration**

The requirement receiving the most attention is a prohibition of mandatory “pre-dispute” arbitration provisions in an admissions agreement. The regulation, at new 42 C.F.R. § 483.70(n)(1), states:

A facility must not enter into a pre-dispute agreement for binding arbitration with any resident or resident’s representative nor require that a resident sign an arbitration agreement as a condition of admission to the LTC facility.

This prohibition, which goes into effect November 28, 2016, goes beyond the draft regulation issued by CMS in 2015. In that earlier proposal, CMS would have permitted “pre-dispute” arbitration, but only if the facility met detailed requirements for the arbitration.

The regulations permit a facility and resident to enter into binding arbitration after a dispute arises, so long as several conditions are met. The “post-dispute” arbitration must be voluntary and in a form that the resident understands, must provide for a neutral arbitrator agreed to by both the facility and the resident, and must not be a condition of continued admission or prevent the resident from communicating with federal, state, or local regulators.
This provision will undoubtedly continue to receive significant attention. The American Health Care Association, for instance, has already claimed that the prohibition violates CMS’s legal authority, signaling a possible legal challenge.

In the meantime, the prohibition will be scrutinized to determine whether facilities can use other non-judicial forums to resolve disputes. Binding “arbitration” typically means that the parties agree to allow a non-judicial private party to resolve the dispute. But may a facility require that, before a dispute goes to court, the parties first go through “mediation,” in which the facility and resident seek to settle their dispute? Is there a role for “non-binding” arbitration? These considerations will need to be addressed soon.

**Definitions and Reorganization**

The RoPs include new definitions for terms including “abuse,” “neglect,” “exploitation,” “misappropriation,” “resident representative,” and “person centered care.” The definition of abuse, for instance, includes in part the “willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish.” Many commentators were concerned that, by including “willful” in the definition, an action that was intentional – such as administering a medication – would be considered abuse if it led to an unintended result, such as the medication causing an unexpected reaction. CMS’s commentary suggests that this was not its intention, but expect this definition to be scrutinized carefully.

CMS has reorganized and renumbered many provisions, combining some prior sections and separating others. The official CMS commentary includes a cross-walk that describes how the regulations have been reordered.

**Resident Rights**

CMS has kept its existing resident rights provisions, and updated the requirements to reflect changes in healthcare and the broader community.

- For instance, “family member” and “legal representative” are replaced with a new term, “resident representative.” The rights of the resident representative must respect state law.
- Residents continue to have the right to see a physician of their choosing, but CMS has dropped a preliminary requirement that the physician be “credentialed” by the facility.
- A same-sex spouse of a resident must be afforded the same rights as an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.
- Residents must have access to the internet “to the extent available to the facility.”
- Facilities must provide residents with immediate access to visitors of their choosing, subject to the resident’s right to deny visitors and in a manner that does not impose on the rights of other residents. The facility must also provide immediate access to any resident by his or her resident representative, as well as representatives of the Department of Health and Human Services, state agencies, ombudsmen, and similar agencies.
- Residents must be involved in their care planning process.

**Freedom from Abuse, Neglect, and Exploitation**

- Facilities may not hire any individual who has a restriction on his or her professional license as the result of a finding of abuse, neglect, exploitation, mistreatment, or misappropriation of resident
property.

Admission, Transfer, and Discharge Rights

- Facilities must disclose in writing to potential residents any “special characteristics or service limitations” of the facility.
- Facilities may discharge a resident for a failure to pay, if the resident has failed to submit paperwork for third-party payment or if the resident submits the paperwork but the payor denies the claim.
- CMS has updated the list of documentation that must be provided to a new provider after a resident is discharged from a facility.

Resident Assessment

- Facilities must coordinate a resident’s assessment with the preadmission screening and resident review (PASARR) program “to the maximum extent possible.”

Care Planning

- Within 48 hours of a resident’s admission, a facility must perform a “baseline care plan” for each resident, to include the “minimum healthcare information necessary to properly care for a resident.” If a comprehensive care plan is prepared within 48 hours, this can serve as the “baseline” care plan.
- The comprehensive care plan team must include a nurse aide, a member of the food and nutrition services staff, and a social worker.
- Discharge planning must be addressed in the comprehensive care plan. The new rules add certain other requirements to the contents of the discharge plan.

Quality of Life and Quality of Care

- The new regulation includes new sections that combine various elements related to quality of life and quality of care. The quality of life language now applies to all care and services provided to facility residents.

Physician Services

- CMS withdrew an earlier proposal that, before an unscheduled transfer of a resident to a hospital, the resident first be evaluated by a physician, physician assistant, nurse practitioner, or clinical nurse specialist.
- Attending physicians have the authority to delegate certain order-writing to qualified nutrition professionals and therapy professionals, if permitted by state law.

Nursing Services
• Facilities must perform a self-assessment, considering resident numbers, acuity, and diagnoses, and must have sufficient nursing staff for this population, including with appropriate competencies and skill sets. CMS declined to impose mandatory nursing minimums, but described its proposal as a “competency-based staffing approach.”

**Behavioral Health Services**

• CMS added a new section related to behavioral health. This requires that each resident must have the necessary behavioral health care and services to attain the highest practicable well-being. CMS states that each facility must have sufficient staff with the appropriate competencies and skill sets.
• In part, the new regulation requires facilities to provide “trauma-informed care” for residents with a history of trauma or post-traumatic stress disorder.

**Pharmacy and Lab Services**

• The final rule imposes several requirements related to pharmacy services, including requiring the pharmacist to report certain events to the attending physician, the director of nursing, and the facility medical director. The regulation also imposes limitations on PRN orders for psychotropic drugs.
• The final rule updates language relating to lab services, including clarifying existing provisions.

**Dental Services**

• Facilities must not charge residents for lost or damaged dentures when that loss or damage is the facility’s responsibility. Referrals for lost or damaged dentures must occur within three business days.

**Food and Nutrition Services**

• Facilities must employ sufficient staff with appropriate competencies to carry out the functions of the food and nutrition service. The new rule clarifies who is a “qualified dietician” for purposes of meeting dietary standards. Directors of food service must be certified or meet certain other standards. The rule also adds new requirements for meals that meet certain religious or dietary preferences of residents.

**Specialized Rehabilitative Services**

• Respiratory therapy is added as a specialized rehabilitative service. The rule also clarifies the relationship between specialized rehabilitative services and PASARR.

**Administration**

• The new rule adds the facility assessment requirement noted in the discussion of nursing services, as well as confidentiality requirements for patient records and the arbitration provisions described
Quality Assurance and Performance Improvement ("QAPI")

- CMS requires that all facilities implement a comprehensive data-driven QAPI program “that focuses on indicators of the outcomes of care and quality of life.” The QAPI requirements are described in some detail, including the requirement that the QAPI plan be presented to state surveyors within one year of the new regulation’s implementation. Other requirements relate to program design, program analysis and action, governance, quality assessment, and disclosure of information.

Infection Control

- Facilities must establish an infection control and prevention program that meets standards established by the new regulation. This includes establishing a system for identifying, reporting, communicating, preventing, and controlling infections and communicable disease. Facilities must have written policies and procedures for infection control and a system of surveillance, and must designate one or more individuals as an “infection preventionist” responsible for the infection control program.
- The regulation includes detailed provisions related to influenza and pneumococcal immunizations.

Compliance and Ethics Programs

- Each facility must implement a compliance and ethics program “that has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations” and in promoting quality of care. The regulation establishes detailed requirements relating to standards and assignment of “high-level personnel” with compliance responsibility, and requires that “sufficient resources” be assigned to compliance tasks to “reasonably assure compliance.”
- For organizations with five or more facilities, the regulation imposes an annual training requirement, the requirement of a designated compliance officer for whom compliance is a “major responsibility,” and the requirement of designated compliance liaisons at each facility.

Physical Environment

- Facilities certified after November 28, 2016 must not have bedrooms accommodating more than two residents. Likewise, all bedrooms in facilities certified after November 28, 2016 must have bathrooms with at least a sink and commode.
- All facilities must implement smoking policies.

Training

- The regulation adds a new section addressing the components of training programs for staff, contract providers, and volunteers. This includes education regarding resident rights, as well as abuse, neglect, and exploitation, QAPI, infection control, and compliance. The new rule also includes in-service requirements for nurse aides.
Implementation

The phased-in implementation will require close attention. CMS has grouped the RoPs into three phases, described below. In order to determine the relevant effective date for any requirement, facilities will need to refer to a CMS-prepared chart that assigns each regulatory section into the appropriate phase. This is not clear from the text of the regulation itself. As just one example, section 483.70 is effective under Phase 1, except sections 483.70(d)(3) and 483.70(e), which fall under Phase 2.

1. **Phase 1**: includes requirements that CMS described as “unchanged or [that] received minor modification.” Providers may disagree that all of these requirements are minor. Phase 1 requirements include the new prohibition on pre-dispute arbitration agreements. Effective Date: **November 28, 2016**.

2. **Phase 2**: includes “brand new requirements and those provisions that required more complex revisions.” This includes certain crime reporting requirements, documentation of transfer/discharge, some care planning requirements, development of the “Facility Assessment,” new pharmacy requirements, sharing QAPI plans with surveyors, “antibiotic stewardship,” and smoking policies. Effective Date: **November 28, 2017**.

3. **Phase 3**: includes all remaining requirements. Phase 3 requirements include those related to “trauma-informed care,” some QAPI requirements, the implementation of effective compliance and ethics programs at all facilities, and a call system by each resident’s bedside. Effective Date: **November 28, 2019**.

CMS expects that after the final phase all new requirements will “be incorporated into the practices of LTC facilities and sufficiently enforced through the updated survey process.”

---

**Event Announcement**

**Williams Mullen Long-Term Care Conference**

Tuesday, October 18, 2016
11:00 a.m. to 3:30 p.m.

**Williams Mullen Center**, Richmond, VA

**Topics**: New CMS “Mega-Rule,” Risk Mitigation, Top Five Employment Law Pitfalls for Long-Term Care Providers, and Strategic Planning for Long-Term Care Networks

This event has ended.

---

**Related People**
Related Services

- Health Care