

Medicare and Medicaid Programs

Reform of Requirements for Long-Term Care Facilities Proposed Rule

Summary adapted from Proposed Rule (with AHCA Comments)

Summary of Major Provisions

- Updates and revises current nursing center Requirements of Participation and includes provision from the Affordable Care Act, including compliance and ethics programs, quality assurance and performance improvement (QAPI) and reporting of suspicion of a crime requirements.

Definitions (§483.5)

- Adds definitions for the words/terms “adverse event,” “documentation,” “posting/displaying,” “resident representative,” “abuse,” “sexual abuse,” “neglect,” “exploitation,” “misappropriation of resident property,” and “person centered care.”

Comment: AHCA suggested a change to the definition of “abuse” which is incorporated into the proposed language.

Resident Rights (§483.10)

- Retains all existing residents’ rights and updates the language and organization of the resident rights provisions to improve logical order and readability, clarify aspects of the regulation where necessary, and to update provisions to include advances such as electronic communications. This includes:
 - Eliminating language, such as “interested family member” and replacing the term “legal representative” with “resident representative.”
 - Addressing roommate choice.
 - Adding 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.

Comment: AHCA believes the credentialing requirement will potentially create a cost and a burden for nursing centers. The definition of “resident representative” requires further analysis and consideration.

Facility Responsibilities (§483.11) New Section

- Adds a new section that focuses on the responsibilities of the facility (that is, protecting the rights of their residents, enhancing a resident’s quality of life) and brings together many of the facility responsibilities currently dispersed throughout existing regulations. This section parallels many residents’ rights provisions.
- Visitation: Revises visitation requirements to establish open visitation, similar to the hospital conditions of participation (CoPs).

- Re-designation of Requirements:
 - Relocates provisions from existing Resident’s Rights (§483.10) section that pertain to the responsibilities of the facility into this section.
 - Relocate the existing requirements in Quality of Life (§483.15) into this section.

Comment: The visitation requirement may be problematic.

Freedom from abuse, neglect, and exploitation (§483.12)

- Revised Title: Formerly “Resident behavior and facility practices” to “Freedom from abuse, neglect, and exploitation.”
- Prohibiting abuse, neglect, and exploitation:
 - Specifies that facilities cannot employ individuals who have had a disciplinary action taken against their professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of their property.
 - Requires facilities to develop and implement written policies and procedures that prohibit and prevent abuse, neglect, and mistreatment of residents or misappropriation of their property.

Transitions of Care (§483.15)

- Revised Title: Formerly “Admission, transfer and discharge rights,” revises title to reflect current terminology that applies to all instances where care of a resident is transferred.
- Transfers or Discharge: Requires not only that a transfer or discharge be documented in the clinical record, but also that specific information, such as history of present illness, reason for transfer and past medical/surgical history, be exchanged with the receiving provider or facility when a resident is transferred. We are not proposing to require a specific form, format, or methodology for this communication.

Resident assessments (§483.20)

- Preadmission Screening and Resident Review (PASARR): Clarifies what constitutes appropriate coordination of a resident’s assessment with the PASARR program under Medicaid.
- Technical Corrections: Adds references to statutory requirements that were inadvertently omitted from the regulation when sections 1819 and 1919 of the Act were first implemented.
- Section 1919(e)(7)(A)(ii) and (iii) of the Act: Adds exceptions to the readmission screening requirements for individuals with mental illness and individuals with intellectual disabilities for admittance into a nursing facility, with respect to transfer to or from a hospital.
- Section 1919(e)(7)(B)(iii) of the Act: Adds a requirement that a nursing facility must notify the state mental health authority or intellectual disability authority for resident evaluation promptly after a significant change in the mental or physical condition of a resident with a mental illness or intellectual disability.

- Replaces the term “mental retardation” with “intellectual disability” throughout the section, as appropriate.

Comprehensive Person-Centered Care Planning (§483.21) *New Section*

- **Baseline Care Plan:** Requires facilities to develop a baseline care plan for each resident, within 48 hours of their admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care.
- **PASARR:** Adds a requirement to include as part of a resident’s care plan any specialized services or specialized rehabilitation services the nursing facility will provide as a result of PASARR recommendations. If a facility disagrees with the findings of the PASARR, it must indicate its rationale in the resident’s medical record.
- **Interdisciplinary Team (IDT):**
 - Adds a nurse aide, a member of the food and nutrition services staff, and a social worker to the required members of the interdisciplinary team that develops the comprehensive care plan.
 - Requires facilities to provide a written explanation in a resident’s medical record if the participation of the resident and their resident representative is determined to not be practicable for the development of the resident’s care plan.
- **Discharge Planning:**
 - The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185) amended Title XVIII of the Social Security Act by, among other things, adding Section 1899B to the Social Security Act. Section 1899B(i) requires that certain providers, including long term care facilities, take into account, quality, resource use, and other measures to inform and assist with the discharge planning process, while also accounting for the treatment preferences and goals of care of residents. This section implements the discharge planning requirements mandated by the IMPACT Act by revising, or adding where appropriate, discharge planning requirements for LTC facilities.
 - Requires facilities to document in a resident’s care plan the resident’s goals for admission, assess the resident’s potential for future discharge, and include discharge planning in the comprehensive care plan, as appropriate.
 - Requires that the resident’s discharge summary include a reconciliation of all discharge medications with the resident’s pre-admission medications (both prescribed and over-the-counter).
 - Adds to the post discharge plan of care a summary of what arrangements have been made for the resident’s follow up care and any post-discharge medical and non-medical services.

Quality of Care and Quality of Life (§483.25)

- **Overarching Principles:** Clarifies that quality of care and quality of life are overarching principles in the delivery of care to residents of nursing homes and should be applied to every service provided.

- Activities of Daily Living (ADLs): Clarifies the requirements regarding a resident's ability to perform ADLs.
- Director of Activities Qualifications: Solicits comments on whether the requirements for the director of the activities program remain appropriate and what should serve as minimum requirements for this position. We are not proposing specific changes at this time.
- Updating Current Practices: Modifies existing requirements for nasogastric tubes to reflect current clinical practice, and to include enteral fluids in the requirements for assisted nutrition and hydration.
- Special Need Issues: Adds a new requirement that facilities must ensure residents receive necessary and appropriate pain management.
- Re-designation of Requirements: Relocates the provisions regarding unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations to §483.45 Pharmacy services.

Comment: AHCA recommended to CMS an update on the requirements for nasogastric tubes.

Physician services (§483.30)

- In-person Evaluation: Requires an in-person evaluation of a resident by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist before an unscheduled transfer to a hospital.
- Delegation of Orders: Allows physicians to delegate dietary orders to dietitians and therapy orders to therapists.

Comment: The requirements for an in-person evaluation by a physician or NPP before an unscheduled transfer to a hospital may be problematic for some nursing centers.

Nursing services (§483.35)

- Sufficient Staffing: Adds a competency requirement for determining sufficient nursing staff based on a facility assessment, which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of care plans.

Comment: It is important that members carefully review and evaluate this proposed new requirement.

Behavioral health services (§483.40) *New Section*

- New Section: Adds a new section that focuses on the requirement to provide the necessary behavioral health care and services to residents in accordance with their comprehensive assessment and plan of care.

- Staffing:
 - Facility Assessment: Requires facilities to determine their direct care staff needs, based on the facility’s assessment.
 - Competency Approach: Requires that staff must have the appropriate competencies and skills to provide behavioral health care and services, which include caring for residents with mental and psychosocial illnesses and implementing non-pharmacological interventions.
 - Social Worker: Adds “gerontology” to the list of possible human services fields from which a bachelor degree could provide the minimum educational requirement for a social worker.

Pharmacy services (§483.45)

- Drug Regimen Review:
 - Adds the requirement that a pharmacist review a resident’s medical chart at least every 6 months and when the resident is new to the facility, a prior resident returns or is transferred from a hospital or other facility, and during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic or any drug the QAA Committee has requested be included in the pharmacist’s monthly drug review.
 - Requires the pharmacist to document in a written report any irregularities noted during the drug regimen review that lists at a minimum, the resident’s name, the relevant drug, and the irregularity identified, to be sent to the attending physician and the facility’s medical director and director of nursing.
 - Requires that the attending physician document in the resident’s medical record that he or she has reviewed the identified irregularity and what, if any, action they have taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident’s medical record.
- Irregularities: Adds a definition of “irregularities” that would include, but not be limited to, the definition of “unnecessary drugs.”
- Psychotropic Drugs: Revises existing requirements regarding “antipsychotic” drugs to refer to “psychotropic” drugs.
 - Requires that facilities ensure residents who have not used psychotropic drugs not be given these drugs unless medically necessary.
 - Requires residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue use of these psychotropic drugs.
 - Defines “psychotropic drug” as any drug that affects brain activities associated with mental processes and behavior.
 - Requires PRN (Pro re nata or as needed) orders for psychotropic drugs be limited to 48 hours. Orders could not be continued beyond that time unless the primary care provider (for example, the resident’s physician) reviewed the need for the medications prior to renewal of the order, and documented the rationale for the order in the resident’s clinical record.

- Re-designation of Requirements: Relocates provisions in §483.25 “Quality of Care” regarding unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations into this section.

Comment: The definition of “psychotropic drug” may be problematic. The requirements related to the drug regimen review must be carefully considered and analyzed.

Laboratory, radiology, and other diagnostic services (§483.50) *New Section*

- Ordering Services: Clarifies that a physician assistant, nurse practitioner or clinical nurse specialist may order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope of practice laws.
- Laboratory Services: Clarifies that the ordering physician; physician assistant; nurse practitioner or clinical nurse specialist, be notified of abnormal laboratory results when they fall outside of clinical reference ranges, in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician’s, physician assistant’s; nurse practitioner’s or clinical nurse specialist’s orders.

Comment: AHCA recommended CMS allow NPPs to practice within their designated scope of work and CMS incorporated this recommendation into the proposed changes.

Dental services (§483.55)

- For Skilled Nursing Facilities (SNFs): Prohibits SNFs from charging a Medicare resident for the loss or damage of dentures determined in accordance with facility policy to be the facility’s responsibility.
- For Nursing Facilities (NFs): Requires NFs to assist residents who are eligible to apply for reimbursement of dental services as an incurred medical expense under the Medicaid state plan.
- For both SNFs and NFs: Clarifies that with regard to a referral for lost or damaged dentures “promptly” means within 3 business days unless there is documentation of extenuating circumstances.

Food and nutrition services (§483.60)

- Staffing: Requires facilities to employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the dietary service while taking into consideration resident assessments, and individual plans of care, including diagnoses and acuity, as well as the facility’s resident census.
- Dietitian Qualification: Clarifies that a “qualified dietitian” is one who is registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics or who meets state licensure or certification requirements. For dietitians hired or contracted with prior to the effective date of these regulations, we propose to allow up to 5 years to meet the new requirements.

- **Director of Food Service:** Adds to the requirement for the designation of a director of food and nutrition service that the person serving in this position be a certified dietary manager, certified food service manager, or have a certification for food service management and safety from a national certifying body or have an associate's or higher degree in food service management or hospitality from an accredited institution of higher learning. In states that have established standards for food service managers, this person must meet state requirements for food service managers.
- **Menus and Nutritional Adequacy:** Adds to the requirements that menus reflect the religious, cultural and ethnic needs and preferences of the residents, be updated periodically, and be reviewed by the facility's qualified dietitian or other clinically qualified nutrition professional for nutritional adequacy while not limiting the resident's right to make personal dietary choices.
- **Providing Food and Drink:** Adds to the requirements that facilities provide food and drink that take into consideration resident allergies, intolerances, and preferences and ensure adequate hydration.
- **Ordering Therapeutic Diets:** Allows the attending physician to delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by state law.
- **Frequency of Meals:** Requires facilities to have available suitable and 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 resident's plan of care.
- **Use of Feeding Assistants:** Requires that facilities document the clinical need of a feeding assistant and the extent to which dining assistance is needed in the resident's comprehensive care plan.
- **Food Safety:**
 - Clarifies that facilities may procure food items obtained directly from local producers and are not prohibited from using produce grown in facility gardens, subject to compliance with applicable safe growing and food handling practices.
 - Clarifies that residents are not prohibited from consuming foods that are not procured by the facility.
 - Requires facilities to have a policy regarding the use and storage of foods brought to residents by family and other visitors.

Comment: This section incorporates some language that has existed in CMS policy. AHCA recommended regulations should never be so restrictive they prevent implementation of new practice, consistent with new models of care and respecting resident choice. Some of the changes in this section reflect this approach.

Specialized rehabilitative services (§483.65)

- **Provision of Services.**
 - Adds respiratory services to those services identified as specialized rehabilitative services.
 - Clarifies what constitutes as rehabilitative services for mental illness and intellectual disability.

Outpatient rehabilitative services (§483.67)

- Providing Services: Establishes new health and safety standards for facilities that choose to provide outpatient rehabilitative therapy services.

Administration (§483.70)

- Organization: Relocates various portions of this section into other sections of the rule as deemed appropriate.
- Facility Assessment: Requires facilities to:
 - Conduct and document 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 facility must review and update that assessment, as necessary, and at least annually.
 - Review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment.
 - Address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.
- Clinical Records: Establishes requirements that mirror some of those found in the HIPAA Privacy Rule (45 CFR part 160, and subparts A and E of part 164).
- Binding Arbitration Agreements: 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 to the residents and they acknowledge that they understand the agreement; the agreements 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 the resident or the resident representative signing a binding arbitration agreement. Moreover, the agreement could not prohibit or discourage the resident or anyone else from communicating with federal, state, or local health care or health-related officials, including representatives of the Office of the State Long-Term Care Ombudsman.

Comment: The proposed rule requires the arbitration agreement be separate from the contract.

Quality assurance and performance improvement (QAPI) (§483.75) New Section

- QAPI Program: Requires all LTC facilities to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care and quality of life.

Comment: This is an extensive section and the preamble of the proposed rule specifies specific areas that must be included in QAPI.

Infection control (§483.80)

- Infection Prevention and Control Program (IPCP): Requires facilities to have a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under an arrangement based upon its facility and resident assessments that is reviewed and updated annually.
- Infection Prevention and Control Officer (IPCO): Requires facilities to designate an 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.

Comment: This section is extensive and should be reviewed in detail. Note: antibiotic stewardship program must be implemented; each center must have an infection prevention and control officer with specialized training; a system of surveillance is required.

Compliance and ethics program (§483.85) New Section

- Compliance and Ethics Program: Requires the operating organization for each facility to have in operation a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 11281(b) of the Act.

Comment: Centers must use internal controls to more efficiently monitor adherence to applicable federal/state laws and regulations, to deter non-compliance, and to improve quality of care. Past OIG Guidance for nursing center Compliance Programs (2000 and 2008) is cited in the preamble and the proposed rule essentially mimics much of that OIG guidance. AHCA has an entire webpage on compliance programs, and has spent significant time and effort to educate our membership on this topic.

Physical environment (§483.90)

- Resident Rooms: Requires facilities initially certified after the effective date of this regulation to accommodate no more than two residents in a bedroom.
- Toilet Facilities: Requires facilities initially certified after the effective date of this regulation to have a bathroom equipped with at least a toilet, sink and shower in each room.
- Smoking: Requires facilities to establish policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety.

Comment: Note changes for "newly certified" centers.

Training requirements (§483.95) New Section

- Adds a new section to the rule that sets forth all the requirements of an effective training program that facilities must develop, implement, and maintain for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. Training topics must include:
 - Communication: Requires facilities to include effective communications as a mandatory training for direct care personnel.
 - Resident Rights and Facility Responsibilities: Requires facilities to ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth in the regulations.
 - Abuse, Neglect, and Exploitation: Requires facilities, at a minimum, to educate staff on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property, and procedures for reporting these incidents.
 - QAPI & Infection Control: Requires facilities to include mandatory training as a part of their QAPI and infection prevention and control programs that educate staff on the written standards, policies, and procedures for each program.
 - Compliance and Ethics: Requires the operating organization for each facility to include training as a part of their compliance and ethics program. Requires annual training if the operating organization operates five or more facilities.
 - In-Service Training for Nurse Aides: Requires dementia management and resident abuse prevention training to be a part of 12 hours per year in-service training for nurse aides.
 - Behavioral Health Training: Requires facilities to provide behavioral health training to its entire staff, based on the facility assessment at §483.70(e).

Comment: It is important for all providers to understand new training requirements.

CMS requests comments on the entire proposed rule and in addition, is specifically soliciting comments on the following:

1. CMS is seeking comments on the scope and type of changes proposed here.

Given the comprehensive nature of our proposed revisions, we are soliciting comments regarding potential unintended consequences or unanticipated risks to SNF and NF residents, either related to a specific proposal or in general, and what those concerns might be. In addition, we are interested in stakeholder comments related to an appropriate timeframe for nursing homes to implement these regulations. CMS generally implements changes to regulatory requirements for the survey and certification process within 12 months of a final rule. Following finalization of this proposed rule, CMS anticipates that it may require a longer period of time to implement the changes outlined in the final rule. The additional time may be needed to develop revised interpretive guidance and survey processes, conduct surveyor training on the changes, and implement the software changes in the Quality Indicator Survey (QIS) system, which would include changing the underlying framework of the QIS system as many of the existing requirements have been reorganized. We also expect that it may take a longer period for nursing facilities to implement these changes and seek stakeholder suggestions regarding an appropriate implementation

timeframes. Lastly, we seek comment on additional streamlining and reduction of outdated policies as a means of balancing the new policies being proposed.

2. Transitions of Care.

We are soliciting comment on both the information elements we are requiring and the time frame for transmission of the required information. While we are not proposing any specific form, format, or methodology for the communication of this information for all facilities, we strongly believe that those facilities that are electronically capturing this information should be doing so using certified health IT that will enable the real time electronic exchange with the receiving provider. By utilizing certified health IT, facilities can ensure that they are transmitting interoperable data that can be used by other settings, supporting more robust care coordination and higher quality care for patients. We are soliciting comments on state and facility bed-hold policies and state reserve bed payment policies, including whether the proposed notices have adequately differentiated these. Further, we are interested in the impact, if any, of reserve bed arrangements between some hospitals and some facilities.

3. Quality of Care and Quality of Life.

We received stakeholder input on the requirements for the director of a facility activities program and considered, but did not modify the requirements for the director of the activities program. However, we are soliciting comments on the current requirements to determine if they remain appropriate and, if not, what the evidence is for changing the current requirements for this position and what stakeholders would recommend as minimum requirements for this position.

4. Pharmacy Services.

We are proposing to use the definition used in the November 2001 OIG report, "Psychotropic Drug Use in Nursing Homes" (OEI-02-00-00490), which is that they are drugs that affect brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (1) anti-psychotic, (2) anti-depressant, (3) antianxiety, (4) hypnotic, (5) opioid analgesic, and (6) any other drug that results in effects similar to the drugs listed above. We are proposing the last category, "(6) any other drug that results in effects similar to the drugs listed above," to address other medications. We are also specifically soliciting comments on this definition and the types of drugs that should be included.

5. Administration and binding arbitration agreements.

Finally, in order to address concerns about conflict of interest when the resident has a guardian that is affiliated with the facility, we propose to specify that the guardians or representatives cannot consent to an agreement for binding arbitration on the resident's behalf unless that individual is allowed to do so under state law, all of the other requirements in this section is met, and the individual has no interest in the facility. We are also aware that there are concerns that these agreements should be prohibited in the case of nursing home residents. Therefore, we are also soliciting comments on whether binding arbitration agreements should be prohibited.