# Nursing Home Regulations Redefined: Implications for Providers

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Abstract:

Centers for Medicare and Medicaid Services (CMS) finalized a comprehensive update to nursing home Requirements of Participation in October 2016. Nearly 10,000 public comments were received regarding the Proposed Rule and CMS made multiple modifications based on comments from providers, advocacy organizations, and others prior to issuing the Final Rule. The Final Rule describing nursing home Requirements of Participation modernizes nursing home regulation. It is being implemented in 3 phases – November 2016, November 2017 and November 2019. There are multiple provisions that have implications for clinicians caring for patients in nursing homes, particularly in terms of management of infections, medication prescribing and monitoring and delegation of medical orders.

Nursing homes are integral to the efficient and effective functioning of our health care system through their roles as providers of short term post-acute services and long-term care. Federal engagement in regulation of the nursing home industry greatly expanded after the creation of the Medicare and Medicaid programs, which provided funding streams for post-acute and long-term care. The industry still relies on government funding for services; while many long-term care costs are borne out-of-pocket, most long stay nursing home residents are dually eligible for both Medicare and Medicaid. As the primary payors for this setting of care, Federal and State agencies have a longstanding practice of regulation of nursing homes.

Clinicians (physicians, nurse practitioners, physician assistants, pharmacists and health professionals from a variety of other disciplines) must understand regulations that govern nursing home care in order to effectively practice in this setting. The purpose of this article is to update clinicians on new nursing home regulations relevant to clinical practice in nursing homes.

Nursing homes are a highly regulated setting of care, subject to survey processes. The bulk of the regulatory framework was put in place after the passage of a highly critical Institute of Medicine (IOM) report in 1986[1] that highlighted multiple areas of quality concerns in nursing homes. The Centers for Medicare & Medicaid Services (CMS) Federal Rule that governs nursing home regulation, codifying the Requirements of Participation, had not been significantly updated since 1991 despite changes in nursing home practice over time.[2] This changed in October 2016, when a comprehensive Final Rule was issued by CMS. [3] This Rule is being

implemented in three phases – Phase 1 set to begin November 2016; Phase 2 set to begin November 2017; and Phase 3, starting November 2019.[3] **(Figure 1)**

One of the main challenges in updating these requirements is the nature of the patient population. Nursing homes serve a heterogeneous population. The post-acute care population continues to grow, and requires rehabilitation, intensive nursing care, and/or frequent visits by clinicians (MDs, NPs, PAs). The goal of post-acute care is to achieve a higher level of functioning, stabilize active medical conditions, and discharge to the community when feasible and safe. The goals of care for long-term residents may be different. Nursing homes also care for many people at the end of life, including patients receiving hospice care in the facility. It is therefore challenging to meet all the needs of these differing patient populations in one common set of requirements.

The Proposed Rule was issued in July 2015 and CMS received nearly 10,000 public comments from individuals, practices, industry and professional organizations. In response to the many public comments the Proposed Rule was changed substantially. For example, a provision in the Proposed Rule that was removed would have required on-site evaluation of patients by medical providers prior to transfers to the hospital. The Final Rule adds additional requirements, eliminates duplicative requirements, reorganizes some domains, and brings the Requirements of Participation in line with legislation, including the Affordable Care Act.

The revamped Requirements of Participation are intended to promote person-centered care and quality of care in nursing homes and modernize the 1991 Rule. Other themes of the

rule include a competency based approach to facility assessment, including ensuring training in dementia care and elder abuse prevention.

Nursing home providers were expected to immediately respond to Phase 1 of these new Requirements and to continue to develop plans to meet Phases 2 and 3. Costs for implementing regulations are to be borne by facilities. CMS estimates these costs at about $62,900 in the first year and about $55,000 per year for subsequent years. Provisions of the new Requirements with implications for clinicians who care for nursing home patients, include management of infections, medications, and delegation of medical orders.[4]

Facilities were required to have an infection control program under the prior regulations. The revised rules greatly expanded requirements in this area; facilities must have an Infection Control and Prevention Program (Phase 1). They are also required to establish an Antimicrobial Stewardship program (Phase 2) that includes protocols for antibiotic use and monitoring. The facility must also have at least one person designated as an Infection Preventionist (Phase 3). Many of the public comments to this section reflected concern over the range of needs of different facilities who may need more or less intensive programs around infection control, and the burden associated with implementation of these programs and roles. In response to comments, CMS created flexibility around the design and implementation of facility Infection Control and Prevention Programs and the Infection Preventionist role, although the person must work at the facility at least part-time. The amount of resources (e.g.- amount of FTE the designated staff Infection Preventionist devotes to the role) are to be determined by the facility after completing a facility assessment of needs. There is also flexibility as to the training and background of the Infection Preventionist, with the Final Rule

stating the person must have "primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field and can be qualified by education, training, experience or certification."[5]

In the Final Rule, CMS defines a psychotropic drug as "any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) anti-psychotic; (ii) anti-depressant; (iii) anti-anxiety; and (iv) hypnotic." There were many comments to CMS regarding the definition of psychotropic medications in the Proposed Rule. The definition is relevant as it has implications for increasing the regulation related to medications under this umbrella; increased regulatory requirements may create barriers to accessing medications. While CMS did modify the more expansive definition they started with, the definition of psychotropic medications has certainly been broadened beyond the previous emphasis on antipsychotic medications. Notably, opioids are excluded from the list although they had been included in the Proposed Rule, in response to many concerns that pain management would be impacted by undue scrutiny. It is possible that other medication classes may be added with guidance that is developed for surveyors. The comments, and the responses by CMS, reflect the continued tension in the care of nursing home patients between reducing inappropriate prescribing and appropriately treating pain, anxiety, depression and behaviors.

Consultant pharmacists were already required to review patient medications and provide recommendations. The revised regulations increase requirements and emphasis on the pharmacist medication review process. Facilities are now required to have a pharmacist review the patient's medical record and medications at least every six months or upon readmission to

the facility after a transfer. In addition, pharmacists must perform monthly medical reviews for any patient on a psychotropic, antibiotic, or any other medication that the facility has determined to be an issue or focus of quality improvement.

Pharmacist recommendations regarding medication irregularities – such as risks, omissions, or appropriateness – must be shared with the Director of Nursing Services, the attending physician, and the Medical Director. Response to recommendations must be documented in the medical record by the attending physician. There is increased emphasis on documentation of clinically pertinent rationales for medication use that are tailored to the context of the individual patient.[6]

Under the Final Rule, the attending physician may delegate the authority to write dietary orders to a qualified dietician or clinically qualified nutrition professional. This includes therapeutic diets (e.g. – low sodium, thickened liquids) but does not include medications intended to promote weight gain. The attending physician may also delegate the authority to write therapy orders to a qualified therapist. This practice is not required; physicians must actively delegate authority. These provisions are also subject to scope of practice laws in states and thus may not be permitted in some states.

A major change also includes allowing nurse practitioners, physician assistants (PAs), and clinical nurse specialists to give initial admission orders for the care of the patient. This is designed to reduce delays in patients receiving initial care prior to more comprehensive care planning taking place, recognizes the expanding role of advance practice nurses (APRN) and PAs, and aims to improve access to timely assessment of new nursing home patients and development of admission orders in within a short time window.[7]

There are numerous other changes and additions to the Requirements of Participation with implications for patients, facilities and providers. A Quality Assurance and Process Improvement (QAPI) program is a requirement and is intended to be the vehicle to achieve multiple objectives including reductions of hospital transfers, psychotropic medications, and infections. Medical Directors are expected to participate in the QAPI process. In Section 6102 of the Affordable Care Act, the Secretary of Health and Human Services was required to establish and implement QAPI requirements for all nursing homes and thus the Requirements of Participation now reflect this requirement. Facilities will be required to submit a QAPI plan to the State agency or federal surveyor at annual recertification visits.

Interdisciplinary care planning, central to nursing home care, is addressed, including a requirement for an initial care plan, developed and implemented within 48 hours of admission, that promotes "effective and person-centered care." Certified nursing assistants (CNAs) and dietary staff are now included as designated members of the interdisciplinary team (IDT). There is also increased emphasis on discharge planning. The facility discharge planning process is required to prepare "residents to be active partners in post-discharge care, in effective transitions, and in the reduction of factors leading to preventable re-admissions".[8] Expectations for patient and family participation are heightened in care planning, and, if the patient or family does not participate, the facility must document the reason. There is also a Requirement that the Ombudsman be notified regarding every transfer from the facility, including hospitalizations.

The Final Rule specifies required trainings for staff. Phase 1 requirements include trainings for abuse and neglect, dementia care, and feeding assistants. In Phase 3, there are

many additional areas where training will be required, covering multiple topics such as communication and behavioral health.

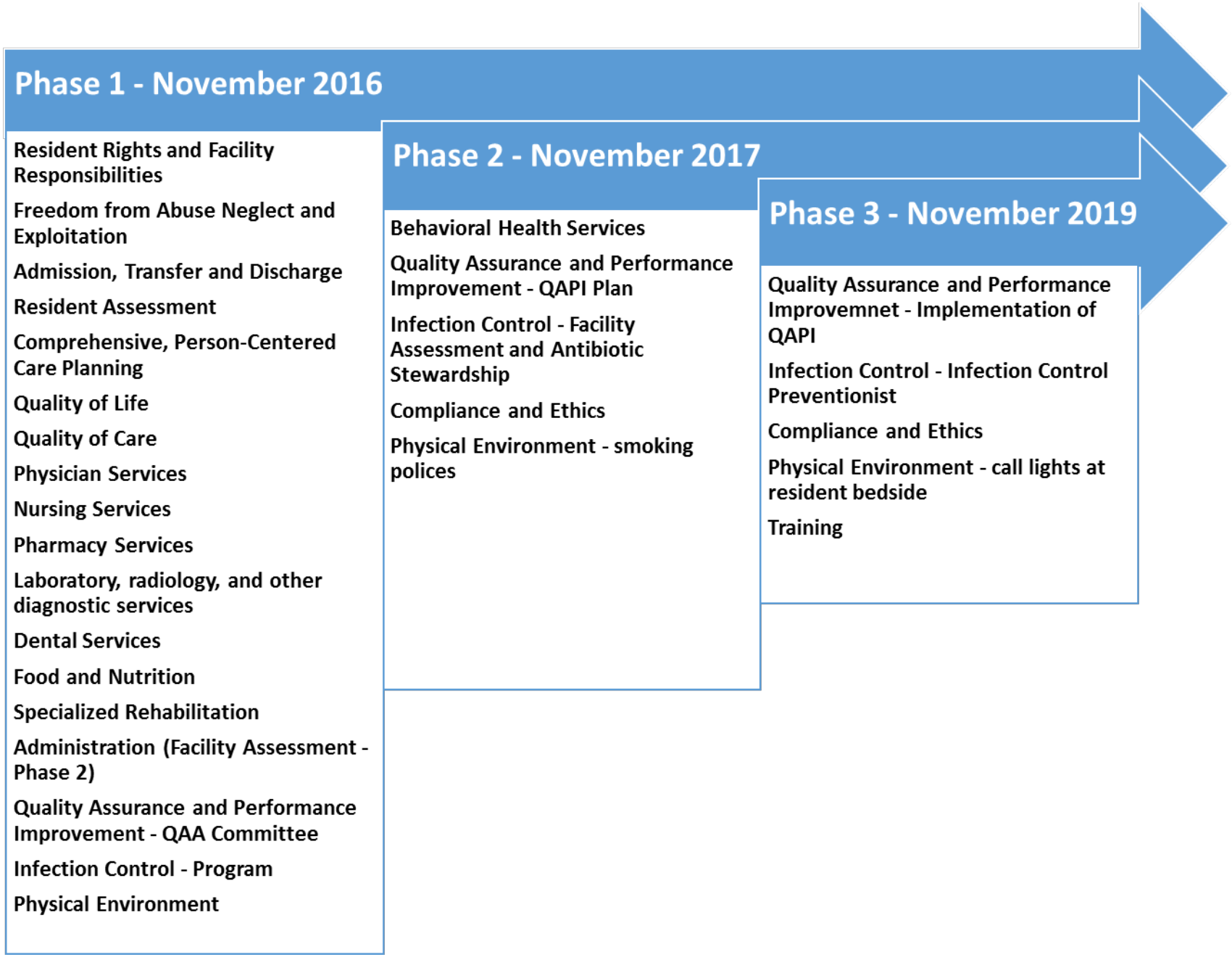
A new section was created for Behavioral Health.[9] This section is intended to complement the focus on appropriate use of anti-psychotic medications and defined areas of competency for staff in non-pharmacologic management of dementia related behaviors. Facilities are required to assess patient needs and ensure they have treatment for mental or psychosocial issues, with a goal that these issues are considered as important as physical concerns. Care from specific disciplines, such as psychiatrists, is not mandated but it is possible that there will be an increased demand for specialized mental health care in nursing homes.[10]

Many provisions of the Final Rule were applauded by advocacy groups and professional organizations, particularly the goals of modernizing the Requirements of Participation and enhancing person-centered care. Some, however, have been controversial, including limits on requiring patients and families to sign arbitration agreements on admission. After inclusion in the revised rules, CMS postponed the requirement and has recently issued a proposed rule to revoke the ban. CMS has produced webinars and professional societies and trade associations have developed educational materials to support facilities and providers in complying with the Requirements of Participation. It is the responsibility of providers in facilities, particularly Medical Directors, and nursing home leadership to understand these Requirements and meet them.

The patient population cared for in nursing home settings is medically complex. Nursing home patients have a high burden of functional and cognitive impairment, medical comorbidities, and psychosocial issues that make care in this setting very challenging. The

comprehensive overhaul of the CMS Requirements of Participation creates new opportunities to improve care of vulnerable patients in nursing homes, particularly around improving patient-centered, goal directed care, dementia care, appropriate prescribing, infection control and management, and reduction of potentially avoidable and unnecessary hospital transfers.

**Figure 1 – Timeline for Implementation of New Nursing Home Regulations**


Phase 1 - November 2016
Resident Rights and Facility Responsibilities
Freedom from Abuse Neglect and Exploitation
Admission, Transfer and Discharge
Resident Assessment
Comprehensive, Person-Centered Care Planning
Quality of Life
Quality of Care
Physician Services
Nursing Services
Pharmacy Services
Laboratory, radiology, and other diagnostic services
Dental Services
Food and Nutrition
Specialized Rehabilitation
Administration (Facility Assessment - Phase 2)
Quality Assurance and Performance Improvement - QAA Committee
Infection Control - Program
Physical Environment
Phase 2 - November 2017
Behavioral Health Services
Quality Assurance and Performance Improvement - QAPI Plan
Infection Control - Facility Assessment and Antibiotic Stewardship
Compliance and Ethics
Physical Environment - smoking polices
Phase 3 - November 2019
Quality Assurance and Performance Improvemnet - Implementation of QAPI
Infection Control - Infection Control Preventionist
Compliance and Ethics
Physical Environment - call lights at resident bedside
Training

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3. Centers for Medicare & Medicaid Services (CMS), HHS. Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities. Final rule. Federal register. 2016 Oct 4;81(192):68688.
4. Infection Control and Prevention; Antimicrobial Stewardship, 80 C.F.R. § 483 (2016).
5. Psychotropic Medications and Medication Regimen Reviews, 45 C.F.R. § 483 (2016).
6. Delegation authority – Physician Services, 30 C.F.R. § 483 (2016).
7. *Other provisions*
8. Comprehensive Resident-Centered Care Planning, 21 C.F.R. *§* 483 (2016).
9. Behavioral Health Services, 40 C.F.R. *§* 483 (2016).
10. *Implications for Clinicians*