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ATTENTION:

CMS Proposes Massive Rewrite of the Nursing Home Code

The federal Centers for Medicare and Medicaid Services (CMS) will publish in the Federal Register Thursday a 403-page update of the nursing home code which is being described as the first major rewrite of long-term care conditions of participation since 1991.

The rule has yet to even been have published and some advocates already are lamenting its failure to include mandatory staffing minimums while some provider groups are labeling the proposal, which will cost nursing homes an estimated \$729 million in the first year it will be in effect, “a large unfunded mandate” in explaining their opposition.

The following is a “brief” analysis of the proposed rule prepared by LeadingAge Director of Health Policy and Regulations Evvie Munley:

- CMS has issued a Proposed Rule: Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities. It is currently on display in PDF format at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-17207.pdf> and weighs in at about 403 pages. The proposed rule will be published in the Federal Register on Thursday, July 16, with a 60-day comment period That will conclude September 16. We’ll provide the Federal Register link at the point of publication.
- CMS notes the Requirements of Participation (RoPs) have not been comprehensively reviewed and updated since 1991.
- This proposed rule adds new requirements [**based on a 1st read many of the new requirements appear to incorporate/originate in what is now guidance*] and reorganizes or eliminates existing language and/or requirements as determined appropriate.
- Among the new requirements are the Affordable Care Act (ACA) provisions on quality assurance and performance improvement -QAPI; compliance and ethics programs; reporting of suspicion of a crime; and training requirements related to dementia and abuse prevention.
- Key in this proposed rule are competencies-based and facility assessment requirements for nursing care staffing and related regulations such as infection control and specialized rehabilitative services. The rule would add a competency requirement for determining sufficient nursing and direct care staff based on a facility assessment, including but not limited to: physical characteristics of the home, # of residents, acuity, range of diagnoses, and care plan content.
- It is important to note that ‘facility-wide assessment’ is identified in the Preamble as a ‘central feature’ to these revisions, applicable to and impacting not only staffing and related requirements as referenced above, but also, e.g., QAPI, resource use, emergency preparedness planning – it is

viewed as multi-purpose / multi-function.

The following is essentially a 'laundry list' of the topics addressed, but will provide an overview/indication of the breadth of the proposed changes. Further details and analyses will follow as we work our way further into the rule.

- **Definitions (§483.5):**
 - Adds definitions for “adverse event”; “documentation”; “posting/displaying”; “resident representative” “abuse”; “sexual abuse”; “neglect”; “exploitation”; “misappropriation of resident property”; and “person centered care”.
- **Resident rights (§483.10):**
 - CMS would retain all existing residents’ rights, but update language and organization to include, e.g., electronic communications. Proposed revisions would:
 - Eliminate language, such as “interested family member”; replace “legal representative” with “resident representative.”
 - Address roommate choice.
 - Add language regarding physician credentialing to specify that the physician chosen by the resident must be licensed to practice medicine in the state where the resident resides, and must meet professional credentialing requirements of the facility.
- **New Section: Facility responsibilities (§483.11)**
 - Focuses on facility responsibilities (protecting the residents’ rights, enhancing quality of life). This section parallels many residents’ rights provisions.
 - Visitation: Would establish open visitation, similar to the hospital conditions of participation (CoPs).
 - Abuse/Neglect/Exploitation (§483.12): Would revise “Resident behavior and facility practices,” to “Freedom from abuse, neglect, and exploitation”; and
 - Prohibit employment of individuals with disciplinary actions against their professional license by a state licensure body following a finding of abuse, neglect, mistreatment, or misappropriation of property.
 - Require implementation of written policies and procedures that prohibit and prevent abuse, neglect, mistreatment and/or misappropriation of property.
- **Transitions of Care (§483.15):** Revises “admission, transfer and discharge rights,” to apply to all transfers of resident care.
 - **Transfers / Discharge:** Would require specific information/data elements, e.g., demographic; history of present illness including, e.g., active diagnoses, functional status, medications; reason for transfer and past medical/surgical history, be exchanged with the receiving provider. CMS is not proposing a specific form, format, or methodology.
- **Resident assessments (§483.20); Preadmission Screening and Resident Review (PASRR):** Would clarify appropriate coordination of resident assessment with PASRR.
 - Would add exceptions to PASRR requirements for mental illness and intellectual disabilities for admission with respect to transfers to or from a hospital.
 - Would require notification of state mental health or intellectual disability authorities promptly after a significant change in the mental or physical condition of a resident with a mental illness or intellectual disability.
- **New Section: Comprehensive Person-Centered Care Planning (§483.21)** – Would require development of a baseline care plan for each resident within 48 hours of admission, including instructions needed to provide effective and person-centered care meeting professional standards.
 - **PASRR:** Would require the care plan to include any specialized services or specialized rehabilitation services the facility will provide as a result of PASRR; a rationale for disagreement with PASRR findings must be documented in the medical record.
 - **Interdisciplinary Team (IDT):** Would add a nurse aide, food and nutrition services, and a social worker to the IDT that develops the comprehensive care plan.
 - Would require written explanation in the medical record if participation of the resident and

their resident representative is determined not practicable .

- **Discharge Planning [as part of Comprehensive Person-Centered Care Planning]:** Would implement IMPACT Act requirements for long term care facilities to take into account quality, resource use, and other measures to inform and assist the discharge planning process, while accounting for resident treatment preferences and goals.
 - Would require facilities to document the resident’s goals for admission in the care plan; assess potential for future discharge; include discharge planning in the comprehensive care plan, as appropriate.
 - Would require the discharge summary to include reconciliation of all discharge medications with pre-admission medications (prescribed and OTC).
 - Would require addition to the post discharge care plan a summary of arrangements made for follow up and any post discharge services.
- **Quality of care and Quality of Life (§483.25) [retitled]** – Would clarify that quality of care and quality of life are overarching principles in all care and services.
 - Would clarify the requirements regarding a resident’s ability to perform ADLs.
 - No proposal, but CMS is seeking comments on whether current requirements for activities’ director are appropriate; what minimum requirements should be.
 - Would modify requirements for nasogastric tubes to reflect current clinical practice, and include enteral fluids in requirements for assisted nutrition and hydration.
 - Would add a new requirement that facilities ensure pain management needs are met
 - Would move current provisions for unnecessary drugs, antipsychotics, medication errors, and influenza and pneumococcal immunizations to Pharmacy services.
- **Physician Services**
 - Would require an in-person evaluation by a physician, a physician assistant (PA), nurse practitioner (NP, or clinical nurse specialist (CNS) before an unscheduled transfer to a hospital.
 - Would allow physicians to delegate dietary orders to dietitians and therapy orders to therapists.
- **Nurse Staffing** - Would add a competencies/skill set requirement for determining sufficient nursing and direct care staff based on a facility assessment, including but not limited to: # of residents, acuity, range of diagnoses, and care plan content.
- **New Section: Behavioral health services (§483.40)** – Would focus on provision of necessary behavioral health care and services to residents in accordance with their comprehensive assessment and plan of care.
 - Would require staff to have appropriate competencies to provide behavioral health care and services, including care of residents with mental and psychosocial illnesses and implementing non-pharmacological interventions.
 - CMS notes in the Preamble that reference to mental health/illness includes substance abuse disorders.
 - Would add “gerontology” bachelor’s degree to the minimum social worker educational requirements. .
- **Pharmacy services (§483.45); Drug Regimen Review**
 - Would require pharmacist review of a resident’s medical chart at least every 6 months and when the resident is new to the facility, a resident returns or is transferred from a hospital or other facility, and during each monthly DRR when a resident has been prescribed or is taking a psychotropic drug, an antibiotic or any drug the QAA Committee has requested be included in the monthly drug review.
 - Would require the pharmacist to document any irregularities noted during the DRR, including at minimum, the resident’s name, the relevant drug and irregularity identified, to be sent to the attending physician, medical director, and director of nursing.
 - Would require the attending physician to document that he/she has reviewed the identified irregularity and what, if any, action they have taken. “Irregularities” would include “unnecessary drugs.”

- Would require facilities to ensure residents who have not used psychotropic drugs not be given these drugs unless medically necessary; receive gradual dose reductions and behavioral interventions unless clinically contraindicated.
 - “Psychotropic drug” would include any drug that affects brain activities associated with mental processes and behavior.
- PRN orders for psychotropic drugs would be limited to 48 hours unless the primary care provider reviews and documents the rationale.
- **New Section: Laboratory, radiology, and other diagnostic services (§483.50)**
 - Would clarify that a PA, NP, or CNS may order laboratory, radiology, and other diagnostic services in accordance with state and scope of practice laws.
 - Would clarify that the ordering practitioner be notified of abnormal laboratory results when they fall outside of clinical reference ranges, in accordance with facility notification policies and procedures.
- **Dental services (§483.55)**
 - Would prohibit SNFs from charging a Medicare resident for the loss or damage of dentures determined to be the facility’s responsibility.
 - Would require NFs to assist eligible residents to apply for reimbursement of dental services under the Medicaid state plan.
 - Would clarify that a referral for lost or damaged dentures “promptly” means within 3 business days absent documentation of any extenuating circumstances.
- **Dietary Services**
 - Would require facilities to employ sufficient staff with appropriate competencies to carry out dietary services in accordance with resident assessments, individual care plans, and facility census.
 - A “qualified dietitian” is registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics or meets state licensure or certification requirements. Dietitians hired/contracted with prior to these regulations, would have 5 years to meet the new requirements.
 - The director of food and nutrition service must be a certified dietary manager, certified food service manager, or be certified for food service management and safety by a national certifying body or have an associate’s or higher degree in food service management or hospitality; would have to meet any state requirements for food service managers.
 - Would require menus to reflect religious, cultural and ethnic needs and preferences, be updated periodically, and reviewed by the qualified dietitian or other clinically qualified nutrition professional for nutritional adequacy while not limiting residents’ right to personal dietary choices.
 - Would require facilities to consider resident allergies, intolerances, and preferences and ensure adequate hydration.
 - Would allow attending physicians to delegate prescribing resident diets to registered or licensed dietitians, including therapeutic diets, in accordance with state law.
 - Would require availability of suitable, nourishing alternative meals and snacks for residents who want to eat at non-traditional times or outside of scheduled meal times in accordance with the plan of care.
 - Would require documentation in the care plan the clinical need for a feeding assistant and the extent of dining assistance needed.
 - Would clarify facilities may procure food items directly from local producers and may use produce grown in facility gardens.
 - Would clarify residents are not prohibited from consuming foods not procured by the facility.
 - Would require a policy regarding use and storage of foods brought to residents by family and other visitors.
- **Specialized rehabilitative services (§483.65)**
 - Would add respiratory services to specialized rehabilitative services.

- Would clarify what constitutes rehabilitative services for mental illness and intellectual disability.
- Would establish new health and safety standards for provision of outpatient rehabilitative therapy services.
- Facility Assessment – would require facilities to conduct, document, and update annually and when needed an assessment to determine resources necessary to care for its residents competently during both day-to-day operations and emergencies.
 - Would include resident population (#, overall care needs and staff competencies required, cultural aspects); resources (e.g., equipment, and overall personnel); and a facility- and community-based risk assessment.
- **Clinical Records** - Would establish requirements that mirror some found in the HIPAA Privacy Rule (45 CFR part 160, and subparts A and E of part 164).
- **Binding Arbitration Agreements**
 - Proposes specific requirements for the facility and the agreement itself to ensure that if a facility presents binding arbitration agreements to its residents that the agreements be explained and acknowledged regarding understanding; that they be entered into voluntarily; and arbitration sessions be conducted by a neutral arbitrator in a location that is convenient to both parties.
 - Admission to the facility could not be contingent upon signing of a binding arbitration agreement.
 - The agreement could not prohibit or discourage communication with federal, state, or local health care or health-related officials, including representatives of the Office of the State Long-Term Care Ombudsman.
- **New Section: Quality assurance and performance improvement (QAPI) (§483.75)**
 - Would require all LTC facilities to develop, implement, and maintain an effective comprehensive, ongoing, data-driven QAPI programs that focus on systems of care, outcomes of care and quality of life.
 - Facilities would submit the QAPI plan at the 1st standard survey after 1 year from the final rule effective date; and at each subsequent standard survey upon request; documentation and evidence of ongoing implementation also required upon request.
 - Facilities would maintain effective feedback systems from staff, residents/resident representatives; establish priorities; have a process for identifying, reporting, analyzing, and preventing adverse/potential adverse events; systematic determination of underlying causes; measure/monitor the success of actions taken and track performance for sustainability; and include Performance Improvement Projects (PIPS).
 - QAA Committee requirements would be maintained with amendment.
- **Infection control (§483.80)**
 - Would require a system (Infection and Control Program – IPCP) for preventing, identifying, surveillance, investigating, and controlling infections and communicable diseases for residents, staff, volunteers, visitors, and other individuals providing services based upon facility and resident assessments as reviewed and updated annually; would also require incorporation of an antibiotic stewardship program.
 - Would require designation of an Infection and Prevention Control Officer (IPCO) for whom the IPCP is their major responsibility and who would serve as a member of the facility's quality assessment and assurance (QAA) committee.
- **New Section: Compliance and ethics program (§483.85)**
 - Would require the operating organization for each facility to have in operation a compliance and ethics program with established written compliance and ethics standards, policies and procedures capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Act.
 - Required components: established written standards, policies, procedures; assignment of high-level personnel; sufficient resources and authority for these individuals; due diligence to prevent delegation to individuals with propensity for criminal, civil, administrative violations;

effective communication and mandatory training; reasonable steps, e.g., monitoring/auditing systems, to achieve compliance; consistent enforcement; appropriate response to correct and prevent future occurrences.

- **Physical environment (§483.90)**

- Facilities initially certified after the effective date of this rule would be limited to two residents per bedroom.
- Facilities initially certified after the effective date of this rule would have to have a bathroom equipped with at least a toilet, sink and shower in each room.
- Would require policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety.

- **New Section: Training requirements (§483.95)**

- Would add a new section setting forth all requirements of an effective training program for new and existing staff, contract staff, and volunteers. Proposed topics include effective communication; resident rights and facility responsibilities; abuse, neglect, and exploitation; QAPI & infection control; compliance and ethics.
- Annual training would be required for organizations operating five or more facilities.
- Would require dementia management and resident abuse prevention training as part of the 12 hours per year in-service training for nurse aides.
- Would require facilities to provide behavioral health training to all staff, based on the facility assessment.

CMS seeks comment on the proposed RoPs and, e.g., "...unintended consequences and unanticipated risks to SNF/NF residents; involvement of stakeholders in developing sub-regulatory requirements and implementing changes..."; and a timeline for compliance/implementation by nursing homes once the rule is final.

Cost of Implementation/Compliance

- CMS estimates the total projected cost for implementation and compliance with this rule to be \$729,495,614 for the 1st year; \$638,386,760 for the 2nd and subsequent years.

LTC Facilities Crosswalk

- Table A [end of the Preamble] provides a crosswalk between current requirements and the proposed rule.

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