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[CMS–3260–F]

RIN 0938–AR61

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. These revisions are also an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

DATES: *Effective date:* These regulations are effective on November 28, 2016.

Implementation date: The regulations included in Phase 1 must be implemented by November 28, 2016.

The regulations included in Phase 2 must be implemented by November 28, 2017.

The regulations included in Phase 3 must be implemented by November 28, 2019.

A detailed discussion regarding the different phases of the implementation timeline can be found in Section B. II ''Implementation Date.''

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SUPPLEMENTARY INFORMATION:

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AAA Area Agencies on Aging
ACL Administration for Community Living
ADL Activities of Daily Living
AHCA American Health Care Association
AHLA American Health Lawyers Association
ANSI American National Standards Institute
ASPE Assistant Secretary for Planning and Evaluation
BPSD Behavioral and Psychological Symptoms of Dementia
CASPER Certification and Survey Provider Enhanced Reports
CIL Centers for Independent Living
CLIA Clinical Laboratory Improvement Amendment
CMS Centers for Medicare & Medicaid Services
CNS Clinical Nurse Specialist
CPR Cardiopulmonary Resuscitation
DoN Director of Nursing
EHR Electronic Health Records
FDA Food and Drug Administration
GAO Government Accountability Office
HACCP Hazard Analysis and Critical Control Point
HAI Healthcare-Associated Infection
HHS U.S. Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
ICN International Council of Nurses
IDT Interdisciplinary Team
IG Interpretive Guidance
IP Infection Preventionist
IPCP Infection Prevention and Control Program
LSC Life Safety Code
LTC Long-Term Care
NATCEP Nurse Aide Training Competency Evaluation Program
MAR Medication Administration Record
MDS Minimum Data Set
NA Nurse Aide
NF Nursing Facility
NP Nurse Practitioner
OIG Office of the Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator
PA Physician Assistant
PASARR Preadmission Screening and Resident Review
PIPs Performance Improvement Projects
PEU Protein-Energy under Nutrition
QA Quality Assurance
QAA Quality Assessment and Assurance
QAPI Quality Assurance and Performance Improvement
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RN Registered Nurse
SNF Skilled Nursing Facility
WHO World Health Organization

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This final rule is organized as follows:

I. Background

A. Executive Summary

1. Purpose

Consolidated Medicare and Medicaid requirements for participation (requirements) for long term care (LTC) facilities (42 CFR part 483, subpart B) were first published in the **Federal Register** on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address a specific issue. However, they have not been comprehensively reviewed and updated since 1991 (56 FR 48826, September 26, 1991), despite substantial changes in service delivery in this setting.

Since the current requirements were developed, significant innovations in resident care and quality assessment practices have emerged. In addition, the population of LTC facilities has changed, and has become more diverse and more clinically complex. Over the last two to three decades, extensive, evidence-based research has been conducted and has enhanced our knowledge about resident safety, health outcomes, individual choice, and quality assurance and performance improvement. In light of these changes, we recognized the need to evaluate the regulations on a comprehensive basis, from both a structural and a content perspective. Therefore, we reviewed regulations in an effort to improve the quality of life, care, and services in LTC

facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations. Specifically, we are adding new requirements where necessary, eliminating duplicative or unnecessary provisions, and reorganizing the regulations as appropriate. Many of the revisions are aimed at aligning requirements with current clinical practice standards to improve resident safety along with the quality and effectiveness of care and services delivered to residents. Additionally, we believe that these revisions will eliminate or significantly reduce those instances where the requirements are duplicative, unnecessary, and/or burdensome.

2. Summary of Provisions

Basis and Scope (§ 483.1)

• We have added the statutory authority citations for sections 1128I(b) and (c) and section 1150B of the Social Security Act (the Act) to include the compliance and ethics program, quality assurance and performance improvement (QAPI), and reporting of suspicion of a crime requirements to this section.

Definitions (§ 483.5)

• We have added the definitions for ''abuse'', ''adverse event'', ''exploitation'', ''misappropriation of resident property'', ''mistreatment'', ''neglect'', ''person-centered care'', ''resident representative'', and ''sexual abuse'' to this section.

Resident Rights (§ 483.10)

• We are retaining all existing residents' rights and updating the language and organization of the resident rights provisions to improve logical order and readability, clarify aspects of the regulation where necessary, and updating provisions to include advances such as electronic communications.

Freedom From Abuse, Neglect, and Exploitation (§ 483.12)

• We are requiring facilities to investigate and report all allegations of abusive conduct. We also are specifying 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.

Admission, Transfer, and Discharge Rights (§ 483.15)

• We are requiring that a transfer or discharge be documented in the medical record and that specific information be exchanged with the receiving provider or facility when a resident is transferred.

Resident Assessments (§ 483.20)

• We are clarifying what constitutes appropriate coordination of a resident's assessment with the Preadmission Screening and Resident Review (PASARR) program under Medicaid. We are also adding references to statutory requirements that were inadvertently omitted from the regulation when we first implemented sections 1819 and 1919 of the Act.

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

• We are requiring facilities to develop and implement 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.

• We are adding a nurse aide and a member of the food and nutrition services staff to the required members of the interdisciplinary team that develops the comprehensive care plan.

• We are requiring that facilities develop and implement a discharge planning process that focuses on the resident's discharge goals and prepares residents to be active partners in post-discharge care, in effective transitions, and in the reduction of factors leading to preventable re-admissions. We are also implementing the discharge planning requirements mandated by The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) by revising, or adding where appropriate, discharge planning requirements for LTC facilities.

Quality of Care (§ 483.24)

• We are requiring that each resident receive and the facility provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

Quality of Life (§ 483.25)

• Based on the comprehensive assessment of a resident, we are requiring facilities to ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the residents' choices.

Physician Services (§ 483.30)

• We are allowing attending physicians to delegate dietary orders to qualified dietitians or other clinically qualified nutrition professionals and therapy orders to therapists.

Nursing Services (§ 483.35)

• We are adding a competency requirement for determining the sufficiency of 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 individual care plans.

Behavioral Health Services (§ 483.40)

• We are adding a new section to subpart B 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.

• We are adding ''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)

• We are requiring that a pharmacist review a resident's medical chart during each monthly drug regimen review.

• We are revising existing requirements regarding ''antipsychotic'' drugs to refer to ''psychotropic'' drugs and define ''psychotropic drug'' as any drug that affects brain activities associated with mental processes and behavior. We are requiring several provisions intended to reduce or eliminate the need for psychotropic drugs, if not clinically contraindicated, to safeguard the resident's health.

Laboratory, Radiology, and Other Diagnostic Services (§ 483.50) *New Section*

• We are clarifying 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.

Dental Services (§ 483.55)

• We are prohibiting SNFs and NFs from charging a Medicare resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility, and we are adding a requirement that the facility have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility. We are requiring NFs to assist residents who are eligible to apply for reimbursement of dental services under the Medicaid state plan, where applicable.

• We are clarifying that with regard to a referral for lost or damaged dentures ''promptly'' means that the referral must be made within 3 business days unless there is documentation of extenuating circumstances.

Food and Nutrition Services (§ 483.60)

• We are requiring facilities to provide each resident with a nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident. We are also requiring facilities to employ sufficient staff, including the designation of a director of food and nutrition service, with the appropriate competencies and skills sets to carry out the functions of dietary services while taking into consideration resident assessments and individual plans of care, including diagnoses and acuity, as well as the facility's resident census.

Specialized Rehabilitative Services (§ 483.65)

• We have added respiratory services to those services identified as specialized rehabilitative services.

Administration (§ 483.70)

• We have largely relocated various portions of this section into other sections of subpart B as deemed appropriate.

• We require facilities to conduct, document, and annually review a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. Facilities are required to 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.

• Binding Arbitration Agreements: We are requiring that facilities must not enter into an agreement for binding arbitration with a resident or their representative until after a dispute arises between the parties. Thus, we are prohibiting the use of pre-dispute binding arbitration agreements.

Quality Assurance and Performance Improvement (QAPI) (§ 483.75)

• We are requiring 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.

Infection Control (§ 483.80)

• We are requiring facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist (IP).

Compliance and Ethics Program (§ 483.85) *New Section*

• We are requiring the operating organization for each facility to have in effect 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 1128I(b) of the Act.

Physical Environment (§ 483.90)

• We are requiring facilities that are constructed, re-constructed, or newly certified after the effective date of this regulation to accommodate no more than two residents in a bedroom. We are also requiring facilities that are constructed, or newly certified after the effective date of this regulation to have a bathroom equipped with at least a commode and sink in each room.

Training Requirements (§ 483.95) *New Section*

• We are adding a new section to subpart B 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.

3. Summary of Costs and Benefits

We estimate the total projected cost of this final rule will be about $831 million in the first year and $736 million per year for subsequent years. While this is a large amount in total, the average costs per facility are estimated to be about $62,900 in the first year and $55,000 per year for subsequent years. Although the overall magnitude of cost related to this regulation is economically significant, we note that these costs are significantly less than the amount of Medicare and Medicaid spending for LTC services. According to the 2015 Annual Report of the Medicare Trustees, payments for SNF services from Medicare Part A were $29.92 billion for fiscal year 2015 and payments for NF services were $50.6 billion for fiscal year 2013 (see *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/2015.html*).

We are unable to quantify the benefits of the final rule; however, this final rule creates new efficiencies and flexibilities for facilities that are likely to reduce avoidable hospital readmissions, increase the rate of improvement in quality throughout facilities, and create positive business benefits for facilities.

B. Statutory and Regulatory Authority of the Requirements for Long-Term Care Facilities

In addition to specific statutory requirements set out in sections 1819 and 1919 and elsewhere in the Act, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act permit the Secretary of the Department of Health and Human Services (the Secretary) to establish any additional requirements relating to the health, safety, and well-being of SNF and NF residents, respectively, as the Secretary finds necessary.

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the state Medicaid agency, as appropriate. LTC facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. LTC facilities include SNFs for Medicare and NFs for Medicaid. The federal participation requirements for SNFs, NFs, or dually certified facilities, are codified in the implementing regulations at 42 CFR part 483, subpart B. Sections 1819(b)(1)(A) and 1919(b)(1)(A) of the Act provide that a SNF or NF must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident. In addition, the IMPACT Act (Pub. L. 113–185) amended Title XVIII of the Act by, among other things, adding Section 1899B to the Act. Section 1899B(i) of the Act 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.

The Affordable Care Act made a number of changes to the Medicare and Medicaid programs. For instance, in an effort to increase accountability for SNFs and NFs, section 6102 of the Affordable Care Act established a new section 1128I of the Act. In general, section 1128I(b) of the Act requires LTC facilities to have in operation an effective compliance and ethics program that is effective in preventing and

detecting criminal, civil, and administrative violations and in promoting quality of care. Section 1128I(b)(2) of the Act specifies that the Secretary, working jointly with the Inspector General of the Department of Health and Human Services (HHS), shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program. Further, section 1128I(c) of the Act adds a requirement for a quality assurance and performance improvement program (QAPI). Lastly, in an effort to promote dementia management and prevent abuse, section 6121 of the Affordable Care Act amended sections 1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Act by requiring dementia and abuse prevention training to be included as part of training requirements for nurse aides (NAs).

C. Why revise the long-term care requirements

On July 16, 2015, we published a proposed rule entitled, ''Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities'' (80 FR 42168). In the proposed rule we included a robust discussion about the history the LTC requirements and how the current care and service delivery practices of LTC facilities have changed over time. We encourage readers to refer to the proposed rule for this discussion. As discussed in the proposed rule, the requirements for LTC facilities have not been comprehensively reviewed and updated since 1991. In addition, the number of individuals accessing SNF care has increased and the health concerns of individuals residing in LTC facilities have become more clinically complex. These factors demonstrated a need to comprehensively review the regulation and informed our approach for revising the regulations. The following discussion highlights our approach for revising the LTC regulations as well as some of the most significant revisions set forth in this final rule.

Facility Assessment and Competency-Based Approach

One of our goals in revising our minimum health and safety requirements for LTC facilities is to ensure that our regulations align with current clinical practice and allow flexibility to accommodate multiple care delivery models to meet the needs of the diverse populations that are provided services in these facilities. We have taken a competency-based approach that focuses on achieving the statutorily mandated outcome of ensuring that each resident is provided care that allows the resident to maintain or attain their highest practicable physical, mental, and psychosocial well-being. As discussed in further detail, we are requiring facilities to assess their facility capabilities and their resident population. This competency-based approach is compatible with existing state requirements and business practices, and promotes both efficiency and effectiveness in care delivery.

Current HHS Quality Initiatives

This final rule is intended to meet the spirit of current HHS quality initiatives that cut across various providers. As an effective steward of public funds, CMS is committed to strengthening and modernizing the nation's health care system to provide access to high quality care and improved health at lower cost. This includes improving the patient experience of care, both quality and satisfaction, improving the health of populations, and reducing the per capita cost of health care. As discussed below, we are implementing several revisions consistent with these efforts.

- Reducing Avoidable Hospitalizations

One goal of the HHS Partnership for Patients Initiative is to reduce the number of individuals who experience a preventable complication requiring rehospitalization. This effort aims to improve the quality of care and services for individuals cared for in LTC facilities. In support of this initiative, CMS launched the ''Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents'' (*http://innovation.cms.gov/initiatives/rahnfr/*) in 2012. This Initiative focuses on long-stay nursing facility residents who are enrolled in the Medicare and Medicaid programs. Additional information and resources are available at *http://innovation.cms.gov/initiatives/rahnfr/index.html.*

Consistent with the HHS focus on reducing unnecessary hospitalization, this final rule strengthens the minimum health and safety standards for LTC facilities in hopes of contributing to a reduction in unnecessary hospital admissions of LTC facility residents. We discuss those changes in more detail in the discussion that follows.

- Healthcare Associated Infections

HHS is also working to reduce the incidence of healthcare associated infections (HAIs) across providers. In recognition of HAIs as an important public health and patient safety issue, HHS is sponsoring the ''National Action Plan to Prevent HAIs.'' This initiative seeks to coordinate and maximize the efficiency of prevention efforts across the federal government (*http://www.hhs.gov/ash/initiatives/hai/actionplan/*). Given the growing number of individuals receiving care in LTC settings and the presence of more complex medical care, these individuals are at an increased risk for HAIs. To advance these initiatives, this final rule implements revisions that we believe will provide more opportunities to achieve broad based improvement and contribute to reduced healthcare costs, while allowing for targeted interventions specific to each LTC facility.

- Behavioral Health

On March 29, 2012, CMS launched an initiative aimed at improving behavioral healthcare and safeguarding LTC facility residents from the use of unnecessary antipsychotic medications, the National Partnership to Improve Dementia Care in Nursing Homes. As part of the initiative, CMS has developed a national action plan that uses a multidimensional approach including public reporting, raising public awareness, regulatory oversight, and technical assistance/training and research. This plan is targeted at enhancing person-centered care for LTC facility residents, particularly those with dementia-related behaviors (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html*).

Similarly, with regard to minimum health and safety standards, this final rule implements regulatory changes that may lead to a reduction in the unnecessary use of antipsychotic medication and improvements in the quality of behavioral healthcare.

- Health Information Technology

HHS also has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange to improve health care. The Department is committed to accelerating health information exchange (HIE) through initiatives including: (1) Establishing a coordinated governance framework and process for nationwide health IT interoperability; (2) improving technical standards and implementation guidance for sharing and using a common clinical data set; (3) enhancing incentives for sharing electronic health information according to common technical standards, starting with a common clinical data set; and (4) clarifying

privacy and security requirements that enable interoperability. This strategy is described in greater detail in ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap'', available at *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*. The use of such technology can effectively and efficiently help facilities and other providers improve internal care delivery practices, support the exchange of important information across care team members (including patients and caregivers) during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs).

- Trauma-Informed Care

HHS has also undertaken broad-based activities to support Americans that have specific needs to be considered in delivering health care and other services. Activities include raising awareness about the special care needs of trauma survivors, including a targeted effort to support the needs of Holocaust survivors living in the United States. Trauma survivors, including veterans, survivors of large-scale natural and human-caused disasters, Holocaust survivors and survivors of abuse, are among those who may be residents of long-term care facilities. For these individuals, the utilization of trauma-informed approaches is an essential part of person-centered care. Person-centered care that reflects the principles set forth in SAMSHA's ''Concept of Trauma and Guidance for a Trauma-Informed Approach,'' HHS Publication No. (SMA) 14–4884, available at *http://store.samhsa.gov/shin/content/SMA14-4884/SMA14-4884.pdf,* will help advance the quality of care that a resident receives and, in turn, can substantially improve a resident's quality of life.

II. Provisions of the Proposed Regulation and Response to Public Comments

In response to our July 16, 2015 proposed rule (80 FR 42168), we received over 9,800 public comments. Commenters included long-term care consumers, advocacy groups for long-term care consumers, organizations representing providers of long-term care and senior service, long-term care ombudsman, state survey agencies, various health care associations, legal organizations, and many individual health care professionals. Below, we have organized our response to comments as follows: A. General Comments; B. Implementation, and C. Public Comments by Regulatory Section.

A. General Comments

Comment: Most commenters expressed overall support for the proposed revisions to the requirements. Commenters agreed that reforms to the existing requirements are necessary to ensure high quality care and quality of life in LTC facilities across the nation.

Specifically, many commenters support the change in focus towards person-centered care. One commenter stated that ''[t]he rule would require that facilities learn more about who the resident is as a person, provide greater support for resident preferences and give residents increased control and choice. This focus on person-centered care and culture change would improve both the resident's quality of life and quality of care.'' Commenters also expressed support for improved protections of resident's rights, protections against abuse and neglect, and a greater emphasis on resident and representative participation in care planning. Commenters also stated that change is necessary to reflect current standards of practice, and support our use of geriatrics-focused medical literature in developing the proposed requirements.

Response: We thank commenters for their support. Our intent in issuing the proposed requirements was to improve the quality of care and quality of life for residents of long term care facilities.

Comment: Some commenters commended CMS for the proposed revisions to the requirements, while stating that CMS should have proposed additional changes and reforms. For example, a few commenters stated that we should have explicitly required facilities to accommodate supported decision making, which is when an individual assists a resident in making his or her own decisions, rather than making decisions on their behalf. Commenters also expressed disappointment that the proposed requirements did not directly address dementia care.

Response: We thank the commenters for their responses, and believe that the flexible, person-centered nature of these requirements will support facilities in addressing each resident's goals and needs. For example, residents and their designated representatives can certainly engage in supported decision making with their care team—nothing in these requirements prohibits it. Further, we do address dementia care in the Behavioral Health sections of this final rule.

Comment: Many commenters expressed general worries that the proposed changes were too broad in scope, and that incremental changes would be easier to implement and better for LTC residents. We directly requested comments on the implementation of the revised requirements and commenters overwhelmingly indicated their preference for a phased implementation. Commenters also requested more time in which to submit comments, due to the depth and volume of the proposed revisions.

Response: We acknowledge that these requirements may be difficult to effectively implement within the standard delayed implementation period (typically 60 days for more comprehensive rulemakings). We are therefore implementing these requirements over a ''phase-in'' period. Please see section II.B. of this rule, ''Implementation,'' for a detailed discussion of the implementation timeframe. Also, in order to allow sufficient time for public review of the proposed rule, we did extend the public comment period by 30 days, instead of closing submissions after the typical 60-day public comment period. We thank the thousands of commenters who provided comments during the extended period.

Comment: Some commenters expressed disappointment that we continue to approach LTC facilities as health care institutions rather than ''homes.'' One commenter suggested we use the word ''nursing home'' instead of ''facility.''

Conversely, many commenters believe we should acknowledge that LTC facilities are no longer necessarily de facto homes, but skilled health care facilities providing more intensive care for shorter periods of time, and that the requirements should address the specific needs of shorter-stay residents, such as those who are rehabilitating after medical events before returning to their private residence. For example, these shorter stay residents (who usually stay for fewer than 30 days) are not likely interested in resident or family councils, or concerned about selecting a roommate. Commenters also expressed that short-stay individuals may not benefit from the same type of care planning as would be appropriate for longer term residents.

Response: We recognize that for many residents, a LTC facility is their home. That said, LTC facilities are specialized health care settings for individuals not capable of living independently and are not directly comparable to private residences. We do support LTC facilities in developing a home-like environment,

and note that residents are indeed recognized as residents, even if their stay is short.

We believe that the person-centered approach to care required in this rulemaking allows for flexibility in care planning and resident accommodations. A resident at the LTC facility for a short period of time may have a shorter or more focused plan of care than a long-term resident. Similarly, a short-term resident may elect not to participate in resident councils.

Comment: One commenter, who stated that their facility provides short-term rehab services following hospitalizations in addition to long-term care, expressed the belief that our proposed requirements would inhibit their ability to accept patients during evenings and weekends. They stated that this may cause ''backups'' in hospital discharges, and lead to patients being inappropriately discharged to their private home.

Response: We do not agree that our revised requirements limit admissions to long-term care facilities outside of weekday business hours. We encourage LTC facilities to work with local hospitals to ensure safe care transitions, and to exercise the flexibility allowed by the requirements to establish admissions and care planning policies appropriate for their community.

Comment: Commenters appreciated that CMS acknowledged and proposed to incorporate the full scopes of practice for non-physician practitioners related to actions that were formerly restricted to physicians. They supported these changes for being both cost effective and responsive to current standards of care.

Response: We agree and thank commenters for their support. Please note that statute restricts some positions and tasks to physicians, such as the requirement at section 1819(b)(6)(A) of the Act, which requires that the care of every resident be provided under the supervision of a physician. Where appropriate and permissible by statute, we have allowed for flexibility in who may perform certain tasks or services within their respective scopes of practice.

Comment: Some commenters stated that they saw no need for CMS to revise requirements for LTC facilities. They expressed concerns that the proposed requirements would be both excessively burdensome and confusing. A few commenters expressly identified the regulatory language of the proposed requirements as confusing. Commenters also stated their belief that the current requirements are adequate, and that changes would be detrimental to care.

Response: We thank the commenters for their input, but disagree that changes to the LTC requirements are unnecessary. Current requirements do not, in some respects, reflect advances in technology and the science of care delivery. In addition, while it is true that many facilities provide excellent care under the current requirements, data and incidents continue to show that there are LTC facilities that have room for improvement. These updated and revised requirements establish a framework for those facilities to raise their quality of care. We have reviewed and considered all comments, and in response to concerns over burden, we have revised some proposed requirements and burden estimates in this final rule. Where commenters brought up specific concerns, we address those in the relevant parts of this rule. Also, we have made clarifying revisions to several parts of the rule, in order to improve understanding.

Comment: Commenters disagreed on whether the proposed requirements align with current standards of practice. Some believe that current standards of practice may be inadequate or stated that they already met many of the newly proposed requirements. Others expressed concerns that a number of the proposed requirements are unrealistic or contrary to sound standards of practice.

Response: We recognize that standards of care are constantly evolving and have therefore tried to create meaningful, yet appropriately flexible, requirements. We thank the commenters for their input, and point out that this regulation establishes revised baseline requirements. These requirements are meant to ensure safe, professional, patient-centered care in all Medicare-and Medicaid-participating LTC facilities, while leaving room for facilities to improve and excel. We commend those facilities who strive to improve upon them and look forward to stakeholder feedback as the requirements are implemented.

Comment: A few commenters stated that they do not support the proposed reorganization of the Requirements of Participation and disagreed with the assertion that the reorganization improves the logical flow of the regulations. Commenters stated that working within the existing structure of the requirements would make it easier to implement new requirements and reduce burden on stakeholders.

Response: We thank the commenters for their input. In response to comments, we have made some changes to the order and arrangement of the requirements from the proposed rule, specifically with respect to proposed §§ 483.10, 483.11, and 483.25. In response to the concerns related to implementation, we again note that we are implementing the requirements over a phase-in period to allow for appropriate clarification and education for facilities, surveyors, and other stakeholders.

Comment: A few commenters were not supportive of the designation of these requirements of participation as ''requirements,'' rather than ''conditions of participation'' that apply to other Medicare-participating providers. Specifically, the commenters are concerned that this terminology effectively makes any violation or unmet requirement a reason for surveyors to close a facility.

Response: The term ''requirements'' reflects the statutory language at sections 1819 and 1919 of the Act. Although this rule establishes requirements for LTC facilities, and not conditions, we note that CMS and state agencies have always taken into consideration the scope and severity of violations. Except in very rare cases of serious, immediate health and safety risks to residents, facilities are always given an opportunity to address and correct deficiencies. The goal of the requirements and their enforcement is to ensure the health and safety of residents, which includes giving facilities the opportunity to improve and come into compliance with the requirements.

Comment: Some commenters expressed concerns that hands-on care would take a backseat to paperwork and documentation under the proposed requirements. Other commenters suggested that we could have gone further and established a detailed data collection program, which could be used to better identify achievement and best practices in LTC settings.

Response: It is not our intention to reduce staff time spent performing direct patient care; however, facilities must be able to demonstrate that care and services meet the requirements for participation. Unfortunately, instances of significant lapses in care continue to occur in facilities. Our requirements, including QAPI, Compliance and Ethics, and Infection Control, as well as requirements for policies and procedures, are intended to protect the health and safety of residents, prevent harm and support quality of life for residents. Establishing a detailed data collection program is outside the scope of this rule.

Comment: Some commenters stated that revisions to the requirements are meaningless without appropriate enforcement. Commenters asked that,

prior to implementation of new requirements, CMS ensure all federal and state surveyors are thoroughly trained about the substance of these new requirements as well as current professional standards of care for all professionals working in nursing centers. One commenter further suggested that surveyors be required to demonstrate competence in all relevant areas, as shown through testing and monitoring. Alternately, one commenter offered their support for ''movement from a punitive survey process to more towards a process which survey agencies and care givers work hand in hand for positive outcomes. Surveyors have a wealth of knowledge and exposure to numerous facilities. Passing on best practices to improve care giving and focusing on training the care givers would be a[n] improvement.''

Other commenters offered concerns about variability and perceived inconsistencies between surveys and surveyors. A few commenters urged CMS to provide defined consequences for noncompliance with the regulations, particularly those related to residents' rights, grievances, and abuse and neglect, including finding of Immediate Jeopardy (as appropriate) and, ultimately, sanctions, including large civil monetary penalties, temporary management, directed corrective actions, and exclusion from participation in Federal health care programs, as appropriate.

Response: We agree that surveyors must be educated and trained on the new requirements and note that such training happens on a regular basis, especially when new requirements are issued. We will consider these comments for future rulemaking. We note that surveyors are not permitted by law to act simultaneously as consultants. Specifying precise consequences for facilities out of compliance with specific requirements is outside the scope of this rulemaking.

Comment: Commenters expressed strong support for stakeholder involvement in the development of sub-regulatory materials. One commenter expressed concerns about the approach CMS has been recently taking utilizing relatively brief conference calls with numerous callers (too numerous to allow effective discussion) allegedly to engage stakeholders in development of critical implementation issues. The commenters felt that this did not constitute sufficient stakeholder engagement. One commenter observed that upon issuance of a final rule, CMS will need to develop sub-regulatory requirements, including interpretive guidelines, to provide much greater detail and guidance on the regulatory revisions. The commenter recommended that provider organizations and association representatives be involved in the development of these specific requirements and guidelines to ensure they are consistent with sound practice, pragmatic in approach, sufficiently flexible, cost-effective and representative of the current realities of providing LTC facility care to an increasingly complex and diverse resident population.

Response: We thank commenters for their input and will consider their views for possible later action.

Comment: Several commenters associated with rural LTC facilities expressed concerns that meeting the proposed requirements would be difficult in rural areas. They identified staffing as a particular hardship in rural areas, especially the proposed requirement for physician evaluation prior to non-emergency hospital transfer. Rural facilities also stated that it was already difficult to hire and retain qualified staff in all skilled positions, simply due to rural population levels. Other commenters pointed to the general labor shortage in health care across much of the country.

Response: We appreciate the commenters' input and note that we have revised the proposed requirements to allow for greater flexibility and in consideration of staffing concerns. Specifically, we are not finalizing the proposed requirement for pre-transfer evaluation by a practitioner. That said, these regulations establish what we have identified as basic staffing needs to ensure appropriate expertise and quality of care. We sympathize with those facilities that are unable to access a large labor pool, but we cannot condone substandard care. We discuss physician services and staffing requirements in greater detail in the relevant sections of this rule.

Comment: Commenters expressed concern about the overall burden of the proposed requirements, and many believe that we may have underestimated the burden on stakeholders. One commenter expressed concern about the cumulative compliance costs associated with the many changes proposed in the regulations. They believe that the additional staffing, credentialing, training, systems and contractual relationships that will be required for compliance will add to the financial stresses that LTC facilities are experiencing from ongoing Medicare and Medicaid cuts. Another commenter protested our issuance of new, burdensome requirements while at the same time ''cutting fee-for-service reimbursements'' and implementing value-based purchasing.

Response: We have revised some provisions, such as the requirement for credentialing, in response to concerns about burden. In addition, we have our burden estimates in response to comments. Please see sections V, ''Collection of Information Requirements,'' and VI, ''Regulatory Impact Analysis (RIA),'' of this rule for more details about regulatory burden estimates.

We acknowledge that the SNF value-based purchasing (VBP) program, which will take effect in FY 2019, is intended to tie SNF payments more closely to rewarding positive patient care outcomes. Under section 1888(h)(6) of the Act, the VBP incentive payments to the higher-performing SNFs are to be funded through a 2 percent reduction in the overall SNF PPS payment rates (again, effective in FY 2019); accordingly, under the terms of the VBP legislation, a SNF's successful performance in meeting the applicable quality measures can help mitigate the actual impact of the overall payment reduction. These payment changes were specifically mandated by Congress when it enacted the SNF VBP legislation in section 215 of the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93). The requirements in this rulemaking share the VBP program's objective of improving the quality of care in the LTC setting. We note in addition that SNF PPS payment rates have increased steadily over recent years, due to market basket updates.

Comment: Many commenters stated concerns about inadequate Medicaid reimbursement, while others pointed out that private payer rates are continually rising to compensate for low Medicare reimbursement. Commenters worry that the current reimbursement rates are barely sufficient, in some cases already insufficient, to meet the current requirements, and that the issue will compound as facilities attempt to comply with the new requirements. Several commenters stated that falling Medicare and Medicaid reimbursement rates, relative to costs, will cause their facilities to close. Many of these commenters identified themselves as the sole LTC facilities within a geographic area, which would severely limit the options of their residents if faced with closure. One commenter suggested that, due to low Medicaid reimbursement rates, this rulemaking would disproportionately affect poor individuals who rely on Medicaid and the facilities that serve them. Another

commenter stated concerns about reduced amounts of Public Aid funding.

Response: Reimbursement rules are outside the scope of this rulemaking, and Medicaid reimbursement rates are determined by the states, with limited involvement by CMS. We do not participate in disbursement of public aid funding. We encourage commenters to address Medicaid reimbursement and public aid concerns to relevant state agencies and departments. Many commenters noted that phased implementation would be helpful in absorbing new costs. Please see Section B. ''Implementation'' for our discussion of phased-in implementation deadlines.

Comment: A number of commenters responded to our request for comments in ways that suggest misunderstandings of either current requirements or the proposed requirements. Notable misconceptions include the:

- Belief that allowing residents to choose their attending physician would be a new requirement.
- Impression that having a RN on the interdisciplinary care team would be a new requirement.
- Concerns that these requirements are entirely new, such that all existing health and safety activities at LTC facilities would need to be recreated or developed from scratch.
- Concerns that new staff would need to be hired to perform tasks already being handled by existing staff.
- Belief that a chaplain would be a mandatory member of the interdisciplinary care team.
- Belief that a complete care plan would have to be developed within a new resident's first 48 hours at the LTC facility.
- Belief that existing facilities would have to limit occupancy to two residents per room, even if that would reduce bed count.
- Impression that the new requirements are simply a duplicate of the old requirements.
- Uncertainty as to whether the LTC requirements are applicable to other healthcare settings, such as hospital ''swing-beds'' or assisted living facilities.

Some commenters also expressed concern that CMS may be unreasonably focused on regulating LTC facilities, to the point of not updating regulations and requirements for other provider types. Commenters also claimed that LTC facilities are ''the most regulated industry in America,'' and that ''the nuclear industry is less regulated'' than the LTC facility industry.

Response: We recognize that the proposed rule and this final rule are large, detailed documents, and that many individuals relied on summaries to learn about the proposed requirements. We understand that working professionals and family caregivers can be very busy, but we are concerned by some of these misinterpretations. Most of the misconceptions fell into three categories: Unfamiliarity with the old requirements, misunderstanding of the proposed requirements, or confusion about which facilities must meet the LTC requirements.

The comments displaying unfamiliarity with the existing requirements are troubling to us. The right of a LTC resident to choose his or her own attending physician is a long-standing patient right, which was established at section 1819(c)(1)(A)(i) of the Act by section 4201 of the Omnibus Budget Reconciliation Act of 1987 and at section 1919(c)(1)(A)(i) by section 4211 of the Omnibus Budget Reconciliation Act of 1987. We included the right to choose a physician in this rulemaking in order to support the statutory requirement, and remind stakeholders that it is not a new requirement and therefore should add no new regulatory burden. Similarly, the requirement that a RN serve as a member of an interdisciplinary team is not new to this rulemaking, but ''carried over'' from the old requirements to the revised requirements as an important foundational aspect of care planning. Also, we do not expect facilities to completely recreate health and safety activities. Existing effective programs may already meet the substance of the revised requirements completely, in which case no additional implementation work is necessary. We address these comments, and others, in greater detail in the relevant sections of this preamble.

For those misunderstood provisions of the proposed rule, we have attempted to clarify the relevant sections of the rule, and note that we did not propose that chaplains must be members of all interdisciplinary teams, only that their inclusion is permitted as deemed appropriate by facilities or residents. Similarly, we did not propose that a full plan of care be developed within a resident's first 48 hours, only that a baseline plan be established. The ''two persons per room'' requirement applies only to those facilities that receive approval to be constructed or reconstructed, or are newly certified after this rulemaking. Existing facilities with larger rooms are effectively grandfathered into compliance.

For those health care providers who are not sure whether these requirements apply to them, we encourage them to work with their facility's administration and governing body to determine applicability. This rulemaking applies to Medicare- and Medicaid-certified long term care facilities as defined at sections 1819 and 1919 of the Act and all facilities receiving payment under such programs. Swing-bed hospital units, for example, would need to meet specific conditions of participation for such units, as set out at 42 CFR 482.58, and which include a subset of the requirements contained 42 CFR 483. We note that CMS does not issue regulations or guidance for assisted living facilities, nor are they eligible for Medicare reimbursement. While some assisted living facilities do provide health services (such as medication supervision, nurse support, and emergency medical assistance for residents), they are not classified as health care providers or suppliers under the Act. Some states do regulate them, often as social service providers rather than health care providers. The requirements in this rulemaking may be helpful to other health care and social service settings, but only LTC facilities are required to meet them.

Comment: One commenter expressed concern about our use of the term ''state plan'' throughout the rule. The commenter felt that this is not meant to exclude those states where all Medicaid services in long term care are covered by a Section 1115 waiver and recommended we add the phrase ''or waiver'' where appropriate.

Response: We thank the commenter for their suggestion, but do not believe it is necessary to add ''or waiver.'' The commenter is correct that the use of the term ''state plan'' does not exclude those states where Medicaid-covered services in long term care facilities are provided pursuant to a CMS-approved demonstration project (often referred to as ''waivers''). Our use of the term ''state plan'' encompasses the plan and any such demonstrations.

B. Implementation Date

Comment: We received a substantial number of comments requesting that we consider delaying the implementation of the proposed requirements. Several commenters noted that the proposed rule was complex and that the comprehensive update of the regulations will be overwhelming for facilities to comply with. However, a few commenters noted that many of the proposed requirements will simply require adjustments in the current process. One commenter specifically noted that facilities should be well on their way with establishing a QAPI program and complying with the

proposed QAPI requirements. Many commenters also indicated concern regarding the financial burden associated with this regulation and suggested that a delayed implementation would allow facilities the time needed to establish compliance with the new requirements.

Commenters provided varying suggestions for a implementation timeframe. Some commenters provided suggestions specific to certain requirements. For example, one commenter recommended a 12- to 18-month implementation timeframe for pharmacy services-related requirements. Other commenters recommended that the entire regulation be implemented by phasing in requirements over a certain time period. In addition, commenters provided varying suggestions for an implementation date of the entire regulation that ranged from 1 to 10 years in the future.

Response: We appreciate the feedback from commenters. Given the comprehensive nature of the regulatory revisions, we agree that a longer period of time is necessary to implement the changes outlined in this final rule. We acknowledge that LTC facilities may find the comprehensive revision to the LTC requirements overwhelming and want to avoid any unintended consequences or unanticipated risks to both facilities and residents. We believe that allowing for a longer implementation period will allow LTC facilities the time necessary to come into compliance with the new requirements. In addition, we anticipate that additional time will 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.

While commenters provided varying suggestions for the appropriate implementation timeframe (ranging between 1 and 10 years), overall all commenters agreed that implementation will require more than a year and the majority of commenters suggested between 3 and 5 years. After considering these proposals, we are finalizing a phased-in implementation of the requirements over a 3 year time period. We believe that a phased-in approach over 3 years will sufficiently allow for LTC facilities to achieve compliance with the revised regulations without jeopardizing resident care. We note that these final regulations will be effective 60 days following the display of this final rule in the **Federal Register**, as discussed under the ''Effective Date'' section. Over the 3 year time period following the effective date of the final rule the requirements will be implemented in three phases. We have categorized the three phases based on the complexity of the revisions and the work necessary to revise the interpretive guidance and survey process based on the revisions. The first phase of implementation will occur upon the effective date of the final rule and include those requirements that were unchanged or received minor modification. We will provide updated training to surveyors on the new regulatory language.

The second phase of implementation will have a deadline of 1 year following the effective date of the final rule and in addition to those requirements implemented in phase one, this phase will also include those brand new requirements and those provisions that required more complex revisions. The additional time for implementation will allow for complete changes in our survey processes as well as updates to the survey guidance. We will provide updated guidance to facilities, update the traditional and QIS survey process, update the survey tags in accordance with the reorganization of the regulations, and provide training to surveyors on the new tags. The third and final phase of implementation will have a deadline of 3 years from the effective date of the final rule and include all the remaining requirements that were not implemented in phases 1 and 2. We expect that this final phase will allow for the complete set of revised requirements to be incorporated into the practices of LTC facilities and sufficiently enforced through the updated survey process.

Below we provide a detailed chart specifying the specific requirements that will be implemented in phases 1, 2, and 3 of the implementation time period for this final rule. We note that some regulatory sections may have certain requirements that are implemented in varying phases. In those instances we highlight the specific requirements in a regulatory section that will be implemented in a different phase.

Implementation Timeframes

****Note:** These final regulations will be *effective* 60 days following the date of public inspection of this final rule in the **Federal Register**. **

Phase 1: Upon the *effective date* of the final rule.

Phase 2: 1 year following the *effective date* of the final rule.

Phase 3: 3 years following the *effective date* of the final rule.

Regulatory section	Implementation deadline
§ 483.1 Basis and scope	This entire section will be implemented in Phase 1.
§ 483.5 Definitions	This entire section will be implemented in Phase 1.
§ 483.10 Resident rights	The section will be implemented in Phase 1 with the following exception: • *(g)(4)(ii)–(v) Providing contact information for State and local advocacy organizations, Medicare and Medicaid eligibility information, Aging and Disability Resources Center and Medicaid Fraud Control Unit*—Implemented in Phase 2.
§ 483.12 Freedom from abuse, neglect, and exploitation	This section will be implemented in Phase 1 with the following exceptions: • *(b)(4) Coordination with QAPI Plan*—Implemented in Phase 3. • *(b)(5) Reporting crimes/1150B*—Implemented in Phase 2.
§ 483.15 Admission, transfer, and discharge rights	This section will be implemented in Phase 1 with the following exceptions: • *(c)(2) Transfer/Discharge Documentation*—Implemented in Phase 2.
§ 483.20 Resident assessment	This entire section will be implemented in Phase 1.
§ 483.21 Comprehensive person-centered care planning	This section will be implemented in Phase 1 with the following exceptions: • *(a) Baseline care plan*—Implemented in Phase 2. • *(b)(3)(iii) Trauma informed care*—Implemented in Phase 3.
§ 483.24 Quality of life	This entire section will be implemented in Phase 1.