**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489**

**[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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## 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:<br>• *(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:<br>• *(b)(4) Coordination with QAPI Plan*—Implemented in Phase 3.<br>• *(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:<br>• *(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:<br>• *(a) Baseline care plan*—Implemented in Phase 2.<br>• *(b)(3)(iii) Trauma informed care*—Implemented in Phase 3. |
| § 483.24 Quality of life | This entire section will be implemented in Phase 1. |

| Regulatory section | Implementation deadline |
|---|---|
| § 483.25 Quality of care | This section will be implemented in Phase 1 with the following exception:<br>• *(m) Trauma-informed care*—Implemented in Phase 3. |
| § 483.30 Physician services | This entire section will be implemented in Phase 1. |
| § 483.35 Nursing services | This section will be implemented in Phase 1 with the following exception:<br>• *Specific usage of the Facility Assessment at § 483.70(e) in the determination of sufficient number and competencies for staff*—Implemented in Phase 2. |
| § 483.40 Behavioral health services | This section will be implemented in Phase 2 with the following exceptions:<br>• *(a)(1) As related to residents with a history of trauma and/or post-traumatic stress disorder*—Implemented in Phase 3.<br>• *(b)(1), (b)(2), and (d) Comprehensive assessment and medically related social services*—Implemented in Phase 1. |
| § 483.45 Pharmacy services | This section will be implemented in Phase 1 with the following exceptions:<br>• *(c)(2) Medical chart review*—Implemented in Phase 2.<br>• *(e) Psychotropic drugs*—Implemented in Phase 2. |
| § 483.50 Laboratory, radiology, and other diagnostic services | This entire section will be implemented in Phase 1. |
| § 483.55 Dental services | This section will be implemented in Phase 1 with the following exceptions:<br>• *(a)(3) and (a)(5) Loss or damage of dentures and policy for referral*—Implemented in Phase 2.<br>• *(b)(3) and (b)(4) Referral for dental services regarding loss or damaged dentures*—Implemented in Phase 2. |
| § 483.60 Food and nutrition services | This section will be implemented in Phase 1 with the following exceptions:<br>• *(a) As linked to Facility Assessment at § 483.70(e)*—Implemented in Phase 2.<br>• *(a)(1)(iv) Dietitians hired or contracted with prior to effective date*—Built in implementation date of 5 years following effective date of the final rule.<br>• *(a)(2)(i) Director of food & nutrition services designated to serve prior to effective*—Built in implementation date of 5 years following the effective date of the final rule.<br>• (a)(2)(i) Dietitians designated to after the effective date—Built in implementation date of 1 year following the effective date of the final rule. |
| § 483.65 Specialized rehabilitative services | This entire section will be implemented in Phase 1. |
| § 483.70 Administration | This section will be implemented in Phase 1 with the following exceptions:<br>• *(d)(3) Governing body responsibility of QAPI program*—Implemented in Phase 3.<br>• *(e) Facility assessment*—Implemented in Phase 2. |
| § 483.75 Quality assurance and performance improvement | This section will be implemented in Phase 3 with the following exceptions:<br>• *(a)(2) Initial QAPI Plan must be provided to State Agency Surveyor at annual survey*—Implemented in Phase 2.<br>• *(g)(1) QAA committee*—All requirements of this section will be implemented in Phase 1 with the exception of subparagraph (iv), the addition of the ICPO, which will be implemented in Phase 3.<br>• *(h) Disclosure of information*—Implemented in Phase 1.<br>• *(i) Sanctions*—Implemented in Phase 1. |
| § 483.80 Infection control | This section will be implemented in Phase 1 with the following exceptions:<br>• *(a) As linked to Facility Assessment at § 483.70(e)*—Implemented in Phase 2.<br>• *(a)(3) Antibiotic stewardship*—Implemented in Phase 2.<br>• *(b) Infection preventionist (IP)*—Implemented in Phase 3.<br>• *(c) IP participation on QAA committee*—Implemented in Phase 3. |
| § 483.85 Compliance and ethics program | This entire section will be implemented in Phase 3. |
| § 483.90 Physical environment | This section will be implemented in Phase 1 with the following exceptions:<br>• *(f)(1) Call system from each resident's bedside*—Implemented in Phase 3.<br>• *(h)(5) Policies regarding smoking*—Implemented in Phase 2. |

| Regulatory section | Implementation deadline |
| --- | --- |
| § 483.95 Training requirements | This entire section will be implemented in Phase 3 with the following exceptions:<br>• *(c) Abuse, neglect, and exploitation training*—Implemented in Phase 1.<br>• *(g)(1) Regarding in-service training, (g)(2) dementia management & abuse prevention training, (g)(4) care of the cognitively impaired*—Implemented in Phase 1.<br>• *(h) Training of feeding assistants*—Implemented in Phase 1. |

*C. Basis and Scope (§ 483.1)*

We proposed to revise § 483.1 ''Basis and Scope'' to include references to sections 1819(f), 1919(f), 1128I(b) and (c), and 1150B of the Act. Sections 1819(f) and 1919(f) of the Act require that the current mandatory on-going training for NAs include dementia management and resident abuse prevention training. New section 1128I(b) of the Act requires the operating organizations for SNFs and NFs to have a compliance and ethics program and new section 1128I(c) of the Act requires the Secretary to establish and implement a QAPI program for facilities. New section 1150B of the Act establishes requirements for reporting to law enforcement suspicion of crimes occurring in federally funded LTC facilities. In addition, we proposed to spell out the term ''skilled nursing facility''.

We did not receive any comments in response to our proposals in this section. Therefore, we are finalizing our proposal without modification.

*D. Definitions (§ 483.5)*

Current regulations at § 483.5 provide definitions for terms commonly used in the LTC requirements. We proposed to revise some of the existing terms for clarity and define new terms that we believe are widely used within the LTC setting, and that we believe will add value to the LTC requirements while promoting resident choice and safety.

We retained the existing definitions for ''facility'' and ''distinct part''. In addition, we retained the definition of ''major modification'', which was added to the LTC regulations in the May 12, 2014 final rule, ''Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II'' (79 FR 27106). We also proposed minor revisions to the definition of ''common area'' to recognize that some facilities have living rooms or other areas where residents gather. We proposed to expand this section to include the following definitions: ''abuse,'' ''adverse event,'' ''exploitation,'' ''misappropriation of resident property,'' ''neglect,'' ''person-centered care,'' ''resident representative,'' and ''sexual abuse''. In addition, we proposed to relocate the definitions for ''licensed health professional'' and ''nurse aide'' to this section from the ''Administration'' section at § 483.75(e)(1). In addition, we proposed to revise the definition of ''nurse aide'' in accordance with amendments to sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Act made by sections 6121(a)(2) and (b)(2) of the Affordable Care Act. ''Nurse aide'' is currently defined as any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide these services without pay. ''Nurse aides'' do not include those individuals who furnish services to residents only as paid feeding assistants, as defined in § 488.301. Section 6121 of the Affordable Care Act added the following clarification to the definition of ''nurse aide'': ''Such term includes an individual who provides such services through an agency or under a contract with the facility.'' We proposed to amend the regulatory definition accordingly. We proposed to add the term ''adverse event'' to ensure clarity in our requirements relating to proposed requirements for QAPI. For purposes of this regulation, we also proposed to define the term ''resident representative'' broadly to include both an individual of the resident's choice who has access to information and participates in healthcare discussions as well as personal representative with legal standing, such as a power of attorney for healthcare, legal guardian, or health care surrogate or proxy appointed in accordance with state law to act in whole or in part on the resident's behalf. We also noted that the same-sex spouse of a resident would be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated. In addition, we proposed to add a definition of ''person-centered care'' to be defined as focusing on the resident as the locus of control and supporting the resident in making their own choices and having control over their daily lives. For purposes of these regulations, we proposed that ''abuse'' would include actions such as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. As used in this definition of ''abuse'', ''willful'' means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm. We proposed that ''abuse'' would also include the deprivation by an individual of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. The term ''sexual abuse'' would extend the meaning of ''abuse'' to include non-consensual sexual contact of any type with a resident. We proposed to define the term ''neglect'' as ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or mental illness.'' We proposed to define ''exploitation'' as ''the unfair treatment or use of a resident or the taking of a selfish or unfair advantage of a resident for personal gain, through manipulation, intimidation, threats, or coercion.''

We also proposed to add the term ''misappropriation of resident property'' and define the term as ''the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.''

Finally, we proposed to move the existing definition of ''transfer and discharge'' from § 483.12(a)(1) to § 483.5.

*Comment:* Several commenters supported the addition of terms to the definitions section and indicated that making the link between terms that are defined in regulation and guidance will support an increased response to elder abuse. Multiple commenters provided suggestions for additional terms to be included in the definitions sections. One commenter indicated that there is a need to define ''behavioral health'' given the addition of the regulatory section focused on behavioral health. Other commenters also suggested that

the definition of ''mistreatment'' be added to the regulations for clarity. Lastly, one commenter suggested that definitions of ''portable order for scope of treatment'' and ''staffing practices'' be added to the regulations.

*Response:* We agree with commenters and believe that improving the definitions section will promote resident safety and choice. For further clarity we have added discussion to the behavioral health section explaining what behavioral health is. Since behavioral health is largely discussed in the ''Behavioral Health'' section we believe it is more appropriate to add the discussion at § 483.40 rather than in the ''Definitions'' section at § 483.5.

We agree with commenters who suggested that the term ''mistreatment'' be defined in the regulation. Regulations at proposed § 483.12(a)(2)(iii) specify that facilities cannot employ or otherwise engage individuals who have had a disciplinary action taken against their professional license as a result of mistreatment. Therefore, based on public comments and the use of the term ''mistreatment'' in § 483.12, we are revising the definitions section to add the term; ''mistreatment'' which means ''to inappropriately treat or exploit a resident.'' Lastly, we do not agree that the terms ''staffing practices'' and ''portable order for scope of treatment'' should be defined because these terms are not used in the regulations.

*Comment:* One commenter supported moving the definition of ''transfer and discharge'' to the ''Definitions'' section, but recommended that the definition also be discussed in the ''Transitions of Care'' section (finalized as ''Admission, Transfer, and Discharge Rights'') so that readers are aware of it. The commenter also recommended that the definition of ''transfer and discharge'' be revised to include language from interpretive guidance in order to help address the failure of LTC facilities to recognize adequately a resident's transfer and discharge rights.

*Response:* We agree with commenters and have added a cross-reference to the definition of ''transfer and discharge'' at § 483.15(b)(1), which discusses the requirements regarding a resident's transfer and discharge rights. We note that the definition of ''transfer and discharge'' aligns with the definition that is in the state operations manual. We are unclear what information the commenter requests to have added into the definition.

*Comment:* Overall, commenters agreed that abuse should be defined in the regulations. Commenters provided varying suggestions aimed to improve the proposed definition. Some commenters communicated support for including the word ''willful'' in the definition of abuse. However, commenters articulated that as proposed, the definition of ''willful'' (as used in abuse) could potentially create major and unreasonable legal complications for facilities and practitioners who are forced to make difficult decisions in unclear circumstances. For example, commenters indicated that unintentional errors, such as deliberately providing medications to a resident that are later discovered to be harmful or differences of clinical opinions, such as withdrawing life-sustaining treatment, will be inappropriately categorized as abuse.

In addition, commenters suggested deleting the clause regarding the deprivation of goods and services from the definition of ''abuse''. Commenters indicated that the use of this clause is problematic and is more appropriately covered by the definition of ''neglect.'' One commenter further suggested that the sentence, ''This presumes that instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish'', also be removed from the definition of abuse. The commenter communicated that definitions should not include presumptions and the phrase ''instances of abuse of all residents'' is unclear. Another commenter recommended that the definition clarify further that abuse facilitated or enabled through the use of technology refers to platforms such as social media.

*Response:* We appreciate the feedback from commenters regarding the definition of ''abuse''. We disagree with commenters and do not believe that the definition of ''abuse'' repeats the definition of ''neglect''. With regard to a deprivation of goods or services, we believe that ''abuse'' requires a willful act, while ''neglect'' does not. We agree with commenters that definitions should not contain presumptions and therefore have revised the language ''this presumes'' to make an explicit statement that instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish.'' We do not believe that the use of the term ''willful'' should be removed from the definition of ''abuse.'' We encourage readers to refer to *Merrimack County Nursing Home,* DAB CR2352 (December 5, 2011) (ALJ Decision) and *Honey Grove Nursing Center,* DAB CR3039 (May 8, 2014) (ALJ Decision), which discusses actions that were deliberate, not inadvertent or accidental or with the intent to inflict injury or harm. We agree that abuse enabled through the use of technology would include the use of social media, as well as the use of cameras or the Internet. Following the publication of the final rule, we will release updated interpretive guidance that will aid facilities in implementing these regulations and provide further clarification for this regulation. The interpretive guidance is the most appropriate place to further clarify and provide examples regarding abuse that is facilitated through the use of technology.

*Comment:* One commenter indicated that an ''adverse event'' is adverse whether or not it is anticipated and suggested that the concept of anticipation be removed from the proposed definition, as it may be misleading. Another commenter recommended that the definition of ''adverse event'' be expanded to include events noted in the February 2014 OIG report entitled, ''Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries'' (OEI–06–11–00370), such as preventable harm due to substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. The commenter indicates that the focus of the definition should be placed on a facility's systematic analysis and action rather than only on one-time events.

*Response:* We appreciate the commenters' feedback. When considering the proposed definition of ''adverse events'' we reviewed the February 2014 Office of the Inspector General (OIG) report referenced by commenters. We believe that increasing the level of specificity in the definition could potentially preclude recognition of additional adverse events. As proposed, the definition encompasses events that harm the patient, that are a result of substandard treatment, inadequate resident monitoring, and failure or delay of necessary care. In addition, we proposed the definition of ''adverse event'' that is currently defined in regulations for transplant centers. As written, the definition does not exclude anticipated events, but rather states ''adverse events'' are ''usually unanticipated.''

*Comment:* Several commenters supported the clarification added to the definition of ''composite distinct part'' which prohibits the use of a composite distinct part designation as a means to segregate residents by payment status or on any other basis other than care needs.

*Response:* We appreciate the support from commenters and believe that the

clarification will help to avoid creating inequitable care situations.

*Comment:* Many commenters supported our proposal to add a definition of ''exploitation'' to the regulations. A few commenters provided suggestions to improve the proposed definition. One commenter indicated that the use of the term ''selfish'' in the definition of ''exploitation'' is misplaced and unnecessary. Another commenter disagreed with the use of the term ''manipulation'' in the definition because manipulation is difficult to identify and pinpoint. The commenter indicated that the definition of ''exploitation'' should not create unanticipated consequences and recommended substituting the use of the term ''manipulation'' with ''deception''.

*Response:* We appreciate the commenters' feedback and believe that further revisions are needed to improve clarity. We agree that the term ''selfish'' may possibly be hard to identify and evaluate. However, we prefer to use the term ''manipulation'' rather than ''deception,'' as recommended by commenters. We believe that the term ''manipulation'' is generally understood and appropriately indicates when power is being used in an unacceptable manner. Overall, in response to comments we have revised the definition of ''exploitation'' to ''taking advantage of a resident for personal gain by using manipulation, intimidation, threats, or coercion.''

*Comment:* A few commenters suggested that the definition of ''licensed health professional'' be expanded to include pharmacists, respiratory therapists, dietitians, and psychologists.

*Response:* The statute at section 1819(b)(5)(G) of the Act defines ''licensed health professional'' as ''a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; registered respiratory therapist or certified respiratory therapy technician.'' Therefore, in an effort to conform our definition to the statute, we have added respiratory therapists to the regulatory definition of ''licensed health professional.'' We have not added ''pharmacists, dietitians, and psychologists,'' since they are not included in the statutory definition.

*Comment:* Several commenters supported including the definition of ''misappropriation of property'' in the ''Definitions'' section. One commenter recommended replacing the term ''deliberate'' with ''willful'' for consistency throughout the definitions, since ''willful'' is used in the definition of ''abuse''. Another commenter requested that the definition of ''misappropriation of property'' be revised to add language to ensure that the facility remains responsible for replacing or reimbursing for items that are lost or stolen.

*Response:* We appreciate the commenters' feedback, but disagree with the suggestions. The term ''willful'' is defined specifically, since it is an element of the definition of ''abuse.'' We believe that the term ''deliberate'' is correctly used in the definition of ''misappropriation of property''. In addition, it is not appropriate to add language regarding facility responsibilities to the definition of ''misappropriation of property''. The definition was added to clarify what constitutes as the misappropriation of a resident's property. Regulations at § 483.12(c) discuss the requirements that must be met in response to allegations of the misappropriation of resident property. While our regulations do not require replacement or reimbursement, facilities have the flexibility to establish their own policies related to internal remedies for replacement or reimbursement of resident property.

*Comment:* Multiple commenters supported the addition of the definition of ''neglect''. One commenter indicated that mental disorder is not a condition that can be attributed to neglect. The commenter recommended modifying the definition of ''neglect'' to explicitly state that neglect could lead to increased psychiatric or behavioral symptoms. Another commenter recommended the definition of ''neglect'' be revised to remove the statement that an individual suspected of neglect must have acted willfully.

*Response:* We agree that the wording in the definition of ''neglect'' can be improved and have revised the definition to clarify that the facility and its employees are neglectful when a reasonable person would conclude that a deprivation of the omitted goods and services would cause, among other things, emotional distress (rather than mental disorder). As proposed, the definition of ''neglect'' does not include the term ''willful''. We have revised the definition of ''neglect'' to read, ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.''

*Comment:* One commenter indicated that ''nursing aide'' is an obsolete term and the correct terminology is ''nursing assistant''.

*Response:* We appreciate the commenter's feedback, however we are maintaining the use of the term ''nursing aide'' since that is the term used in the statute.

*Comment:* Several commenters supported promoting individual choices and individualized care and agreed that adding a definition of ''person-centered care'' is necessary. Commenters suggested additional terms to replace ''person-centered care''. A few commenters provided suggestions to improve the definition. One commenter indicated that the proposed definition only addresses resident choice and is too narrow. The commenter notes that the concept of ''focusing on the resident as the locus of control'' is vague and unsurveyable. Furthermore the commenter suggests that the definition should specify the actions that facilitate individualized care and not just focus on the resident as the locus of control.

Another commenter recommended that the definition of ''person-centered care'' be modified to include that the relationship between residents and providers is a collaborative partnership.

*Response:* The term ''person-centered care'' is recognized in the long-term care community. However, we understand that some facilities and health care professionals may use alternative terms and wording to describe a similar care model. We have used the term ''person-centered care'', but facilities have the flexibility to use any term they choose internally as long as the principles described in the regulation are met. Facilities should implement the principle of ''person-centered care'' by developing internal guidelines that promote resident choice and control over their individual care. The definition of ''person-centered care'' has been added to the regulation to assist in meeting these requirements and to provide some guidance regarding our intent and expectations. We note that the interpretive guidance for this regulation will also provide more detailed information and best practices for implementing person-centered care.

*Comment:* Many commenters believe that as proposed the definition of ''resident representative'' may create potential problems and supersede state law, regulations, or case law regarding a resident's surrogate decision makers. The commenters indicated that allowing for both a representative of the resident's choice as well as a representative with legal standing might create issues in instances where these

two individuals disagree. They note that the regulation is not clear as to who supersedes and these types of decisions should not be made by the facility.

Other commenters recommended that the definition of ''resident representative'' be revised to appropriately capture the many relationships that individuals may have with the resident. Commenters indicated that the definition should clearly identify the rights that such individuals have acting on behalf of or advocating with the resident. Commenters also noted that it is important to clarify that residents are not obligated to choose or designate anyone as a representative. Commenters recommended the use of terms, such as ''resident enabler'' and ''resident supporter'' to more appropriately incorporate the concept of supported decision-making. One commenter recommended that our definition be revised to align with the definition in the State Long-Term Care Ombudsman Program regulations found at 45 CFR 1327.1 (recently relocated to 45 CFR 1324.1; see the final rule, ''Administration for Community Living Regulatory Consolidation'' (81 FR 35644, June 3, 2016).

One commenter affirmed the need to highlight the equal treatment of same-sex spouses, while another commenter suggested that the discussion regarding the selection of a same-sex spouse as a representative be removed from the definition. The commenter notes that same-sex spouses are now covered under state law and it is unnecessary to specify one particular group in this definition while omitting others.

*Response:* We appreciate the feedback from commenters and agree that the definition of ''resident representative'' can be improved. Our intent behind proposing the definition of ''resident representative'' was to recognize that a resident has the right to designate an individual or individuals who can support them in their decision-making. We did not intend to expand the scope of authority of any representative or to supersede state law, regulations, or case law regarding a resident's surrogate decision makers. As one commenter noted, a definition of ''resident representative'' can be found in existing HHS regulations. The regulations at 45 CFR 1324.1 define a ''resident representative'' as ''(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (2) A person authorized by state or federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications ; (3) Legal Representative, as used in 712 of the Older Americans Act; or (4) The court-appointed guardian or conservator of a resident. (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.''

We believe that this definition matches our intent behind defining ''resident representative'' in the LTC regulations and to align with existing HHS regulation, we are revising the definition of ''resident representative'' to match the definition found at 45 CFR 1324.1. Generally speaking, the authority of an individual vested with decision-making power under state law would exceed that of an individual without formal legal recognition.

*Comment:* One commenter recommended that the definition of ''sexual abuse'' be modified in an effort to avoid categorizing accidental touching, which may occur while moving or cleaning a resident, as abuse. Another commenter recommended that the definition of ''sexual abuse'' be modified to include the use of technology to sexually abuse a resident.

*Response:* We understand that accidental touching is possible; however the term ''sexual abuse'' has been added to the regulations in an effort to prevent harmful acts. It was not added to prevent or complicate care, but to ensure that residents are protected especially in vulnerable situations. For acts such as bathing a resident or assisting a resident with using the restroom, it is the facility's responsibility to have procedures and guidelines in place for what is acceptable and appropriate for providing assistance. We believe that the use of technology to harm a resident is covered by the definition of ''abuse'' which speaks specifically to abusive situations facilitated through technology.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications. We have—

- Revised the definition of ''abuse'' to read, ''the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means that the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.''
- Revised the definition of ''exploitation'' to read, ''taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.''
- Revised the definition of ''licensed health professional'' by adding ''registered respiratory therapist or certified respiratory therapy technician.''
- Added a definition of ''mistreatment'' and defined it as ''inappropriate treatment or exploitation of a resident.''
- Revised the definition of ''neglect'' to read, ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.''
- Revised the definition of ''resident representative'' to read (in accordance with 45 CFR 1324.1), ''(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (3) Legal representative, as used in section 712 of the Older Americans Act; or (4) The court-appointed guardian or conservator of a resident. (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.''

*E. Resident Rights (§ 483.10)*

Current regulations at § 483.10 address a number of resident rights and facility requirements, including those establishing a resident's right to exercise his or her rights, including rights associated with a dignified existence, self-determination, planning and implementing care, access to information, privacy and confidentiality. Resident rights are also addressed in existing § 483.15. Based on a review of these regulations, we proposed to retain all existing residents' rights, but update the language and organization of the resident rights provisions to improve logical order and readability, to clarify aspects of the regulation that warranted it, and to update provisions to include technological advances such as electronic communications. In order to achieve these objectives, we proposed to revise existing § 483.10 to include only those provisions specifying resident rights, including a number of provisions that are currently included in § 483.15. We further proposed to add a new § 483.11, to focus on the responsibilities of the facility, including relevant provisions currently included in § 483.10 and § 483.15. As with § 483.10, we proposed multiple re-designations and revisions to improve logical order and readability, clarify aspects of the regulation that warranted it, and reflect technological advances such as electronic communications. Under our proposal, some existing provisions would have components in both § 483.10 and § 483.11. We discuss below our proposed revisions to those provisions retained in or moved to § 483.10 and note that regulatory citations have been updated throughout to reflect the proposed new structure.

We proposed to revise § 483.10 to focus specifically on resident rights. In proposed § 483.10(a)(2), we clarified the resident's right to be supported in his or her exercise of rights under this subpart. In proposed § 483.10(a)(3), we clarified the resident's right to designate a representative to exercise only those rights delegated by the resident, and the resident's retention of rights not delegated, including the right to revoke a delegation.

In § 483.10(a)(4) we proposed to clarify that a resident who was adjudged incompetent under the laws of a state would retain the right to exercise those rights not addressed by a court order, that the resident representative can only exercise the rights that devolve to them as a result of the court order, that the resident's wishes and preferences should continue to be considered, and that the resident should continue to be involved in the care planning process to the extent practicable, as the resident is at the center of the care team. Lastly, in our December 12, 2014 proposed rule ''Medicare and Medicaid Programs; Revisions to Certain Patient's Rights Conditions of Participation and Conditions for Coverage'' (79 FR 73873), we proposed at § 483.10(a)(4) to require that the same-sex spouse of a resident be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated. We proposed to re-designate this requirement from § 483.10(a)(4) (as set out in the December 2014 proposed rule at 79 FR 73811) to § 483.10(a)(5).

In proposed § 483.10(b), we included resident rights related to planning and implementing care. We proposed to re-designate and revise current § 483.10(b)(3), § 483.10(b)(4) and § 483.10(b)(8), relating to the resident's right to be informed of his or her total health status, including medical conditions; the right to be informed in advance of the risks and benefits of proposed care, including treatment and treatment alternatives or treatment options so that the resident can choose the alternative or option he or she prefers; the right to request, refuse and/or discontinue treatment, including participating in or refusing to participate in experimental research; and the right to formulate advance directives. We proposed to add new requirements in § 483.10(b)(5) to specify that the resident has the right to participate in the care planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person-centered plan of care. We further specified in § 483.10(b)(5)(iv) that the resident has the right to receive the services and items included in the plan of care. We also proposed to re-designate and revise existing § 483.10(d)(2) to specify that the resident has the right, in advance, to be informed of and to participate in, his or her care and treatment, including the right to be informed, in advance, of the care to be furnished and the disciplines that will furnish care. In addition, we proposed to specify the resident's right to participate in the development of his or her comprehensive care plan. We also proposed at § 483.10(b)(6) to include the resident's right to self-administer medication if the interdisciplinary team has determined that doing so would be clinically appropriate. Finally, we proposed to add a new section at § 483.10(b)(7) to specify that these rights cannot be construed as a right to receive medical care that is not medically necessary or appropriate.

We proposed to require that the facility ensure that the attending physician is appropriately licensed and credentialed to provide care and meet the requirements of applicable regulations. In proposed § 483.10(c), we added new paragraphs § 483.10(c)(1), (2) and (3) to specify that the physician chosen by the resident must be licensed to practice medicine, and must meet professional credentialing requirements of the facility.

In § 483.10(d), we proposed to re-designate a number of provisions relating to resident respect and dignity, based on existing § 483.13(a) and § 483.15. We further proposed to add a new § 483.10(d)(5) to specify that a resident has the right to share a room with his or her roommate of choice, when both residents live in the same facility, both residents consent to the arrangement, and the facility can reasonably accommodate the arrangement. We noted that married couples, whether opposite or same sex, are addressed by § 483.10(d)(5). Our proposed provision provided for a rooming arrangement that could include a same-sex couple, siblings, other relatives, long-term friends or any other combination as long as the requirements above are met.

In proposed § 483.10(e), we proposed to revise a number of provisions relating to resident self-determination. We proposed to revise § 483.10(e)(3) to ensure not only that specified individuals and/or organizations have access to the resident, but also to ensure that the resident can receive his or her visitors of choice at the time of his or her choosing. We proposed to revise § 483.10(e)(4) and (5), clarifying that it is the resident's right to participate in family groups and have his or her family members or resident representatives participate in family groups in the facility.

In § 483.10(f), we proposed to re-designate and revise a number of provisions relating to resident access to information. We proposed to specify in § 483.10(f)(2) that the resident has the right to receive notices verbally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands. We also proposed to add a new § 483.10(f)(2)(i) to reference required notices and a new § 483.10(f)(2)(iv) to ensure residents are aware of and can contact an Aging and Disability Resource Center or other ''No Wrong Door'' program.

Federal requirements and expectations related to the privacy and confidentiality of patient records, in particular regulations governing protected health information, changed substantially with the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequent issuance of the HIPAA Privacy and Security Rules (see 45 CFR part 160 and subparts A, C, and E of part 164), the Health Information Technology for Economic and Clinical Health (HITECH) Act and the issuance of the HIPAA Breach Notification Rule and HIPAA Final Rule (45 CFR part 160 and subpart D of part 164; 78 FR 5566, January 25,2013). For simplicity, we hereinafter collectively refer to these laws and their implementing regulations as ''HIPAA.'' We note that administration and enforcement of the privacy, security, and breach-related portions of the HIPAA regulatory scheme are delegated to the HHS Office for Civil Rights (OCR) and more detailed information related to these regulations can be accessed through the OCR Web site at *http://www.hhs.gov/ocr/privacy*.

We proposed to retain the requirements of current § 483.10(b)(2)(i) and (ii), subject to the clarifying revisions described below, at new § 483.10(f)(3). In doing so, we recognized that the HIPAA rules establish a federal floor of privacy and security protections and individual rights with respect to protected health information held by covered entities (and their business associates), and the rights granted in the proposed regulation do not conflict in any way with the HIPAA regulations. In addition, to the extent that HIPAA provides additional rights to individuals (that is, residents, in the long-term care context) beyond what is provided in this proposal, covered entities and business associates must comply with the requirements in HIPAA to ensure individuals are afforded these additional rights. Therefore, we proposed revisions to clarify the relationship between the requirements of 45 CFR 164.524 and the revised version of § 483.10(f)(3)(i) and (ii). We proposed to specify in paragraph (f)(3) that the resident has the right to access medical records pertaining to him or herself and to further specify in proposed (f)(3)(i) that the resident, upon oral or written request, has the right to receive requested medical records in the form and format requested by the resident, if it is readily producible in such form and format (including in an electronic form or format when such records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual. This is consistent with the requirements of 45 CFR 164.524(c)(2). Finally, we proposed to specify in paragraph (f)(3)(ii) that the facility could impose a reasonable, cost-based fee for providing copies of the medical records, provided that the fee included only the cost of labor for copying the health information requested by the individual, whether in paper or electronic form; the supplies for creating the paper copy or electronic media if the individual requested that the electronic copy be provided on portable media; and postage, when the individual requested that the copy be mailed. This is consistent with 45 CFR 164.524(c)(4). We noted in the proposed rule that this proposal does not address the creation or provision of summary reports, which could be provided in accordance with applicable law. More detailed information about the HIPAA right to access at 45 CFR 164.524 can be found at *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/*.

In § 483.10(g)(1) we proposed to revise a number of provisions related to resident privacy and confidentiality to update the language to accommodate electronic communications. We proposed to retain existing § 483.10(c)(1) at proposed § 483.10(g)(2), reiterate the residents' right to a secure and confidential medical record at proposed § 483.10 (g)(3) and, in proposed § 483.10(g)(4), we retained the provisions of existing § 483.10(e)(2) and (3).

In § 483.10(h), we proposed to re-designate and revise a number of provisions relating to resident communications. Specifically, we proposed a new § 483.10(h) Communications, with § 483.10(h)(1) revised to include Teletypewriter (TTY) and Telecommunications Device for the Deaf (TDD) services and cellular telephones; and a new § 483.10(h)(2) to provide reasonable access and privacy for electronic communications such as email or internet-based interpersonal video communications.

In § 483.10(i), we proposed to revise the language to state that the resident has a right to a safe, clean, comfortable, home-like environment, and a right to receive treatment safely. In § 483.10(j), we proposed to revise language relating to resident grievances to add that a resident could not be deterred from voicing a grievance for fear of reprisal or discrimination.

*Comment:* A number of commenters expressed concern about the way in which CMS proposed to restructure the section on Resident Rights, and particularly the fact that there was not complete parity between residents' rights and facility responsibilities. One commenter stated that, since residents, their families and advocates look at the residents' rights language to know what residents' rights are (and they may be given copies of the federal rights), it is important that the statement of residents' rights be thorough, comprehensive, and accurate. The commenter recommended that CMS add rights currently found under Facility Responsibilities but not under Resident Rights to the Resident Rights section. Another commenter stated that the list of residents' rights should be complete and comprehensive and should not require review of other requirements of participation (RoPs) in order to identify all residents' rights.

One commenter stated that they were concerned with the likely disruption of administrative and judicial decisions over the past 25 years interpreting the current regulations. Administrative Law Judges and state and federal court judges could view changes in regulatory language as signaling changes in administrative interpretation of the Nursing Home Reform Law. They will view prior long-standing interpretations of similar current regulations as no longer legally binding as they interpret new regulatory language, following the legal principle that an agency intends a new interpretation when it changes the language of a regulation. They believed that an agency does not change regulatory language unless it wants to make a change in the prior interpretation of that language.

The commenter further objected to the reorganization of existing RoPs because the commenter felt it would inevitably involve unnecessarily long (but avoidable) delay. The commenter stated that CMS would need to draft the final standards in response to public comments, give facilities time to understand and implement the new Requirements, create a new survey protocol, and train state and federal surveyors in the new protocol, at the very least. As these multiple changes are made, effective enforcement of RoPs, already weak, will be further postponed.

The commenter noted that, to maintain the same regulatory standards within the definition of substandard quality of care requires CMS to combine subsections of multiple RoPs. The commenter recommended that, instead of reorganizing the regulations, as CMS proposes, CMS should retain the current regulatory structure as much as possible and to make all revisions within that existing, familiar structure. Keeping the current structure will save time and

effort on the part of CMS, surveyors, advocates, and providers alike, time and effort that would be better spent on addressing RoPs that actually reflect substantive change and improvement.

*Response:* We considered commenters' concerns regarding proposed § 483.10 and § 483.11. Rather than increase duplication by adding language to both sections, we have combined these two sections for a comprehensive section that includes in a single location both statements of resident rights and, co-located, the attendant facility responsibilities to support those rights. We believe this addresses commenters' concerns and meets the commenter's suggestion that the statement of resident rights be thorough, comprehensive and accurate. This reorganization, to the extent that the regulatory language is unchanged, does not reflect any intent by CMS to change prior interpretations of regulatory language. Rather, our intent, as stated in the preamble to the proposed rule, is to improve the logical order, readability, and clarity of the regulations. We continue to believe that it is helpful to ensure that regulatory section titles reflect the content of the section. Thus, we have included provisions that state ''the resident has a right to . . .'', in general, in a regulatory section titled ''Residents Rights,'' we have included provisions about prohibiting and preventing abuse, neglect and exploitation in a section titled ''Freedom from Abuse, Neglect, and Exploitation,'' and we have withdrawn our proposal to rename ''Admission, Discharge, and Transfer Rights'' to retain the title that most clearly relays the content of the section to the non-expert reader. We further clearly expressed in the preamble to the proposed rule that we do not intend in this update to diminish resident rights or protections. Rather, we want to ensure that those rights and protections encompass advancements, such as in the area of telecommunications, that were not envisioned when the original regulations were written.

With regard to concerns that this revision will delay enforcement of the requirements and that keeping the current structure would save time and effort in updating facilities, surveyors, advocates, providers, and, we would add, current and future residents, we disagree that this effort is unnecessary or poorly focused. The commenter contends that enforcement of the current requirements is already weak. The efforts that we will undertake as a result of this rule to update and improve interpretive guidance, to train surveyors, and to outreach to the affected community of providers, residents, and caregivers will lead to stakeholders' improved understanding of our higher expectations, could result in improved efficiencies, and improve the effectiveness of our survey process. This final rule will be effective 60 days after its publication, maintaining existing protections for residents, with delayed implementation deadlines for certain sections, where there are new expectations and requirements that require additional time for providers to implement. Please see our discussion of implementation in section II.B. of this preamble for additional detail.

We received a significant number of specific comments on both proposed sections § 483.10 and § 483.11. As we will finalize these sections as a single section, we respond to all specific comments on both proposed sections, following our description of our proposals regarding facility responsibilities, below.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We finalize a consolidated section § 483.10, which contains provisions proposed in § 483.10 and § 483.11. Specific revisions are addressed in the following section.

*F. Facility Responsibilities (§ 483.11)*

We proposed a new § 483.11 ''Facility Responsibilities,'' in which we combined many of the regulations addressing facility responsibilities which are currently dispersed throughout the existing provisions regarding resident rights and quality of life.

Consistent with § 483.10 and based on existing requirements, the introductory language for proposed § 483.11 would have established that the facility would have to treat its residents with respect and dignity and provide care and services for its residents in a manner and in an environment that promotes maintenance or enhancement of the resident's quality of life, and would be required to protect and promote the resident's rights, as specified in § 483.10. Further, the facility would be required to recognize each resident's individuality and provide services in a person-centered manner. We proposed to establish sections similar to those proposed in § 483.10. The proposed sections are ''Exercise of Rights,'' ''Planning and Implementing Care,'' ''Attending Physician,'' ''Self-Determination,'' ''Information and Communication,'' ''Privacy and Confidentiality,'' ''Safe Environment,'' and Grievances.''

In a new section proposed at § 483.11(a), ''Exercise of Rights,'' we proposed a requirement that the facility would have to promote and protect the rights of the resident. These are not new requirements, and are already set out in our regulations as residents' rights. In order to ensure clarity, we restated clearly in this provision that it would be the responsibility of the facility to recognize and effectuate those rights. Proposed § 483.11(a)(1) provided that the facility ensure that the resident could exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility. We proposed to re-designate current § 483.12(c)(1) as new § 483.11(a)(2) and move to this section the requirement that the facility provide equal access to quality care regardless of diagnosis, severity of condition, or payment source and establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services for all residents, regardless of source of payment. In proposed § 483.11(a)(3) and (4), we specified that the facility would have to treat the decisions of a resident representative as the decisions of the resident to the extent required by a court, or as delegated by the resident, with the condition that the facility could not extend greater authority to the resident representative than would be permitted under applicable law. In addition, we proposed to add a new § 483.11(a)(5) to clarify for facilities that if facility staff believed that a resident representative was making decisions or taking actions that are not in the best interest of the resident, the facility would have to comply with any state reporting requirements that might apply.

In proposed § 483.11(b), ''Facility responsibilities'' would include ensuring that the resident was informed of, and participated in, his or her treatment to the extent practicable, consistent with § 483.10(b). The resident could participate in care planning, making informed decisions, and self-administering drugs when appropriate. We also proposed new requirements in § 483.11(b)(1) to require that the facility ensured that the care planning process facilitated the inclusion of the resident or resident representative, included an assessment of the resident's strengths and needs, and incorporated the resident's personal and cultural preferences in developing goals of care. We proposed to re-designate § 483.10(b)(9) as § 483.11(c)(1) and revise it to add other primary care providers to ensure that the resident would know the name, specialty and

means of contacting the professionals officially responsible for his or her care, whether that provider was a physician, nurse practitioner, physician assistant, or clinical nurse specialist. We further proposed to add a new § 483.11(c)(2), consistent with our proposed § 483.10(c)(1), (2) and (3), to clarify that the facility would have a responsibility to ensure that the resident's attending physician had appropriate professional credentials and met the requirements of this subpart. If the physician was not appropriately credentialed or was unwilling or unable to meet the requirements of this subpart, the facility could seek an alternate physician after informing and discussing this matter with the resident. In order to ensure that the resident could seek out a suitable alternative, we proposed to add a new § 483.11(c)(3) to specify that if the resident subsequently found a new physician who met the necessary requirements, the facility would be required to honor that selection.

We proposed a new § 483.11(d) to address the facility's responsibilities related to resident self-determination. We proposed to re-designate § 483.10(j), regarding access to the resident, as § 483.11(d)(1), and revised it to include visitors as specified in our ''Resident Rights'' provision, including immediate access to the resident by the resident representative, and to update the languages and references for the Office of the State long term care ombudsman and the protection and advocacy system. In addition, we proposed to add a new § 483.11(d)(2) to require that the facility have written policies and procedures regarding visitation rights of residents. We proposed to re-designate § 483.15(c)(5) as § 483.11(d)(3)(ii) and revised it to clarify that the facility-designated staff person who participates in a resident or family group must be approved by the resident or family group and the facility. In the proposed rule, we clarified that this provision does not require a facility to implement every recommendation of a resident or family group, but that the facility should be able to provide the rationale for their response. We proposed a new § 483.11(d)(4), to incorporate requirements currently specified in § 483.10(h) and specify that the facility is responsible for ensuring that a resident is not required to perform services for the facility.

We proposed a new § 483.11(d)(5), to incorporate requirements from § 483.10(c) that focus on the facility's responsibility related to the protection of resident funds. Specifically, we proposed in § 483.11(d)(5)(ii) to reflect the different dollar threshold requirements of sections 1819(c)(6)(B)(i) and 1919(c)(6)(B)(i) of the Act and establish the statutory requirement for deposit of resident funds in excess of $100 in an interest-bearing account for Medicare and other non-Medicaid SNF residents, consistent with section 1819(c)(6)(B)(i) of the Act, and funds in excess of $50 for Medicaid beneficiaries, consistent with section 1919(c)(6)(B)(i) of the Act. We proposed in § 483.11(d)(5)(v) to include the return of funds to residents upon discharge or eviction, in accordance with state law in addition to the already existing regulatory requirement for conveyance to the estate upon death.

We proposed to add a new § 483.11(d)(6)(i)(G) to indicate that the facility may not charge the resident for hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan, whether provided directly by the SNF, NF or by a hospice provider under agreement with the SNF or NF.

We proposed in § 483.11(d)(6)(ii), re-designated from § 483.10(c)(8)(ii), to add to the limitations on charges to residents' funds. We proposed to add new § 483.11(d)(6)(ii)(L)(*1*) and (*2*) to clarify that the facility may not charge for special food and meals ordered for a resident by a physician, physician assistant, nurse practitioner, clinical nurse specialist, dietitian or other clinically qualified nutrition professional and to cross-reference to provisions regarding the expectation that the foods and meals a facility generally prepares should be developed taking into consideration residents' needs and individual preferences in addition to the overall cultural and religious make-up of the facility's population. We proposed a clarification in proposed § 483.11(d)(6)(iii) by adding the term ''non-covered'' before ''item or service,'' as this provision would only apply to non-covered items or services.

We proposed to establish a new § 483.11(e) to incorporate multiple provisions related to information and communication. With the exception of medical records, we proposed in § 483.11(e)(1) to specify that the facility is responsible for ensuring that information provided to the resident is provided in a form and manner that the resident can access and understand, including in a language that the resident can understand.

We proposed in § 483.11(e)(2) to revise facility requirements currently in § 483.10(b)(2)(i) through (ii), consistent with our proposal at § 483.10(f)(3). We proposed in paragraph (e)(2)(i) to require that facilities provide residents with access to their medical records in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if it is not readily producible in such form and format, in a readable hard copy form or other form and format as may be agreed to by the facility and the individual. This proposal included the existing requirement that access be provided upon oral or written request, redesignated from § 483.10(b)(2)(i), and that this access be provided within 24 hours, excluding weekends and holidays, as required by sections 1819(c)(1)(A)(iv) and 1919(c)(1)(A)(iv) of the Act. We proposed at § 483.11(e)(2)(i) to require that the facility allow the resident, after receipt of his or her medical records for inspection, to purchase a copy of the medical records or any portion thereof upon request and with 2 working days advance notice to the facility. We further proposed at § 483.11(e)(2)(iii) to revise the standard for the fee a facility may charge for the requested information from a community standard to a cost-based standard under which the fee includes only the cost of labor for copying the requested health information, whether in paper or electronic form; the supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media, postage when the individual requested the copy be mailed. This is consistent with the requirements of 45 CFR 164.524(c)(4).

We proposed to add a new § 483.11(e)(3), incorporating and re-designating part of existing § 483.10(g)(1), with revisions required by section 6103(c) of the Affordable Care Act, which added new sections 1819(d)(1)(C) and 1919(d)(1)(V) of the Act. Those provisions require that individuals have access to surveys of the facility conducted by federal or state surveyors and any plan of correction in effect with respect to the facility for the preceding 3 years. We note that this provision does not require a specific format, but consistent with proposed § 483.11(e)(1), it must be in a form and manner accessible to and understandable by the resident.

We proposed to add a new § 483.11(e)(4)(i) and (ii) to require the facility to post, in a form and manner easily accessible and understandable to residents, resident representatives and support persons, information that would allow individuals to contact pertinent client advocacy groups, including the State Survey Agency, the state licensure

office, the State Long-Term Care Ombudsman Program, the Protection and Advocacy Network, and the Medicaid Fraud Control Unit. We also proposed to require that the facility post a statement that a resident may file a complaint with the State Survey Agency. The facility is already required at existing § 483.10(b)(7) to provide this information in the written description of legal rights provided to the resident. The provision would be re-designated at proposed § 483.11(e)(12).

We proposed to add a new paragraph § 483.11(e)(7)(i) to specify that when a facility notifies a physician of a change in a resident's status, the facility must ensure that certain pertinent information is available and is provided to the physician upon request.

We proposed to revise the language of § 483.10(b)(11)(i) and re-designate it as new § 483.11(e)(7)(i) to provide that the facility would be required to notify the resident representatives, rather than the current requirement that the facility notify ''. . . the resident's legal representative or an interested family member . . .'' The proposed language allows a guardian or other legal representative as well as any other individuals the resident identifies, including family members, other relatives, close personal friends, or any other persons identified by the resident, to receive the required notifications and thus remain informed of important information about the resident.

We proposed to re-designate § 483.10(b)(1), which addresses the facility requirement to provide a notice of rights and services, as § 483.11(e)(9)(i) through (iii). We proposed one minor revision for clarity in § 483.11(e)(9)(ii) to state ''the State-developed notice of Medicaid rights, if any'' instead of the current language ''notice (if any) of the State developed under 1919(e) of the Act''.

We proposed to revise § 483.10(b)(5)(i) and (ii) and re-designate them as § 483.11(e)(10). The revised provision specifies that the facility must inform each resident, in writing, at the time of admission to a Medicaid-participating nursing facility and when the resident becomes eligible for Medicaid—(1) of the items and services that are included in nursing facility services under the state plan and for which the resident may not be charged; (2) of those items for which the resident may be charged, and the amount of charges for those services; and (3) inform Medicaid-eligible residents when changes are made to the items and services in paragraph (e)(11)(i) of this section.

We proposed to revise and re-designate § 483.10(b)(6) as new § 483.11(e)(11). In addition, we proposed to add new paragraphs (i) through (v) to require the facility to provide notice to residents when changes are made to the items and services covered by Medicare and/or Medicaid or to the amount that the facility charges for items and services.

To improve clarity, we proposed to re-designate § 483.10(b)(7) as new § 483.11(e)(12) and revise current paragraph (b)(7)(iii) to require that the facility provide the resident with ''a list of names, addresses (mailing and email), and telephone numbers of all pertinent state regulatory and informational agencies, resident advocacy groups such as the State Survey Agency, the state licensure office, the State Long-Term Care Ombudsman Program, the protection and advocacy agency, adult protective services, the state or local contact agencies for information about returning to the community and the Medicaid Fraud Control Unit.'' Additionally, we proposed to revise current paragraph (b)(7)(iv) to require that the facility include in the written description of legal rights ''a statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of LTC requirements, including but not limited to resident abuse, neglect, misappropriation of resident property in the facility, non-compliance with the advance directives requirements, and requests for information regarding returning to the community.''

We proposed a new § 483.11(e)(13) that establishes that the facility must protect and facilitate a resident's right to communicate with individuals and entities both inside and external to the facility, including at § 483.11(e)(13)(ii) reasonable access to the internet, to the extent it is available to the facility. Section 483.11(e)(13)((i) replaces § 483.10(k) and § 483.11(e)(13)((iii) revises and replaces § 483.10(i)(2) with regard to reasonable access to a telephone, including TTY and TDD services, and to stationery, postage, writing implements and the ability to send mail, respectively.

We proposed a new § 483.11(f) to include provisions related to privacy and confidentiality. Proposed § 483.11(f)(1) requires that the facility respect the resident's right to personal privacy. Proposed (f)(1)(ii) incorporates the definition of personal privacy currently set out at § 483.10(e)(1). We proposed to replace the requirements of existing § 483.10(e)(2) with new § 483.11(f)(2) which requires the facility to comply with the requirements of proposed § 483.10(g)(3). We proposed to re-designate existing § 483.10(j)(3) as § 483.11(f)(3) and revise it to require that the facility allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with state law. This is consistent with the requirements of section 712(b)(1) of the Older Americans Act.

We propose a new § 483.11(g) that would include provisions related to a safe environment. Specifically, we propose to re-designate § 483.15(h)(1) through (7) as § 483.11(g)(1) through (7) and revise paragraph (g)(1) to include paragraphs (g)(1)(i) specifying that the facility must ensure an environment where care and services can be delivered safely, and (g)(1)(ii) specifying that the facility must ensure that the physical layout of the facility maximizes independence and does not pose a safety risk.

We proposed a new § 483.11(h) Grievances, to incorporate the facility responsibilities expressed in existing § 483.10(f) and also require that facilities ensure that residents know how to file grievances. The proposed provision also requires that the facility establish a grievance policy to ensure the prompt resolution of grievances, and identify a Grievance Officer. Additionally, the facility is required to provide a copy of this policy upon request, as well as make information about filing grievances available to residents. Furthermore, the facility would be required to take a number of actions in response to a grievance, including:

1. Preventing further violations of resident rights during an investigation,

2. Immediately reporting allegations of neglect, abuse (including injuries of unknown source), and/or misappropriation of resident property, by anyone furnishing services on behalf of the facility, to the administrator of the facility and as required by state law,

3. Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concerns, a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued,

4. Taking appropriate corrective action in accordance with state law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction confirms a violation of any of these residents' rights within its area of responsibility; and

5. Maintain evidence demonstrating the resolution of complaints and grievances for at least 3 years.

Finally, we proposed a new § 483.11(i) which requires that a facility not prevent or discourage a resident from communicating with Federal, State, or local officials, including but not limited to Federal and State surveyors, other Federal or State health department employees, including representatives of the Office of the State Long-Term Care Ombudsman and of the protection and advocacy system.

General

*Comment:* Many commenters supported specific aspects or the overall intent of our proposed revisions to resident rights and facility responsibilities, and provided wording suggestions or relocations, identified specific improvements, or raised concerns about specific provisions. Some commenters recommended we retain the existing language for a number of sections.

*Response:* We appreciate commenters support. We have considered each wording suggestion, suggested improvement and area of concern. We did not accept some wording changes or relocations that did not affect the meaning of or add substantial clarity to the regulatory requirement, or that were more appropriate to sub-regulatory guidance. Although we considered them, we do not specifically address all of those suggestions below. We also considered retaining existing language where suggested but do not specifically address each suggestion below. We discuss our response to comments on restructuring in section C. Resident Rights (§ 483.10) of this preamble and address other specific concerns and suggestions for change in the subsequent sections.

*Comment:* Some commenters suggested we use the term ''oral'' instead of ''verbal'' in a number of places.

*Response:* While both terms are accurate, we agree we should be consistent. Therefore, we have replaced the term ''verbal'' with ''oral'' throughout the regulation.

*Comment:* One commenter stated, with regard to resident rights as enumerated at § 483.10, that the proposed rule encourages a culture change towards a more resident-focused approach towards long term care. They note that improving quality of life and quality of care, allowing choices in daily living, and assisting individuals to make informed health care decisions are all major goals of culture change and person-centered care. They further state that involving individuals in choices about food and dining such as food selections, dining locations, and meal times can help them maintain a sense of dignity, control, and autonomy and they applaud CMS for proposing to revise its regulations in accordance with this resident-focused philosophy.

*Response:* We thank the commenter for their support. Person-centered care was one over-arching principle of our proposal. In addition, we believe that principles of quality of life and quality of care are also over-arching principles that apply to all the requirements for long-term care facilities. Many of the items the commenter mentions speak directly to each of these principles.

*Comment:* Some commenters stated that these requirements involve costly measures for nursing facilities. One commenter stated this would require them to employ translators, procure translation technology, or overhaul facility communications.

*Response:* Facilities should already have access to these services. Facilities are currently required to have the ability to communicate effectively, verbally and in writing, with residents. For example, facilities must inform residents in a language they can understand of their total health status and to provide notice of rights and services both orally and in writing in a language the resident understands.

Resident's Rights

*Comment:* Some commenters expressed concern that proposed revisions would diminish resident rights.

*Response:* We have maintained existing resident rights and protections, and have made revisions to ensure that those rights and protections encompass advancements, such as in the area of telecommunications, that were not envisioned when the original regulations were written.

*Comment:* One commenter recommended strengthening the wording of § 483.10(b)(5)(ii) to include asking residents their goals first. The commenter stated that the best and most respectful practice relative to establishing goals with residents starts with inquiry of the resident as to their preferred goals.

*Response:* This provision establishes the resident's right to participate in the care planning process. Section 483.21 addresses comprehensive person-centered care planning and is responsive to the commenter's concern. Please see our discussion of § 483.21(b), comprehensive care plans.

*Comment:* One commenter strongly support the new language that reads: ''A facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of his or her quality of life, recognizing each resident's individuality.'' Several commenters suggested that ''facility'' be changed to ''home or nursing home.''

*Response:* We thank the commenters for their support and their suggestion. We have retained the term ''facility'' throughout the regulation in keeping with the statutory language that serves as the basis for these regulations.

Exercise of Rights

*Comment:* A few commenters recommended that CMS explicitly include the right to vote and to require facilities to have policies and procedures to support voting. One commenter suggests that such policies and procedures include:

- A process for informing new residents about voting registration or change of address procedures;
- assistance in registering as needed and desired by the resident;
- procedures for informing residents of elections, including date, time, and location of voting places and community resources available to provide assistance;
- assistance with transportation to polling places;
- processes for reaching out to election officials to develop a plan for officials to come to the facility to register residents and conduct voting to the maximum extent election officials have the ability to do this;
- the designation of staff charged with assisting with voting; and
- training of designated staff in how to help a resident who requires assistance to vote where election officials are unable to provide that service to the extent needed.

The commenters contend that currently, residency in a LTC facility poses an enormous obstacle to exercising voting rights.

*Response:* The regulations, as proposed, state that the resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States, that the facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility, and that the resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart. Furthermore, facility staff

must be trained with regard to these rights and the facility responsibilities with regard to these rights, and residents must be informed of their rights. These requirements certainly include the right to vote. The suggested policies and procedures represent best practices, but we are concerned that some of the suggestions, such as requiring that facilities train designated staff to help a resident who requires assistance to vote where election officials are unable to provide that service, are overly prescriptive and burdensome. We would defer additional specificity with regard to this section to interpretive guidance.

*Comment:* A number of commenters expressed concern about the role of the resident's representative. One commenter urged CMS to encourage an appropriately expansive view of the representative's role while ensuring respect for the resident's right to self-determination. One commenter strongly supports proposed requirements that clarify that representatives can only exercise the rights delegated to them. Another commenter recommended that nursing facilities be required to have clearly defined procedures regarding resident representatives. The commenter recognized that a resident may not be prepared to designate a representative at the time of admission due to other pressing issues and suggests that nursing facilities should periodically remind residents that they have the option to select one or more representatives. Some commenters were concerned that nursing facility staff may not become aware of the resident's selection of a representative and recommended that CMS require nursing facilities to establish a mechanism for formally recording the designation of a representative and informing staff of the resident's selection and scope of delegation of responsibilities. Commenters also recommended that nursing facilities have a process for the residents to designate what they want to happen in the event that a resident is adjudged to be incompetent under the state law.

Some commenters stated that they disagreed that a resident has ''the right to revoke delegation'' of a court-appointed guardian when they have been deemed incompetent by a court. Similarly, if the practitioner in their professional opinion has determined the resident's medical condition impairs their decision-making capacity such that a resident's representative appointed by advanced directive or durable power of attorney needs to make decisions, a resident cannot revoke that representative. Some commenters expressed that the resident representative should be making decisions in the best interest of the resident or consistent with the resident's specified wishes and that the facility should try to resolve discrepancies and, if unresolvable, seek to legally remove the assigned representative.

Some commenters objected to allowing residents to have more than one representative. One commenter expressed concern that having a resident representative in addition to one appointed by the court or by the resident's own authorization through advance directives or a durable power of attorney will slow notifications and increase the likelihood of disagreements which may delay health-care decisions and necessary care. The commenter recommended that the definition of resident representative be modified to apply only when the resident does not have either a court-appointed guardian or an already designated health care proxy such as a durable power of attorney for health care or person specified in a living will to avoid having multiple resident representatives that will delay decision-making while differences are reconciled and requiring multiple notifications of numerous parties.

With regard to residents who have been adjudged incompetent, some commenters agreed that residents should retain as many rights as possible and their preferences be elicited and honored whenever possible. Once commenter felt that our proposed language will likely add confusion and is not internally consistent. The commenter stated that the court order for scope of decisions is not always clearly defined and the distinction between medical care decisions in the context of frail elderly in LTC facilities and personal decisions regarding quality of life often is not clear, resulting in confusion about who is the appropriate decision maker. The commenter is concerned that multiple decision makers will make this situation worse.

One commenter recommended that the definition of ''resident representative'' be modified to apply only when the resident has neither a court-appointed guardian nor a designated healthcare proxy through advance directives nor an identified durable power of attorney.

*Response:* We believe we have taken a comprehensive view of the role of resident representatives and the right of residents to choose whomever they want to assist them in making healthcare and other decisions both while the resident retains decision-making capacity and in the event a resident should not have or would lose after admission this capacity. See our discussion above, regarding the definition of ''resident representative.'' The term is not intended to create a new role, but instead is a general term intended to encompass several terms used to describe an individual who a resident or court provides with authority, in accordance with federal or state law, to participate in health care discussions or to make decisions on behalf of a resident. Nothing in this paragraph requires that a resident appoint or have a resident representative. We agree that a resident who is adjudicated incompetent cannot revoke a court's delegation of authority to a representative, which is why § 483.10(b)(3)(ii) defers to state law. In addition, residents adjudged incompetent by a court of competent jurisdiction are separately addressed in § 483.10(b)(7). With regard to limiting the rights of residents to have more than one representative, we decline to do so and defer to state law, to the extent that state law does or does not address this concern. While we acknowledge that multiple representatives could create complexity in decision making, we do not believe it is necessary or appropriate for us to limit the resident's ability to do so when state law would allow this. With regard to medical determinations of incapacity, we again defer to state law. Physicians can and do make determinations regarding an individual's decision-making capacity. We are aware that, at least in some states, if a patient disputes a determination of incapacity, a surrogate's decision-making cannot be substituted for the patient's until a court decides the matter. For certain situations, more than one physician's determination that a patient lacks decision-making capacity is required. With regard to the comprehensive nature of court decisions, we agree that generally such a decision would be in regard to an individual's ability to make all decisions. However, should a court's determination be more limited, we believe it is important that a resident be allowed to exercise his or her rights and to not have the facility extend the court's decision in deferring to a court-appointed representative. With regard to our reference to a court's order, generally, a court's determination would be formalized through a court order. However, for clarity in the event that a court's determination does not result in an order, we have modified our language to refer to the court's determination. We note that, in

§ 483.10(b)(4), we require that the facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law. This requirement presumes that a facility knows when a resident has a representative and the nature of the representative's appointment. We will not, at this time, be prescriptive regarding what a facility must do to fulfill this obligation, however, we would expect a facility to have process in place in order to ensure that they meet this requirement.

*Comment:* One commenter requested that CMS explicitly incorporate the concept of negotiated risk into proposed § 483.10(a)(2), which states that the resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility, and to be supported by the facility in exercising his or her rights.

*Response:* The rights of the resident to be informed about and agree to, refuse, and/or discontinue treatments are established under planning and implementing care, § 483.10(c), and further addressed section § 483.21, ''Care Planning.'' We defer any additional discussion to sub-regulatory guidance.

*Comment:* Another commenter recommended that we amend language at proposed § 483.10(a)(4) (iii) to read: ''The resident's wishes and preferences must be considered in the exercise of rights by the court-appointed representative'' rather than ''the resident's wishes and preferences must be considered in the exercise of rights by the representative.''

*Response:* A resident representative, whether court-appointed or not, should take the resident's wishes and preferences into consideration in the exercise of delegated authority. However, CMS has no authority to compel any action on the part of representatives, regardless of status.

*Comment:* One commenter suggested that the intent of proposed § 483.10(a)(4)(i) was unclear.

*Response:* Our intent is to ensure that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian, when a court's determination does not require it. While guardianships are often general in nature, giving all decision making authority to a guardian, in some case a guardianship may be limited. A limited guardian has the authority to make decisions only in specific areas, such as financial or residential. Typically, a court's findings of fact and orders or the guardian's letters of appointment will identify these areas. Facilities are expected to be aware of when a guardianship is limited and not automatically defer all decisions to a guardian. We are finalizing this provision at § 483.10(b)(7)(i) and have revised it to state that, in the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decision outside the representative's authority.

*Comment:* One commenter stated that in proposed § 483.10(a)(5), the first sentence in this section covers everyone who is covered under state law. Therefore, it is superfluous to single out a specific group later on in the paragraph.

*Response:* The provision in question states that ''In the case of a resident who has not been adjudged incompetent by the state court, the resident has the right to designate a representative, in accordance with state law and any legal surrogate so designated may exercise the resident's rights to the extent provided by state law. The same-sex spouse of a resident must be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.'' We originally included this language to account for State law that did not recognize the validity of same sex marriages. Although all states must now, pursuant to the Supreme Court's decision in *Obergefell* v. *Hodges* (576 U.S. ____, 135 S.Ct. 2584 (2015)) both issue same-sex marriage licenses and recognize the validity of such licenses issued in other states, in order to emphasize the importance of this provision, we are finalizing it as proposed.

*Comment:* One commenter asked if proposed § 483.11(a)(3) and (4) overrides a state statute that permits a NF provider to refuse to comply with health care agents' directives where they question the agent's ''good faith'' and to have the issue resolved by a court or agency as needed. The comments asked if the NF provider had to comply with a resident representative's decision until and unless the NF obtains court authority pursuant to § 483.11(a)(5).

*Response:* Proposed § 483.11(a)(3) and(4) are finalized as § 483.10(b)(4) and (5). Both provisions state that the requirement is ''in accordance with applicable law,'' which would include applicable state law. Proposed § 483.11(a)(5), finalized at § 483.10(b)(6), requires the facility to report, when a resident representative is making decisions or taking actions that the facility believes are not in the best interests of the resident as required by state law. Our regulations defer to state laws rather than preempt them.

*Comment:* One commenter was concerned that proposed § 483.11(a)(5) is confusing and could lead to underreporting of suspicion of crimes.

*Response:* We agree our language could be confusing and have modified it to state: ''[i]f the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns in the manner required under State law'', finalizing it at § 483.10(b)(6).

*Comment:* One commenter suggested that the order of proposed § 483.11(d)(3)(iii)(A) (limiting the requirement to act on residents' of families' requests and grievances) and (B) (requiring that facilities demonstrate that they have responded to such requests and grievances) should be reversed to emphasize that while a facility must have a response for every grievance or recommendation from a resident or family group, not every request has to be adopted as recommended.

*Response:* We agree that the suggested modification better conveys the information and have the provision accordingly, finalizing it at § 483.10(f)(5)(iv)(A)&(B).

*Comment:* One commenter requested that we clarify that proposed § 483.11(d)(5)(v) precludes a facility from taking resident funds for past due balances before the facility conveys any personal funds to a resident or resident representative.

*Response:* Proposed § 483.11(d)(6), which we finalize at § 483.10(f)(11), addresses those items and services for which a facility may or may not impose a charge against the resident's personal funds.

*Comment:* CMS begins the newly-named ''Facility Responsibilities'' section by expanding on existing requirements that facilities must treat residents with respect and dignity, and provide care and services that maintain or enhance the resident's quality of life and protect the resident's rights. The commenter supported the new ''Exercise of Rights'' § 483.11(a), including proposed § 483.11(a)(2)'s requirement that facilities provide ''equal access to quality care regardless of diagnosis, severity of condition, or payment source and establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services for all residents regardless of source of payment.'' The commenter encouraged CMS to provide greater clarity on proposed § 483.11(a)(3) and (4) over the

expectations of facilities deferring to resident representatives for decisions that exceed the scope of a court order, resident delegation, or other applicable law. Similarly, proposed § 483.11(a)(5)'s language of expectations for facilities complying with state requirements in the case of a resident representative making decisions not in the best interest of the resident seems rather vague and may provide potential for abuse.

*Response:* We thank the commenter for their support. Please see our previous response with regard to resident representatives. As we discussed in the preamble, we understand that there is a potential for abuse in the relationship between a resident and his or her resident representative, such as a guardian, and we want to ensure that facilities recognize their role in identifying and reporting such concerns in accordance with applicable state law. We would defer more detailed discussion to interpretive guidance.

*Comment:* Some commenters were concerned about the requirement that ''[t]he facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source.'' One commenter felt that this suggests that every facility must provide care for every individual regardless of the facility's care expertise or the ability to care for every condition any individual might have. For example, a person may require the use of a ventilator yet not every facility has the ability to provide care for such patients. Similarly, a facility that provides care for frail elders is unlikely to have the expertise to care for a child who requires facility care. The commenter suggested we delete ''diagnosis.'' One commenter pointed out that facilities, like clinics, may specialize in providing services to residents with specific conditions. Another commenter, while supporting the expectation to provide quality care (that is, safe, effective, person-centered, equitable, efficient, and timely) to everyone, recommends deleting ''equal access to,'' stating that terms such as ''equal access'' can easily be misconstrued as requiring the same amount of care or comparable treatments regardless of need or condition.

*Response:* We note that the phrase ''equal access to quality care'' is statutory language, specifically identified as a requirement relating to residents' rights in both sections 1819(c)(4) and 1919(c)(4) of the Act, and refers to the issue of possible discrimination in treatment based on the source of payment. We therefore are retaining the language as proposed in § 483.11(a)(2), finalizing it at § 483.10(a)(2).

This provision is not intended to require that every facility have every possible capability and unlimited capacity. However, a facility cannot choose, deliberately or inadvertently, to provide higher quality care to some residents over other residents in the facility based on diagnosis, severity of condition, or payment source. For example, if two residents require the same care, one resident cannot receive a lesser quality because the payer is Medicaid rather than Medicare. The amount and type of care is based on the resident's needs and goals, as evidenced by the care plan.

These provisions are also not intended to facilitate selective admissions or transfers. We considered, but did not include, admissions when we reviewed the existing requirement that requires a facility to establish and maintain identical policies and practices regarding transfer and discharge. Facilities are expected, as required by our provision for a facility assessment, to know their own capabilities and capacities when making admissions decisions. This expectation would apply to the second example provided by the commenter. Once an individual is a resident of the facility, the facility is obligated to provide equal access to quality of care, as stated in this provision. Thus, a facility that admits a pediatric resident is expected to provide quality care to that resident, based on that resident's needs. If a resident's condition changes such that a facility does not have the ability and is unable make accommodations to provide the care that a resident requires, that is an acceptable reason for discharge or transfer under § 483.15, as it is permissible to discharge or transfer a resident when it is necessary for the resident's welfare and the resident's needs cannot be met in the facility. This provision would apply in the instance where a resident's condition declines such that a ventilator is required in a facility that does not have the expertise or equipment to provide care to a ventilator dependent resident. However, the facility will have to include in its documentation the specific resident needs that it cannot meet, facility attempts to meet the resident needs, and the service(s) available at the receiving facility that will meet the resident's needs.

*Comment:* Some commenters were concerned that we do not include admission in the statement regarding equal access to quality of care and are concerned that this can result in discrimination in violation of Title VI of the Civil Rights Act of 1964. Another suggested that we expressly prohibit all forms of discrimination against residents.

*Response:* Nothing in these regulations allows facilities to violate other statutes or regulations. Furthermore, facilities are expressly required by § 483.70(b) to operate in compliance with all applicable Federal, State, and local laws, regulations, and codes. This includes, for example, the Americans with Disabilities Act and section 504 of the Rehabilitation Act. In addition, § 483.70(c) explicitly requires compliance with other HHS regulations. This would include but not be limited to those regulations pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); non-discrimination on the basis of race, color, national origin, sex, age, or disability (45 CFR part 92); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). These provisions cover all phases of patient care, including, but not limited to, admissions.

Planning and Implementing Care

*Comment:* One commenter supported proposed changes to ensure that the resident is informed of, and participates in, his or her treatment, and that the resident participates in care planning. However, the commenter urged CMS to include stronger language with regard to including the resident or the resident's representative. The commenter strongly suggested that CMS include specific language that would require nursing facilities to provide reasonable advance notice to resident representatives of the care planning meeting, establish alternative means of participating (for example, via telephone or video conferencing), offer a reasonable choice of dates and times, and document the same. This would help facilitate the participation of resident representatives in care planning.

*Response:* We thank the commenter for their support of our proposal at § 483.11(b), which we are finalizing at § 483.10(c), and for their comments regarding care planning. We refer readers to our discussion of § 483.21 for further discussion of care planning.

*Comment:* Some commenters suggested that we add that residents have a right to a copy of the care plan.

*Response:* We appreciate the comments that were submitted on this

issue. While we agree that a resident should be able to review their own comprehensive care plan, we also understand that the comprehensive care plan is a clinically oriented document that is frequently reviewed and updated based on the needs of the resident. Therefore, in an effort to further promote a resident's right to be informed, while balancing the burden imposed on facilities, we have revised § 483.21(a)(3) to require facilities to provide residents and their resident representatives with a summary of their baseline care plan. This summary must include, but is not limited to, the initial goals of the resident, a summary of the resident's medications and dietary instructions, any services and treatments to be administered by the facility and personnel acting on behalf of the facility, and any updated information based on the details of the comprehensive care plan, as necessary. Note that this summary is subject to the provisions at § 483.10(g)(3) and must be provided in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

Furthermore, we note that § 483.10(c)(2)(v) gives the resident the right to see the care plan, along with the right to sign it after significant changes. The intent is to ensure that the resident, to the extent practicable and consistent with the resident's choices, demonstrates his or her participation in and review of his or her care planning and that participation is evident to care-givers, surveyors, and other interested parties. We believe that the combination of these resident rights, with the responsibility of the facility to provide a summary of the baseline care plan and include the resident as a member of the interdisciplinary care team, will actively engage residents in their care planning process.

Lastly, we would encourage a facility to provide a copy of the full comprehensive care plan upon request; with the understanding that care plans are dynamic documents that may change frequently. We believe that the comprehensive care plan should serve as an important tool for delivering patient-centered care and encourage facilities to explore ways to allow residents, families, and other representatives to access the care plan on a routine basis as appropriate, for instance, using technology solutions that enable real-time access for authorized users and dynamic updating by members of the care team. In addition, as finalized, residents have a right to review and obtain a copy of their medical record, or any portion thereof under § 483.10(g)(2)(ii). The care plan is included in the medical records. Sections 1819(b)(6)(C) and 1919(b)(6)(C) of the Act state that clinical records on all residents include the plans of care and the residents' assessments. We discuss our use of the term ''medical record'' in our discussion of § 483.70(i). As noted in that discussion, we regard the terms ''medical record'' and ''clinical record'' as synonymous.

*Comment:* Some commenters expressed concern about proposed requirements to inform the resident in advance of changes to the care plan and the right to see and sign the care plan after the changes are made. Commenters stated that the care plan is an evolving document and suggested that care could be delayed to wait on getting a signature, placing residents at risk for fall, skin breakdown, weight loss, and other undesirable outcomes.

*Response:* The right of the resident to be informed, in advance, about care and treatment and of changes in care and treatment that may affect the resident's well-being is not new. It is important that the resident receives information necessary to make a health care decision, including information about his or her medical condition and changes in medical condition, about the benefits and reasonable risks of the treatment, and about reasonable available alternatives. Care necessary to prevent an adverse event or outcome should not be delayed just to obtain a signature on a care plan. However, we expect that residents will be involved, to the extent possible and as desired by the resident, in care planning. This includes seeing the care plan initially and after changes are made. Allowing the resident to sign the care plan after changes are made documents the resident's involvement. Furthermore, it supports both staff and resident perceptions that the resident is a vital member of the care planning team. We understand that care plans are evolving documents and would not expect that facilities would ask residents to sign care plans on a daily basis, and, therefore, have modified § 483.10(c)(2)(v), as finalized, to state that the resident has the right to sign the care plan after significant changes.

*Comment:* Some commenters suggested that CMS specifically include language related to informed consent. Others felt that language in proposed § 483.10(b)(2)(iii) needed further definition. One commenter appreciated CMS' proposed language recognizing the residents' right to be informed in advance of the risks and benefits of proposed care and treatment, especially with respect to the use of antipsychotic drugs often without first obtaining informed consent. The commenter believed that nursing facilities should be required to document that the attending physician discussed the benefits, risks, and alternatives of a drug with the resident and/or the resident's representative and that the doctor obtain informed consent prior to administering the drug(s). Some commenters suggested that this language was too restrictive and could delay care. One commenter suggested we revise the regulatory language to say ''the right to be informed, to the extent practicable, in advance of changes to the plan of care.'' Another commenter stated that advising the resident of the risks and benefits of proposed care, treatment and treatment alternatives or options are the responsibilities of the practitioner, not the facility, and recommends we revise the language accordingly. The commenter also stated that the resident should be informed of his or her right to refuse the medication and of alternative behavioral interventions, and this should be documented, as well. With respect to a resident's right to refuse a particular treatment or medication, the commenter was concerned that language stating that ''nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate'', as currently worded, could be used by nursing facility physicians and staff to deny a resident's/representative's request for alternative behavioral interventions on the basis that a physician or nursing facility nurse believes that a drug regimen is a better or more appropriate treatment. The commenter suggested that, in order to protect the resident's right to self-autonomy, CMS should clarify the definition of ''medically unnecessary or inappropriate'' in this context to make it clear that such decisions should be evidence-based. Another commenter suggested that CMS clarify the meaning of ''clinically appropriate.''

*Response:* Antipsychotic medications are addressed in § 483.45. Please see our discussion of comments related to that section. Although the requirements do not use the term ''informed consent,'' and informed consent laws may vary from state to state, the elements of informed consent are generally contained in the statements of resident rights. Proposed § 483.10(b)(3) establishes the resident's right to be informed in advance of the risks and

benefits of proposed care, of treatment and treatment alternative or treatment options, and to choose the alternative or option that the resident prefers. We note that the right to be informed in advance about care and treatment is not a new right and the facilities are already required to meet this requirement. Proposed § 483.10(b)(4) establishes the resident's right to request, refuse, or discontinue treatment. We agree that it is the responsibility of the practitioner to discuss the risks and benefits of proposed care, treatment and treatment alternatives or options with a resident or their representative and have modified the provision accordingly, now at § 483.10(c)(5). In addition, the practitioner is responsible for documenting this discussion in the medical record. The facility has a role in supporting the resident's rights, for example, by ensuring a resident or resident representative knows how to contact a provider. As one commenter noted, facilities can help residents facilitate existing informed consent rights, but may not abridge or abrogate them. With regard to clarifying the definition of medically unnecessary or inappropriate, we believe that there is a clear distinction between an alternative that a provider may not prefer and a treatment or service that is medically unnecessary or inappropriate. We defer additional discussion/examples of ''medically unnecessary'' as well as ''clinically appropriate'' to interpretive guidance.

*Comment:* Some commenters stated that they were pleased to see that the proposed regulations support the resident's right to participate in care planning. One commenter suggests we require that CMS require the planning process to identify staffing practices that maximize staff's delivery of person-centered care and the prevention of adverse events.

*Response:* We considered these suggestions, but are not incorporating them at this time. Staffing provisions address the need to ensure that nursing and other staff have the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e). Adverse events, including monitoring and prevention, are addressed by QAPI.

*Comment:* One commenter was concerned that the use of some terms is unclear. The commenter stated that the use of the term ''roles'' in proposed § 483.10(b)(5)(i) was confusing and should be replaced with a word that is clearer as to the intent. Other commenters asked if this meant that the resident could choose which nurse/therapist/aide would participate in the care plan meeting or if the meeting could not proceed if that individual was unable to participate. One commenter was concerned that the meaning of the phrase ''and the disciplines that will furnish care'' in proposed § 483.10(b)(2) was unclear and suggested ''The right to be informed, in advance, of the care to be furnished and the professions/practitioners/departments that will furnish care.'' The commenter offered other specific language alternatives.

*Response:* We reviewed these sections. We believe the term ''roles'' is appropriate. A resident may not be able to identify a specific person they want included in the planning process, or a specific individual may be unable to participate, but that should not prevent the resident from including a role, such as an individual to provide spiritual, nutritional, or behavioral health input. With regard to the term ''disciplines,'' to improve clarity, we have revised it to read ''type of care giver or professional'' that will furnish care.

*Comment:* Some commenters were concerned about adequate resident involvement in the care planning process. One commenter stated that ''often the resident or their representative is not aware of the right to participate in the development and implementation of his or her person-centered plan of care.'' The commenter was concerned that, although proposed § 483.10(b)(5)(i) allows the resident to request the right to participate in the planning process, if the resident isn't aware of the right, they are unable to implement it. The commenter recommended that CMS add language requiring the facility to ask the resident or resident representative at least quarterly if they choose to participate in the planning process, and to inform the resident of the date and time of the meeting. Another commenter suggested setting a minimum number of care planning meetings per year, such as monthly or quarterly, that the facility must invite the resident or representative to attend.

*Response:* We believe that our proposed requirements adequately address resident involvement in the care planning process. Regulations at § 483.21(b)(2)(ii)(E) require that to the extent possible the resident and/or their representative(s) must participate on the IDT that develops the resident's care plan. In addition, regulations at § 483.21(b)(2)(ii)(E) require that the facility provide an explanation in the resident's medical record if the participation of the resident and their representative is determined not practicable for the development of the resident's care plan. We encourage readers to refer to section H, ''Comprehensive Person-Centered Care Planning'' (§ 483.21) for a detailed discussion regarding the care planning requirements.

*Comment:* Some commenters applauded CMS's inclusion of advance directives in several provisions of the proposed rule and recommended that CMS incorporate other advance care planning tools in all provisions relating to advance directives. Commenters specifically recommended CMS incorporate recognition of Physician Orders for Life Sustaining Treatment (POLST) in several sections of the regulation, including defining ''Portable Order for Scope of Treatment.'' Commenters further suggested adding such orders as required documentation in the resident's medical record, if applicable and with the resident's consent, including such orders in both the baseline and comprehensive care plan, when applicable, and a review and update of such orders as part of the discharge planning process. One commenter recommended that CMS encourage repeated conversations related to advance care planning throughout a resident's stay.

*Response:* We thank the commenters for their support for the inclusion of advance directives. We note that advance directives are currently included in the requirements for participation and our proposed revisions were primarily to improve clarity and readability. We also thank the commenters for their suggestions but decline to add additional regulatory requirements regarding portable orders for scope of treatment at this time. We recognize that these tools serve a function beyond advance directives. Several of our requirements are also intended to facilitate shared, informed decision making and communication between health care professionals and residents with serious, progressive illness or frailty. These requirements apply both to the resident's care within a facility and to communication with other providers when a resident is transferred or discharge. We would expect that the issues that are addressed by portable orders for scope of treatment would be raised in the context of advanced directives as well in ongoing

discussions related to care planning and keeping in mind residents' goals of care and treatment preferences. To the extent applicable, such concerns should also be reflected in resident's discharge plan and discharge summary. All physician orders are documented in a residents' care plans. We note that a few states have developed POLST programs, a few states do not have such a program, and many states are in the process of developing such programs. Consistent with state law, it would be appropriate for facilities to inform residents about portable orders for scope of treatment, as those tools are referenced and recognized within the state. We note that current requirements already require a facility to provide written information to residents that includes a description of the facilities policies to implement advance directives and applicable state law.

*Comment:* One commenter was concerned with regard to Advance Directives that providing information is inadequate unless the facility explains what the information means, and suggested that CMS add language to require that an explanation to the resident or resident representative about what the various advance directives mean, including different code statuses, and that it can be changed if desired in the future.

*Response:* Facilities are required to provide written advance directive information in accordance with 42 CFR part 489, subpart I. In addition, residents have a right to be informed of their total health status; the right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care; of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers; and the right to request, refuse, and/or discontinue treatment. We also proposed and are finalizing provisions related to resident and resident representative participation in the care planning process, which includes discussion of resident goals of care and preferences. We would expect that the discussions resulting from these rights would include discussions tailored to the resident's specific situation, including, as appropriate, discussions around the types of care that would be covered by advance directives.

*Comment:* Some commenters supported CMS's proposal to strengthen resident rights related to care planning, but believed the proposed rule does not go far enough in creating truly person-centered planning and saw no reason why the person-centered planning process in nursing facilities should not be more consistent with the process mandated for Medicaid-funded home and community-based services. Some commenters recommended changes that would give more control to residents and permit residents to play a greater role in directing their own care. One commenter recommended specific revisions to the proposed regulatory language, including incorporating the term 'informed consent' and emphasizing the resident's right to direct the care-planning process.

*Response:* Our proposed regulatory language establishes that each resident has the right to be fully informed, in language that he or she can understand, of his or her total health status, and to make many types of decisions regarding his or her care. We believe that the rights set out in this section comprise the essential elements of informed consent, and are phrased in language that residents and their representatives can easily understand.

As we noted in the preamble to the proposed rule, our proposals support the guidance issued by HHS for implementing person-centered planning and self-direction in home and community-based services programs, as set forth in section 2402(a) of the Affordable Care Act. We agree that the principles in that guidance regarding dignity and self-direction apply equally to individuals who reside in a nursing facility. Although nursing facilities are expressly not considered home and community based settings (42 CFR 441.301(b)(1)(ii)), we have incorporated many requirements that are supportive of the principles reflected in the process mandated for Medicaid-funded home and community-based services. We refer readers to our discussion of § 483.21 regarding comprehensive person-centered care planning.

Choice of Attending Physician

*Comment:* Many commenters were concerned about facilities' requirement or ability to establish credentialing requirements for physicians. Commenters supported the right of residents to choose their own attending physicians and to require facilities to protect and promote that right. One commenter specifically supported changes designed to ensure that residents are the driving force in their care, so they can make choices that preserve their dignity, reflect their preferences, and support their independence. Nevertheless, the commenter was concerned by the lack of clarity around what is meant by the ''professional credentialing requirements of the facility,'' which is not otherwise defined in existing regulations. The commenter was concerned that leaving this level of flexibility to facilities could allow facilities inclined to not accept residents' choices with a potentially fairly easy way to undermine this right, and urges CMS to make clear that credentialing requirements cannot be used for the purpose of denying a resident's right to choose their own physician without good cause and/or right of appeal. The commenter requested clarification about how this right would be maintained when residents are in facilities that have closed medical staff models or facilities that employ their own physicians. The commenter also noted that credentialing itself does nothing to ensure adequate performance or competent care so they urge CMS to ensure that quality programs incorporate physician performance indicators and measures.

Another commenter urged CMS to confirm that this requirement applies to the attending physician only and not to a covering physician since that list can be extremely long and may change frequently. To the extent that CMS would apply this requirement to covering physicians, this would likely result in the unintended consequences of significant on-call coverage problems as well as potentially discouraging physicians from caring for SNF residents at a time when the agency is striving for greater and more frequent physician involvement in SNF care.

The commenter also pointed out that verification of professional credentialing requirements can take time which may result in a resident's physician being unable to serve as the attending physician upon admission. Thus, the resident would be under the care of another ''credentialed'' attending physician until their physician completes the facility's credentialing process. This switching of physicians is not a best practice and may result in resident's experiencing adverse events, as such attending physician may not be familiar with the resident. The commenter recommended amending § 483.10(c) to read: ''Choice of attending physician. The resident has the right to choose his or her attending physician. (1) The facility must develop its own credentialing process that does not require primary source verification, which is typically conducted by state licensure entities or the process for conveying hospital admitting privileges or managed care certification. (2) The physician must be licensed to practice, and (3) The physician must meet the professional credentialing requirements of the facility within a timely manner

following the resident's admission to the facility.''

Yet another commenter recommended additional wording in order to support the role of the medical director in ensuring practitioner accountability for improved performance. The commenter stated that credentialing refers only to background, education, training, licensing, etc. Just requiring credentialing is not enough to ensure adequate physician performance (for example, timely visits and competent care). Addressing the challenges of medical care requires holding people accountable for their performance and practice, not just their credentials. The commenter suggested that we modify the requirement to read: ''(c) Choice of attending physician. The resident has the right to choose his or her attending physician. (1) The physician must be licensed to practice, and (2) The physician must meet the professional credentialing, practice, and performance requirements of the facility.''

Other commenters recommended that CMS delete the credentialing requirement entirely. The commenters stated that CMS proposes, without explanation, to limit residents' free choice of physician to physicians who meet their facilities' credentialing requirements and that the commenters do not see a need for such a requirement. Further, one commenter is concerned that the proposal does not provide any standards for credentialing. The commenter stated that the public policy concerns about physicians have always been the lack of appropriate medical care in LTC facilities and how few physicians actually provide care to residents and that the new credentialing requirement would not improve the medical care of residents and could further reduce the number of qualified physicians providing care to residents. One commenter stated that, if the intent of the requirement is to improve the care provided by attending physicians, CMS should pull stakeholders together to determine how that could best be done and assess whether credentialing would accomplish that goal. If the intent is to remove a physician of the resident's choosing who is failing to fulfill a given requirement (for example, frequency of physician visits, unnecessary drugs), the current interpretive guidelines that outline such a process could be retained (''the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment''). The commenter further states that the proposed requirement is contrary to federal law at section 1819(c)(1)(A)(i) of the Act, which gives residents an unfettered right to choose their physician. The commenter stated that they oppose the proposed requirement as it is written and recommends it be deleted.

*Response:* Based on commenter concerns, we have withdrawn the proposed requirement related to physician credentialing. We are finalizing the requirements that the physician must be licensed to practice and must meet applicable regulatory requirements as well as the requirement that, in the event that it becomes necessary for a facility to seek alternate physician participation, the facility must discuss this with the resident and honor the resident's selection of a new attending physician.

*Comment:* Some commenters suggested that the resident's right to select his or her attending physician was a new right and stated that this could be burdensome and problematic.

*Response:* The right of a resident to choose his or her attending physician is not new. It is in current regulations and is a statutory requirement at both sections 1819(c)(1)(A)(i) and 1919(c)(1)(A)(i) of the Act. All facilities should already be in compliance with this requirement. We proposed requirements to ensure that physicians chosen by resident complied with requirements for licensing and credentialing. As a result of public comments, we are withdrawing our proposal regarding credentialing. Please see our previous response on this issue.

*Comment:* One commenter stated that the requirement to honor a resident's preference regarding a physician must be related to the physician's responsibility to practice appropriately and provide quality care and that the failure to hold physicians to this standard has major adverse consequences for long-term and post-acute care residents/patients. The commenter suggests adding the word ''relevant'' to emphasize that the choice needs to consider the physician's performance and practice as well as other factors.

*Response:* We have revised these requirements to state that the physician must be licensed to practice and must meet applicable regulatory requirements as well as a requirement that, in the event that it becomes necessary for a facility to seek alternate physician participation, the facility must discuss this with the resident and honor the resident's selection of a new attending physician. We do not agree that the requested revision is necessary and defer additional specificity to sub-regulatory guidance.

*Comment:* A commenter is concerned that proposed revisions relating to choice of physician in proposed § 483.10(c)(2) and (3) and proposed § 483.11(c)(2) conflict.

*Response:* We have withdrawn proposed § 483.10(c)(2) and have co-located the provisions related to choice of physician in § 483.10(d).

Respect and Dignity

*Comment:* A few commenters are concerned that the proposed rules require facilities to allow residents to use their personal belongings, but do not impose any obligations on facilities to assure the security of residents' property from loss or theft. These commenters recommend that CMS add additional requirements relating to the protection of residents' belongings. Others stated that CMS should specify that the use of person possession must meet fire code.

*Response:* Our proposed rule requires that a facility provide to a resident a safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible. A safe, home-like environment includes the security of the residents' personal belongings. Therefore, in response to commenters' suggestions, we have added language at proposed paragraph (j), safe environment, finalized at § 483.10(i) stating that the facility shall exercise reasonable care for the protection of the resident's property from loss or theft. We defer additional detail to interpretive guidance. We agree that the use of personal possessions must comply with fire safety. We note that we require that such use must not infringe upon the safety of other residents. Furthermore, facilities are required to comply with requirements related to Life Safety Code, which are located at § 483.90(a).

*Comment:* Commenters both supported and opposed our proposed changes to visitation requirements. One commenter strongly supports the language requiring that the ''facility'' provide immediate access to a resident by immediate family member and other relatives of the resident, and by others who are visiting with the consent of the resident, subject to the resident's right to deny or withdraw consent at any time. The commenter noted that this was included in the 2009 interpretive guidelines but having it in the regulations makes it an even stronger requirement. One commenter strongly supports changes to expand the rights of residents related to self-determination, to enable immediate access to the resident by the resident representative,

and the requirement that facilities must have written policies and procedures regarding visitation rights of residents. The commenter further supports providing residents with more flexibility around when they receive visitors and who may visit. Some commenters support proposed visitation provisions that enable residents to receive visitors of the resident's choosing, at the time of the resident's choosing, stating that this is an essential element of self-determination and, since the facility is the resident's home, residents should have the same 24-hour access to visitors as those who live in the community. Some commenters felt that residents don't want visitors late at night and prefer that the doors are locked. These commenters felt that our proposal unreasonably imposed visitors upon residents.

Many commenters expressed safety concerns with regard to open visitation. Some commenters stated that having unexpected visitors entering the facility at any time of day or night is unreasonable, disruptive, and potentially dangerous, but suggested that pre-arranged visits during ''off-hours'' could be accommodated and felt that, in order for a facility to provide a safe and secure environment for all patients and residents, there must be reasonable parameters applied to this visiting provision. One commenter suggested establishing specific time frames. Another commenter stated that their facility used a security code to ensure that staff knows when a visitor is in the facility. Some commenters stated that it is important that residents, visitors and staff understand that visitation privileges does not include a visitor living in the facility. Another concern is visitors who are extremely boisterous, confrontational, under the influence of drugs or alcohol. One commenter stated that a center must have the ability to protect staff and residents from this disruptive behavior. Other commenters noted that the rights of other facility residents must considered in an ''open visitation'' policy. One commenter highlighted important distinctions between hospitals and LTC facilities that should be considered, including concerns that LTC facilities do not employ distinct security personnel, or, if they do employ security personnel, they are typically not present around the clock. The commenter stated that it is more common for a LTC facility to have a receptionist at the main entrance who welcomes and guides visitors and that reception staff are present until early evening hours. The commenter stated that around the clock visitation would require increased staffing, at a minimum, which did not seem to be included in CMS' estimate of costs per facility for implementation of these rules. Commenters noted that, currently, facilities accommodate visitors at any time when a request is made or the clinical situation of the resident is such that the presence of visitors is essential. This provides everyone involved with the time to prepare and to accommodate everyone's needs. Mandatory ''open visitation'' in what is both a home and a health care facility means there will be more unanticipated visitors, and this could lead to facility resources being diverted to quickly arrange for an appropriate visiting environment for all involved, as opposed to attending to other needs. The commenter urges CMS to clarify this section of the proposed rule to ensure that facilities maintain the ability to limit visitations if those limitations are based on clinical or safety considerations that are outlined in the facility's policies and procedures and shared with each resident.

One commenter expressed concern about facilities establishing their own policies and procedures for visitation. For example, the commenter suggested that rather than allowing a facility to make its own decisions about restricting visits in the event of an infectious disease, the commenter suggested instead that the facility should follow CDC guidelines, which are evidence-based. The commenter also expressed a concern about permitting 24-hour visitation, stating that 24-hour visitation is already allowed but questions about 24-hour visitation still arise and many facilities still post signs indicating only specific hours for visitation. The commenter recommends that the regulations clarify this point.

Some commenters felt that the regulatory language impermissibly limited visits to residents from CMS, the State Survey Agency, family members and was concerned that CMS proposed to redefine access and visitation rights, currently at § 483.10(j), as a subcategory under ''self-determination,'' both for residents' rights (§ 483.10) and facility responsibilities (§ 483.11), with some language only included in proposed § 483.11. Some commenters object to the proposed language that would make visits from other visitors subject to reasonable ''clinical and safety restrictions'' and allow the facility to create written policies and procedures restricting resident access to visitors for clinical or safety reasons. One commenter stated that these requirements would gut resident visitation rights by giving facilities complete latitude to create whatever policies they want. Other commenters were concerned that proposed language erodes resident visitation rights by placing restrictions on visits that go beyond what is permitted under the Nursing Home Reform Law. Some commenters recommended that CMS delete proposed § 483.11(d)(2) in its entirety as inconsistent with the requirements of the Nursing Home Reform Law.

One commenter notes that relatives are not ''subject to reasonable clinical and safety restrictions'' in the way ''others who are visiting with a resident'' are and recommended that CMS delete all references to ''clinically necessary or reasonable restriction or limitation or safety restriction or limitation'' and that the facility policies and procedures clearly state that residents have the right to 24-hour visitation by anyone they choose. Another commenter stated that sometimes the facility needs to protect the resident against certain visitors.

*Response:* As noted above, several commenters suggested that our proposed provisions related to visitation were in conflict with statutory requirements. We have reviewed and revised this section to eliminate any confusion. Sections 1819 and 1919 of the Act establish specific requirements regarding access and visitation for residents of long term care facilities. Specifically, the statute requires that a facility permit immediate access to any resident by any representative of the Secretary, by any representative of the state, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident's individual physician; (B) permit immediate access to a resident, subject to the resident's right to deny or withdraw consent at any time, by immediate family or other relatives of the resident; (C) permit immediate access to a resident, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, by others who are visiting with the consent of the resident; (D) permit reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and (E) permit representatives of the State ombudsman (described in paragraph (2)(B)(iii)(II)), with the permission of the resident (or the resident's legal representative) and consistent with state law, to examine a resident's clinical records. Our regulations are intended to be fully compliant with these statutory requirements. We have revised the

language related to the resident's right to receive visitors to clarify that restrictions on visitation apply only to those categories of visitors where such restriction is permitted by statute. As noted earlier, in order to be responsive to public comments, we have revised § 483.10 and § 483.11 into a single regulatory section, so that all of the provisions relating to visitation are now located at § 483.10(f).

We note that, in the proposed rule, in addition to the statutorily mandated individuals (any representative of the Secretary, by any representative of the state, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident's individual physician) we expanded the individuals who must be provided immediate access to the resident to include the resident's representative as well as any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106–402, codified at 42 U.S.C. 15001 *et seq.*), and any representative of the agency responsible for the protection and advocacy system for individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (Pub. L. 99–319, codified at 42 U.S.C. 10801 *et seq.*) as we believe that immediate access to a resident by these entities is important to the health and safety of a resident.

With respect to statutory language regarding reasonable restrictions and reasonable access, we proposed to add the caveat that those restrictions or limitations on access must be based on clinical or safety concerns. Furthermore, such restrictions and the rationale for such restrictions must be included in a facility policy on visitation that is consistent with the regulatory requirements. We believe limiting the bases for restrictions to reasons of health (that is, clinical concerns) and safety as well as requiring that the facility have their procedures and restrictions, including rationale, included in written procedures are useful in identifying and preventing inappropriate restrictions on visitation. We note that these limitations apply only to ''others who are visiting with the consent of the resident,'' based on the statute's language regarding ''reasonable restrictions'' and to ''any entity or individual that provides health, social, legal, or other services to the resident,'' based on the statute's language requiring ''reasonable access.'' As noted above, we believe that ''reasonable restrictions'' as well as ''reasonable access'' should only be limited based on clinical or safety concerns, such as those commenters identified. Commenters identified a number of safety restrictions that may be imposed by facilities. These restrictions protect the security of all the facility's residents, and include requirements such as keeping the facility locked at night; visitors making prior arrangements for late night access, denying access or providing limited and supervised access to a visitor if that individual has been found to be abusing, exploiting, or coercing a resident; denying access to a visitor who has been found to have been committing criminal acts such as theft; or denying access to visitors who are inebriated and disruptive. In addition, we agree that clinical restrictions in order to prevent the spread of communicable disease are appropriate.

With regard to ''imposing'' visitors upon residents, we have, consistent with the statute, included language that defers to a resident's choice when allowing visitors. Generally, residents do not have to have visitors unless they choose to have visitors.

*Comment:* One commenter objects to the word ''visitation'' as it can be defined as ''an official or formal visit, a disaster or difficulty regarded as a divine punishment. . .'' and recommends changing it to ''visit'' or ''visiting,'' which is not the same thing as ''visitation.''

*Response:* We appreciate the commenter's suggestion; however decline to make this change. We acknowledge that there are multiple definitions of the term ''visitation,'' including, perhaps most simply, as ''the act of visiting,'' which is applicable to the context in which we use it. Further, the term ''visitation'' is in the statute, specifically at sections 1819(c)(3) and 1919(c)(3) of the Act, to establish the specific right upon which this regulatory right is premised and in other regulations addressing similar subject matter, such as the hospital and critical access hospital conditions of participation.

*Comment:* Some commenters expressed concerns about provisions relating to resident and family groups. One commenter suggested that we expand those who have a right to participate to include ''friends of the resident who have his or her permission''. Another commenter recommended that it be clarified that it is also the right of family members or resident representatives themselves as well as other persons interested in the welfare of the resident or residents to participate in family groups. The commenter supports the intent of the proposed language that requires nursing facilities to provide a resident or family group, if one exists with private space, but believes that the facility should be prohibited from impeding and should be required to facilitate the formation or continued existence of such groups. The commenter believes that nursing facilities should be required to, with the approval of the groups, take reasonable steps to notify, through conspicuous postings, and other means, residents and family members of the groups and of upcoming meetings in a timely manner. The commenter supports our clarification that the designated staff person who participates in a resident or family group must be approved by the resident or family group and by the facility, but suggests CMS be clear that the designated staff person does not necessarily have to be the same person for both the resident group and the family group. The commenter also suggested CMS clarify that resident and family groups can convene without a facility staff member present and may convene off-site. Commenters support the proposal that the grievances and recommendations of the groups must be addressed, and if not implemented, the rationale for this must be provided to the group but recommend that we require a written response to the group within a specific timeframe.

*Response:* CMS fully supports family and caregiver engagement. However, we believe that the right of family members to participate in a family group is a result of and subordinate to the resident's right in this instance. We can envision circumstances where a resident would not want and it would not be appropriate to allow a family member, such as an estranged spouse or an abusive relative, to participate in a family group as a result of a residents' presence in a facility. Therefore, we have retained this language as written. We proposed to expand this right to include resident representatives in order to ensure that individuals of the resident's choosing, whether a familial relation or not, can also participate in these groups. We believe this supports the resident's ability to choose who they consider 'family.' We also provide that visitors may attend at the groups' request. We decline to give ''friends'' or ''other persons interested in the welfare of the resident or residents'' a right to participate independently of an invitation from the group, as this additional participation should be determined by the group rather than imposed upon it. Other provisions require that facilities make residents aware of contact information for State

and local advocacy organizations, such as the State Long-Term Care Ombudsman program, and the Aging and Disability Resource Center or other program in the No Wrong Door System, should residents wish to invite such entities to a resident- or family group. In addition, nothing precludes an individual interested in the welfare of the resident or residents from requesting such an invitation. With regard to group meetings outside of the facility, nothing in these requirements precludes a resident or family group from meeting outside the facility and the resident has a right to interact with members of the community and participate in community activities both inside and outside the facility. We agree that facilities should take reasonable steps to ensure that residents and family members are aware of upcoming group meetings and have revised accordingly, finalizing this provision at § 483.10(f)(5)(i).

We defer to sub-regulatory guidance further discussion of the designated staff person(s) assigned to provide resident or family groups with assistance and response. We note that we already state that staff or visitors may attend group meetings at the group's invitation.

We require that facilities must respond to a grievance voiced by a resident or family group with a response and a corresponding rationale. We expect that such response would generally be a written response, but might also take another form. For example, if a resident group requests a specific action and the facility can show that the action has been taken, there may be no need for a written response. We have clarified that the facility response must be timely, but decline at this time to specify a time frame, given the potential variation in such grievances and recommendations.

We require the facility to provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay, both orally and in writing in a language that the resident understands. This includes all of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. We further require notification if those rights change. These rights include the right of the resident to organize and participate in resident groups.

*Comment:* One commenter recommended that CMS explicitly prohibit the facility from taking any action that would discourage the formation and/or activities of resident and family groups, and that CMS require the facility to (1) provide the resident or family group access to a bulletin board or other public notice space for their exclusive use to communicate with other residents, friends, and family, and (2) provide, at the group's request, a roster of the group members, including name and contact information, excluding information of those member who have declined such inclusion in writing.

*Response:* We appreciate the commenter's suggestion, but are concerned that these requirements are overly prescriptive. Furthermore, we believe that the underlying concerns can be addressed either by individuals through the grievance process or by the resident and family groups' facility representative and complaints/recommendations made by the group to the facility.

*Comment:* One commenter stated that both residents and families need to be able to freely raise and discuss issues in their respective groups and the presence of one or more residents at a family group would likely prevent at least some family members from speaking out candidly or at all. The commenter stated that this undermines the purpose of such a group and suggests revisions to these provisions to address participation across groups.

*Response:* The requirements as written provide for both resident groups and family groups. We have clarified that staff, visitors, or other guests may attend the resident group or family group at the respective group's invitation. We understand the commenter's concern and believe that family groups can determine how to best manage this issue. We would not prohibit residents from participating in family groups. We defer additional discussion to sub-regulatory guidance.

*Comment:* Some commenters were concerned about the protection of resident personal funds and recommend additional requirements. One commenter supported CMS efforts to pull provisions related to the protection of residents' funds together into one place for clarity, to update those requirements and to add limitations on the kinds of things for which facilities may charge residents. Suggestions to strengthen these requirements included requiring that facilities periodically review accounts of resident funds for suspicious withdrawals, requiring administrators to take training in protecting resident accounts, and providing the residents or resident representative monthly accounting statements so that any changes are noticed as quickly as possible. Another commenter expressed concern that the proposed rules under residents' rights as they relate to protection of resident funds are extremely limited, and the other specific current rights at § 483.10(c) are shifted solely to the proposed § 483.11(d)(5). The commenter stated that residents' rights provisions need to include sufficient detail to ensure that residents and their families and representatives know what the rights are. The commenter suggested that we restore all of the language at current § 483.10(c) to proposed § 483.10(e)(9) and restore an independent title ''Protection of resident funds'', stating that resident funds should not be a subcategory of the term ''self-determination.''

*Response:* We thank the commenters. As addressed earlier in this section, we have consolidated proposed § 483.10 and § 483.11, which addresses commenter concerns about residents rights containing sufficient detail to ensure that resident know both their rights and the facility's responsibility to support those rights. We maintain that it is appropriate to retain all of this information in the section relating to the resident's right to manage his or her financial affairs, and therefore have not restored an independent title of ''protection of resident funds.'' Under current requirements, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, including establishing and maintaining a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf and providing the individual financial record through a quarterly statement as well as on request. Current interpretive guidance establishes that ''hold, safeguard, manage and account for'' means that the facility must act as fiduciary of the resident's funds, report at least quarterly on the status of these funds in a clear and understandable manner, and includes money that an individual gives to the facility for the sake of providing a resident with a non-covered service. We have revised paragraph § 483.10(f)(10)(i), as finalized, to state that the facility must act as a fiduciary of a resident's funds. According to Cornell University Law School, a fiduciary duty is a legal duty to act solely in another party's interests. Parties owing this duty are called fiduciaries. The individuals to whom they owe a duty are called principals. Fiduciaries may not profit from their relationship with their principals unless they have the principals' express

informed consent. They also have a duty to avoid any conflicts of interest between themselves and their principals or between their principals and the fiduciaries' other clients. A fiduciary duty is the strictest duty of care recognized by the U.S. legal system. (see *https://www.law.cornell.edu/wex/fiduciary_duty*)

Although current sub-regulatory guidance already identifies the facilities responsibility for resident accounts as a fiduciary responsibility, we would strengthen this expectation by spelling it out in regulation. We believe that this addresses the commenters concern but allows for some flexibility in implementation. We defer additional specificity to sub-regulatory guidance.

*Comment:* One commenter recommended stricter oversight of resident funds, including the use of auditors with an accounting background.

*Response:* We have strengthened the requirements related to resident funds, as discussed in the previous response. Establishing requirements that facilities hire independent auditors to audit resident accounts is outside the scope of the current rulemaking, but we will keep this suggestion in mind for future occasions.

*Comment:* Several commenters supported revisions to a resident's choice of roommate. One commenter strongly supported new language that states: ''The right to share a room with her or his roommate of choice when practicable, when both residents live in the same home and both residents consent to the arrangement,'' which could include same sex or opposite sex couples or individuals choosing to share a room.

*Response:* We thank the commenter for their support. We agree that choice of roommate is significant to a resident's quality of life and an important aspect of treating a resident with respect and dignity.

*Comment:* Some commenters objected to our proposed provision regarding choice of roommate. One commenter expressed concern that the right of one resident to have a roommate of choice could violate the rights of an existing roommate. Other commenters suggested that this meant that a resident who didn't want a roommate would have to be provided a private room.

*Response:* Section 483.10(e)(5) states that the resident has the right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement. It does not require the provision of a private room. Furthermore, we have included the phrase ''when practicable'', as we realize that such arrangements may not always be possible, or may require some delay in order to accommodate. For example, such a move may require waiting until a room is available for both residents who want to be roommates to move into. We would not expect a facility to accommodate such a request when doing so would violate the rights of another resident.

*Comment:* Some commenters recommended that we strengthen language related to involuntary changes in room or roommate. One requested that we better define notice. Another suggested that we qualify a resident's right to refuse a transfer to not apply when the resident's medical needs can't be met. Another commenter stated that the impact of moving residents against their will is well documented, and can lead to both psychosocial and physical harm and suggests that, given the potential risk of any move that is not the resident's choice, such moves should only be permitted for certain reasons and written notice should be provided within a set timeframe. The commenter noted that several states, including Connecticut, Colorado, Texas and Indiana, require written notice when the facility is proposing to move a resident. The commenter further stated that facilities should be required to prepare a resident for a transfer in the same way as required for a transferred or discharged. The commenter suggested that involuntary changes in room only be allowed if the transfer is necessary for medical reasons as determined by the attending physician; or the transfer is necessary for the welfare of the resident or other residents, and the resident must be given notice, including the name, address, and telephone number of the local and state long term care ombudsman and, if applicable, the mailing address and telephone number of the agency responsible for the protection and advocacy at least 5 business days before relocation. In addition, the commenter suggested that the facility be required to develop a relocation plan to orient and prepare the resident for the move, including taking the resident to see his or her new room and unit and meeting staff who will be assigned to him or her.

*Response:* We agree that, absent extenuating circumstances, many of the commenters' suggestions make sense. Involuntary transfers should not be undertaken solely for the convenience of the staff. However, there are circumstances, generally involving safety, where advance notice and preparation may not be appropriate. Examples could include when one roommate is diagnosed with a communicable illness or when a move is necessary for the safety of either resident in a room, even if one of the roommates disagrees. We have revised § 483.10(e)(6), to require written notice, including the reason for the change, and paragraph (e)(7), to give the resident the right to refuse a transfer that is made solely for the convenience of the staff. We will consider requirements for a specific timeframe and preparation for a room change for inclusion in future rule-making.

*Comment:* One commenter requested that we clarify our use of the term ''eviction'' as opposed to ''discharge''.

*Response:* The term ''eviction'' is used to reflect an involuntary discharge from a place of residence. To ''evict'' is to make a person leave a place (*http://www.merriam-webster.com/dictionary/evict*). Not all residents consider the LTC facility his or her place of residence, but for those who do, an involuntary discharge is equivalent to an eviction.

Self-Determination

*Comment:* Some commenters were pleased to see that the proposed regulations include the resident's right to choose schedules. One commenter suggested we require that these choices are communicated to staff who are assigned using staffing practices that maximize staff's ability to fulfill the resident's choices and that we further state that residents must be able to choose from a range of activities that correspond to their interests. Other commenters expressed concern that they would be unable to accommodate every request every time and would be penalized as a result. Some commenters pointed out that these rights must be balanced with other residents' rights.

*Response:* While we considered these suggestions, we will defer to interpretive guidance for more detailed discussion of how a facility can meet the requirement that residents have the right to choose activities and schedules.

*Comment:* One commenter stated that, with regard to proposed § 483.10(e)(2), not all patients/residents are realistically able to participate in activities outside the facility. The commenter suggests that we amend this paragraph to by adding ''as appropriate based on the resident's functional capability.'' Other commenters suggest that residents should have free access both inside and outside of the facility.

*Response:* Some residents may not, realistically, be able to participate in activities outside the facility. However, many may be able to do so, particularly

with family or other assistance or planning. The facility has a responsibility to promote and facilitate resident self-determination, rather than act as a hindrance or barrier. At the same time, we recognize that there may be safety and security concerns with unfettered access to outside spaces and in and out of the facility. These competing interests must be balanced, taking into consideration the needs and preferences of residents in the facility.

*Comment:* One commenter stated that, with regard to proposed § 483.10(e)(5), not all facilities have family groups and in those centers that provide care for post-acute, short-stay patients, it is seldom that these individuals and their families have interest in participating in a family group. The commenter suggests we add the qualifier ''if any.''

*Response:* There is no requirement for a facility to have a resident or family group if the residents or their representatives do not want one. However, if interest does exist, the facility should support the formation of such a group, as required by this section. Adding ''if available'' may imply that if such a group does not already exist, the right to participate does not exist. This is not accurate.

*Comment:* One commenter is concerned that, as written, proposed § 483.10(e) could be interpreted to require that a facility contract with any and all hospice providers, therapists/therapy companies, etc. and conflicts with the proposed § 483.10(c) Choice of attending physician. The commenter recommends amending the provision by adding ''consistent with § 483.10(c) and other relevant contracting requirements''

*Response:* We considered the commenters concern and added ''and other applicable provisions of this Part'' to the provision.

*Comment:* Some commenters were concerned that the residents' right to choose health care and providers of health care services consistent with their interests, assessments, and plan of care would require facilities contract with, utilize, or arrange for a health care subcontractor that had not previously been contracted with or approved by the facility. They were concerned that such entities might be on the OIG's list of excluded individuals or entities, might have failed background checks, or might be operating outside of their legally permissible scope of service. They also suggested that such entities might not be not properly licensed or insured, might not meet the quality standards of the facility, or could potentially create an unsafe situation for the resident. The commenters further contend that the facility must be able to control the expenses related to who provides services due to bundled payments.

*Response:* Facilities cannot subcontract to health care entities that are on the OIG's list of excluded individuals or entities, and should not contract for any services with entities otherwise unsuitable for providing services. However, residents should not be required to accept services from providers to which they object, or entities that impose unreasonable charges on the resident's personal funds. We would expect facilities to work with residents to reach agreements.

*Comment:* One organization stated that they support CMS's proposal ''to clarify that the facility may not charge for special food and meals ordered for a resident by a physician, physician assistant, nurse practitioner, clinical nurse specialist, dietitian or other clinically qualified nutrition professional.'' The commenter noted that client satisfaction is critical and expressed support for the resident-centered concept of care. The commenter further stated that many of their members believe it is their duty to provide residents with everything they need during their stay and that members report that client satisfaction improves oral intake, nutritional status, quality of life and well-being and is likely to result in fewer hospitalizations. They suggested that comparable and reasonable substitutions, as determined by the registered dietitian, should be permitted. The commenter sought confirmation that the special food and meals purchased for a resident must be in alignment with a required specific diet order as a therapeutic diet in order for the items not to be charged to the resident. In addition, they request guidance as to whether facilities could require residents or their families to provide their own special supplements or functional foods if the facilities did not have them in their formularies.

*Response:* Facilities are required to provide the services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with a written plan of care. If a special diet is included in a resident's plan of care, the facility is obligated to provide it. For situations in which special foods are requested without being part of the plan of care, we defer the matter to sub-regulatory guidance.

*Comment:* Some commenters objected to the requirement that facilities convey the resident's funds and a final accounting of those funds to the resident or the resident's estate, within 30 days of death, eviction, or discharge. Commenters stated that this time frame is too short, that third-party payers do not pay the facility in a timely manner and that an accurate accounting is likely to take longer. Other commenters felt that the resident's funds should be returned more quickly.

*Response:* The existing requirement for the final accounting and return of funds is already 30 days in the event of death, and no changes were proposed to this standard in the proposed rule. We are therefore retaining this standard as proposed.

Information and Communication

*Comment:* One commenter stated that, since all facilities must convey their MDS data electronically, all facilities have Internet access and proposed language related to facility access and expense is not needed and could be used to deny residents electronic access. The commenter finds limits placed on resident access to electronic communication problematic. Other commenters objected to the burden of requiring an expanded electronic footprint.

*Response:* We disagree that our requirement that facilities convey MDS data electronically means, consequently, that all facilities will have Internet access that can be made available to residents. Some facilities may utilize a vendor to submit MDS data and may not have onsite Internet access. Other facilities may have Internet access, but that access might not include capacity sufficient to accommodate expanded user access. We did not propose to require facilities to expand their Internet access. We are finalizing proposed § 483.11(e)(13) at § 483.10(g)(7).

*Comment:* Some commenters stated that, with regard to proposed § 483.10(h)(2), it is important that whatever Internet research is being done by residents is legal. For example, access to sites that promote child pornography or other illegal activities must be limited. Furthermore, providing absolute privacy for each resident wanting to use email and video communication may require advance planning. For example, if a facility has one room with several computer terminals available for residents' use, privacy may require a resident to schedule private use in advance, during which time no other resident may use a terminal in that room. The commenter suggested we revise the provision to read ''The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and

for Internet research. All such activities are limited to legal Web sites/activities as determined by state and federal laws. If absolute privacy is required, the facility may require advance scheduling of a computer to assure such privacy.'' Some commenters asked if the facility was required to ensure that communications were secure.

*Response:* We agree that use of the Internet, or any form of communication, including the U.S. Postal service, must be in compliance with other legal limitations and restrictions relating to those devices or systems. We have added language to that effect at finalized § 483.10(g)(9)(iii). We acknowledge that for devices provided for the community, advance planning may be required. Further, one resident's use of video communications must not infringe upon the rights of other residents. These were considerations when we used the term ''reasonable access.''

*Comment:* Several commenters were concerned that our proposal limits the type of information that residents can access, including their records. One commenter stated that CMS provides no rationale for restricting residents' access solely to medical records other than to conform the requirements to 45 CFR 164.524(c)(4) and stated that such justification is not sufficient. Some commenters recommended that CMS retain the current language. One commenter supported the expansion of accessibility to information by the resident (proposed § 483.11(e)), including the language stating ''that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.'' The commenter supported the requirement that facilities provide residents with access to medical records in the form and format requested by the individual if they are readily producible, and if not, then in written form or in another form as agreed to by the individual and the facility. This requirement builds on the existing requirements that such information be made available within 24 hours, and upon oral and written request. Reflecting the reality that many nursing facility residents cannot access records electronically, the commenter appreciated that the proposed rule leaves the decision to the resident as to whether to access records electronically or in another ''readily producible'' format. One commenter suggested that retrieving electronic information in a format that is user friendly is actually more difficult than non-electronic information. Another commenter was concerned that our proposal mandated that facilities be able to provide an electronic copy of the medical record. One commenter suggested that access to a person's own medical record should not be contingent on weekday staffing and recommends striking the parenthetical statement, ''excluding weekends and holidays,'' as well as the requirement for inspection prior to purchase of the medical record. One commenter believed that CMS should clarify that a resident is entitled to his or her complete set of medical records, and proposed that the definition of ''medical records'' include all records concerning the resident during the period of time the resident was in the nursing facility's care. Without clarification, the commenter was concerned that nursing facilities may self-define what records it considers to be ''medical records'' for the purposes of responding to resident requests to the exclusion of records related to outside consultations, financial records, and other records that may be kept outside of the facility medical records. Allowing nursing facilities this degree of flexibility may undermine the resident's right to access his or her own records and allow a nursing facility to conceal any deficient care provided to the resident.

Some commenters were concerned that 2 working days advance notice may not be adequate time depending upon the size of the records. One commenter stated that this should be 30 days, consistent with HIPAA. Other commenters suggested that there should be a definition of ''working day.'' These commenters suggested we amend proposed § 483.10(f) (3)(ii) to read: ''After receipt of his or her medical records for inspection, to purchase, a copy of the medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and 2 to 5 working days (working days defined as between 8 a.m. and 6 p.m., Monday through Friday) advance notice to the facility. Some commenters recommended that residents have access to their records 24 hours a day, 7 days a week so that they can review records with family members at any time, including weekends and holidays.

*Response:* We thank those commenters who supported our proposals. We agree that flexibility, contingent upon the resident's ability to access and understand the information, is important. It is not our intent to reduce a resident's access to information. Although sections 1819(c)(1)(iv) and 1919(c)(1)(iv) of the Act only require access to current clinical records, we agree that it is important that LTC facility residents also have access to certain other records about themselves that may be held by a long-term care facility, such as their financial or social records. We have reviewed our proposals and expanded the language which we are finalizing at § 483.10(g)(2) and at § 483.10(h) to include both personal and medical records. We acknowledged in the proposed rule that we were proposing changes related to facilities providing access to and copies of medical records in order to ensure consistency with HIPAA. Federal requirements and expectations related to the privacy and confidentiality of patient records, especially with regard to protected health information, changed substantially with the enactment of HIPAA. Thus, aligning with other statutory requirements that apply to long-term care facilities was one aspect of updating the requirements for long-term care facilities.

With regard to medical records, the resident has access to the medical record itself and the right to access a copy of that record, not a version of the medical record that has been revised to ensure the resident's understanding. Summaries of medical records are addressed by the privacy regulations at 45 CFR 164.524. We retain the access limitations related to weekends and holidays based on statutory requirements in section 1819(c)(1)(A)(iv) of the Act. We disagree that 48 hours is not sufficient time to provide a copy of the resident's record. This is a long-standing standard and we did not propose to change the time frame. Further, for those facilities using electronic records, the electronic record may simplify the effort needed to print or create an electronic copy of the record, depending on the specific software system used by the facility. We do not mandate that facilities be able to provide an electronic copy of the medical record, unless the records are maintained in an electronic format and are readily producible in that format. We also agree that, while residents or their representatives may wish to do so, they should not be required to inspect a record prior to purchasing it. Therefore, we have removed this requirement at finalized § 483.10(g)(2)(ii).

With regard to our use of the term ''medical record'', please see our discussion of § 483.70(i). As noted in that discussion, we regard the terms ''medical record'' and ''clinical record'' as synonymous. Section 1819(b)(6)(C) of the Act states that clinical records on all residents include the plans of care and

the residents' assessments. We further note that for ''covered entities'' as defined at 45 CFR 160.103, individuals have a right to access protected health information in a ''designated record set.'' A ''designated record set'' is defined at 45 CFR 164.501 as a group of records maintained by or for a covered entity that comprises the medical records and billing records about individuals maintained by or for a covered health care provider; enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or other records that are used, in whole or in part, by or for the covered entity to make decisions about individuals. The term ''record'' means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity. Thus, individuals have a right to a broad array of health information about themselves maintained by or for covered entities, including: Medical records; billing and payment records; insurance information; clinical laboratory test results; medical images, such as X-rays; wellness and disease management program files; and clinical case notes; among other information used to make decisions about individuals. In responding to a request for access, a covered entity is not, however, required to create new information, such as explanatory materials or analyses that does not already exist in the designated record set. A ''designated record set'' under HIPAA is not synonymous with ''personal and medical records'' under these requirements. However, as noted earlier, to the extent that HIPAA provides additional rights to individuals (that is, residents, in the long-term care context) beyond what is provided in this final rule, covered entities and business associates must comply with the requirements in HIPAA to ensure individuals are afforded these additional rights. As noted in a separate response under this section, we expect that most, if not all, long-term care facilities are covered entities who must comply with HIPAA.

*Comment:* Some commenters thought that we were requiring facilities to provide electronic copies of medical records and expressed concern that this would require the purchase of new equipment and new staff to manage the task.

*Response:* Proposed § 483.10(f)(3)(i) specified that the resident would have a right to receive medical records in the form and format requested if the requested records are readily producible in such form and format. We are not requiring facilities to provide records in an electronic format if the record is not maintained or readily producible in an electronic format. We are finalizing this provision at § 483.10(g)(2)(i).

*Comment:* Several commenters object to our proposed standards for the fees that facilities may charge for these records. Some oppose the proposal to move from a community standard to a cost-based standard under which the fee may include the cost of labor for copying the requested health information, the supplies for creating the paper copy or electronic media, and postage, which could be abused and could inappropriately and unfairly impede a resident's access to his or her own health records. The commenter recommends, at a minimum, a limit on fees that can be charged, and to ensure that said fee includes any labor charges (research fees, clerical fees, handling fees or related costs). One commenter recommends the establishment of a ''hardship exemption'' for low-income residents, allowing them to receive copies of their records at no charge, perhaps upon providing an affidavit of inability to pay or otherwise demonstrating an inability to pay fees. Another commenter stated that there are a large number of residents who use Medicaid who are required to contribute most of their income to their care and are left with a small personal needs allowance, a minimum of $25 per month, who cannot afford these larger amounts to get copies of their records. The commenter suggests we restore the existing regulatory language and include parallel language as a resident's right. Commenters are concerned that the costs CMS proposes to allow, specifically labor costs, in this section create an opportunity for a nursing facility to create a financial burden and barrier to a resident's right to receive a copy of their own medical record. Some commenters recommend that facilities provide a copy of the medical record on an annual basis at no charge to the resident, and otherwise, costs should be limited to supplies and postage.

*Response:* We thank the commenters for their concern. Prior to development of the proposed rule, we received input regarding the definition of ''community standard'' and concern about exorbitant charges for medical records. Commenters to the proposed rule have suggested the community standard be set at the amount charged by a local library, Post Office, or commercial copy center, or a set fee. We considered these options. However, the cost that providers who are subject to HIPAA (''covered entities'') may charge for medical records is established by the HIPAA Privacy Rule at 45 CFR 164.524(c)(4). Our proposal is consistent with that standard, which states that a facility may charge a reasonable, cost-based fee that can include only cost of copying, including supplies and labor, and postage, if the patient requests that the copy be mailed. The fee may not include costs associated with reviewing the request, searching for and retrieving the requested records, and segregating or otherwise preparing the record that is responsive to the request for copying. Given that long-term care facilities are generally likely to be subject to HIPAA and we require in § 483.70 that facilities comply with other HHS regulations, we believe that our policy here should be consistent with the HIPAA Privacy rule at 45 CFR 164.524(c)(4). Therefore, we will finalize our proposal at § 483.10(g)(2)(ii) without change. We again refer readers to recently released HHS guidance on individuals' right under HIPAA to access their health information *http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html*).

*Comment:* One commenter stated that they are pleased that CMS is proposing to require facilities to make reports related to surveys, certifications, complaint investigations, and plans of correction available for individuals to review, and to post a notice of this information's availability. Other information the commenter recommends be made available to residents includes:

- Results from independent resident/family caregiver experience surveys (resident and family)—such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Nursing Home Surveys;
- Whether or not the facility provides special care services and if so, the kinds of services provided;
- Policies of the facility. For example, whether it has family groups, allows pets, etc.; and
- Information available in other languages, as appropriate.

CMS may wish to consider, where appropriate, whether the existing standards that apply to medical records—that they be made available within 24 hours and upon oral and written request should be extended to the other types of information that are required to be made available under proposed § 483.11(e).

*Response:* We thank the commenter for their support. We considered but are not, at this time, expanding the information which must be provided to every resident. We note that facilities are required at finalized § 483.10(g)(16)

to provide a notice of rights and services to the resident prior to or upon admission and are generally required at finalized § 483.10(g)(3) to ensure that information is provided in a form and manner that a resident can understand. As a result of comments concerned that our proposal limited the information about themselves that residents have access to, we have expanded our provisions relating to medical records to include personal records, to the extent applicable.

*Comment:* One commenter requested that we clarify in the regulations that ''readily accessible'' means not having to ask a staff person for access in order to review survey reports or plans of correction. Another commenter stated that it was unreasonable to require the availability of 3 years of reports.

*Response:* Section 1919(c)(8) of the Act requires that a nursing facility must post in a place readily accessible to residents, and family members and legal representatives of residents, the results of the most recent survey of the facility. This requirement is not premised upon a request. In contrast, section 1819(c)(1)(A)(ix) of the Act imposes this same requirement premised upon a ''reasonable request.'' We note that we generally deem all requests to be reasonable unless the requestor demands unreasonable deadlines or more information than is contained in the document. We have revised § 483.10(g)(11) to reflect the stricter standard imposed by the statutory language in section 1919(c)(8) of the Act, which does not require a request. With regard to 3 years of survey, certification, complaint investigation reports, both sections 1819(d) and 1919(d) of the Act states that these must be available ''upon request.'' We have revised this language, with the addition of availability of any plan of correction in effect with respect to the facility, as we proposed, to better reflect the statutory requirements, including the requirements that the notice of availability of such reports are prominent and accessible to the public and shall not make available identifying information about complainants or residents.

*Comment:* One commenter stated that providing every survey, certification, and complaint report available ''in a form understandable by residents'' is excessive and incomprehensively burdensome.

*Response:* We understand that these reports are in specific formats and may be lengthy, and that an unaltered copy of the report is the expected document. Therefore, in finalized § 483.10(g)(11) we have eliminated the phrase as recommended, as well as added these reports to the documents excepted from the requirement at finalized § 483.10(g)(3) that the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

*Comment:* One commenter supported many of the provisions in proposed § 483.11(e)(7) requiring that facilities immediately notify the resident, consult with the resident's physician and notify the resident's representative when there is a change in the resident's condition, when treatment needs to be altered in a significant way, or when the resident is to be transferred or discharged. One commenter stated that physicians should be involved in managing significant injures, and that it is reasonable to allow facilities to notify physicians when the injury is significant enough to require a medical assessment and/or intervention. The commenter suggested that each facility have and use a protocol for physician notification and that the staff make a preliminary assessment and then monitor for delayed complications. Another commenter suggested that we add ''or change'' to the provision ''a need to alter treatment significantly (that is, a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment).'' One commenter was concerned that this requirement must be consistent with resident representative state law, or the authority granted by the court in instances of a resident who has been adjudged incompetent, or the authority granted to the individual with the durable power of attorney and another was concerned about the number of notifications that could be required. Another commenter was concerned that the term ''immediately'' was not defined and an expectation on the part of CMS that multiple individuals be notified simultaneously is unreasonable.

*Response:* We thank the commenters for their support. As suggested, we have added ''or change'' to the parenthetical in finalized § 483.10(g)(14)(i)(C). We believe that a protocol, as suggested by the commenter, could be consistent with our proposal. As written, the requirement is that a facility immediately inform the physician when there is an accident that involves injury that has the potential to require the physician's intervention. A protocol, as suggested, would be a useful tool to help a facility objectively and consistently determine when an injury has the potential to require physician intervention. We noted in the preamble to the proposed rule that effective communication among caregivers is helpful in improving outcomes and quality of care. In addition, with have added ''consistent with his or her authority'' in reference to notifying a resident representative. With regard to the term ''immediately,'' we note that this requirement is not new. We would expect facilities to make such notifications without delay, and, in the case of a resident's death, in accordance with state law.

*Comment:* A commenter supports proposed changes to information that must be provided to residents, but states that there are differences between proposed § 483.10 and proposed § 483.11 and recommends that we add 'exploitation' consistent with the incorporation of this concept in other areas addressing abuse and neglect.

*Response:* In response to other comments we have combined § 483.10 and § 483.11. The information in question is now located in § 483.10(g)(4). We have also incorporated 'exploitation' into that provision, as suggested. Information includes both information that must be included in the written description of legal rights and other information of importance to the resident. For example, the written description of legal rights must include a statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community. In addition, the resident has a right to receive, information and contact information for filing grievances or complaints and the facility must post similar information, in a form and manner accessible and understandable to residents, and resident representatives.

*Comment:* One commenter notes that the term ''support person'' is not defined and appears nowhere else in the proposed regulations.

*Response:* A patient's ''support person'' does not necessarily have to be the resident's representative who is legally responsible for making medical decisions on the resident's behalf. A support person could be a family member, friend, or other individual who is there to support the resident during the course of the stay. We refer readers to our discussion of the meaning of

''support person'' in the preamble to the final rule, ''Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation To Ensure Visitation Rights for All Patients'' (75 FR 70833, November 19, 2010).

*Comment:* Commenters recommended that the prohibition regarding admission contracts conflicting with regulatory requirements apply to all admission contracts, whether required by the facility or not.

*Response:* We agree and have modified final § 483.10(g)(18)(v) to refer to all admission contracts. We emphasize that no language in a contract may permissibly require LTC facility residents or prospective residents to waive any of the rights set out in this provision, and that review of admissions contacts may be part of our facility surveys.

*Comment:* One commenter recommended that we require the facility to post a list of the names, titles, dates of service and addresses (mailing and email), and telephone number of the members of the facility's governing body, the administrator, and the director of nursing, stating that this would implement section 6106 of the Affordable Care Act.

*Response:* We thank the commenter for their suggestion. Section 6106 of the ACA added section 1128I(g) to the Act, Affordable Care Act. Section 1128I(g) pertains to the submission of staffing data by LTC facilities, and specifies that the Secretary, after consulting with certain stakeholders, require a facility to electronically submit to the Secretary direct care staffing information based on payroll and other verifiable and auditable data in a uniform format according to specifications established by the Secretary in consultation with such programs, groups, and parties. CMS finalized requirements implementing section 6106 of the ACA on August 4, 2015 in the final rule ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (80 FR 46390). That rule added a new § 483.75(u) ''Mandatory submission of staffing information based on payroll data in a uniform format''. Section 6106 of the ACA does not include reporting requirements for management/ownership information.

Privacy and Confidentiality

*Comment:* Some commenters support our proposed changes to this section.

*Response:* We thank the commenters for their support. This section now includes language accommodating electronic communications, among other changes. We believe this changes are important in updating the requirements of participation for long-term care facilities.

*Comment:* One commenter recommended that CMS limit representatives of the Office of the State Long-Term Care Ombudsman access to resident records based on requirements established at 45 CFR 1327.11.

*Response:* We thank the comment for their suggestion. We note that the Administration for Community Living (ACL) published a final rule amending its regulations to reflect the creation of ACL in 2012 and consolidate all of its regulations under a single subchapter (see 81 FR 35645, 35646, June 3, 2016). As a result, the regulations that the commenter referred to are now found at 45 CFR 1324.11. We have reviewed the language at 45 CFR 1324.11(e)(2), which sets forth requirements for the State Long-Term Care Ombudsman or the State agency to establish policies and procedures for timely access to facilities, residents, and appropriate records. Proposed § 483.10(f)(2) does not conflict with the requirements at 45 CFR 1324.11(e)(2) and reflects the statutory language found in sections 1819(c)(3)(C) and 1919(c)(3)(C) of the Act. Therefore, proposed § 483.10(f)(2) is finalized at § 483.10(h)(3)(ii) without change.

Safe Environment

*Comment:* Some commenters supported our proposed changes to this section.

*Response:* We thank the commenters for their support.

*Comment:* With respect to the resident's right to a safe, clean, comfortable, homelike, environment, one commenter recommended amending the requirement to state that the resident has a right to an equitable balance of a safe, clean, comfortable, homelike environment, and a right to receive treatment safely, as no one right should outweigh nor compromise another right. Some commenters felt that we should use language more reflective of the fact that the long-term care facility is home for many residents. Some commenters recommended avoiding institutional language and changing ''. . . homelike'' environment to ''. . . home''

*Response:* We thank the commenters for their suggestions. As noted in the preamble to the proposed rule, long-term care facilities are likely to serve multiple populations. Throughout this rule, CMS has tried to maintain an appropriate balance reflecting these multiple populations. While for many residents, the LTC facility is a home and we have striven to make sure this fact is reflected in the regulations, for others, the LTC facility is a temporary stay as they regain the physical capacity to return to their home. Both of these populations deserve high quality care in a safe, clean, comfortable, and homelike environment. We agree that no single right outweighs another right and sometimes this requires balance; however, we believe that residents can and should live in a safe, clean, comfortable, and homelike environment that is also provides safe treatment.

*Comment:* Some commenters expressed concern that residents could receive contraband or harmful items through the mail and wanted to know what rights the facility has with regard to monitoring for such items.

*Response:* The right of residents to receive unopened mail is not new. We would expect facilities to already be in compliance with this requirement and have processes in place to address situations where resident rights and resident safety are of concern.

*Comment:* One commenter requested that we clarify under ''safe environment'' that the physical layout of the facility should maximize resident independence.

*Response:* We thank the commenter for their suggestion and have revised the requirement, finalized at § 483.10(i)(1)(i) to include ''resident independence.''

*Comment:* One commenter agreed that facility temperatures should not be extreme, but suggested that CMS add a qualifier to the regulations that would require Medicare and Medicaid-participating facilities to adjust temperatures in different areas of the facility based on resident needs and comfort and/or scientific evidence.

*Response:* We thank the commenter for their suggestion. We would expect facilities to make adjustments, as suggested, within the permissible range of 71 to 81 degrees Fahrenheit. We note that this is a long-standing requirement on which we received very few comments. We would want to seek specific public input on a specific proposal to change this requirement before making such a change.

Grievances

*Comment:* Some commenters supported our proposals related to grievances. One commenter commended CMS for significantly enhancing residents' rights to voice grievances, stating that this emphasizes the importance and seriousness of resident concerns. Another commenter stated

that the ability to make a grievance and to have it taken seriously by the facility is an important right and protection for residents. One commenter was pleased to see that facilities must create a grievance policy and appoint a grievance official. Another commenter stated that they are pleased to see that this right has been expanded to give residents the right to voice grievances without fear of discrimination or reprisal. One commenter was pleased to see that CMS is proposing that grievances be investigated and written decisions issued to residents and urges CMS to include this information about grievances in the Resident's Rights section as well. Another commenter was pleased that CMS proposed that the official issue written grievance decisions, and supports the proposed content of the decisions. One commenter stated that it is very helpful to have a person specifically tasked with handling grievances from beginning to end who is required to take immediate action to prevent further potential violations, although this should include any violations of state and federal requirements, not just resident rights.

Some commenters recommended revisions to our proposal. Some suggested we establish timeframes for resolution. One commenter recommended that CMS delete all language from proposed § 483.11(h) regarding the grievance policy and incorporate the policy requirements into § 483.75, QAPI. Some commenters objected to the requirement for a grievance official, stating this this is unnecessary and burdensome. One commenter suggested that designating one individual could hinder timely resolution.

Some commenters were concerned about the scope of actionable grievances. Some commenters feel we have limited the scope of grievances. One commenter stated that the proposed rules omits current language ''including those with respect to the behavior of other residents'' from resident rights, noting it is included in proposed § 483.11(h)(2) and recommends that CMS restore the full language of § 483.10(f)(2).'' Other commenters suggested that we broaden the scope of actionable grievances. One commenter is concerned that the proposed language does not state that the resident can file grievances with the State Survey Agency and another recommends we add adult protective services to the list of independent entities with which grievances may be filed. Some commenters recommended that the subsection be revised to require that facilities make information on how to file a grievance available to the resident upon admission and upon request and also give a copy of the grievance policy to every resident. Some commenters suggested that there are other formats more useful to a resident than a copy of the policy, such as a question and answer document. One commenter suggested that the grievance official should be responsible for protecting the complainant from retaliation, since many residents will not speak up because they fear reprisal. One commenter recommended that residents be given the room number in the facility if the official is housed within the facility and a toll free number if not, and be provided with information about where they can turn within the facility organization if they are not satisfied with the decision. The commenter also suggested that CMS require that the grievance decision be provided to each resident in a form and manner the resident can access and understand and that the grievance official take corrective action in conjunction with the administrator and other appropriate staff. One commenter suggested that the grievance policy include the establishment of a grievance committee that would consist, at a minimum, of the administrator of the facility or his or her designee, a resident selected by the resident population of the facility, the facility social worker, and the grievance official. The commenter further suggested that the work of the grievance official would be reviewed by the full committee so he or she is not operating in a vacuum and there would be resident involvement in the process.

Some commenters were concerned about maintaining evidence related to grievances for 3 years and felt that creating and maintaining such files would be burdensome. Others were concerned about the potential for these requirements to negatively influence surveyors and asked if every complaint would be deemed a grievance. Another commenter suggested that we specifically require that facilities maintain all investigative documentation related to the grievance for three years. This commenter also suggested that, with regard to reporting, we reference federal law. Several commenters offered other specific recommendations for regulatory language.

*Response:* We thank commenters for their support and their suggestions. We agree that resident concerns should be taken seriously and that the ability to voice a grievance is an important right and protection for residents. The timeframes required to resolve a grievance may depend largely on the issue associated with the grievance and other situation-specific factors. We are not, at this time, requiring prescriptive timeframes, and defer to guidance to suggest what constitutes timely. The purpose of requiring the facility to have a grievance official is to ensure that there is an individual who has both the responsibility and authority for ensuring, through direct action or coordination with others, that grievances are appropriately managed and resolved. This person would be a resource for residents, staff, and oversight entities. We expect that most facilities already have a person or persons who serve this function, if not with the specific title, and that the work of a grievance official would be coordinated with the LTC facility administrator and the director of nursing. It is not our expectation that every facility hire a new, full-time individual to perform this function, but, instead, that every facility have a designated individual to serve this function, consistent with the needs of that facility. We do not agree that this would hinder timely resolution of grievances.

Evidence demonstrating the results of all grievances for a period of no less than 3 years provides a record of this work and can serve as a valuable information resource for facilities. However, we do not agree it is necessary to explicitly require that all investigation documentation be retained for 3 years. Further, such evidence may be maintained electronically, rather than utilizing physical storage space. We defer additional specificity to sub-regulatory guidance.

Grievances may provide valuable input to a facilities QAPI program. In fact, grievances are one likely source of data and feedback from residents and resident representatives; however, we do not believe that addressing grievances should be relegated solely to the QAPI program. Depending on the size of the facility and the number or grievances received, duties associated with grievances may only consume a small portion of the individual's time. In very large facilities, or in facilities with many grievances, more time may be required. Either way, we maintain that it is important that all facilities have a designated point of contact for grievances. While we agree that a grievance official cannot and should not resolve grievances in a vacuum, we are concerned that a grievance committee is not feasible for every facility, and therefore are not requiring such a committee at this time.

With regard to the scope of grievances, we have revised our

proposed requirement, finalizing it at § 483.10(j), to state that grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay. We will finalize proposed requirements regarding notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system. We also finalize the requirement to provide a copy of the grievance policy to the resident upon request. We agree that other formats may be useful to the resident and could be used to provide information on how to file a grievance available to the resident, but if the resident requests a copy of the facility policy, it must be provided. The facility is required, at final § 483.10(g)(16) to provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay; this includes the right to file a grievance. We have added ''federal'' to § 483.10(j)((4)(iv) so that it reads ''immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriate of resident property, by anyone furnishing services on behalf of the provider; and as required by federal or state law.'' Requirements for reporting suspicion of a crime are separately addressed in § 483.12(b). We defer additional detailed information relating to grievances to sub-regulatory guidance.

Contact With External Entity

*Comment:* One commenter felt that the requirement stating that facilities must not prohibit or discourage a resident from communicating with state and federal representatives was unnecessary.

*Response:* We disagree. It is imperative that residents and their representatives feel free to discuss concerns, particularly safety and quality of care concerns, with representatives of the state and federal government, surveyors, ombudsmen, and representatives of the protection and advocacy system.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have consolidated proposed § 483.10 and proposed § 483.11 into a single section, § 483.10, ''Resident rights'' and removed or updated all cross-references as appropriate.
- We have replaced the term ''verbal'' with ''oral'' throughout this section.
- Introductory language from proposed § 483.10 and proposed § 482.11, as well as proposed § 483.11(a)(2) are now finalized in § 483.10(a) ''Resident rights.''
- Proposed § 483.10(a)(1) through (5), and proposed § 483.11(a)(1), and (a)(3) through (5) have been consolidated into final § 483.10(b), ''Exercise of rights.''
- We have revised proposed § 483.10(a)(3), finalizing it at § 483.10(b)(3) and incorporating previously existing language clarifying that the provision applies to residents who have not been adjudged incompetent by a state court.
- We have revised language from proposed § 483.11(a)(4), as consolidated in finalized § 483.10(b)(7)(i), to clarify that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian, when a court's determination does not require it.
- We have consolidated proposed § 483.10(b) and proposed § 483.11(b) into § 483.10(c), ''Planning and implementing care.''
- We have changed the term ''disciplines'' in proposed § 483.10(b)(2) to ''the type of care giver or professional,'' finalizing it at § 483.10(c)(4).
- We have revised proposed § 483.10(b)(5)(v) to state ''the right to sign after significant changes to the plan of care,'' finalizing it at § 483.10(c)(2)(v).
- We have clarified in § 483.10(c)(5) that the physician or other practitioner or professional informs the resident of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options.
- We have consolidated § 483.10(b)(6) and § 483.11(b)(2), finalizing these requirements at § 483.10(c)(7) which now states ''The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.''
- We have withdrawn proposed § 483.10(c)(2) to require that physician's meet facility credentialing requirements and consolidated proposed § 483.10(c)(1) and (3), and proposed § 483.11(c)(1) through (3), finalizing these provisions at § 483.10(d).
- We have re-designated proposed § 483.10(d) at § 483.10(e), revised finalized paragraph (e)(6) to specify that the resident has a right to receive written notice, including the reason for the change when the resident's room or roommate in the facility is change and added a new, final (e)(7)(iii) to clarify that a room change cannot be solely for the convenience of staff.
- We have consolidated proposed § 483.10(e) and proposed § 483.11(d), finalizing these provisions at § 483.10(f), Self-determination.
- We have added ''and other applicable provisions of this Part'' to proposed § 483.10(e)(1) and finalize this provision at § 483.10(f)(1).
- We have consolidated proposed § 483.10(e)(3) and proposed § 483.11(d)(1), finalizing these provisions at § 483.10(f)(4), and clarifying that: (1) The resident's right to deny visitation is ''when applicable;'' (2) a facility must have written policies and procedures for visitation that includes restrictions, when such limitation may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation; and (3) the facility must inform each resident not only of any limitation, but also to whom the restrictions apply.
- We have added a new § 483.10(f)(5)(i) to specify that a facility must take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.
- We have added ''or other guests'' to the list of individuals who may only attend a resident or family group meeting at the group's invitation at finalized § 483.10(f)(5)(ii).
- We have consolidated proposed § 483.10(e)(8) and proposed § 483.11(d)(4) into finalized § 483.10(f)(9).
- We have consolidated proposed § 483.10(e)(9) and proposed § 483.11(d)(5) into finalized § 483.10(f)(10).
- We have changed ''may'' to ''must'' in finalized § 483.10(f)(11)(i).
- We have changed ''health care provider'' to ''physician, physician assistant, nurse practitioner, or clinical nurse specialist'' in finalized § 483.10(f)(11)(ii)(L)(1).

• We have consolidated proposed § 483.10(f) and (h) and proposed § 483.11(e) into finalized § 483.10(g).

• We revised proposed § 483.10(f)(3) to include both personal and medical records and finalized it at § 483.10(g)(2).

• We revised proposed § 483.10(g)(3)(ii) to remove the requirement that a resident must inspect a medical record prior to requesting to purchase a copy and finalized it at § 483.10(g)(2)(ii).

• We updated the cross-reference to § 483.11(e)(2) in proposed § 483.11(e)(1), to cross-reference § 483.10(g)(2) and (g)(11) to reflect that we do not require facilities to translate or summarize personal and medical records and survey reports. Proposed § 483.11(e)(1) is finalized at § 483.10(g)(3).

• We added ''State Survey Agency'' to proposed § 483.10(f)(2), finalized § 483.10(g)(4)(ii), and added ''any suspected violation of state or federal nursing facility regulations'' to proposed § 483.10(f)(2)(vi), finalized at (g)(4)(vi).

• We added ''requests for information regarding returning to the community'' to proposed § 483.11(e)(4), finalized at § 483.10(g)(5)(ii).

• We require at finalized § 483.10(g)(9)(iii) that electronic communications under this section must comply with state and federal law.

• We have revised proposed § 483.11(e)(3), finalized at § 483.10(g)(11), to reflect the stricter standard imposed by the section 1919(c)(8) of the Act, statutory language and to better reflect both sections 1819(d) and 1919(d) of the Act, retaining the addition of availability of any plan of correction in effect with respect to facility, as proposed, and including the requirements that the notice of availability of such reports are prominent and accessible to the public and shall not make available identifying information about complainants or residents.

• We have revised proposed § 483.11(e)(11)(v), finalized at § 483.10(g)(18)(v), to specify that any admission contract, whether the facility requires it or not, must not conflict with the requirements of these regulations.

• We have consolidated proposed § 483.10(g) and proposed § 483.11(f), finalized at § 483.10(h), consolidating duplicative language in proposed § 483.10(g)(2) and proposed § 483.11(f)(1)(ii) at finalized § 483.10(h)(1), consolidating proposed § 483.11(f)(1) and (f)(1)(i), finalized at § 483.10(h)(2), and deleting proposed § 483.11(f)(2) as an unnecessary cross-reference.

• We have consolidated proposed § 483.10(i) and proposed § 483.11(g), ''Safe environment'', finalized at § 483.10(i).

• We have added a new § 483.10(i)(1)(ii) to require that the facility exercise reasonable care for the protection of the resident's property from loss or theft.

• We have consolidated proposed § 483.10(j) and proposed § 483.11(h), ''Grievances'' at finalized § 483.10(j).

• We have revised proposed § 483.10(j)(1) by adding ''the behavior of staff and of other residents; and other concerns regarding their LTC facility stay'' to the statement regarding what grievances may include.

• We finalize, as proposed, § 483.11(i) at § 483.10(k).

*G. Freedom From Abuse, Neglect, and Exploitation (§ 483.12)*

Currently, § 483.13 is titled ''Resident Behavior and Facility Practices.'' We proposed to re-designate and revise this section as § 483.12, ''Freedom from Abuse, Neglect and Exploitation,'' to more accurately reflect the contents and intent.

Currently, paragraph § 483.13(a) addresses the use of restraints. We proposed to address restraints in both the introductory paragraph to proposed § 483.12 and in proposed § 483.25(d)(1). In the introductory paragraph to proposed § 483.12, we maintained the prohibition of the inappropriate use of restraints. We proposed to further address restraints in proposed section § 483.25(d)(1) on Quality of Care and Quality of Life.

We proposed that existing paragraph § 483.13(b) also be included in the new introductory paragraph to revised § 483.12. We proposed to re-designate existing § 483.13(c)(1) as § 483.12(a)(2) and modify the language to clarify that a facility must not employ or otherwise engage individuals who have been found guilty of abuse, neglect, or mistreatment of residents by a court of law; had a finding of abuse, neglect, mistreatment of resident or misappropriation of property reported into a state nurse aide registry, or had a disciplinary action taken against a professional license by a state licensure body as a result of a finding of abuse, neglect, or mistreatment of residents or a finding of misappropriation of property.

Currently, the regulations require that a facility must not employ an individual who has had a finding entered against them into a state nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of property. We proposed to add a new § 483.12(a)(2)(iii) to expand this employment prohibition to include licensed professionals who have had a disciplinary action taken against them by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.

We proposed to re-designate existing § 483.13(c) as § 483.12(b) and to revise it to also require that the facility develop and implement written policies and procedures that prohibit and prevent abuse, neglect, exploitation of residents and misappropriation of resident property. We proposed to add a new § 483.12(b)(2) to require that the facility establish policies and procedures to investigate any allegations of abuse, neglect, exploitation, or misappropriation of property. We also proposed to add a new § 483.12(b)(3) to require that the policies and procedures include training as required by proposed § 483.95. Finally, we proposed a new § 483.12(b)(5) to require that facilities establish policies and procedures to ensure reporting of crimes in accordance with section 1150B of the Act. The policies and procedures have to include, at a minimum, annual notification of covered individuals, posting a conspicuous notice of employee rights, and prohibiting and preventing retaliation.

Annual notification of covered individuals, as defined at section 1150B(a)(3) of the Act, includes notification of that individual's obligation, as specified at section 1150B(b)(1) of the Act, to report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility. Reporting to the State Agency fulfills the statutory directive to report to the Secretary. In accordance with section 1150B(b)(2) of the Act, the reporting required by 1150B(b)(1) must occur immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

We proposed to re-designate existing § 483.13(c)(1)(iii) as proposed § 483.12(a)(3) and revise existing § 483.13(c)(2), (3) and (4) as proposed § 483.12(c)(1), (2), (3) and (4). Specifically, we proposed to add the term ''exploitation'' in paragraph (c)(1) and add adult protective services where state law provides for jurisdiction in long-term care facilities to the list of officials who must be notified in accordance with state law; otherwise the

language would be unchanged from § 483.12(c)(2). We proposed to divide existing § 483.13(c)(3) into two paragraphs, § 483.12(c)(2) and (3), making the investigation of alleged violations distinct from the facility's obligation to prevent further abuse of the allegedly abused resident or other residents while the investigation is in progress.

*Comment:* One commenter expressed concern that we had moved § 483.13 into § 483.10, ''Resident rights,'' stating that downplayed the seriousness of alleged or confirmed acts of abuse neglect, misappropriation or mistreatment of residents by staff, visitors, family and other residents. The commenter suggested that it should remain its own section.

*Response:* The provisions of § 483.13 are maintained, with revision, in proposed § 483.12, under a new title ''Freedom from abuse, neglect and exploitation.'' We believed this new title highlights, rather than downplays, the need to ensure that residents of long-term care facilities are free from to abuse, neglect, or exploitation.

*Comment:* One commenter is concerned that CMS did not address the use of resident alarms (bed alarms, tabs alarms, etc.) in the section addressing restraints. The commenter supports CMS including language to eliminate the use of resident alarms in light of the absence of any documented evidence that alarms are effective in reducing resident falls. In fact, alarms are often used to in place of facility staff to ensure that residents are provided with adequate care and supervision.

*Response:* We did not address the use of alarms in the proposed rule and would seek additional input prior to considering banning or specifically regulating the use of alarms. We would expect the use of a position alarm to be addressed in a resident's comprehensive care plan. If an alarm is used as a restraint, it is subject to our provisions relating to restraints. We understand that some alarms may have a limited use for diagnostic purposes and a useful role in the assessment process, as facility staff are learning about an individual. In addition, we recognize that there is a clear distinction between position change alarms and door alarms. We will continue to evaluate this issue, address it in sub-regulatory guidance, and consider it for future rule-making.

*Comment:* A number of commenters supported the addition of this section to emphasize the protection of residents from abuse, neglect and exploitation. Commenters specifically appreciated the reference to chemical and physical restraints, and the inclusion of language that complies with the Affordable Care Act regarding the reporting of crimes. Some commenters also stated that they supported the inclusion of violations in this section in the definition of ''substandard quality of care.''

*Response:* We thank the commenters for their support. Ensuring that residents of long-term care facilities are protected is an important purpose of these requirements.

*Comment:* One commenter suggested that we add ''exploitation'' to paragraphs (a)(2)(i) and (a)(2)(ii).

*Response:* Thank you. We have added ''exploitation'' to proposed paragraphs (a)(2)(i), (ii), and (iii), as finalized at § 483.12(a)(3)(i), (ii), and (iii), since we believe that the comment was intended to apply to all the situations described in what we have now re-designated as § 483.12(a)(3).

*Comment:* One commenter urges CMS to carefully describe the consequences for violations of the proposed provisions relating to prohibiting certain hiring and urged that they be implemented consistent with the HHS Office of Inspector General's statutory provision related to hiring or retaining people who have been excluded from participating in federally funded health care programs, including but not limited to civil monetary penalties. By increasing the severity of adverse consequences for hiring staff that could potentially harm residents, CMS will properly encourage facilities' compliance with these requirements.

*Response:* Enforcement is outside the scope of these regulations. We will take this matter under consideration and share this suggestion with the HHS OIG.

*Comment:* Some commenters supported our proposed revisions at § 483.12(a)(2) to prohibit facilities not only from employing certain individuals, but also from engaging these individuals through other mechanisms and for expanding the prohibition on employment to 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 or mistreatment of residents or misappropriation of resident property. Some commenters expressed concern about the impact of (a)(2) on volunteers and one commenter asked we clarify its application to volunteers or to employees of contracted services such as when a facility hires a contractor to perform renovations. One commenter strongly recommended that subsections (a)(2)(ii) and (a)(2)(iii) be broadened to apply to abuse, neglect, exploitation, or misappropriation of property of any persons serving as nurse aides or other direct care workers and that this requirement be expanded to include all staff employed by the LTC facility.

*Response:* We thank the commenters for their suggestions and support. Our primary concern is to protect the health and safety of residents. We are not, at this time, requiring criminal background checks on volunteers, but would expect facilities to exercise reasonable care consistent with the volunteers' expected roles and not knowingly engage volunteers who have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law. With regard to the employees of contractors such as those performing renovations, who would not be providing care to or interacting directly with residents, we would expect the facility to exercise reasonable care in selecting the contractor. We defer additional discussion to subregulatory guidance. We are not further expanding the prohibition at this time, but will evaluate the issue and consider it for future rule-making.

*Comment:* Some commenters expressed concern that these employment prohibitions could involve the application of long-resolved findings against a person. A potential employee might be able to demonstrate extenuating circumstances or rehabilitation after time has passed. The commenters noted that these prohibitions could disqualify a person for life, even if the previous findings were unrelated to their care of LTC facility patients. One commenter asked if the regulations can address a process by which nurse aides and licensed personnel can show successful rehabilitation and be eligible to work in an LTC setting again. Another suggested that it would be appropriate to look at the circumstances and details of each situation, and not exclude all individuals, as proposed. One commenter suggested that the prohibition on employment be based only on felony convictions related to care or services for an individual. Another commenter suggested that CMS consider issuing guidance that would urge states to extend the due process requirements that govern the National Background Check Program, including those requiring an independent process for appealing or disputing the accuracy of the information obtained, and for consideration of the passage of time, extenuating circumstances, demonstration of rehabilitation, and relevancy of the particular disqualifying information with respect to the current employment of the individual.

*Response:* In response to these comments, we have modified proposed § 483.12(a)(2)(iii) relating to licensed personnel to prohibit employment based on disciplinary action for those actions currently in effect, which we will finalize as § 483.12(a)(3)(iii). This provision, as finalized, will prohibit facilities from employing certain individuals who have a disciplinary action in effect against a professional license. We believe that this provides facilities some flexibility to exercise discretion with regard to previous disciplinary actions. Where a facility is aware of previous disciplinary actions against a professional license, but those actions have been resolved, the facility makes their own hiring decisions based on the specific nature and circumstances of those previous disciplinary actions and in keeping with their responsibility to protect the health and safety of residents.

Proposed § 483.12(a)(2)(i) and (ii), which we will finalize as § 483.12(a)(3)(i) and (ii), prohibit facilities from employing or otherwise engaging individuals who have been found guilty of abusing, neglecting or mistreating residents by a court of law, or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property. We believe additional consideration and research is necessary before we propose to further modify these provisions. Any additional changes would be proposed in future rule-making.

With regard to the suggestion that CMS consider issuing guidance that would urge states to extend the due process requirements that govern the National Background Check Program, including those requiring an independent process for appealing or disputing the accuracy of the information obtained, and for consideration of the passage of time, extenuating circumstances, demonstration of rehabilitation, and relevancy of the particular disqualifying information with respect to the current employment of the individual, we will consider this for future action.

*Comment:* One commenter stated that, without a centralized registry for actions against an individual's state licensure, it is impossible for a facility to check with all 50 states for disciplinary action against a professional license. One commenter recommended we delete the language at § 483.12(a)(2)(iii). Another stated that without a centralized registry, it was unreasonable to expect a facility to check for disciplinary action against a professional license and raised the question of what would constitute a disciplinary action. The commenter further stated that his state does not indicate when disciplinary action has been taken against an individual.

*Response:* We agree that a facility is not expected to query 50 states for information on each licensed individual. We would expect the facility to check with the state in which the facility is located and care is delivered and potentially bordering states or other states that the individual is known to have been licensed in, based on the individuals resume or other employment information available to the facility. We checked the Web site for state nursing board for the state mentioned and found that it does indicate the status of the license (active, revoked, probation, etc.). We would expect facilities to exercise reasonable efforts to determine if a state licensing board has taken disciplinary action against a professional license, based on the licensing board's definition of disciplinary action. We have revised the provision to state ''. . . a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.'' We defer additional discussion the sub-regulatory guidance.

*Comment:* One commenter recommended that we clarify here or in the definition section what is meant by ''unfitness for service'' and discuss what the State Survey Agency would do with this information once reported as required under § 483.12(a)(4).

*Response:* Section 483.12(a)(4) requires that the facility report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law which would indicate unfitness for services as a nurse aide or facility staff. Sub-regulatory guidance provides additional information to assist facilities and surveyors in implementing this provision. If a facility determined that action by a court of law against an employee are such that they indicate that the individual is unsuited to work in a LTC facility, or ''unfit for service'', (for example, felony conviction of child abuse, sexual assault, or assault with a deadly weapon), we would expect the facility to report that individual to the nurse aide registry (if a nurse aide) or to the state licensing authorities (if a licensed staff member). Facility reporting to the state nurse aide registry or licensing authorities is not limited to mistreatment, neglect and abuse of residents and misappropriation of their property, but to any treatment of residents or others inside or outside the facility which the facility determines to be such that the individual should not work in a LTC facility environment. Federal requirements related to the state administration of the nurse aide registry, including information disclosure requirements and State Survey Agency responsibilities, are set forth at 42 CFR 483.156 and 488.335.

*Comment:* One commenter notes that provisions relating to reporting of a crime have already been incorporated into the current survey process and therefore these provisions could be implemented one year following adoption of a final rule.

*Response:* We deliberately established regulatory requirements based on existing expectations of facilities based on the statutory language. We would expect that all facilities are currently in compliance with the Act.

*Comment:* A commenter recommends that in § 483.12(b)(4), we say ''coordinate'' instead of ''establish coordination.''

*Response:* We agree and have made this change.

*Comment:* Several commenters asked that we harmonize the reporting requirements for reporting a reasonable suspicion of a crime in § 483.12(b) and the requirements for reporting allegations of abuse, neglect, and exploitation to the LTC facility administrator in § 483.12(c). Commenters state that the two provisions should use the same timeframes.

*Response:* We generally agree and have revised § 483.12(c)(1) to require that all allegations of abuse be reported immediately, but not later than 2 hours after allegation is made, and allegations of neglect or exploitation to be reported to the administrator of the facility immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury. We note that all allegations of abuse, with or without injury, fall into the immediate reporting category, as we believe it is imprudent to allow delay reporting of any abuse. Furthermore, we note that the 2-hour and 24-hour time frames represent maximums and we would expect that most reports would occur more quickly. In all cases, we would expect prompt action to protect individuals and address concerns, and delays in reporting, even within the allowable time frames, must be reasonable and not be related to attempts to obscure events or evade responsibility.

*Comment:* Several commenters are concerned about the inclusion of the resident representative in proposed § 483.12(c)(4). A few commenters suggested that this was a technical error and should have referred to the administrator's designee.

*Response:* The commenters are correct that the reference in this paragraph was intended to be to the LTC facility administrator's designee or designated representative. We have corrected the provision.

*Comment:* One commenter suggests that we add ''as required by state law'' at the end of § 483.12(b)(5).

*Response:* While facilities are expected to comply with state law, this provision is specific to compliance with section 1150B of the Act. We are not revising at this time.

*Comment:* One commenter stated that giving covered individuals up to 2 hours to report to law enforcement and the state agency in cases of serious bodily injury is unacceptable.

*Response:* We revised § 483.12(b)(5)(i)(B) to state ''. . . shall report immediately, but not later than 2 hours . . .'' in accordance with 1150B of the Act.

*Comment:* One commenter stated that individuals living in the community would immediately call the police if they had reason to believe items had been stolen from their home and the same expectations should apply in a LTC facility, where theft of resident personal possessions continues to be a serious problem. Reporting suspected theft as a crime could serve as a deterrent and send a message that stealing will not be tolerated. The commenter recommends that CMS clarify in guidelines that suspicion of theft of resident property is considered a reportable crime.

*Response:* This regulation does not preclude a covered individual from reporting theft immediately. However, covered individuals must report suspicion of crimes not resulting in harm no later than 24 hours. Crimes are defined by laws of the applicable political subdivision where the facility is located, therefore, we will defer further discussion of reportable crimes to sub-regulatory guidance.

*Comment:* One commenter suggests that current CMS sub-regulatory guidelines related to subsection (b) be put into regulation to ensure resident safety, with additional language to specify the rights of staff during investigations, since far too often staff members are inappropriately terminated without a substantiated investigation.

*Response:* We will review the sub-regulatory guidance and evaluate the appropriateness of incorporating it into regulations in future rulemaking.

*Comment:* One commenter recommended adding an express prohibition of all forms of discrimination against residents.

*Response:* We did not propose such a prohibition; however, facilities are expressly required by § 483.70(b) to operate in compliance with all applicable Federal, State, and local laws, regulations, and codes. This includes, for example, the Americans with Disabilities Act and section 504 of the Rehabilitation Act. In addition, § 483.70(c) explicitly requires compliance with other HHS regulations. This would include but not be limited to those regulations pertaining to non-discrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). We note that 45 CFR part 92, non-discrimination on the basis of race, color, national origin, sex, age, or disability, was finalized after the issuance of our proposed rule. Based on this comment, we have added it to the list of regulations at § 483.70(c). We will consider an express prohibition in future rule-making.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We revised paragraphs (a)(2)(i),(ii), and (iii) to include ''exploitation.''
- We revised paragraph (a)(2)(iii) to read ''. . . Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, . . .''
- We revised paragraph (b)(5)(i)(B) to read ''Each covered individual shall report immediately, but not later than 2 hours . . .''
- We revised paragraph (c)(1) to require that allegations of abuse, neglect, or exploitation to be reported to the administrator of the facility immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not involve abuse and do not result in serious bodily injury.
- We corrected paragraph (c)(4) to read ''Report the results of all investigations to the administrator or his designated representative and . . .''

*H. Admission, Transfer, and Discharge Rights (§ 483.15)*

We proposed to re-designate current § 483.12 ''Admission, transfer, and discharge rights'' as new § 483.15, and revised the general title to ''Transitions of care'' in order to reflect current terminology that applies to all instances where care of a resident is transitioned between care settings.

In new § 482.15(a) we proposed to include requirements for admissions policies and moved these requirements to the beginning of the section to reflect chronological order. We proposed a new paragraph (a)(1) to require that the facility establish an admissions policy.

Additionally, we proposed to re-designate current § 483.12(d)(1) as § 483.15(a)(2) to state that facilities cannot request or require residents or potential residents to waive their rights to Medicare or Medicaid benefits or to any rights conferred by applicable state, federal and local licensing or certification laws. We proposed to add a new paragraph (a)(2)(iii) to prohibit facilities from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. We further proposed to add a new paragraph (a)(6) to specify that a nursing facility must disclose and provide to a resident or potential resident, prior to time of admission, notice of any special characteristics or service limitations of the facility.

We also proposed to relocate existing § 483.10(b)(12) to new § 483.15(a)(7). This section addresses admission disclosure requirements for composite distinct part nursing facility, and is more appropriately located in the section on admissions.

We proposed to re-designate § 483.12(a) as proposed § 483.15(b) and address transfers and discharges. We proposed at § 483.15(b)(1)(ii)(C) to revise existing § 483.12(a)(2)(iii) and clarify that a resident could be discharged when the safety of other individuals is endangered due to the clinical or behavioral status of that resident. In § 483.15(b)(1)(ii)(E), we proposed to revise existing § 483.12(a)(2)(v) and clarify that provisions for discharge as a result of non-payment of facility charges would not apply unless the resident did not submit the necessary paperwork for third party payment or until the third party, including Medicare or Medicaid, denied the claim and the resident refused to pay for his or her stay. Finally, we proposed a new § 483.15(b)(1)(iii) to specify that the facility may not transfer or discharge the

resident while the appeal is pending, pursuant to 42 CFR 431.230 when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to 42 CFR 431.220(a)(3).

In the proposed revision to paragraph § 483.15(b)(2), we made a number of revisions based on the importance of effective communication between providers during transitions of care. First, we proposed to clarify that the transfer or discharge would be documented in the resident's clinical record and that appropriate information would be communicated to the receiving setting. In addition, we proposed to require that, when a facility transfers or discharges a resident because the transfer or discharge is necessary for the resident's safety and welfare, the facility would include in its documentation the specific resident needs that it cannot meet, facility attempts to meet the resident needs, and the service(s) available at the receiving facility that will meet the resident's needs.

We proposed to add a new requirement at § 483.15(b)(2)(i) that the transferring facility provide necessary information to the resident's receiving provider, whether it is an acute care hospital, a LTC hospital, a psychiatric facility, another LTC facility, a hospice, home health agency, or another community-based provider or practitioner. We did not propose a specific form, format, or methodology for this communication. Instead, we proposed specific data elements or a set of information that must be communicated during the transfer process. This includes demographic information, including but not limited to name, sex, date of birth, race, ethnicity, and preferred language, resident representative information including contact information, advanced directive information, history of present illness/reason for transfer, including primary care team contact information, past medical/surgical history, including procedures, active diagnoses/current problem list, laboratory tests and the results of pertinent laboratory and other diagnostic testing, functional status, psychosocial assessment including cognitive status, social supports, behavioral health issues, medications, allergies including medication allergies, immunizations, smoking status, vital signs, unique identifier(s) for a resident's implantable device(s), if any, comprehensive care plan including health concerns, assessment and plan, goals, resident preferences, other interventions, efforts to meet resident needs, and resident status. We did not establish a time frame for this communication, as this may vary based on the circumstances surrounding the transfer; however, in the proposed rule we indicated that we expect communication to occur shortly before or as close as possible to the actual time of transfer and that the facility would document that communication has occurred.

In paragraph (b)(3)(i), we proposed to update the language currently in § 483.12(a)(4)(i) to reflect our ''resident representative'' language and proposed to require that the facility send a copy of the notice of transfer or discharge to the State Long-Term Care Ombudsman with the resident's consent. In paragraph (b)(3)(ii), we proposed a minor revision to the language currently in § 483.12(a)(4)(ii) to clarify that the facility records the reasons for the transfer or discharge, in accordance with proposed § 483.15(b)(2).

In § 483.15(b)(5)(iii), we proposed to modify language currently in § 483.12(a)(6)(iii) by adding the phrase ''expected to be'' to reflect our understanding that when a notice of transfer or discharge is issued 30 days prior to transfer, the transfer or discharge destination may subsequently change. We also proposed in paragraph (b)(5)(iv) to require that the notice include the name, address (mailing and email), and telephone number of the state entity which receives discharge or transfer appeal requests; and information on how to obtain an appeal form, how to obtain assistance in completing the form, and how to submit the appeal request. We also proposed to add a new paragraph § 483.15(b)(6) to require that when information in the notice changes, the facility must update the recipients of the notice as soon as practicable with the new information to ensure that residents are aware of and can respond appropriately to discharge information. We proposed to re-designate § 483.12(a)(7) as § 483.15(b)(7) and revised it to require that the facility provide to the resident an orientation regarding his or her transfer or discharge in a form and manner that the resident can understand. Finally, in § 483.15(b)(9), we proposed to clarify that room changes in a composite distinct part are subject to the requirements of proposed § 483.10(d)(7).

In paragraph § 483.15(c) we proposed to add language to require that the facility provide information to the resident that informs the resident of and distinguishes and explains the difference between the duration of the state bed-hold policy, if any, as well as the reserve bed payment policy in the state plan, required under 42 CFR 447.40, if any. In § 483.15(c)(1)(iv), we proposed to add a new requirement that a facility's notice of its bed-hold policy and readmission must also include information on the facility's policy for readmission, as required under proposed § 483.15(c)(3), for a resident whose hospitalization or therapeutic leave exceeds the bed-hold period under the state plan. Finally, we proposed to redesignate existing § 483.12(a)(3) as § 483.15(c)(3) and revised it to add a new requirement that a resident who is hospitalized or placed on therapeutic leave with an expectation of returning to the facility must be notified in writing by the facility when the facility determines that the resident cannot be readmitted to the facility, the reason the resident cannot be readmitted to the facility, and the appeal and contact information specified in § 483.15(b)(5)(iv) through (vii).

*Comment:* One commenter found the reorganization of this section confusing.

*Response:* We thank the commenter for their comment. We have incorporated many suggestions from commenters and believe that the resulting provisions are much clearer.

*Comment:* Some commenters supported our proposal to re-designate § 483.12 ''Admission, transfer, and discharge rights as new § 483.15 to address all transitions of care. We also received several comments suggesting that the title change from ''Admission, transfer, and discharge rights'' to ''Transitions of care'' may make it more difficult for some readers, particularly residents of LTC facilities and their representatives, to find information on admissions, transfers and discharges and that the term ''transitions'' was not easily understandable and could have unintended implications. In addition, many commenters were very concerned that the term ''rights'' was removed from the title and felt this could negatively impact residents. Several commenters suggested we retain the original title. One commenter suggested we revise the title to ''Resident's Rights and Transitions of Care.'' One commenter suggests moving all content describing resident rights in § 483.15 be moved to § 483.10, Resident rights.

*Response:* We acknowledge these concerns. Therefore, we will retain the original title ''Admission, transfer, and discharge rights''.

*Comment:* Several commenters suggested specific wording and punctuation changes throughout this section. This included several changes to make the language used in the regulation less institutional. One commenter stated that some person-

centered language would require a distinction between long-stay and short-stay residents.

*Response:* We reviewed and considered each suggested wording and punctuation change, but do not discuss each one separately below. If we felt that the suggested change improved clarity, we have incorporated it. If the suggested change does not improve clarity, we have not incorporated it. Comments suggesting wording changes that substantively alter our intended meaning are discussed below.

*Comment:* Some commenters recommended that we implement similar requirements for exchanging information for hospitals.

*Response:* Conditions of participation for hospitals are outside the scope of this rule. However, we refer commenters to a proposed rule, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies'' published on November, 1, 2015 (80 FR 68126) which can be viewed at *https://www.gpo.gov/fdsys/pkg/FR-2015-11-03/pdf/2015-27840.pdf.* This rule addresses discharge planning requirements for hospitals and other post-acute care providers, including requirements for exchange of information upon transfer.

*Comment:* Some commenters expressed support for the addition of ''request'' in subsections (a)(2)(i) through (iii) and (3). These commenters felt this would help prevent attempts to evade current law by using the term ''request'' to seek what is intended as a requirement.

*Response:* We thank the commenter and agree that sometimes the word ''request'' can be used for what is effectively a requirement.

*Comment:* One commenter suggested that CMS modify the language in § 483.15(a)(2)(iii) to reflect a relatively recent statutory provision that allow a continuing care retirement community to require residents to spend on their care resources declared for the purposes of admission before such residents can apply for medical assistance.

*Response:* We thank the commenter for this suggestion. We have reviewed the Medicaid requirements at section 1919(c)(5)(B)(v) of the Act. We will develop any necessary regulatory requirements and propose to incorporate them in future notice and comment rule-making. However, we note that LTC facility requirements are for purposes of surveying the facility and the provision applies to a select subset of LTC facilities.

*Comment:* One commenter was concerned that the term ''service limitations'' is not defined. A number of commenters felt that this provision could allow facilities to improperly discriminate in admissions, transfers, and discharges. One commenter felt that this would allow facilities to reduce or eliminate their responsibility for complying with our requirements. One commenter suggested that it would be more helpful for a resident to understand the services a facility provides instead of requiring disclosure of special characteristics or services limitations. Another commenter suggested we clearly state that facilities must provide all services required by federal law and regulation and cannot refuse to provide any services that it is required by federal law to provide to residents who need such services. Some commenters recommend we delete this provision in its entirety. One commenter recommended that if the provision is retained, any disclosure of special characteristics or service limitations must occur prior to the time of admission.

*Response:* We agree that this disclosure should occur prior to admission and have modified the regulations text accordingly. We considered deleting this provision or changing it to require that facilities disclose the services they do provide, however, we believe that the proposed requirement is the option that is likely to ensure prospective residents receive information they are not likely to receive absent a requirement and which can inform decision making. We do not agree that providing this information allows or encourages providers to discriminate in the admissions process, nor does requiring it allow a facility to fail to provide required services.

*Comment:* One commenter suggested removing ''of the residents'' and ''or other responsible parties'' from subsection (b)(8), as these phrases are redundant and create confusion.

*Response:* We thank the commenter and have revised the paragraph, now (c)(8), as suggested.

*Comment:* One commenter supported new language at § 483.15(a)(7) requiring facilities that are a composite distinct part to disclose in its admission agreement its physical configurations, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations.

*Response:* We thank the commenter and agree that this important information for residents and their representatives.

*Comment:* Several comments objected to our addition of the phrase ''expected to be'' in proposed § 483.15(b)(5)(iii). The commenters suggested this will allow a facility to get the resident's agreement to a transfer and subsequently change the location to a location the resident objects without giving the resident 30 day notice, taking away important resident protections. Commenters suggested either not finalizing the proposal or establishing that the 30 day notice ''resets'' if the notice is changed.

*Response:* We agree and have removed the phrase ''expected to be'' from this provision, which we finalize at § 483.15(c)(5)(iii), as suggested.

*Comment:* Several commenters appreciated the addition of ''and implement'' to the statement that facilities must establish an admissions policy. One commenter was concerned that CMS does not clarify what is anticipated by this requirement.

*Response:* We thank the commenters for their support and agree that implementation of policies at § 483.15(a)(1) is essential to making requirements effective. Our expectations that a facility ''establish and implement'' an admissions policy means that a facility must have such a policy, that the policy must be compliant with the requirements for participation, and that the facility must follow its policy.

*Comment:* Commenters supported the proposed provision requiring facilities to establish, maintain, and implement identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment.

*Response:* We thank the commenter for support. We have re-designated this provision as new § 483.15(b)(1).

*Comment:* Some commenters supported our proposal to revise ''safety'' in paragraph (c)(1)(i)(C) as ''safety due to the clinical or behavioral status of the resident.'' Some commenters suggested that CMS require facilities to demonstrate that the resident poses a legitimate safety concern, what steps it has taken before discharging or transferring, and how it provided access to mental health services for the resident. One commenter felt that this language is too broad and could result in inappropriate discharges of residents whose behavior is challenging.

*Response:* We thank the commenters who support this revision. Currently, the language simply states that a resident can be discharged if safety of individuals in the facility is endangered. We do not agree that adding the caveat ''due the clinical or behavioral status of the resident'' is broader and would

create greater opportunity for inappropriate discharges. We are implementing requirements in this rule regarding the information that must be documented when a resident is transferred or discharged. Those requirements include the basis for the transfer or discharge. When the basis for the transfer or discharge is the clinical or behavioral status of the resident, we expect that status to be part of the documentation.

*Comment:* Some commenters suggested that CMS explicitly require that the discharging facility facilitate a transition to another facility.

*Response:* Facilities are required to provide specific information to the receiving provider and to provide sufficient preparation and orientation to the resident for the transfer to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand. These requirements are intended to facilitate a transition to another facility.

*Comment:* One commenter stated that they strongly support improved approaches to managing behavior, but opposed the proposal to create a topic called ''behavioral health'' that is not, and cannot be, adequately defined. The commenter feels behavior issues can be covered under other sections; for example, psychosocial assessment and functional status, and underlying causes can be covered under active diagnoses, history of present illness, and current problem list. The commenter stated that, ultimately, regardless of the name, the issue to be conveyed is whether behavior is personally and socially appropriate, or at least not excessively disruptive or destructive to the individual and to others.

*Response:* We disagree. Please see our discussion of § 483.40 in section L. Behavioral Health of this preamble.

*Comment:* Some commenters were concerned about charges related to bed-hold policies. One commenter suggested CMS prohibit facilities from asking a family member to hold a bed or at least restrict the fee a nursing facility can charge to no more than the Medicaid per diem direct rate or no more than the amount the state would pay to hold the bed. In addition, the commenter suggested that CMS require facilities to provide information on the current occupancy rate.

*Response:* We appreciate the commenters' suggestions. We will evaluate the implications of such a policy and consider it for future notice and comment rule-making.

*Comment:* Some commenters objected to the requirement that facilities not request or require residents or potential residents to waive potential liability for losses of personal property. Commenters felt that, while a facility should offer a secure place to store valuables, it is unreasonable for a facility to be responsible for all losses of resident's personal property and that other requirements addressed the issue. One commenter recommended that facilities include in their admissions policy information on how a resident can safely store personal items to prevent potential loss of personal property. Others suggested that facilities only be liable for items included on an official inventory of the resident's personal items. Several other commenters supported the proposed provision that prohibits waivers of a facility's liability for loss of personal property, but felt that the prohibition should apply to all waivers of liability.

*Response:* A resident's broad waiver of liability could allow a facility to avoid liability even when the facility is responsible for a loss of personal property. This provision does not make the facility automatically liable for every loss of personal property, nor preclude the facility from having policies that establish when the facility is liable. Rather, we would protect the resident from facilities inappropriately avoiding liability by failing to take reasonable care in protecting residents' personal property.

*Comment:* Some commenters were concerned that facilities evade the prohibition on requiring a third-party to guarantee payment, which we are finalizing at 483.15(a)(3), by using contracts that require a resident representative to commit to paying facility charges out of resident resources and suing the representative for breach of contract if the resident's bill is unpaid.

*Response:* We need to further investigate this concern and consider it for future notice and comment rule-making.

*Comment:* Several commenters were concerned about provisions relating to non-payment. Some commenters were concerned about having to wait for a third-party denial. One commenter felt that residents should have to demonstrate that they have applied for Medicaid or other third-party payment under § 483.15(c)(1)(i)(E) within a specified period of time from the date a facility notifies the resident that Medicare payment will expire in order to be protected by the prohibition on discharging a resident who has applied for third party payment. Another commenter suggested we reword our provision regarding non-payment to state that non-payment only applies if the resident has submitted the necessary paperwork for third party payment or after the third party payor, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. Another commenter suggested that we clarify that non-payment does not apply if the resident is in the process of submitting the paperwork for third-party and that conversion from the private pay rate to payment at the Medicaid rate does not constitute non-payment.

*Response:* We thank the commenters for their suggestions. In addition to the proposed language regarding reasonable and appropriate notice, we have revised the provision to state that non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party payor denies the claim and the resident refuses to pay for his or her stay. We defer additional discussion to sub-regulatory guidance.

*Comment:* One commenter stated that equal access to quality of care, proposed § 483.12(b)(1) does not make sense in its new location and that equal access to quality of care needs to be its own subsection or added to an entirely new and independent location such as residents rights.

*Response:* We agree with the commenter that this section should have been its own subsection. We have corrected this and it is now § 483.15(b).

*Comment:* One commenter was concerned that the prohibition on discharging a resident while an appeal is pending could result in forcing a facility to keep a resident whose care the facility is not able to adequately and safely provide. In addition, the commenter felt that, if the facility cannot discharge the resident, Medicaid must be required to pay for the cost of the resident's care while the appeal is pending. Other commenters supported the prohibition on involuntary transfer or discharge while an appeal is pending. One commenter recommended instituting high dollar fines for any facility that improperly transfers, discharges, or refuses to readmit a resident.

*Response:* We have clarified that this provision applies unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals in the facility. In the event that failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility, the facility must document what danger the failure to transfer would pose. Instituting fines for improper transfers, discharges, or

refusals to allow a resident to return to the facility are beyond the scope of this regulation. However, we will take these comments into consideration for future rulemaking.

*Comment:* Generally, all commenters supported efforts to improve transitions of care. We received comments both supporting and objecting to the specific pieces of information we proposed to require facilities to send to a receiving provider when a resident is transferred. Some commenters want CMS to add additional elements to the list of information that a facility must include in transfer documentation. For example, one commenter suggested that we include the name and contact information of the resident's family member(s). Others suggested a number of elements related to diet and nutritional needs and status and another suggest we add behavioral symptoms and triggers to the list of specific information. Other suggestions included indicating the resident's assisted technology, durable medical requirement needs, and communication methods. One commenter felt that transfer information should include portable orders for scope of treatment, if applicable. Another commenter suggested the proposed list includes items that may be irrelevant in many cases and is more extensive than what is required when a hospital discharges a patient. Some commenters oppose this requirement as proposed. One commenter stated that this requirement would be difficult to meet in a timely and accurate manner without interoperable health information exchange, yet LTC facilities did not receive incentives for the adoption of health information technology that would help to enable such exchange. Some commenters suggest that the federal government should provide meaningful use incentives or other funding to LTC facilities if we finalize this requirement.

*Response:* We thank commenters for their support and their suggestions. We have reviewed our proposed list, concerns about the applicability of items in the proposed list, and suggestions for additional items that could be added. While we continue to believe that much of the information we proposed should be exchanged for residents to whom it applies, as well as many of the additional suggestions we received, at this time, we are requiring a more flexible set of requirements. We understand that the information required may vary based on the circumstances of an individual's discharge or transfer, including the urgency of the transfer. We defer to sub-regulatory guidance for additional discussion of circumstances when a discharge summary would be expected, as in a discharge to home and community based services, versus when it would not be appropriate to delay, such as when a resident requires an emergency transfer. The revised set of requirements includes the following:

- Contact information of the practitioner responsible for the care of the resident,
- resident representative information including contact information,
- advance directive information,
- special instructions or precautions for ongoing care,
- the resident's comprehensive care plan goals,
- all other necessary information, including a copy of the resident's discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include the medication reconciliation, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. Please see our discussion of portable orders for scope of treatment in section D, in the comments and responses relating to planning and implementing care.

While we have increased the flexibility in these requirements, we continue to support alignment discussed in the proposed rule between this approach and the common clinical data set which providers participating in the EHR Incentive Program(s) have focused on electronically exchanging through the use of certified EHR technology (80 FR 62693). We encourage facilities to identify opportunities to streamline data collection and exchange by using data they are already capturing electronically, for instance, as part of the MDS data collection.

*Comment:* One commenter suggested that CMS mandate a specific form and format for the transmission of discharge information.

*Response:* No specific form or format has been developed at this time. In addition, some states have their own mandated form. We are not mandating a specific form at this time, but we will consider this for future development and rule-making.

*Comment:* One commenter supported the requirement that the discharge notice include information on the agency for the protection and advocacy of individuals with intellectual and developmental disabilities when individuals discharged have such disabilities and on the agency for the protection and advocacy of individuals with a mental disorder when discharged residents have a mental disorder, and suggested that we extend this to individuals with related disabilities, such as traumatic or acquired brain injury.

*Response:* We thank the commenter for their suggestion and have modified these provisions to include individuals with related disabilities.

*Comment:* One commenter suggested that the information required to be in the discharge notice, as specified as proposed § 483.15(b)(5) include the name, address, and telephone number of the representative of the Office of the State Long-Term Care Ombudsman.

*Response:* In this final rule, we are requiring that this information be provided to the resident in the written description of legal rights (§ 483.10(g)(4)(ii)), and posted in an accessible manner (§ 483.10(g)(5)). In addition, a copy of the notice must be sent to the Long-Term Care Ombudsman (§ 483.15(c)(3)(i)).

*Comment:* A number of commenters were concerned that the obligation at proposed § 483.15(b)(5)(iv) to assist a resident with completing and submitting an appeal unfairly turns the facility into the resident's legal representative. Furthermore, the notice of discharge provides contact information for the Ombudsman, who helps residents get in touch with legal resources to file hearing requests.

*Response:* This provision does not make a facility or any of its employees the legal representative of the resident under state laws; moreover, a facility cannot engage in the practice of law. The provision does not require that the facility provide legal advice or counsel. It does mean that a facility must, as it does in other ways, physically assist a resident in obtaining access to services, and, importantly, cannot act as a barrier to a resident exercising a right. ''Assistance with completing'' could be helping the resident to contact the Ombudsman or helping the resident get a copy of the pertinent form. ''Submitting'' could mean putting a letter in outgoing mail. We defer further discussion to sub-regulatory guidance.

*Comment:* Some commenters supported our proposal to require that discharge notices be sent to a representative of the Office of the State Long Term Care Ombudsman. Several commenters suggested that requiring resident agreement for sending the notice to the LTC Ombudsman was potentially confusing and unnecessary.

Others suggested that we specify that the notice go to the local ombudsman. Another requested clarification on the intended effect of sending the notice and whether or not sending the notice constituted a request for assistance and if not, what the resident would need to do to make such a request. One commenter stated that it is unclear why the ombudsman's office would need notification of every routine discharge or transfer and that such notification should be reserved for situations where the transfer or discharge is contested. The commenter doubted that ombudsman offices have the capacity to receive and act upon even a small portion of this information.

*Response:* We have eliminated language requiring resident consent. We consulted with the Administration for Community Living in the development of this proposal and believe that sending these notices to the State Long-Term Care Ombudsman will provide added protection to the resident and assist the State Long-Term Care Ombudsman to keep informed of facility activities.

*Comment:* Some commenters were concerned that our proposed revision at § 483.15(b)(4)(ii), which changes ''may'' to ''must,'' could imply that a facility has an obligation to always provide the most limited notice period possible and recommend that we retain ''may.''

*Response:* The facility must give notice at least 30 days in advance unless an exception is met. When an exception is met, the facility must give the notice as soon as it can. The facility does not have the discretion to delay as long as possible because an exception applies. The ''must'' in this provision requires the facility to provide notice as soon as practicable when it cannot provide notice at least 30 days in advance of the transfer or discharge. We defer to sub-regulatory guidance to further explicate this requirement.

*Comment:* Several commenters supported our proposed requirement that residents who are being readmitted (following a hospitalization or other absence) to a facility should be assigned to the same room he or she was in previously, if such room is available.

*Response:* We thank the commenters for their support. Particularly for residents whose home is the facility, returning to the same room is important.

*Comment:* One commenter asked, since we do not regulate private-pay rates, why we include proposed § 483.15(b)(1)(i)(B), which authorizes facilities to charge ''any amount for services furnished to non-Medicaid residents . . .'' The commenter was further concerned that the restriction of state law is too limited if it means solely statutory or regulatory law specifically addressing payment by private pay residents.

*Response:* As with the provision of the Social Security Act which it tracks, § 483.15(b)(2) is intended as a modifier to § 483.15(b)(1), and is consistent with section 1919(4)(c)(B)(i) of the Act, which states: ''Nothing prohibiting any charges for non-Medicaid patients.—Subparagraph (A) [regarding identical policies and practices regarding transfer, discharge, and the provision of services required under the state plan for all individuals regardless of source of payment] shall not be construed as prohibiting a nursing facility from charging any amount for services furnished, consistent with the notice in paragraph (1)(B) describing such charges.'' We do not intend to limit the application of state law and proposed to add ''unless otherwise limited by state law'' in recognition of the fact that some states may have regulator or statutory law that addresses limits on charges to private pay residents, consumer protection statutes that would prohibit exorbitant charges, or case law that addresses the concern. The Medicare program has a similar provision with respect to equal access to care, but no specific provision regarding statutory construction with respect to private pay residents.

*Comment:* One commenter suggested that we clarify that documentation requirements in proposed paragraph (b)(2) only apply in non-emergency circumstances.

*Response:* We have revised the documentation requirements at proposed § 483.15(b)(2)(ii), which we are finalizing at § 483.15(c)(2)(ii), to provide greater flexibility for facilities when providing information about a transferring resident. However, even in an emergency, the receiving facility will need information about the resident.

*Comment:* One commenter felt that requiring the physician to directly document the information required for transfers was not feasible, especially during an urgent transfer. The commenter suggested we revise this section to state that the documentation must be made by or based on information from the physician. The commenter stated that sending the physician's previously documented history and physical, pertinent progress notes, consultations, and laboratory tests, supplemented by nursing documentation of the events and rationale leading to the transfer, should suffice.

*Response:* We thank the commenter for their suggestion. This comment is in reference to § 483.15(c)(2)(ii), which specifies the information that a physician must document in the resident's record under certain transfer/discharge scenarios. We have clarified that the physician must document the basis for the transfer, the resident's needs that cannot be met at the facility, the facility attempts to meet the resident's needs, and the services available at the receiving facility to meet the resident's needs. This does not include all of the information required by § 483.15(c)(2)(iii). We agree that sending the physician's previously documented history and physical, pertinent progress notes, consultations, and laboratory tests, supplemented by nursing documentation of the events and rationale leading to the transfer is appropriate when addressing the requirements of § 483.15(c)(2)(iii).

*Comment:* One commenter suggested that the proposed requirement at proposed § 483.15(b)(2) appeared to ignore the growing presence of telemedicine, which is often highly effective at managing condition changes appropriately and preventing hospitalization. Other commenters more generally recommended that the requirements for LTC facilities address telemedicine.

*Response:* We are aware of the growing presence of telemedicine and agree it may be useful in managing condition changes and preventing hospitalization. However, when a transfer does occur, it is important that both the sending and receiving facilities communicate effectively with each other, including the exchange of pertinent clinical and non-clinical information. We will consider further addressing telemedicine in future rule making.

*Comment:* Some commenters supported our proposal to require facilities to document their attempts to meet the resident's needs, and the service available at the receiving facility to meet the need(s). One commenter suggested that this could result in fewer transfer and discharge notices.

*Response:* We thank the commenters. We believe that this requirement will help ensure that residents are transferred appropriately.

*Comment:* One commenter suggested we include a cross-reference to § 483.15(b) in § 483.21(c)(1).

*Response:* We are finalizing proposed § 483.15(b) at § 483.15(c). We have added a cross-reference to § 483.15(c) at § 483.21(c)(1) based on the commenter's suggestion. Please refer to section J. Comprehensive Person-Centered Care Planning (§ 483.21) for a more detailed explanation.

*Comment:* Some commenters supported our proposal to require facilities to notify a resident who has been transferred to another facility, expecting that he/she will return to the facility, in writing, of the reason the resident cannot be readmitted and the information required in the notice before transfer. One commenter believed this may reduce inappropriate discharges or transfers. Some commenters opposed this proposal. One commenter was concerned that this language encourages and supports the practice of facility dumping.

*Response:* At the time a facility determines that a resident cannot be readmitted to the facility, the resident is effectively discharged from the facility. We have revised our language to acknowledge this. Specifically, we use the term ''return'' instead of ''readmit'' and we require facilities, at the time they determine a resident cannot return to the facility, to comply with the requirements of paragraph § 483.15(c) as they pertain to discharges.

*Comment:* Some commenters were concerned that some facilities charge their private pay rate to hold a bed under the bed-hold requirements and suggested that we limit this charge to no more than the Medicaid rate.

*Response:* We thank the commenters for their suggestion. We need to further investigate and evaluate this practice. Payment rates for bed-hold charges are beyond the scope of this rulemaking, but we will consider addressing it in future notice and comment rule-making.

*Comment:* One commenter stated that it is not feasible to provide a bed-hold notice upon transfer. The commenter stated that the focus should be on the resident's well-being and not money.

*Response:* This is an existing requirement which we did not propose to eliminate or substantially modify. We would expect all facilities to already be in compliance with this requirement. We agree that the resident's well-being is of utmost importance. However, the information provided may be very important to the resident or their representative in order to ensure their ability to return to the facility at an appropriate time.

*Comment:* One commenter suggested that we create a new subsection to address readmission after a state's fair hearing regarding entitlement to continuing coverage or other issues.

*Response:* Medicaid's State plan requirements with respect to Medicaid fair hearing processes for applicants and beneficiaries are set forth at 42 CFR 431 subpart E. Corrective action is addressed at § 431.246.

*Comment:* One commenter recommended adding the specific language at proposed § 483.15(b)(5) to the definition of ''substandard quality of care'' at § 488.301.

*Response:* The provision in question includes information on the contents of a discharge notice. We agree that it is important that this information is provided to the resident and that failure to do so should be addressed, we do not agree that this language should be included in the definition of ''substandard quality of care''.

*Comment:* Some commenters requested that CMS clarify that residents would have an appeal right of a facility's refusal to readmit a resident after a hospitalization or other therapeutic leave. The commenters further recommended that the regulation specify that a facility could only refuse a bed-hold or a readmission right if the resident's needs could not be met in the facility, the resident's presence in the facility would endanger others' safety or health, or the resident's condition would not allow for the facility to follow the standard notice procedures for involuntary transfers and discharges. The commenter stated that a hospitalization should not be a means for a facility to evade the normal procedural requirements applicable to involuntary transfers and discharges.

*Response:* As previously noted, our Medicaid State requirements with respect to state fair hearings for applicants and beneficiaries are set forth at 42 CFR part 431 subpart E. Provisions regarding when a hearing is required are set out at § 431.220. Medicare beneficiaries may have separate appeal rights under Medicare. We have revised paragraph (c)(3), ''Notice before transfer'' to better address concerns that, as proposed, it would allow patient dumping.

*Comment:* One commenter suggests that at proposed paragraph (b)(8), we require that the administrator also be required to notify staff members of the impending closure.

*Response:* We thank the commenter for their suggestion. In the event of an impending closure, facilities are required to ensure the safe and orderly transfer, discharge and adequate relocation of all residents. As a part of the process, the facility must have closure plans and procedures. The plans and procedures should include, among other items, notification of all facility staff, vendors, contractors, and unions, as appropriate. However, we cannot require notice to staff unless such notice is related to the health and safety of residents.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have withdrawn our proposal to rename proposed section § 483.15, ''Transitions of Care'' and add introductory language, and retain the current title ''Admission, transfer, and discharge rights.''
- We corrected references to ''clinical record'' to ''medical record.''
- We eliminated the introductory language which defined transitions of care, as the term is no longer used.
- We revised paragraph (a)(6) to require that a facility disclose to a resident or potential resident, prior to admission, notice of special characteristics or service limitations of the facility. We redesignated proposed (b)(1) as paragraph (b), and added a cross-reference to the definition of transfer and discharge in § 483.5 and a cross-reference to resident rights at § 483.10(a)(2).
- We redesignated proposed (b) Transfer and discharge, as (c), and renumbered paragraphs (ii) through (iii) to (i) through (ii).
- In paragraph (c)(1)(i)(E), we have revised the provision to state that non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party payor denies the claim and the resident refuses to pay for his or her stay.
- We have clarified that paragraph (c)(1)(ii) applies unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals in the facility. In the event that failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility, the facility must document what danger the failure to transfer would pose.
- We revised paragraph (c)(2)(ii) to clarify that the term ''documentation'' refers to the documentation specified in paragraph (2)(i).
- We revised paragraph (c)(2)(iii), documentation, to reflect a more flexible list of elements to be documented in the resident's medical record and communicated to the receiving health care institution or provider. The documentation must include: Contact information of the practitioner responsible for the care of the resident, resident representative information including contact information, advance directive information, all special instructions or precautions for ongoing care, as appropriate, the resident's comprehensive care plan goals, all other necessary information, including a copy

of the residents discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

- We removed the requirement for resident consent in paragraph (c)(3).
- We revised paragraph (c)(5)(iii) to remove the phrase ''expected to be.''
- We revised paragraph (c)(5)(iv) to require the discharge notice to include a statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request; and expanded paragraphs (vi) and (vii) to include individuals with related disabilities.
- We revised paragraph (c)(8) by removing ''of the residents or other responsible parties.''
- We revised ''readmissions'' to ''returns'' in paragraphs (d) and (e).
- We revised proposed paragraph (c)(3) as paragraph (e). Paragraph (e)(1) is revised to state that ''a facility must establish . . .'' and (e)(1)(i)(B) is revised to read ''Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services'' and revised proposed paragraph (c)(3)(ii) as (e)(2)(ii) to state that if the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

*I. Resident Assessment (§ 483.20)*

Current regulations at § 483.20 require that a facility must initially and periodically conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity and sets forth the requirements a facility must meet to be in compliance. As part of the restructuring of subpart B, we proposed to remove and re-designate current § 483.20(k) and § 483.20(l), which set forth requirements for care plans and discharge planning, to § 483.21(b) and § 483.21(c), respectively. Similarly, we proposed to re-designate § 483.20(m) as § 483.20(k). The removal and re-designation of paragraphs (k) and (l) are discussed below in the section entitled, ''§ 483.21 Comprehensive Person-Centered Care Planning.''

Existing § 483.20(b) sets forth the information that must be included in a resident's comprehensive assessment using the resident assessment instrument. We proposed to revise this section to clarify that the assessment is not merely for the purpose of understanding a resident needs, but also to understand their strengths, goals, life history, and preferences. We also proposed to revise the regulations to specify that CMS (not the State) prescribes the resident assessment instrument. At § 483.20(b)(1)(xvi) we proposed to revise the text from ''discharge potential'' to read, ''discharge planning'' in an effort to encourage facilities to move the discussion of possible discharge away from a facility's judgment and towards a resident's preference and expectation.

Existing regulations at § 483.20(e) require facilities to coordinate assessments with the PASARR program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and efforts. We proposed to add new § 483.20(e)(1) and § 483.20(e)(2). In new § 483.20(e)(1), we proposed to clarify that coordination with PASARR includes incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care. In new § 483.20(e)(2), we proposed to clarify that PASARR coordination also includes referring all level II residents and all residents with newly evident or possible serious a mental disorder, intellectual disability, or related conditions for level II resident review upon a significant change in status assessment (that is, a decline or improvement in a resident's status).

As mentioned earlier in this section, we are proposed to re-designate existing § 483.20(m) as § 483.20(k). In addition, we proposed to make a few technical corrections at proposed § 483.20(k). First, we proposed to re-designate existing § 483.20(k)(2) as (k)(3), and add a new paragraph (k)(2). Sections 1919(e)(7)(A)(ii) and (iii) of the Act provide exceptions to the preadmission screening for individuals with a mental disorder and individuals with intellectual disability for admittance into a nursing facility. We proposed at § 483.20(k)(2) to add these statutory exceptions that were inadvertently omitted when this regulation was initially written. Second, we proposed to add a new paragraph at § 482.20(k)(4). Section 1919(e)(7)(B)(iii) of the Act requires a NF to notify the state mental health authority or state intellectual disability authority when there has been a significant change in the resident's physical or mental condition so that a resident review can be conducted. We proposed at § 483.20(k)(4) to add this statutory requirement that was inadvertently omitted when CMS first implemented sections 1819 and 1919 of the Act). Lastly, we proposed to replace ''mental retardation'' with the term ''intellectual disability'' throughout § 483.20(k), as appropriate.

*Comment:* Commenters supported CMS' revisions to clarify that the comprehensive assessment of each resident extends to assessing residents' strengths, goals, life history, and preferences. Commenters indicated that such changes are instrumental to providing person-centered care and engaging residents as partners in their care. One commenter noted that information, such as life history and preferences, may not be possible to obtain and this factor should be noted in the regulation. Another commenter indicated that the MDS does not include information such as resident's strengths and life history, so the addition of this requirement is not useful.

*Response:* We appreciate the feedback from commenters. We agree that information such as a resident's life history may not be readily available; however we believe that facilities have an obligation to make their best attempts to obtain this information because the information could prove to be valuable to the resident's care. While the MDS is not completely structured around a resident's life history, the MDS does have a person-centered focus and contains questions that ask about preferences (see Section F for activity preferences), life history in terms of socioeconomic status, marital status, and prior care. In addition, new Section GG of the MDS addresses a resident's goals related to function and has a person-centered focus on items such as pain. We understand that the MDS is an evolving assessment tool, and we will consider the feedback from commenters for possible efforts to improve the assessment in the future.

*Comment:* Commenters also asked whether the proposed changes related to coordinating assessments with the preadmission screening and resident review (PASARR) program under Medicaid in subpart C of part 483 will add any meaningful benefit to residents. Commenters noted that the current PASARR reporting process is flawed and many residents are admitted into facilities with incorrect or missing diagnoses, confusing medication regiments, and barely controlled symptoms. Commenters further questioned the efficacy of PASARR and whether PASARR continues to serve a purpose for nursing home residents. Another commenter noted that the regulation uses the acronym ''PASARR'', which is inconsistent with the acronym that is used on the *Medicaid.gov* Web site.

*Response:* The regulations for LTC facilities found in subpart B include some PASARR regulations that apply strictly to nursing facilities. The July 2015 proposed rule provided updates to the regulations for clarity, but did not change the PASARR program or procedures in any state. The requirements specific to the PASARR program are found in subpart C of part 483, which pertain to all entities and includes the responsibilities of various state agencies. The PASARR Technical Assistance Center (PTAC) at *www.PASRRassist.org* is a useful resource for finding answers to questions regarding the PASARR program and for providing feedback regarding how the program can be improved. We are aware that the acronym varies between what is used in the Code of Federal Regulations (CFR) and what is used on the Medicaid Web site. For consistency we are continuing to use the acronym PASARR for purposes of the CFR. We may revise the term in future rulemaking.

*Comment:* Several commenters requested clarification regarding the meaning of ''direct care/direct access staff members'' as used at § 483.20(b)(1)(xviii) and suggested that the term ''direct access staff'' be defined in the ''Definitions'' section. One commenter suggested that the phrase be replaced with ''staff members of all shifts who provide services directly to the resident.'' Another commenter indicated that the phrase should include housekeeping and maintenance staff, as they often have contact and interaction with residents and may be able to provide valuable information regarding a resident's preferences and needs.

*Response:* On August 4, 2015 we published a final rule entitled, ''Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (80 FR 46389), which established a definition of ''direct care staff'' in 42 CFR part 483. When we use the term ''direct care/direct access staff'' we are referring to those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. We were not referring to individuals whose primary duty is maintaining the physical environment of the long term care facility (for example, housekeeping). For clarity we have removed the reference to ''direct access staff'' at § 483.20(b)(1)(xvii) and elsewhere throughout the regulatory text as appropriate.

*Comment:* One commenter provided comment regarding the language at § 483.20(k)(2)(ii)(C) which indicates that the state may choose to not apply the preadmission screening program for individuals with a mental disorder if it is anticipated by a physician that the individual will be in a nursing facility for less than 30 days. The commenter noted that if it is discovered that the individual requires more than a 30 day stay, they are not protected against transfer. The commenter suggested that CMS add language ensuring that residents affected by this section be given the same protections as other residents with regard to the transfer/eviction process.

*Response:* We appreciate the commenters' feedback. However, we believe that the intention of the policy was to limit the program to those with an expectation of staying 30 days or more.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following revision:

- Remove the reference to ''direct access staff'' at § 483.20(b)(1)(xviii).

*J. Comprehensive Person-Centered Care Planning (§ 483.21)*

In accordance with the proposed reorganization of part 483, subpart B, we proposed to add a new § 483.21 ''Comprehensive Person-Centered Care Planning''. We proposed to retain in this section certain existing provisions of current § 483.20 as well as other additions and revisions discussed in detail below. Currently, the requirements for care plans and discharge planning are set out at § 483.20 along with the requirements for conducting an assessment of each resident's health and completing the MDS. We proposed to remove the requirements for care plans from current § 483.20(k) and discharge planning in current § 483.20(l) (collectively referred to here as care planning) and relocate them to a new § 483.21. In addition to relocating existing provisions, we also proposed to add new requirements as discussed in detail below.

Proposed § 483.21(a)

We proposed to add a new § 483.21(a)(1) to the current care planning regulations and require that facilities complete a baseline interim care plan for each resident upon their admission to the facility. We proposed to require that the baseline care plan be completed within 48 hours of a resident's admission. At § 483.21(a)(1)(ii), we proposed to list the information that would, at a minimum, be necessary for inclusion in a baseline care plan, but would not limit the contents of the care plan to only this information. In the proposed rule, we indicated that information such as initial goals based on admission orders, physician orders, dietary orders, therapy services, social services, and PASARR recommendations as appropriate would be the type of information that would be necessary to provide appropriate immediate care for a resident. However, since care plans are developed specifically for each resident, a facility could decide to include additional information as appropriate.

At § 483.21(a)(2), we proposed to allow facilities to complete a comprehensive care plan instead of completing both a baseline care plan and then a comprehensive care plan. In this circumstance, the comprehensive care plan would be completed within 48 hours of admission and comply with the requirements for a comprehensive care plan at proposed § 483.21(b). We discuss those requirements below.

Proposed § 483.21(b)

Current regulations at § 483.20(k) set forth the requirements for developing a comprehensive care plan. As mentioned above, we proposed to re-designate this section as a new § 483.21(b). In addition, we also proposed to add a new § 483.21(b)(1)(iii), requiring that any specialized services or specialized rehabilitation services that a nursing facility provided pursuant to a PASARR recommendation be included in the resident's care plan.

We also proposed to add a new § 483.21(b)(1)(iv)(B) to require that discharge assessment and planning to be a part of developing the comprehensive care plan. We proposed to require facilities to assess a resident's potential for future discharge, as appropriate, as early as upon admission, to ensure that residents are given every opportunity to attain their highest quality of life. We proposed to require at § 483.21(b)(1)(iv) that facilities document whether a resident's desire for information regarding returning to the community is assessed and any referrals that are made for this purpose.

The IDT is responsible for developing a comprehensive care plan for each resident at proposed § 483.21(b)(2)(ii). Under current § 483.20(k)(2)(ii), the attending physician, a registered nurse with responsibility for the resident, other appropriate staff in disciplines as determined by the resident's needs, and to the extent possible the resident or the

resident's family/legal representative are all required to participate in the IDT. We proposed to add the term ''other appropriate staff'', which should be determined based on the specific needs of the resident or at the request of the resident. We proposed to also explicitly require a NA with responsibility for the resident, an appropriate member of the food and nutrition services staff, and a social worker to be a part of the IDT. Additionally, we proposed to revise § 483.21(b)(2)(ii)(F), to provide that to the extent practicable, the IDT must include the participation of the resident and the resident representatives. Further, at § 483.21(b)(2)(ii)(F) we proposed to add the requirement that an explanation must be included in a resident's medical record if the IDT decides not to include the resident and/or their resident representative in the development of the resident's care plan or if a resident or their representative chooses not to participate.

Lastly, we proposed to add a new requirement at § 483.21(b)(3)(iii) to require that the services provided or arranged by the facility be culturally-competent and trauma-informed.

Proposed § 483.21(c)

Current regulations at § 483.20(l) set forth the requirements for a discharge summary. As mentioned above, we proposed to re-designate this section as a new § 483.21(c). At § 483.21(c)(1) we proposed to improve the discharge planning for LTC facilities by adding a requirement that facilities must develop and implement an effective discharge planning process. In the proposed rule, we indicated that the facility's discharge planning process must ensure that the discharge goals and needs of each resident are identified. This process should also result in the development of a discharge plan for each resident and any referrals to local contact agencies or other appropriate entities, should the resident have a desire to receive information about returning to the community. We note that in compliance with the Supreme Court *Olmstead* decision (*Olmstead* v. *L.C ex rel. Zimring,* 527 U.S. 581, 119 S. Ct. 2176 (1999)), we encourage facilities and their community partners to strive to serve individuals in their preferred settings, when feasible. In addition, we proposed to require that the facility's discharge planning process require the regular re-evaluation of residents to identify changes that require modification of the discharge plan. We proposed that the discharge plan must also be updated, as needed, to reflect these changes. We also proposed to require that the IDT responsible for the developing a resident's comprehensive care plan be involved in the ongoing process of developing the discharge plan.

Furthermore, we proposed to require that the facility consider caregiver/support person availability, and the resident's or caregiver support persons' capacity and capability to perform the required care, as part of the identification of discharge needs. We also proposed to require that the discharge plan address the resident's goals of care and treatment preferences. In the proposed rule, we indicated that facilities have to document in the discharge plan that a resident has been asked about their interest in receiving information regarding returning to the community. If the resident indicates interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose and update a resident's comprehensive care plan and discharge plan in response to information received from such referrals. Likewise, if discharge to the community were determined to not be feasible, the facility must document who made the determination and why. We note that on May 20, 2016 the HHS Office for Civil Rights' issued a report entitled ''Guidance and Resources for Long Term Care Facilities: Using the Minimum Data Set to Facilitate Opportunities to Live in the Most Integrated Setting'' (see *http://www.pasrrassist.org/events/webinar/ocr-guidance-and-resources-long-term-care-facilities-using-minimum-data-set*). We encourage facilities to review this guidance for information to assist facilities in complying with civil rights obligations by administering the Minimum Data Set (MDS) appropriately so that their residents receive services in the most integrated setting appropriate to their needs. In addition, the IMPACT Act amended title XVIII of the Act by adding Section 1899B to require that post-acute care (PAC) providers, home health agencies (HHAs), SNFs, inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs) report standardized patient assessment data, data on quality measures, and data on resource use and other measures. The IMPACT Act also requires that this data be standardized and interoperable to allow for the exchange of data among PAC providers and other providers. The IMPACT Act requires the modification of PAC assessment instruments to allow for the submission of standardized patient assessment data and enable comparison of this assessment data across providers. Additionally, the IMPACT Act requires that standardized patient data, quality measures, and resource use measures, along with patient treatment goals and preferences, be taken into account in discharge planning.

As required under section 1899B(i)(1) of the Act, to help inform the discharge planning process, we proposed to require LTC facilities to take into account, consistent with the applicable reporting provisions, standardized patient assessment data, quality measures and resource use measures that pertain to the IMPACT Act domains, as well as other relevant measures specified by the Secretary. For those residents who are transferred to another LTC facility or who are discharged to a HHA, IRF, or LTCH, we proposed at § 483.21(c)(1)(viii) to require that the facility assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use to the extent the data are available. Further, we proposed that the facility must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use are relevant and applicable to the resident's goals of care and treatment preferences.

Finally, at § 483.21(c)(1)(viii), we proposed that facilities must document in the discharge plan whether a determination is made by the resident, resident representative, or interdisciplinary team that discharge to the community is not feasible. At § 483.21(c)(1)(ix), we proposed to require that the evaluation of the resident's discharge needs and discharge plan must be documented, completed on a timely basis based on the resident's needs, and included in the clinical record. The results of the evaluation must be discussed with the resident or resident's representative. Furthermore, all relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

At § 483.21(c)(2), we proposed to set forth the existing requirements for providing a resident with a discharge summary when discharge from the facility is anticipated. At § 483.21(c)(2)(i) we proposed to revise the current requirements for the post-discharge plan of care to specify that a recapitulation of a resident's stay include, but not be limited to,

diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results. We also proposed to explicitly include a requirement for facilities to include what arrangements have been made with other providers for the resident's follow-up care and any post-discharge medical and non-medical services as needed. These arrangements include any community care options, resources, and available supports and services presented and arranged by the community care provider as needed.

At § 483.21(c)(2)(iii), we proposed to add a new requirement to require facilities to reconcile all pre-discharge medications both prescribed and non-prescription, with the resident's post discharge medications. We proposed that this medication reconciliation be included as part of the discharge summary. Lastly, we also proposed at § 483.21(c)(2)(iv) to require that the post-discharge plan be developed along with the participation of the resident and, with the resident's consent, his or her resident representative.

*Comment:* Commenters supported the recognition of the need to plan for person-centered care and the incorporation of person-centered care into the care planning process. One commenter did not support specifying that a resident's care plan be person-centered. The commenter noted that the Institute of Medicine (IOM) has identified several major quality attributes including safety, effectiveness, efficiency, timeliness, patient-centeredness, and equitability. The commenter suggests that the regulations should recognize all elements of quality and not just selected ones.

*Response:* We appreciate the commenters' feedback. The intent of creating a section devoted to person-centered care planning was not to diminish the necessity of other quality attributes. We received insight and recommendations from the OIG ((OEI–02–09–00201), *https://oig.hhs.gov/oei/reports/oei-02-09-00201.asp*), internal workgroups, and stakeholders regarding the lack of resident involvement in the care planning process. In response, we determined that it is necessary to highlight the importance of focusing on the resident as the locus of control when developing care plans. The regulation as a whole focuses on the additional quality attributes mentioned by commenters; safety, effectiveness, efficiency, timeliness, and equitability. Some of the proposals that focus on these attributes include the addition of the QAPI requirements, strengthening the rights of residents, and the overall promotion of resident choice.

*Comment:* Commenters also supported the need to include discharge planning as part of the comprehensive care plan. Commenters insisted that discharge planning, including referrals for community transition, be initiated as early in the admission process as possible to prevent any unnecessary period of institutionalization.

*Response:* We agree that discharge planning should be initiated as early as possible in the admission process. In addition to requiring discharge assessment and planning to be a part of developing the comprehensive care plan, we also proposed at § 483.21(b)(1)(iv)(B) that facilities document whether the facility assessed a resident's desire to return the community. We noted in the proposed rule that the discharge assessment may include referral to a community transition planning agency to explore community living options, resources, and available supports and services.

*Comment:* Multiple commenters questioned whether a qualified mental health professional and a member of clergy would be required to participate on the IDT. Commenters indicated that ''qualified mental health professional'' should be defined and that such a requirement would be costly, while noting that access to these professionals is limited. Some commenters indicated that they offer clergy services to residents and a few noted that many residents may request that their own religious leaders come into the facility to provide them services.

*Response:* In the preamble discussion of the proposed rule (see 80 FR 42193) we indicated that we proposed to add the term ''other appropriate staff'' to the requirement for the individuals who must participate on a resident's IDT at § 483.21(b)(2)(ii). We provided examples for ''other appropriate staff'' that may be appropriate for participation on the IDT and for inclusion in the development of a resident's care plan. We used the examples of a mental health professional for a resident who is diagnosed with a mental health disorder or a chaplain based on a resident's needs. We did not require that these individuals participate in the IDT. For clarity, we proposed at § 483.21(b)(2)(ii) that a resident's care plan must be developed by an IDT that includes but is not limited to the attending physician, a registered nurse with responsibility for the resident, a nurse aide with responsibility for the resident, a member of food and nutrition services staff, a social worker, the resident or the resident's representative, and other appropriate staff as indicated by the resident's needs.

*Comment:* Many commenters supported our proposal to add a requirement for a baseline care plan. Commenters indicated that the requirement for a baseline care plan recognizes the planning needed to meet the immediate, short-term needs of newly admitted patients. One commenter recommended that the baseline care plan also include information about the current health condition and diagnosis of a resident rather than be based on admission orders from another facility in order to determine if they are still relevant. Another commenter recommended that the baseline care plan also include information about a resident's customary routines and preferences. A few commenters indicated that the proposed 48 hour timeframe for completing the baseline care plan may be problematic if an individual is admitted on a Friday afternoon or on a holiday. Another commenter indicated that the proposed 48 hour timeframe was too long and stated that the plan should be developed upon admission. One commenter indicated that staff with specific or specialized training would be required to complete the baseline care plan and this would have a negative financial impact of facilities.

*Response:* We expect that a resident's current health status and diagnosis will be included in the admission orders. Section 483.15(c)(2)(iii) of this final rule requires that certain information be provided to a receiving provider for a transfer including all special instructions or precautions for ongoing care and the contact information of the practitioner responsible for the care of the resident. If a resident is transferred from another facility, the requirements at § 483.15(c)(2)(iii) would apply. If the information provided is missing or unclear, the facility or admitting professional is not precluded from following up to gain additional information. Furthermore, we believe the information necessary to complete the baseline care plan will be readily available or accessible through discussions and follow-up upon admission. Therefore, we do not agree with the commenter who indicated that additional staff with specialized or specific training is necessary to complete the baseline care plan causing a negative financial impact on facilities. While a resident's customary routine and preferences provide valuable information regarding a resident's care, we believe it would be overly burdensome to include this information in the baseline care plan. The purpose

of the baseline care plan is to serve as an interim care plan within the initial period of residency to avoid poor quality care and reduce the risk of hospital readmission as a result of missing information. The comprehensive care plan required at § 483.21(b) is a more detailed and exhaustive plan of care for each resident that is person-centered and includes a resident's needs and preferences.

In addition, we understand that admissions to a facility can take place on a weekend or over a holiday, however we expect that quality care will still be provided including the need to formulate a plan of care for the resident. Furthermore, regulations at § 483.35(b)(1) require the facility to use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week. Therefore, we expect, at a minimum, that a registered nurse will be available to develop a baseline care plan regardless of whether it is a holiday or a weekend. Finally, we expect that facilities will begin developing the baseline care plan upon admission in order to meet the 48 hour timeframe. The 48 hour timeframe serves as a deadline for having the plan completed and does not preclude facilities from completing the plan sooner. We believe that 48 hours is an appropriate timeframe as it will allow the facility sufficient time to obtain necessary information to complete the baseline care plan while also addressing the need for continuity of care during transition, a high-risk period when residents are particularly vulnerable to adverse health events.

*Comment:* One commenter recommended that the language at § 483.21(a) be revised to clearly state that facilities must not only develop a baseline care plan, but must also implement the plan. The proposed language only stated that the plan must be developed and implied that it must also be implemented. The commenter request that CMS clearly state that the plan must be also be implemented.

*Response:* We agree and have revised the language at § 483.21(a) to indicate that facilities must both develop and implement a baseline care plan. Similarly, the proposed language only stated that the comprehensive person-centered care plan must be ''developed.'' Therefore, for consistency, we have also revised the language at § 483.21(b) to indicate that facilities must both develop and implement a comprehensive person-centered care plan.

*Comment:* One commenter recommended that we consider the care plan requirements in regard to short-stay vs long-stay residents due to the significant variation in their treatment regimens. The commenter suggests that residents receive a short-term interim care plan for a period of up to 100 days from admission. Once a resident is no longer ''short-stay'' then the requirement for a comprehensive assessment and care plan to be completed with 14 days of the change could then be completed.

*Response:* We disagree with the commenter. We believe that a comprehensive person-centered care plan should be developed for all residents regardless of length of stay. The need for an assessment and a plan of care is not dependent on the length of time an individual spends in a facility. Rather comprehensive assessments and care planning is necessary to provide all residents with the proper care and services that will help them to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

*Comment:* One commenter recommended revising the language at § 483.21(b)(1) by replacing the term ''timetables'' with ''timeframe'' as they are not the same. The commenter notes that timetables are rigid and predictable unlike timeframes. Another commenter requested that § 483.21(b)(1) be revised to also address a resident's goals not just their needs.

*Response:* We have replaced the term ''timetables'' and revised the language at § 483.21(b)(1) to ''the facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with § 483.10(c)(2) and § 483.10(c)(3), that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment.''

*Comment:* One commenter suggested that medications or pharmacy services should be added to the list of information necessary for completing the baseline care plan. Another commenter suggested that the terms ''prescriptions'' or ''recommendations'' be used in place of ''orders''. The commenter indicated that the term ''order'' is used in the military which reinforces a resident's feelings that they are ''inmates'' at the LTC facility.

*Response:* Regulations at § 483.21(a)(1)(ii)(B) require that the baseline care plan include the physicians orders. We expect that the physician orders will include any initial medications and pharmacy services that are needed for the resident. We do not agree that the term ''orders'' as used in ''admission orders'', ''physician orders'', and ''dietary orders'' should be removed. The term ''orders'' is a widely used term throughout the medical field and understood by medical professionals of all specialties and skills.

*Comment:* A few commenters were against requiring that a nursing assistant with responsibility for the resident and a member of dietary services to be a part of the IDT, while some commenters indicated support for the proposal. Overall commenters supported the intent of the requirement; however commenters opposing the proposal stated that participating on the IDT would require a significant amount of time and would reduce the amount of time that the nursing assistant would be available to provide direct care to residents. Commenters also noted shortages in the number of dietary staff and their limited availability to participate in meetings. Commenters recommended that each facility have the flexibility to determine how best to obtain input from direct-care staff in a manner that is more cost effective and less disruptive to resident care. One commenter noted that they do not hire nursing assistants to provide primary care to their Medicare Part A rehab patients, but rather uses Licensed Practical Nurses (LPNs) and RNs to provide care.

*Response:* We continue to believe that it is most appropriate for a nursing assistant with responsibility for the resident to be a part of the IDT. Nursing assistants spend much of their time interacting directly with residents providing them day-to day care. In addition, their knowledge of a resident's care plan and medical needs directly relates to how well they can care for a resident and including them on the IDT may also contribute to improved outcomes. For those facilities that do not hire nursing assistants, as indicated by the commenter, we note that the regulation at § 483.21(b)(ii) also requires a RN with responsibility of the resident to participate on the IDT as well. We expect that these facilities will meet these additional requirements for IDT members and be able to demonstrate their lack of nursing assistants on staff. Likewise, we also believe that nutrition is a fundamental part of a resident's overall health and well-being and that a member of nutrition services will provide invaluable information to the IDT. We do not require that any of the members of the IDT participate in person. Facilities have the flexibility to determine how to hold IDT meetings whether in person or by conference call. The facility may determine that participation by the nursing assistant or

any member, may be best met through email participation or written notes. We believe that this added flexibility will help to alleviate concerns of shortage and availability.

*Comment:* One commenter requested that we provide an explanation for how we expect the social worker to participate on the IDT when facilities with 120 or fewer beds are not mandated to have a social worker and those with more than 120 are only required to have one social worker.

*Response:* We appreciate the feedback from the commenter. After further consideration, we are removing our proposal that requires the social worker to participate on the IDT. We agree that the proposal would not be appropriate given that all facilities are not required to employ a social worker. However, we strongly encourage facilities to leverage the many valuable assets that social workers can provide to LTC residents and their families. Often social workers can serve as a critical link between the facility and families of the residents, including arranging post-discharge services and addressing mental and behavioral health care needs. In addition, social services can be used by the facilities to promote resident choices and enhance the individualized quality of care and life specific to each resident.

*Comment:* One commenter recommended that a pharmacist should also be required to participate on the IDT to highlight the importance of medication therapy as part of the care plan. Another commenter suggested that an activity professional should also be required to participate in the IDT and that many activity professionals are already a part of the resident assessment and the IDT.

*Response:* We considered requiring the pharmacist to participate on the IDT and determined that it would be overly burdensome. However, the pharmacist is not precluded from participating in the IDT if it is determined to be necessary for a particular resident. In addition, we believe that the proposed requirements at § 483.45 strengthen the involvement of the pharmacist in a resident's care including the need for a pharmacist to review the drug regimen of each resident at least once a month and the need to review a resident's medical chart every 6 months (§ 483.45(c)(1) and (2)). Similarly, the activity professional is not precluded from participating on the IDT if it is determined to be necessary for a particular resident, even though they are not specifically listed at § 483.21(2)(ii). Those facilities that currently involve the activity professional may continue to include these individuals.

*Comment:* One commenter recommended that members of the IDT be required to provide explanation in the resident's medical record if they are unable to attend IDT meeting that discuss the resident.

*Response:* Given the diversity of long term care providers, we have attempted to develop health and safety standards that can be applied across all types. We want to allow facilities the flexibility to determine how to ensure that the necessary professionals are involved in the development of each resident's care plan. We believe that adding a requirement for each member of the IDT to provide explanation in the resident's medical record of when they miss a meeting would be too burdensome.

*Comment:* One commenter noted that a cost is associated with having additional individuals participate on the IDT and that CMS did not adequately identify the costs. To reduce the cost, the commenter suggested that instead the additional individuals could be interviewed prior to the meeting to obtain their valuable information.

*Response:* In the regulatory impact analysis section of the proposed rule we indicated that we estimated that it will cost all long-term facilities $97,911,840 to have the additional individuals participate on the IDT (see FR 80 42237). We envision that these staff members are already regularly discussing resident's needs and their plans of care. In addition, we did not specify the type of communication the IDT must use for their meetings. In the proposed rule, we noted that to reduce cost, the IDT members may use electronic communication to participate in the IDT meetings. Facilities have the flexibility to determine how to conduct the IDT meetings and incorporate the staff who have been added to participate.

*Comment:* One commenter indicated that the proposed rule does not reflect the expectation that a comprehensive person-centered care plan must include the participation of the resident or their representative. The commenter notes that the regulation includes the participation ''to the extent practicable.'' The commenter noted the failure of facilities to include resident's in the development of the care plan sited in the July 2012 OIG report, ''Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs'' ((OEI–07–08–00151), *https://oig.hhs.gov/oei/reports/oei-07-08-00151.asp*). The commenter further notes that the OIG report references different types of resident representatives including the resident's family or legal representative.

*Response:* Our proposed regulations at § 483.21(b)(2)(ii)(F) would require that to the extent possible the resident and/or their representative(s) must participate on the IDT that develops the resident's care plan. For clarity, one example of when it may not be practical for a resident to participate in the development of their care plan may be in the case of a resident whose ability to make decisions about care and treatment is impaired, or a resident who has been formally declared incompetent by a court. We would expect that to the extent practicable these residents would be kept informed and consulted on personal preferences regarding their care.

In the preamble of the proposed rule (see 80 FR 42192) we noted the gaps in care planning revealed by the July 2012 OIG report referenced by the commenter as well as another OIG report, ''Skilled Nursing Facilities Often Fail to Meet Care Planning and Discharge Planning Requirements'' ((OEI–02–09–00201), *https://oig.hhs.gov/oei/reports/oei-02-09-00201.asp*), conducted in February of 2013. In response to these reports and the gaps revealed, we also proposed at § 483.21(b)(2)(ii)(F) that the facility must provide an explanation in the resident's medical record if the participation of the resident and their representative is determined not practicable for the development of the resident's care plan. We note that the definition of ''resident representative'' includes individuals of the resident's choice (which may include family members) and individuals with legal standing.

*Comment:* One commenter recommended that the requirement for a written explanation be provided when a resident or their representative does not participate in the development of their care plan be removed from the regulations and discussed in the interpretive guidance.

*Response:* We disagree with the commenter. The July 2012 OIG report discussed previously and in the proposed rule (see 80 FR 42192) revealed that 91 percent of the care plans reviewed in the study did not contain evidence that the resident or a representative participated in the care planning process. Given this evidence and feedback from stakeholders, we continue to believe that residents should be involved in making decisions about their care and that it is appropriate for facilities to be held accountable for whether or not they actively include the resident and their representatives in the development of their care plan.

*Comment:* One commenter indicated that the resident or their representative

should be invited to participate in the review or revision of their care plan in order for it to truly be person-centered.

*Response:* Regulations at § 483.21(b)(2)(ii)(E) require that the resident and/or their resident representative participate on the IDT that develops their care plan. In addition, regulations at § 483.21(b)(2)(iii) require that the care plan be reviewed and revised by the IDT. Therefore, the resident and/or their representative have the right to participate in the review or revision of their care plan under our proposal.

*Comment:* Several commenters recommended that the regulations require a resident's participation in developing their care plan be strengthened by adding that the facility must provide advance written notice of the date and time of the care plan meeting, make reasonable accommodation of the schedules of the resident and any resident representatives invited to participate, and arrange for conference calls or video conferencing if necessary to enable resident participation.

*Response:* Regulations at § 483.10(c)(2) set forth the rights a resident has regarding their participation in the development and implementation of their plan of care which includes, among other rights, the right to request meetings, request revisions to their care plan, and the right to be informed, in advance, of changes to their plan of care. Regulations at § 483.10(c)(3) provide that the facility has a responsibility to inform the resident of their right to participate in his or her treatment and support the resident in this right. Therefore, we believe that the regulations address the commenters' concerns and revisions are not necessary.

*Comment:* A few commenter asked that ''trauma-informed care'' be defined as used at § 483.21(b)(3)(iii) and added to the definitions section. One commenter noted that it is reasonable to tailor interventions to cultural preferences and difference, but indicated that this is different from requiring facilities to adhere to concepts such as ''culturally competent'' or ''trauma-informed''. The commenter indicated concern for surveyors to consistently and fairly identify whether a facility's efforts are sufficient. The commenter suggested instead requiring that facilities be mindful of and tailor services outlined by a resident's care plan to cultural differences and preferences. Another commenter noted that staff would need to be trained on trauma-informed care and that additional implementation time should be provided to allow for such training.

*Response:* Culturally-competent and trauma-informed care are approaches that help to minimize triggers and re-traumatization. Care that addresses the unique needs of Holocaust survivors and survivors of war, disasters, and other profound trauma are an important aspect of person-centered care for these individuals. We noted in the proposed rule that 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*, would help advance the quality of care that a resident receives and, in turn, can substantially improve a resident's quality of life. We do not believe that a definition of trauma-informed care should be added to the definitions section, but note that the interpretative guidelines and the resource noted previously will provide further information regarding culturally-competent and trauma-informed care. In addition, as with all of our requirements, surveyors will use uniform sub-regulatory guidance and surveyor training will be provided to promote consistent enforcement. In addition, we note that the requirement related to trauma-informed care at § 483.21(b)(3)(iii) has a delayed implementation deadline that is 3 years following the effective date of this final rule. For more detailed information regarding the implementation timeframe of this final rule, readers may refer to Section II.B., ''Implementation Date''.

*Comment:* One commenter provided resources for facilities to refer to for information and material addressing culturally competent and trauma-informed care. The resources include The Council on Social Work Education, NASW's standards and indicators for cultural competence (available at *http://www.socialworkers.org/practice/standards/index.asp*), and The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care (developed by the Office of Minority Health in HHS).

*Response:* We appreciate the commenter's feedback and encourage readers to refer to these resources for information.

*Comment:* One commenter recommended that the final rule make a better connection between care planning and a resident's quality of life. The commenter suggested that facilities should be encouraged to develop and share care planning documents that highlight resident goals. The commenter notes that a care plan that includes a wheelchair dependent resident's desire to gain strength to walk or a resident's food preference would be more beneficial to a activities director and member of food and nutrition services.

*Response:* Regulations at § 483.21(b)(1)(iv)(A) require that a resident's comprehensive care plan describe a resident's goals for admission and desired outcomes. In addition, we expect that any person who is involved in the implementation of a resident's plan of care will have access to their care plan. In order to fulfil a resident's plan of care it is necessary for facilities to share information with the appropriate members of a resident's care team. We expect that facilities are already doing this.

*Comment:* One commenter suggested that facilities be required to provide copies of the care plan to residents when the plan is revised and require facilities to ensure that the plan is written in a manner that is understandable to the resident, not in medical jargon.

*Response:* Since the comprehensive care plan is intended to be a working document that is constantly being reviewed and updated based on the needs of the resident, we believe that it would be overly burdensome to require facilities to make copies of the comprehensive care plan every time it is updated. However, we note that regulations at § 483.10(c)(2)(iii) indicate that a resident has the right to be informed, in advance, of changes made to their plan of care and regulations at § 483.10(c)(2)(v) indicate that the resident has the right to see their care plan including the right to sign after significant changes are made to their plan of care.

In addition, we note that as discussed previously we received comments requesting that the right to receive a copy of the care plan be added to the list of resident rights discussed in § 483.10. In response to these comments we have added a provision at § 483.21(a)(3) that requires facilities to provide residents and their resident representatives with a summary of their baseline care plan. This summary must include, but is not limited to, the initial goals of the resident, a summary of the resident's medications and dietary instructions, any services and treatments to be administered by the facility and personnel acting on behalf of the facility, and any updated information based on the details of the comprehensive care plan, as necessary. Note that this summary is subject to the provisions at § 483.10(g)(3) and must be

provided in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand.

Furthermore, we believe that the comprehensive care plan should serve as an important tool for delivering patient-centered care and encourage facilities to explore ways to allow residents, families, and other representatives to access the care plan on a routine basis as appropriate, for instance, using technology solutions that enable real-time access for authorized users and dynamic updating by members of the care team.

*Comment:* One commenter recommended that a new subsection be added to the care planning regulations to require facilities to engage in an ongoing process of advance care planning that may include the completion of advance directives, education on the National Physician Orders for Life-Sustaining Treatment (POLST) Paradigm, and education regarding do-not-resuscitate and similar state-specific forms. This process should include assisting residents and their representatives to complete any related forms if desired.

*Response:* We thank the commenter for their recommendations but decline to add additional requirements regarding advance directives and physician orders for life-sustaining treatment at this time. We note that advance directives are currently included in the requirements for participation and we proposed revisions that were primarily to improve clarity and readability (See our discussion of § 483.10 Resident Rights). We recognize that the tools and education recommended by commenters may serve a function beyond advance directives and several of our requirements are also intended to facilitate shared, informed decision making and communication between health care professionals and residents with serious, progressive illness or frailty. We would expect that the issues that are addressed by physician orders for life-sustaining treatment would be raised in the context of advance directives as well in ongoing discussions related to care planning and keeping in mind residents' goals of care and treatment preferences. To the extent applicable, such concerns should also be reflected in resident's discharge plan and discharge summary. All physician orders are documented in a residents' care plans. We note that a few states have developed POLST programs, a few states do not have such a program, and many states are in the process of developing such programs. Consistent with State law, it would be appropriate for facilities to inform residents about POLST, as those tools are referenced and recognized within the state. We note that current requirements already require a facility to provide written information to residents that includes a description of the facilities policies with respect to advance directives and applicable State law.

Discharge Planning

*Comment:* Several commenters supported the addition of the Discharge Planning section. Commenters noted support for involving the IDT in the ongoing process of developing the discharge plan. Commenters also noted that the proposed requirements are superior to existing regulations and will help protect residents from the dangerous consequences of unexpected discharges. A few commenters indicated that discharge planning starts on the day of admission and is therefore a very time consuming and lengthy process.

*Response:* We appreciate the commenters' feedback. We believe that the proposed requirements help to highlight the importance of safe transitions across care settings and support the need to safely reduce hospital readmissions and unnecessary hospitalizations.

*Comment:* One commenter indicated that the discharge planning requirements should be revised to include transfer and discharge rights. The commenter noted that the proposed requirements may be misconstrued to authorize facilitates to discharge residents who still need LTC facility care after their Medicare coverage ends.

*Response:* Facilities are required to adhere to all of the requirements for participation set forth in subpart B. Therefore, while meeting the discharge planning requirements at § 483.21(c), facilities are also responsible for adhering to the requirements set forth in § 483.15 regarding admission, transfer, and discharge rights and the requirements set forth at § 483.10 regarding the rights of a resident and a facility's responsibility to support those rights. However, to avoid any confusion, we have added to the stem statement of § 483.21(c)(1) a cross-reference to the regulations at § 483.15 which sets forth the requirements related to transitions of care and requires facilities to establish, maintain, and implement identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment. Specifically, we have added language to indicate that a facility must develop and implement a discharge planning process that is consistent with the discharge rights set forth at § 483.15(b) as applicable.

*Comment:* One commenter requested that § 483.21(c)(1)(i) require that the discharge planning process address a resident's goals not just their needs. The commenter indicated that the revision would be consistent with Section Q of the Resident Assessment Instrument Minimum Data Set (MDS 3.0) which focuses on residents' ability and desire to return to the community.

*Response:* Regulations at § 483.21(c)(1)(vi) require that the facility's discharge planning process must also address the resident's goals of care and treatment preferences.

*Comment:* Commenters supported the need to consider the availability of family caregivers, and support persons, during the discharge planning process since these individuals are often involved in a resident's care following discharge from a facility. Commenters suggested that the regulation also require that facilities note whether an individual has a caregiver and their contact information, whether the family caregiver has voluntarily agreed to provide assistance, and whether the caregiver was provided with supports.

*Response:* We appreciate the commenters' feedback and agree that the availability of a support system is crucial following discharge from a facility. We believe that the requirement at § 483.21(c)(1)(iv) for a facility to consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs, reflects the concerns raised by the commenter. The interpretative guidelines for this final rule would be the appropriate place to discuss specific questions/discussions that can be used to engage with the resident and their caregiver during the discharge process.

*Comment:* Most commenters supported strengthening the requirements for the discharge summary and the proposal for facilities to reconcile all pre-discharge medications with residents' post discharge medications and to include this information as part of the discharge summary. The majority of commenters noted that strengthening the discharge summary will help to avoid unnecessary medication, prevent adverse drug interactions, and assist individuals and their caregivers post-discharge. One commenter questioned whether the requirement to reconcile all pre-discharge medications with a residents' post-discharge medication would be

necessary in a LTC facility, given that many individuals are there for long periods of time. The commenter suggested that this requirement would be more appropriate for a hospital. Also, one commenter noted that often ''pre-hospitalization medication'' is often inaccurate or not shared with the facility. Another commenter recommended that facilities include a rationale for all the medications that a resident is receiving in the discharge summary. The commenter notes that pre-discharge medications are often not needed and hospitals do not reconsider the need for continuing medications after discharge or advise the next facility that certain medications could potentially be stopped, reduced, or changed. Similarly, another commenter recommended that the discharge summary should also include the rationale for interventions, not just the diagnosis for interventions that a resident received. The commenter indicated that providing the rationale provides a basis for the diagnosis and not just the conclusion. Another commenter recommended that facilities be required to provide the discharge summary in a written manner that is understandable by the resident.

*Response:* We appreciate the feedback from commenters and agree that strengthening the discharge summary requirements will lead to better outcomes for residents post-discharge. We note that the discharge summary is intended to be a recapitulation of a resident's stay and final summary of the resident's status. We believe that including a rationale for the medications that a resident is receiving and the services that they received for care would be overly burdensome and unnecessary since this information is included in a resident's medical record and available upon request. In addition, regulations at § 483.10(g) of this final rule discuss the extensive requirements that facilities must meet related to providing residents with information. Specifically, the regulations require the facility to ensure that information is provided to each resident in a form and manner that the resident can access and understand, including in an alternative format or in a language that the resident can understand. These requirements would have to be met by the facility in regards to the discharge summary; therefore we believe the need to provide the discharge summary in a written manner that is understandable by the resident is already covered in the regulations.

We note that while some residents may reside in the facility for lengthy periods, that is not always the case. Our regulations are developed in an effort to address the varying services provided by a LTC facility and the different individuals that may reside in the facility. We have not required facilities to reconcile ''pre-hospitalization medication'' but rather those medications a resident was prescribed prior to being discharged from the facility to those they are prescribed when leaving the facility. We expect that this information is readily available and is maintained as a standard practice by a facility in order to provide sufficient care.

*Comment:* One commenter indicated discontent with the requirements added by the IMPACT Act, stating that the requirement is problematic and unenforceable. Also the commenter noted that it would not be practical or pertinent to use the data mandated by the IMPACT Act. The commenter noted further that the most pertinent information to provide to residents and families about facilities they are being transferred to should include actual experience with care provided, such as case reviews of individuals sent to the facility. The commenter also questioned whether there could be a conflict of interest in requiring facilities to recommend others. Furthermore, the commenter questioned how facilities should use the data to inform residents and how surveyors should judge whether facilities have done so adequately.

*Response:* We appreciate the feedback from the commenter and agree that additional information may prove to be valuable to residents and their families for purposes of effectively transitioning from one care setting to another. However, we have proposed the requirements specifically mandated by the IMPACT Act. Facilities have the flexibility to present residents with additional information as long as the statutory requirements are met. Once the requirements of the IMPACT Act are implemented we may consider additional ways to improve the information that residents receive. We expect that facilities will not use the data to recommend facilities, but rather present the data to residents and their families in order to assist them in making an informed decision regarding the selection of a post-acute care provider. We note that the data presented must be based on the individual goals and preferences of the resident. In addition, we expect that facilities will demonstrate compliance with this requirement by showing evidence that the relevant data was presented to a resident and their family for consideration. As with any regulation, this final rule will also have sub-regulatory guidance that provides additional resources for how these requirements can be met by facilities.

*Comment:* A few commenters questioned whether the IMPACT Act requirements at proposed § 483.21(c)(1)(viii) apply to SNFs only or both Medicare certified SNFs and Medicaid certified NFs. Another commenter recommend that the statement at proposed § 483.21(c)(1), ''transition of the resident from SNF to post-SNF care'', be revised to include NFs also.

*Response:* The IMPACT Act specifically refers to requirements for SNFs and at this time we are aligning our regulations with the statute. Following the implementation of the IMPACT Act we may consider how these requirements may also be applied to NFs. We note that the all of the requirements in § 483.21(c) apply to both SNFs and NFs with the exception of those requirements related specifically to the IMPACT Act at § 483.21(c)(1)(viii). Therefore, to improve clarity, we have revised the text at § 483.21(c)(1) by removing the reference to ''post-SNF care''. We believe that this revision clarifies that the discharge planning process must focus on all residents.

*Comment:* One commenter indicated that facilities should be required to assist, if requested, with tasks necessary for relocation, such as making phone calls, packing, and obtaining prescriptions.

*Response:* As part of the discharge summary, regulations at § 483.21(c)(2)(iv) require that resident's receive a post-discharge plan of care that is developed with the resident, which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the resident plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services. We believe that it would be overly burdensome for facilities to also be required to assist residents with relocation tasks such as packing. In addition, we do not consider packing and other relocation tasks to be ''health services'' within the meaning of the Act and therefore these tasks would not be covered under Medicare and Medicaid.

*Comment:* One commenter indicated that residents should be provided with copies of their discharge plans and the evaluation of the resident's discharge needs.

*Response:* Existing regulations provide residents with the right to

obtain copies of their medical records, which would include their discharge plan. Specifically, the regulations at § 483.10(g) discuss the extensive requirements that facilities must meet related to providing residents with information. In this final rule the regulations require facilities to allow the resident to obtain a copy of their medical records or any portions thereof (including in an electronic form or format when such medical records are maintained electronically) upon request and 2 working days advance notice to the facility. In addition, while we are not requiring the facility provide the resident with a copy of the discharge plan, existing provisions require the facility to provide the resident with a discharge summary when discharge is anticipated, including the post-discharge plan of care (see § 483.21(c)(2) of this final rule).

*Comment:* One commenter indicated that § 483.21(c)(2)(iv) should be revised to not limit the additional individuals that may be included in the development of the post-discharge plan of care to just a resident's family. The commenter suggests revising the language to state that a resident's representative or family (as defined by the resident) should be involved.

*Response:* We have removed the language ''his or her family.'' The text § 483.21(c)(2)(iv) is revised to ''a post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative (s), which will assist the resident to adjust to his or her new living environment.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- At § 483.21(a), we have clarified that the facility must implement the baseline care plan.
- At § 483.21(a)(3), we have added a new requirement that facilities must provide residents and their representatives with a summary of their baseline care plan.
- At § 483.21(b), we have clarified that the facility must implement the comprehensive person-centered care plan.
- At § 483.21(b)(1), we have replaced the word ''timetables'' with ''timeframe.''
- At § 483.21(b)(2)(ii)(E), we have removed the requirement for a social worker to participate on the IDT.
- At § 483.21(c)(1), we have added that a facility must develop and implement a discharge planning process that is consistent with the discharge rights set forth at § 483.15(b) as applicable. We have also removed the reference to ''post-SNF care'' to clarify that the discharge planning process applies to both SNFs and NFs.
- At § 483.21(c)(2)(iv), we have removed the language ''his or her family'' and replaced it with ''the resident representative(s).''

*K. Quality of Care and Quality of Life (§ 483.25)*

Current regulations at § 483.25 establish requirements for numerous aspects of care and special needs of LTC facility residents under the general heading of ''Quality of Care.'' Quality of Care and Quality of Life are two separate and overarching principles in the delivery of care to residents of LTC facilities. We proposed to comprehensively revise and re-organize the current § 483.25 to ensure person-centered, quality care and quality of life for this vulnerable population.

First, we proposed to retitle this section ''Quality of Care and Quality of Life'' and revise the introductory paragraph to reiterate the requirement that each resident must receive and the facility must 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.

Second, in § 483.25(a), we proposed to address the residents' ability to perform activities of daily living (ADLs) and establish that, based on the comprehensive assessment of a resident and consistent with the resident's needs, choices, and preferences, the facility must provide the necessary care and services to maintain or improve, to the extent practicable, the resident's abilities to perform his or her activities of daily living and to ensure that those abilities do not diminish unless the diminution is unavoidable as a result of the individual's clinical condition. We proposed to divide the requirements of existing § 483.25(a)(1) into proposed § 483.25(a) and (b). We proposed to re-designate existing paragraphs § 483.25(a)(2) and (a)(3) as § 483.25(a)(1) and (a)(2), respectively. We proposed to add a new § 483.25(a)(3) to clarify that a facility must ensure that appropriate personnel provide basic life support, including cardiopulmonary resuscitation (CPR) to a resident requiring this emergency care prior to the arrival of emergency medical personnel and subject to accepted professional guidelines and the resident's advance directives.

In § 483.25(b), we proposed to establish those activities that we include as ADLs. These activities are currently listed in § 483.25(a)(1)(i) through (v). We proposed to update the language of that list, although the underlying activities remain unchanged. We proposed to establish as ADLs: (1) Hygiene, such as bathing, dressing, grooming, and oral care; (2) mobility, which includes transfers and ambulation; (3) toileting and use of the bathroom; (4) dining, including eating meals and snacks; and (5) communication, including speech, language and other functional communication systems.

In § 483.25(c), we proposed to relocate the current requirements related to an activities program as required in existing § 483.15(f). We proposed to revise the language to include a required consideration of the comprehensive assessment, care plan and the preferences of the resident as well as potential for independence and ability to interact with the community.

We also proposed a new § 483.25(d), ''Special Care Issues,'' which we revised, re-located, and added requirements for specific special concerns, including restraints; bed rails; vision and hearing; skin integrity; mobility; incontinence; colostomy, ureterostomy, or ileostomy; assisted nutrition and hydration; parenteral fluids, accidents, respiratory care, prostheses, pain management, dialysis, and trauma-informed care. As many of the concerns in this section were previously included in § 483.25, we discuss here only the provisions we proposed to add or modify.

Specifically, we proposed to re-designate and revise § 483.13(a), ''Restraints,'' as § 483.25(d)(1). In the proposed rule, we indicated that while we prohibit the use of any physical or chemical restraint not required to treat the resident's medical symptoms in the introductory language to proposed § 483.12, in proposed § 483.25(d)(1), we require that the facility ensure that residents are free from restraints that are imposed for purposes of discipline or convenience, in addition to ensuring that residents are free from restraints not required to treat the resident's medical symptoms. In addition, we proposed to add new requirements to specify that, if used, restraints must be the least restrictive alternative for the least amount of time. Further, documentation of ongoing evaluation of the need for the restraints is required.

We proposed a new § 483.25(d)(2) to establish specific requirements when a facility uses bed rails on a resident's bed. Specifically, we proposed to require that the facility ensure correct installation, use and maintenance of bed rails, including attempting to use alternatives prior to installing a side or

bed rail, assessing the resident for risk of entrapment from bed rails prior to installation, reviewing the risks and benefits of bed rails with the resident and obtaining informed consent prior to installation, ensuring that the resident's size and weight are appropriate for the bed's dimensions, and following the manufacturers' recommendations and specifications for installing and maintaining bed rails.

We also proposed to revise existing language at § 483.25(c) and § 483.25(k)(7) and re-designate them under a new § 483.25(d)(4), ''Skin Integrity.'' In this section, we proposed to revise the language to include a statement that care must be consistent with professional standards of practice and to clarify that foot care includes care to prevent complications from the resident's medical conditions such as diabetes, peripheral vascular disease, or immobility, and also includes assistance in making and keeping necessary appointments with qualified healthcare providers such as podiatrists.

In § 483.25(d)(5), we proposed to address mobility both range of motion and other limitations of mobility. We proposed to retain, unchanged, the provisions related to range of motion, but to add a new provision to require that residents with limited mobility receive appropriate services and equipment to maintain or improve mobility unless reduced mobility is unavoidable based on the resident's clinical condition.

In § 483.25(d)(6), we proposed to retain existing provisions on urinary incontinence, add a new § 483.25(d)(5)(B) to address residents who are admitted with an indwelling urinary catheter, and add a new § 483.25(d)(6)(iii) to require that residents with fecal incontinence receive the appropriate treatment and services to restore as much normal bowel function as possible. We proposed to retain, unchanged, colostomy, ureterostomy, and ileostomy care in § 483.25(d)(7). In § 483.25(d)(8), we proposed to modify existing provisions on nasogastric tubes to reflect current clinical practice and to include enteral fluids. Other methods of providing assisted nutrition are now common practice. Therefore, we proposed to include gastrostomy tubes with nasogastric tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy. We also proposed to include in this paragraph requirements regarding both assisted nutrition and hydration and specify that the facility must ensure that the resident maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and protein levels, unless the resident's clinical condition demonstrates that this is not possible and that the resident receives sufficient fluid intake to maintain proper hydration and health. Additionally, we proposed to modify the requirement for a therapeutic diet to require that the resident is offered a therapeutic diet when appropriate, recognizing that the resident has a right to choose to eat a therapeutic diet or not. Finally, we proposed to specify that based on the comprehensive assessment of a resident, the facility must ensure that a resident who has been able to eat enough on his or her own or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and a resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding.

In § 483.25(d)(9), we proposed to address only parenteral fluids. We included enteral fluids in § 483.25(d)(8), our proposed provisions on assisted nutrition and hydration, as discussed earlier.

We proposed to add a new § 483.25(d)(13) to ensure that residents receive necessary and appropriate pain management. We proposed that the facility, based on the resident's comprehensive assessment and choices, must ensure that residents receive treatment and care for pain management in accordance with professional standards of practice.

We also proposed to add a new § 483.25(d)(14) to ensure that residents who require dialysis receive those services in accordance with professional standards of practice and the residents choices.

We further proposed to add a new § 483.25(d)(15) to ensure that trauma survivors, including Holocaust survivors, survivors of abuse, military veterans with post-traumatic stress disorder, and survivors of other trauma receive care that addresses the special needs of trauma survivors. Specifically, we proposed to require that facilities ensure that residents who are trauma survivors receive care and treatment that is trauma-informed, takes into consideration the resident's experiences and preferences in order to avoid triggers that may cause re-traumatization, and meet professional standards of practice.

Finally, we proposed to revise and relocate to § 483.45, ''Pharmacy services'', the provisions related to unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations. These provisions are further discussed later in our section on pharmacy services.

*Comment:* Some commenters support our proposed changes to § 483.25, particularly requiring facilities to take into account a resident's comprehensive assessment, their preferences and choices in activities program and to provide activities that are designed to encourage independence and interaction in the community; and including oral care as a component of a basic hygiene activity of daily living (ADL). One commenter particularly supports proposed regulatory revisions related to nasogastric tubes and assisted nutrition and hydration and notes the importance of nutritional assessment, nutrition and hydration, and eating assistance to the physical and emotional well-being of residents. The commenter further supports sufficient regulatory flexibility to enable incorporation of new theories and emerging research into practice. One commenter recommended more specificity related to the use of nasogastric tubes. Other commenters support the addition of CPR, oral care, fecal incontinence, foot care, mobility, pain-management and/or trauma informed care.

*Response:* We thank the commenters for their support. In our proposal, we added requirements that support person-centered care as well as those that support the resident in attaining or maintaining his or her highest practicable well-being.

*Comment:* Many commenters objected to our restructuring of this section and felt that it was very important that quality of life be recognized in its own regulatory section. One commenter strongly opposed combining Quality of Life and Quality of Care into a single requirement, believing that it would distort and erase the focus on quality of life intended by the Nursing Home Reform Law. One commenter suggested we restore Quality of Life as its own section that includes language from the beginning of proposed rule § 483.11; (treat each resident with respect and dignity, etc.); self-determination language from proposed rule § 483.11(e); social services provisions (proposed rule § 483.40(d)); and safe environment language (proposed rule § 483.11(g), in addition to the language in the proposed rule about activities. One commenter believed that the proposed rules diluted the strength and power of the current quality of care regulations and recommends we keep totally intact the quality of care regulations as a separate

requirement. Another commenter stated that deleting quality of life sends a strong message that quality of life is not essential. Some commenters stated that they are troubled by the fact that CMS has scattered the provisions included in the current Quality of Life section throughout the proposed regulations and the only provision remaining in the proposed Quality of Care and Quality of Life section is proposed § 483.25(c), ''Activities''. These commenters object to, for example, moving requirements about unnecessary drugs to the section on pharmacy services. These commenters recommend that Quality of Life be restored as its own section that includes language from self-determination (proposed § 483.11(e)), social services (proposed § 483.40(d)), and safe environment (proposed § 483.11(g)).

*Response:* We have retained our proposed restructuring that moves the statements of resident rights previously contained in the Quality of Life section to the Resident rights section, § 483.10. This section now also includes all of the provisions in proposed § 483.11, Facility responsibilities. However, we have separated quality of life and quality of care by establishing a new § 483.24, Quality of life, which will establish quality of life as a separate overarching principle in the delivery of care to residents of LTC facilities. Section 483.24 contains proposed § 483.35(a), (b), and (c), which addresses requirements related to activities of daily living, basic life support, and activities programs. Proposed § 483.25(d), special care issues, is retained in § 483.25, ''Quality of care''. With regard to other specific sections, please also see our discussions at sections N. ''Behavioral health services'' (§ 483.40) and O. ''Pharmacy services'' (§ 483.45) of this preamble.

*Comment:* Some commenters suggested CMS require additional training topics related to quality of care and quality of life for facility staff. One commenter also recommended that facilities be required to use a standardized care needs assessment tool that the public has an opportunity to comment on prior to adoption. The commenter recommends that this tool should include a specific space for facility staff to document why the loss of functioning was ''demonstrably unavoidable''; and facility should set up an internal review process that reviews this section to determine if more training is needed on conditions that could have been improved or maintained with current standards or assistive technology or mental health services and supports.

*Response:* Please see our discussion of § 483.95 in section Z. of this preamble for comments and responses related to training, including recommendations for additional training topics.

*Comment:* A number of commenters felt that CMS should further address staffing. One commenter stated that residents cannot maintain or improve their highest level of well-being without good staffing practices and stated that CMS should reinforce the need for strong staffing practices in the proposed rule. Commenters suggest that good staffing practices include adequate numbers of competent, consistently assigned staff working well with the whole care team. Some commenters suggested mandating consistent or dedicated staffing. One commenter suggested regulatory language requiring staffing practices that maximize competency, continuity, and coordination of care.

*Response:* Please see section K. ''Nursing services'', for our discussion of staffing.

*Comment:* Some commenters recommend wording changes to make the language less institutional.

*Response:* We have reviewed and considered each suggested wording change, but do not address each one individually. Where we felt the wording change improved clarity, we have accepted it. In one case, we added the term ''walking'' in addition to the word ''ambulation'' rather than as a replacement because, while ''walking'' is a less institutional term and therefore may be preferable, ''ambulation'' has other meanings, such as in reference to a resident in a wheelchair, where it means the ability to move around.

*Comment:* One commenter expresses concerns about ''odd terminology'', stating that CMS gives ''titles'' to activities of daily living (ADLs), proposed § 483.25(b)—for example, ''hygiene'' to refer to bathing, dressing, grooming, and oral care. The commenter stated that the term ''hygiene'' does not provide further explanation of the requirements and interferes with ease of reading and understanding. The commenter further suggests that the new modifiers for activities of daily living are unnecessary and should be deleted.

*Response:* We believe the titles are useful to group similar activities and have retained them as proposed.

*Comment:* One commenter stated that moving ''activities'' at proposed § 483.25(b) from ''quality of life'', § 483.15(f), to this new section, with its broader language, is not objectionable, but listing professional credentials in this regulation is odd. The commenter stated that all requirements for staff credentials should be located in a single section and recommended that we retain proposed § 483.25(b)(1), but move proposed § 483.25(b)(2) to a new section addressing staff credentials. Another commenter supported language added to this section regarding an ongoing program to support residents in their choice of activities, both group and individual, and the requirement for a facility to encourage independence and interaction in the community.

*Response:* We often list credentials for specific staff in the sections that address the care the staff provide. For example, we do this for Food and Nutrition Services, Infection Control, and for certified nursing assistants under Nursing Services. We believe it is appropriate to include the credentials for an Activities Director in the section where the activities program is addressed. However, we will evaluate the suggestion for a single section to address all staff credentials and consider it for future rule-making.

*Comment:* Many commenters recommended that we add board certified music therapist to the list of qualified professions who could serve as an activities program director. These commenters stated that the educational requirements for a music therapist prepare them to become excellent activities directors. Others suggested that an individual with a Master's degree in gerontology or aging studies, or other degree-based qualifications, be added to the list of qualified professionals who could serve as an activities program director. Some commenters did not want us to change the requirements, fearing that this would eliminate qualified candidates. Some commenters wanted to ensure that we did not change the requirements to specify a specific recognized accrediting body, while others suggested specifying a specific recognized accrediting body. Additional suggestions and options were offered as well.

*Response:* We thank all the commenters for responding to our solicitation of comments regarding whether the requirements for the director of the activities program remain appropriate and what should serve as minimum requirements for this position. We have reviewed all of the comments and believe we need additional time to further evaluate the many suggestions we received. We are not making any changes at this time.

*Comment:* A commenter felt that the section on ADLs needed an introductory statement as to the expectations for the facility related to the ADL list.

*Response:* We have added introductory language to state that the

facility must provide care and services in accordance with paragraph (a) for the listed activities of daily living

*Comment:* One commenter stated that in proposed § 483.25(d) CMS has gathered an odd collection of care concerns and labeled them as ''special care issues,'' some of which are issues common to most residents while other issues are truly ''special,'' in the sense of less common. The commenter recommends that care requirements common to all or most residents should be separately identified, without the modifier of ''special care needs'' and the term ''special care issues'' should be restricted to issues that are truly special, in the sense of uncommon. The commenter suggests that the subsections under the ''Quality of Care'' requirement should be retained in the order that they are in current § 483.25 and language in proposed § 483.25(a) should be incorporated into the preliminary language of the regulation so that the current order can be retained.

*Response:* In order to more clearly express our intention, we have eliminated the modifier ''special care needs'' and revised this section in consideration of this and other comments.

*Comment:* Some commenters felt that CMS should provide more information/clarification related to colostomy, ureteostomy, or ilesostomy; parenteral fluids; prosthesis; pain management; and dialysis. In addition, two commenters stated that ''urostomy'' is the correct terminology and should be used instead of ureterostomy.

*Response:* We thank the commenter for their suggestion. We have changed ''ureterostomy'' to ''urostomy.'' We have also added language to final sections (f) ''Colostomy, urostomy, or ileostomy care,'' (h) ''Parenteral fluids,'' (j) ''Prostheses,'' (k) ''Pain management,'' and (l) ''Dialysis.'' For each section, we have specified that care must be provided consistent with professional standards of practice applicable to that care. We defer to sub-regulatory guidance for additional detailed discussion.

*Comment:* Some commenter suggested CMS add other documents besides advance directives to the requirements relating to providing basic life support.

*Response:* We have added related physician orders to paragraph (a)(3). We defer to sub-regulatory guidance for additional discussion.

*Comment:* One commenter requested that CMS clarify that, where CMS proposes that a resident receive care that is consistent with professional standards of practice, a standard of care that is ''consistent with professional standards of practice'' is not to be interpreted as a maximum standard or to limit care options for residents with complex conditions or unique needs. The commenter urged CMS to clarify that when providing care that is consistent with professional standards of practice, the care also take into account individual residents' needs and complexity of individual residents' conditions.

*Response:* The requirement that that care be provided in accordance with professional standards of practice is neither a maximum standard nor a limitation on care options. We would expect the resident and/or his or her representative to be informed about care and treatment as required by § 483.10(c), as contained in the comprehensive care plan. The care and services provided to the resident must be provided in a manner that meets the professional standards and principles that apply to such care and services and to the professionals that provide those services.

*Comment:* One commenter stated that some provisions are already incorporated into the current survey process and can be implemented one year following adoption of the final rule, including proposed § 483.25(a)(3), and (d)(13).

*Response:* We deliberately included a number of provisions in the regulations that were previously in sub-regulatory guidance as we felt that doing so strengthens the requirements for some very important issues. Please refer to our discussion in Section B, Implementation, for additional information.

*Comment:* Some commenters expressed concern that facilities would have to hire additional staff in order to meet proposed requirements that residents be assisted to make appointments and to arrange for transportation to appointments.

*Response:* While we have revised and reorganized this section, the requirement to provide residents with assistance in making appointments and arranging transportation is an existing obligation. Similarly, while prior regulations did not explicitly require that facilities assist individuals to make podiatric appointments, facilities were already required to ensure that residents received proper treatment and foot care. Furthermore, we understand that some facilities have arrangements to provide these services on site, providing added comfort and convenience for residents while negating the need for at least some work to make transportation arrangements. We do not agree that our revised requirements impose a significant new burden.

*Comment:* Several commenters commented on our proposed requirements regarding bed rails. One commenter stated that proposed § 483.25(d)(2), as written, declares that the existence of a side or bed rail is a deficient practice and recommends we amend the provision to read ''engaging'' a side or bed rail rather than ''installing'' a side or bed rail. The commenter stated that deficient practice is reflected by not implementing/attempting alternatives prior to the use or engagement of a side or bed rails. Another commenter was concerned that this provision lacks adequate qualifiers to all for various real-life situations and puts the facility in violation of the requirement when no viable alternative exists and suggests specific revisions to the regulatory language. Other commenters recommended extensive provisions addressing bed rails as restraints and the criteria to use bed rails when not used as a restraints. Some commenters objected to our including requirements related to bed rails. One stated that there was no clinically justifiable reason to use bed rails. Others stated that few LTC facilities use bed rails. Other commenters stated that some beds have quarter rails to house the bed and TV controls and it would be burdensome to take these on and off as residents are admitted and discharged. Many commenters supported the requirement that facilities try alternatives to bed rails.

*Response:* We thank the commenters for their suggestions and support. Proposed paragraph (2) sets out several requirements to be met before the bed or side rail is installed. We believe these requirements are important for resident safety before installation can create an expectation of use. We have re-designated this as paragraph (n) and, based on a combination of commenter suggestions, revised it to require that the facility must attempt to use appropriate alternatives prior to installing a side or bed rail, then to require that if a side or be rail is used, such use must meet specific requirements. In addition, we have reworded the provision so that the bed's dimension is appropriate for the resident's size and weight rather than the resident's size and weight being consistent with the bed's dimension, as recommended by a commenter. We defer additional discussion to sub-regulatory guidance. We expect that surveyors will conduct a fair and consistent review of these situations based on the facts of each case.

*Comment:* One commenter objected to the addition to proposed § 483.25(d)(8)(i) of ''or resident preferences indicated otherwise'' and recommended we delete it. The commenter was concerned that a facility could use this as a means to not meet a resident's nutritional needs. The commenter stated that the facility would need to demonstrate that it served nutritious and appetizing food; identified the resident's food preferences; offered appropriate alternative foods to the resident; had sufficient numbers of trained staff to assist the resident in eating; maintained a pleasant environment for meals; provided assistive devices, as needed; addressed the resident's mental health needs; had received a medical determination from the resident's physician that the resident's medical condition indicated that weight loss was unavoidable; and took other necessary steps before it could justify not meeting a resident's nutritional needs.

*Response:* This provision addresses assisted nutrition and hydration, and, like all treatments, residents have the right to accept or refuse. Accepting a resident's refusal, or deferring to their documented preferences, does not absolve a facility of its responsibilities to provide adequate nutrition or permit the facility not to meet a resident's nutritional needs. It does recognize that a competent resident has the right to make choices about assisted nutrition and hydration and that there are circumstances where failure to maintain acceptable parameters of nutritional status are not a reflection of failure(s) of care.

*Comment:* Several commenters supported our proposal to add trauma-informed care at § 483.25(d)(15). Some commenters suggested additional related requirements, including adopting trauma informed care approaches, and requiring facilities to provide training regarding trauma informed care to all staff at all levels. Some commenters recommended deleting this provision entirely. One commenter stated that providing ''trauma-informed care'' is prudent and extremely important for those individuals who have experienced trauma in their lives and continue to live with residual effects from these experiences, but had several concerns about the requirement. The commenter noted that the link to the SAMHSA guidance does not work, and furthermore, SAMHSA's mission is focused on recovery and resilience. In addition, the reference to utilizing ''professional standards of care'' does not provide specific professional standards of care for individuals who are trauma survivors. Without specific identification of recognized and acceptable standards, determining compliance with this requirement will be varied and subjective. Furthermore, there was no clear definition provided for the term ''culturally competent care.'' Another commenter stated that there are other issues and concerns that are equally or more important to other individuals with other conditions that are not specified in regulation or mentioned in guidance.

*Response:* Culturally-competent and trauma-informed care are approaches that help to minimize triggers and re-traumatization, including care that addresses the unique needs of Holocaust survivors and survivors of war, disasters, and other profound trauma are an important aspect of person-centered care for these individuals. We noted in the proposed rule that 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*, would help advance the quality of care that a resident receives and, in turn, can substantially improve a resident's quality of life. We were able to access this document via the link provided; alternatively, it is available through the SAMSHA.gov Web site by clicking on ''publications'' on the upper right and searching for SMA 14–4884. As discussed in our comments and responses section H, ''Comprehensive Care Planning,'' we do not believe that a definition of trauma-informed care should be added to the ''Definitions'' section, but note that the interpretative guidelines and the resource noted previously will provide further information regarding culturally-competent and trauma-informed care. In addition, as with all of our requirements, surveyors will use uniform sub regulatory guidance and surveyor training will be provided to promote consistent enforcement. Please see our discussion of trauma-informed care in section J. ''Comprehensive care planning.'' We note in the comments and response for that section that one commenter provided resources for facilities to refer to for information and material addressing culturally competent and trauma-informed care. The resources include The Council on Social Work Education (see *http://www.cswe.org*), NASW's standards and indicators for cultural competence available at *http://www.socialworkers.org/practice/standards/index.asp*, and The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care developed by the Office of Minority Health in HHS (see *https://www.thinkculturalhealth.hhs.gov/index.asp*).

*Comment:* One commenter recommended we amend the requirement to provide trauma-informed care, § 483.25(d)(15), to say ''When a facility is aware that a resident/patient is a trauma survivor, the facility must ensure these residents/patients receive care that takes into account the residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.''

*Response:* We do not agree with adding the qualifier ''when a facility is aware'' nor do we agree with deleting reference to culturally competent, trauma-informed care in accordance with professional standards of practice. Please see our earlier discussion in this section as well as the discussion in section J, ''Comprehensive Care Planning.''

*Comment:* One commenter suggested that any requirements related to trauma-informed care have a 5-year phase in period.

*Response:* Please see our discussion of implementation deadlines in section II.B, ''Implementation.''

*Comment:* One commenter stated that the current regulation, at § 483.25(c)(1), begins with the statement that the resident who enters the facility without pressure ulcers should not develop them unless the resident's clinical condition demonstrated that they were unavoidable, but the proposed § 483.25(d)(4)(i)(A) omits that language entirely, beginning with the requirement that the facility provide care to prevent development of pressure ulcers. The commenter stated that current language should be restored as a new (A) with the proposed subsections (A) and (B) moved to (B) and (C), respectively.

*Response:* The commenter is correct that the proposed language omits the statement ''the resident who enters the facility without a pressure ulcer.'' The remaining language is included in the proposed provision. Any resident at any time who does not have a pressure ulcer, even if the resident had one upon admission and it has resolved, must receive care and services to prevent the formation of pressure ulcers unless the resident's clinical condition demonstrates that the development of pressure ulcers was unavoidable. Similarly, any resident who has a

pressure ulcer, no matter when or why it developed, must receive care and services to promote healing, prevent infection, and prevent new ulcers from developing.

*Comment:* One commenter stated that proposed paragraph (d)(5) mobility should be correctly title ''range of motion'' as in the current rule.

*Response:* We disagree. Range of motion, defined as the full movement potential of a joint, is important to mobility, but it does not encompass the full extent of the proposed provision. Proposed paragraph (d)(5) includes in (i) and (ii) requirements to ensure that a resident does not lose range of motion and, if the resident has a limited range of motion, receives services to, at a minimum, maintain existing range of motion and, if feasible, to improve range of motion. The proposed provision goes on to address mobility, defined as the ability to move, and to require that residents with limited mobility receive appropriate services to maintain or improve his or her mobility. Each of the three provisions is about a resident's ability to move, thus we have included them together is a provision about mobility.

*Comment:* A number of commenters expressed concern about our provisions related to the use of restraints in facilities. One commenter stated that although new language about using the least restrictive alternative for the least amount of time and documenting ongoing evaluation of the need for the physical and chemical restraints was helpful, the proposed regulation does not adequately protect residents. Several commenters suggested a separate section specifically addressing restraints. Some commenters recommended additional requirements such as reporting any death which may have resulted from the use of a restraint; an environmental assessment; an in-person evaluation by a physician; informed consent; an in-person evaluation by the resident's physician; one-on-one monitoring; or release and monitoring when the use of restraints is indicated. Some commenters noted that there are more extensive requirements for other provider types (community mental health centers, hospitals). Some commenters requested that we explicitly include bed rails as restraints and strengthen our provisions related to bed rails. Some commenters suggested we only allow the use of bed rails if the resident requests them for mobility or other assistance and any time a bed rail is considered, a safety assessment be conducted using protocols that require an evaluation of residents and bed systems by an interdisciplinary team that includes specific professional staff. Some commenters requested that regulations more explicitly address chemical restraints and that we specifically address the use of wheelchairs as a restraint. One commenter suggested we relocate requirements related to restraints and bed rails to the section on facility responsibilities because inclusion here could imply they were a special treatment or care. The commenter also recommended addressing bed rails as restraints because not doing so implies that bed rails are not restraints. One commenter stated that restraint should be a requirement separate from quality of care because restraints are not an appropriate method for providing care. Other commenters discuss restraints in the context of trauma-informed care.

*Response:* We acknowledge the commenter's concern that including restraints in this section could create an impression that the use of restraints is acceptable. We have relocated this provision to § 483.12(a) and added a cross reference to § 483.12(a)(2) in § 483.10(e)(1) to ensure that the resident's right to be free of restraints is considered in the context of the requirement now in § 483.12(a)(2). We will continue to review our provisions related to restraints and will consider adding additional, more prescriptive requirements through future notice and comment rule-making.

We considered similarly relocating our provision regarding bed rails, but do not believe that these requirements as clearly belong in § 483.12. Therefore, we have retained this provision as § 483.25(n).

*Comment:* One commenter suggested we retain assisted nutrition and hydration, prostheses, dialysis, and trauma-informed care as special care issues and move the rest of the issues to another part of the section.

*Response:* We thank the commenter for their suggestion. We have modified this section based on other comments, however, believe it is appropriate to retain all of the proposed requirements in the section.

*Comment:* One commenter recommended adding a separate section on honoring sleep.

*Response:* We thank the commenter for their suggestion. We currently address sleep and wake times at § 483.10(f)(1). We defer additional discussion to sub-regulatory guidance.

*Comment:* Commenters supported the added specificity of proposed requirements regarding skin integrity, foot care, incontinence, and enteral feeding.

*Response:* We thank the commenter for their support. We believe the proposed additions will assist in ensuring that LTC facility residents receive necessary care.

*Comment:* One commenter suggested that in proposed paragraph (d)(4) we clarify that the standard is professional current clinical standards of practice.

*Response:* We do not agree that this clarification is necessary. The statement ''professional standards of practice'' applies whether or not the issue is clinical, as in direct care delivery, or non-clinical, such as some administrative or physical plant concerns might be considered. In addition, ''professional standards of practice'' inherently means the professional standards that apply at the time that the care or service is delivered.

*Comment:* Some commenters supported our proposed provision (d)(6) regarding incontinence. One commenter stated that the urinary tract includes more than just the bladder (that is, kidneys, ureters, urethra, prostate) and that various conditions and factors (for example, delirium, metabolic disorders, functional impairments, diuretic use) may affect continence. The commenter suggested that proposed (d)(6)(ii)(C) be revised to more accurately reflect that the goal is to try to improve continence by stating that the resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible. Another commenter suggested we require that if a resident becomes incontinent, a determination regarding why be made. A different commenter recommended requiring that a resident's bathroom needs be anticipated and met to reduce the development of incontinence on because the resident did not get the help she or he needed to get to the bathroom on time.

*Response:* We thank the commenters for their suggestions. We have modified proposed § 483.25(d)(6)(ii)(C), finalized at paragraph § 483.25(e)(2)(iii), to focus on continence as suggested. We require that a resident who is continent of bladder receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain. We believe that in order to meet this requirement, both assistance to use the bathroom to prevent incontinence in a continent resident and an assessment of the cause of new incontinence would be necessary. We defer additional discussion to interpretive guidance.

*Comment:* One commenter noted that nutrition status is complex and

recommended revising paragraph (d)(8) to include total parenteral nutrition, to eliminate protein levels as a parameter of nutritional status based on recent research, to add electrolyte balance as a co-equal concern to hydration, and to add the qualifier ''unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise.'' The commenter stated that serum protein levels have significant limitations as a parameter of nutritional status and should not be listed as a measure. The commenter further stated that hydration maintenance is about more than just providing fluids, and should consider electrolyte balance as well and that some dehydration is unavoidable such as occurs with residents on palliative care who are not eating and drinking. Another commenter stated that this proposed provision inappropriately combines two existing sections, mislabeling them, and minimizing the critical importance of nutrition and hydration for residents. The commenter stated that CMS should restore the original two separate regulatory requirements.

*Response:* We thank the commenters for their suggestions and agree that nutrition status is complex. We have eliminated the requirement for protein levels and added electrolyte balance. We believe it is appropriate to address parenteral fluids separately, as this involves the intravenous infusion of fluids. We also believe the requirements, as proposed, acknowledge the potential for unavoidable variations and recognize the resident's right to refuse treatment. We defer any additional discussion to sub-regulatory guidance. We disagree that nutrition and hydration should be two separate sections. Fluids are a source of nutrition and food is a source of hydration.

*Comment:* One commenter stated that the proposed change in § 483.25(j) from providing sufficient fluids to offering sufficient fluids is objectionable.

*Response:* This change was proposed in response to anecdotal accounts of fluids being placed in a resident room without ensuring that the resident was actually able to drink them. While residents' have the right to refuse to drink the fluids, it is not enough for a facility to simply place fluids in a resident room. We would expect that the fluids actually be offered to the resident and assistance provided so that the resident can drink, if they so desire.

*Comment:* One commenter recommended that proposed § 483.25(c) be amended to read: ''Based on the comprehensive assessment and care plan and the preferences of each resident, the home/community must provide ongoing opportunities for engagement with life or meaningful engagement via group, individual and independent opportunities designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.'' This change in language would remind everyone that individual resident preferences for engagement in meaningful ways should be identified and followed.

*Response:* We agree and thank the commenter for their support. We have incorporated the commenter's suggestion and are finalizing this provision at § 483.24(c)(1).

*Comment:* One commenter suggested addressing the use of personal bed, chair, floor mat and laser alarms as devices with restraint qualities.

*Response:* We discuss alarms in section E of this preamble. As noted there, if such devices are used as restraints, their use must comply with our requirements related to restraints.

*Comment:* One commenter requested that we clarify that a new intervention is not required after each fall or incident, but that a root cause analysis should be conducted.

*Response:* We agree that the response to a fall or incident should be episode specific, that a new intervention may not always be necessary, and that frequently a root cause analysis will be necessary. We defer to sub-regulatory guidance for additional discussion.

*Comment:* One commenter supported our proposed change that a resident be offered a therapeutic diet instead of mandating a therapeutic diet.

*Response:* We thank the commenter for their support and note that this change is consistent with our person-centered approach.

*Comment:* Some commenters suggested that CMS address wheelchair use, including need, premature use, a plan of care for maintaining strength and mobility, and other concerns.

*Response:* We thank the commenter for these suggestions. We believe that these issues should be addressed in the person-centered plan of care. However, we will further evaluate these concerns and consider them for inclusion in future notice and comment rule-making.

*Comment:* Some commenters requested that we add a new section to special care issue to address dementia care. Others suggested that requirements for dementia care be added to the quality of care requirements. Commenters offered suggestions for such a section, including current language from sub-regulatory guidance.

*Response:* We thank the commenters for these suggestions. We considered, but did not propose dementia-specific provisions for this rule. We agree that residents with dementia have specific needs as a result of their disease. Resident rights, person-centered care planning, and other provisions of this subpart work together to require that the individual's needs be met. Even among residents who have this diagnosis in common, needs may differ significantly. Residents with different diagnoses may benefit from similar care. We expect all residents to receive care to meet their needs, based on a comprehensive, person-centered care plan that reflects the resident's needs, goals, and preferences. We believe that the person-centered approach to care reflected throughout these regulations will best serve individual residents based on individualized diagnosis and needs. We will continue to evaluate this issue and may consider it for inclusion in future notice and comment rule-making.

*Comment:* One commenter discussed the importance of a culture of safety and recommended that we incorporate a new section to address worker and resident safety issues, including safe resident handling and lifting, hazard protections, workplace violence, and other safety issues.

*Response:* We thank the commenter for their suggestions. A culture of safety and worker safety are important issues. However, many of the suggestions provided are outside the scope of this regulation and many are already regulated by the Occupational Safety and Health Administration. Moreover, our statutory authority is limited to regulations that protect the health and safety of residents; we hope that our rules also protect the safety and well-being of staff and employees, but such results cannot be the basis for our authority. We will continue to evaluate the best way to identify and incorporate those elements that may be appropriate for incorporation into requirements for participation and consider them in future rule-making.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have established § 483.24, Quality of life, which contains proposed § 483.35(a), (b), and (c) re-designated as § 483.24(a), (b), and (c), respectively, and revised the introductory language to clarify that quality of life applies to all care and services provided to facility residents.
- We have added an introductory statement to new paragraph § 483.24(b).

• We have added the word ''walking'' in addition to ''ambulation'' at § 483.24(b)(2).

• We have revised the title of § 483.25 to read ''Quality of care,'' eliminated the modifier ''special care issues,'' revised the introductory language to clarify that quality of care applies to all care and services provided by the facility, and re-designated § 483.25(d)(3) through (15) as § 483.25(a) through (m), respectively.

• We have added ''related physician orders'' to paragraph § 483.24(a)(3) regarding the provision of basic life support.

• In § 483.25, we removed (d)(1) relating to restraints and relocated it at § 483.12(a)(2).

• We have re-designated proposed § 483.25(d)(2) Bed rails as paragraph § 483.25(n), added an appropriateness qualifier to the regulatory text and reworded the provision about the bed's dimension for clarity.

• We have re-designated § 483.25(d)(6)(ii)(C) as § 483.25(e)(2)(iii) and revised it to state ''restore continence to the extent possible.''

• We have added language to § 483.25(f), (h), (i), (j), (k), and (l) to require that care be provided consistent with professional standards of practice applicable to that care as well as the comprehensive person-centered care plan, and the residents' goals and preferences.

• In § 483.25(g)(1), we have eliminated the reference to protein levels as a nutritional parameter and add reference to electrolyte balance.

*L. Physician Services (§ 483.30)*

Under the reorganization discussed earlier, requirements regarding physician services currently located at § 483.40 were proposed to be moved to new § 483.30. We proposed to retain the current requirements but proposed a few additions as discussed below.

We proposed to revise the introductory text of § 483.30 to specify that, in addition to a physician's recommendation that the individual be admitted to a facility, a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist must provide orders for the resident's immediate care and needs.

We also proposed to add a new § 483.30(e) to require that a facility, prior to an unscheduled transfer of a resident to a hospital, provide or arrange for an in-person evaluation of a resident, to be conducted expeditiously, by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital, unless the transfer is emergent and obtaining the in-person evaluation would endanger the health or safety of the individual or unreasonably delay the transfer.

At § 483.30(f)(2), we proposed to provide the physician with the flexibility to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, to the extent the dietitian or other clinically qualified nutrition professional is permitted to do so under state law.

Similarly, at § 483.30(f)(3), we proposed to provide the physician with the flexibility to delegate to a qualified therapist under proposed § 483.65 below the task of writing therapy orders, to the extent that the therapist is permitted to do so under state law.

*Comment:* We received a comment in support of our revision to the introductory language to § 483.30 allowing a physician, physician assistant, nurse practitioner, or clinical nurse specialist to write orders for a resident's immediate care and needs upon admission. The commenter stated that they believed this would help ensure more immediate access to care.

*Response:* We thank the commenter for his support. We understand that the time period around a transition of care, including admission to a facility, can pose added risk. We expect that this provision will help ensure that the resident receives care for his or her specific needs until a comprehensive assessment and care planning can be completed.

*Comment:* We received a significant number of comments on our proposal to add a new § 483.30(e) to require that a facility, prior to an unscheduled transfer of a resident to a hospital, provide or arrange for an in-person evaluation of a resident, to be conducted expeditiously, by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital, unless the transfer is emergent and obtaining the in-person evaluation would endanger the health or safety of the individual or unreasonably delay the transfer. Although a few commenters supported the proposal, the majority disagreed with the proposal, for a variety of reasons. The comments reflected significant concern about the burden this requirement would place on facilities, particularly small and rural facilities. Some commenters were concerned about added expense and suggested this requirement could not be implemented without payment reform. Beyond the cost issue, many facilities were concerned about the impact this requirement would have on their ability to recruit physicians, NPs, PAs, and CNS's to fill this role. In particular, rural facilities suggested that this requirement could not be met in areas where there are professional shortages. Further, some commenters suggested that this requirement would drive practitioners of all types away from working in LTC facilities and would ultimately result in reduced access and reduced quality of care and safety for residents.

In addition, some commenters felt that this proposal would result in delayed access to care, resulting in harm to patients. Some commenters also felt that this requirement could conflict with resident rights, specifically, the resident's or resident representative's right to request such a transfer. One commenter stated that, in many circumstances, a practitioner can make an adequate assessment over the phone and that CMS had shown no reason to adopt this requirement, and facilities already have incentives to avoid unnecessary hospital transfers. Many commenters asked what was wrong with the current system of the nurse and physician speaking about the plan of care over the phone, stating that this is sufficient. Finally, some commenters stated that this proposal failed to recognize an appropriate role for registered nurses, in coordination with a practitioner. Commenters suggested we allow this requirement to be completed through a telehealth mechanism or using registered nurses.

*Response:* The intent of this provision was to encourage the identification of opportunities to treat residents in their facilities, reducing the risks associated with the transfer to a hospital. In August of 2012, CMS launched ''The Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents'' (see *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/InitiativetoReduceAvoidableHospitalizations/AvoidableHospitalizationsamongNursingFacilityResidents.html*). This effort aims to improve the quality of care for people residing in nursing facilities by reducing avoidable hospitalizations. Under the initiative, CMS supports enhanced care & coordination provider organizations that each partner with a group of nursing facilities to implement evidence-based clinical and educational interventions that both improve care and lower costs. The initiative is focused on long-stay nursing facility residents who are enrolled in both the Medicare and Medicaid programs, with the goal of reducing potentially avoidable inpatient hospitalizations. CMS announced a second phase of ''The Initiative to Reduce Avoidable

Hospitalizations among Nursing Facility Residents'' on August 27, 2015. Under the new phase, a new funding opportunity will allow the organizations currently participating in the initiative to apply to test whether a new payment model for nursing facilities and practitioners, together with the clinical and educational interventions in place under the current initiative, will improve quality of care by reducing avoidable hospitalizations while also lowering combined Medicare and Medicaid spending (see *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/InitiativetoReduceAvoidableHospitalizations/AvoidableHospitalizationsamongNursingFacilityResidents.html*). After consideration of the comments and pending the outcome of the second phase of the initiative discussed above as well as in order to allow further time to evaluate suggested alternatives, we have decided not to finalize this requirement at this time. Therefore, we are withdrawing proposed § 483.30(e) as well as our proposal to redesignate paragraphs (e) and (f) as (f) and (g).

*Comment:* A commenter noted that existing § 483.40(f) states that at the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician. We proposed to re-designate existing § 483.40(f) as § 483.30(g). The commenter recommended that we remove the phrase ''who is not an employee of the facility but'' from the language in § 483.30(g). Another commenter noted that the provision creates a difference between SNFs and NFs and suggests that the requirement should apply to both SNFs and NFs.

*Response:* We proposed to re-designate § 483.40(f) as § 483.30(g) but did not propose any changes to the language contained in the current requirement. Therefore, we cannot make any changes at this time, but will evaluate these comments and consider them for future regulatory proposals. Section 1919(b)(6) of the Act permits States to give NFs the discretion to allow a nurse practitioner, clinical nurse specialist, or physician assistant who is ''not an employee of the facility'' but working in collaboration with a physician to supervise the provision of healthcare at an NF. We do not have the authority to modify this.

*Comment:* We received comments in support of our proposal to allow physicians to delegate the authority to write dietary orders to dietitians acting within their scope of practice under state law and under the supervision of the physician. One commenter noted that these professionals may actually know the resident better than the attending physician. Another stated that this would allow better use of professional's time. One commenter suggested that this authority should be limited to the attending physician or his or her designee. Another suggested that a physician, physician assistant, nurse practitioner, or clinical nurse practitioner should be able to make this delegation.

*Response:* We appreciate comments in support of this proposal. We agree that it would be appropriate to limit this authority to the attending physician, as that individual retains primary responsibility for the care of the resident. We have modified the regulatory text at proposed § 483.30(f)(2) and § 483.30(f)(3) accordingly and finalize these provisions at § 483.30(e)(2) and § 483.30(e)(3).

*Comment:* We received comments objecting to our proposal to allow physicians to delegate writing orders to qualified dietitians or other clinically qualified nutrition professionals and to qualified therapists for diets and therapy, respectively. One commenter felt that these proposals were focused on reimbursement concerns or amounted to condoning violation of current regulations. The commenter goes on to state that CMS should not authorize the physician to shift all authority to the therapist and that this would exacerbate the abuse of therapy. Another commenter suggested that such orders could be written without adequate consideration of the whole picture.

*Response:* Our proposal is intended to improve responsiveness to a resident's needs and is implemented at the discretion of the physician. It does not allow a physician to shift all authority to either a dietitian or a therapist, as the qualified professional to whom the task is delegated must not only be acting within their scope of practice under state law, they must also be under the supervision of the physician. Nothing in this provision would permit ordering of inappropriate or excessive therapy. As professionals acting within their scope of practice and having more frequent direct contact with and observation of the resident, therapists may be able to be more responsive to a resident's needs and to changes in a resident's condition. This could actually reduce the amount of inappropriate therapy. Furthermore, as noted above, the resident's care remains under the supervision of the physician. As one commenter noted, our proposal provides for both oversight and accountability. Finally, based on other comments, we have modified this proposal to limit this authority to the attending physician who is responsible for the care of the resident and who should be aware of the full spectrum of issues and concerns regarding the resident.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have withdrawn proposed § 483.30(e).
- We have removed our proposal to redesignate paragraphs (e) and (f) as paragraphs (f) and (g).
- We have modified the regulatory text at § 483.30(e)(2) and § 483.30(e)(3), respectively, to specify that it is the attending physician who has the authority to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, and to delegate to a qualified therapist the task of writing therapy orders, to the extent that these professionals are permitted to perform these tasks under state law.

*M. Nursing Services (§ 483.35)*

Under the proposed reorganization, requirements for nursing services currently located at § 483.30 were proposed to be relocated to § 483.35. The current regulations at § 483.30 address certain aspects of LTC facility staffing but leave gaps related to a number of areas such as the competencies of licensed nurses and the need to take into account resident acuity.

We proposed a competency-based staffing approach that requires the facility to evaluate its population and its resources in accordance with § 483.70(e), including the number and acuity of the residents, the range of diagnoses and resident needs and the training, experience, and skill sets of staff, and base staffing plans and assignments on these assessments. In § 483.35, we proposed to clarify that the facility must take into account its assessment of all residents as well as the skill-sets of individual staff when making staffing decisions. We also proposed revisions to improve the logical order and readability of these regulatory provisions. In the proposed rule, we included a robust discussion regarding the long-standing interest in increasing the required hours of nurse staffing per day and the various

literature surrounding the issue of minimum nurse staffing standard in LTC facilities (See 80 FR 42199). We refer readers to the proposed rule for this background information.

We proposed to clarify at § 483.35(a)(1)(ii) that NAs are included in the term ''other nursing personnel.'' We proposed to add § 483.35(a)(3) and (4) to specify that the facility ensure that licensed nurses have the competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and as described in each resident's individual plan of care. We further proposed to specify that caring for a resident's needs would include but not be limited to assessing, evaluating, planning and implementing resident care plans and responding to each resident's needs.

Consistent with our clarification that NAs are included in the term ''other nursing personnel,'' we proposed to move most of the provisions relating to NAs previously located in § 483.75 to proposed § 483.35. Specifically, we proposed to re-designate § 483.75(f) ''Proficiency of Nurse Aides'' as § 483.35(c). We proposed to re-designate § 483.75(e) as § 483.35(d) and re-title the provision as ''Requirements for facility hiring and use of nursing aides'' to reflect its contents more accurately. We proposed to re-designate the regulations at § 483.75(e) to § 483.35(d)(2) and address non-permanent employees. Non-permanent caregivers are expected to meet competency, knowledge and skill requirements to the same extent as permanent personnel. We also proposed to add the term ''minimum'' to § 483.35(c)(3) to clarify that this paragraph identifies the minimum requirements for hiring a nurse aide.

*Comment:* Some commenters agreed that CMS should not impose mandatory staffing ratios, including the requirement for a 24/7 registered nurse on the premises. These commenters acknowledged the importance of staffing levels but did not feel that such mandates were the best way to clarify ''sufficient'' and felt that mandatory staffing ratios are not supported by empirical evidence. Some commenters felt that current oversight of staffing was already burdensome. A number of commenters stated that it was often a daily struggle to ensure that the appropriate number and level of staff was available while striving to maintain quality of care and that our proposed requirements would only makes that struggle more difficult.

*Response:* We thank these commenters. We concur that staffing is important. We continue to be concerned that a mandated ratio could result in unintended consequences, such as staffing to the minimum, input substitution (hiring for one position by eliminating another), and task diversion (assigning non-standard tasks to a position), as well as stifling innovation, and would not result in the improved quality and person-centered care that we seek in facilities. However, we continue to believe that our proposed requirement is necessary to address concerns about inadequate staffing and resulting harm to residents.

*Comment:* Some commenters supported CMS's proposed competency-based staffing approach, but felt that it should be in addition to minimum staffing standards. One commenter noted that minimum staffing levels and a competency-based approach are not necessarily mutually exclusive. For example, a facility may meet minimum staffing levels and further increase its staffing based on the results of the facility assessment referenced below. This commenter urged CMS to give further serious consideration to these issues. One commenter stated that they recognize the many diverse skills nurses need and the responsibility to have nursing staff with demonstrated competency to care for residents. Their skills need to match resident needs and the scope of services they are expected to provide.

*Response:* We thank these commenters. We did re-consider our approach, but, ultimately, returned to our original proposal. We agree that staff competency, in addition to sufficient numbers of staff, is critical to quality of care and resident safety. We continue to have concerns about establishing appropriate minimum standards as well as concerns that facilities will justify staffing to the minimum standard even when more are required in the context of a competency based approach. We further address comments regarding minimum staffing ratios below.

*Comment:* Many commenters stated that CMS needs to establish and require minimum staffing levels and require a registered nurse to be in the LTC facility 24 hours a day, 7 days a week. One commenter stated that CMS is fully aware that facilities are understaffed and that understaffing harms and kills residents and that CMS must do more to strengthen nurse staffing requirements. The commenter further stated that CMS's assertion that it needs more accurate payroll-based staffing data is disingenuous and that CMS's refusal to set nurse staffing ratios and, as the Institute of Medicine recommended in in 1996 and again in 2001, to require a registered nurse 24 hours per day, seven days a week will mean that many residents will continue to receive inadequate, life-threatening care. Other commenters reviewed the literature supporting the need for and value of increasing staffing and RN presence. Several commenters provided examples of instances where insufficient staffing resulted in harm or where sufficient staffing prevented harm. Several commenters provided information on the fiscal impact of insufficient staffing and the cost savings associated with sufficient staffing. One commenter provided information on the changing nature of the LTC facility industry and the advent of for-profit LTC facilities, the purchase of LTC facilities by private equity firms, and the move towards Medicaid managed long-term services and support, all of which create incentives to staff at the lowest possible levels.

Several commenters specifically advocated for CMS to require a 24-hour registered nurse (RN) in every facility. One commenter stated that the current Requirements of Participation only mandate that facilities use a RN 8 continuous hours each day, 7 days a week. These 8 hours would not have to be spent providing care; they could be used to carry out any type of administrative tasks. Registered nurses by training and licensure have skills that are essential for timely assessment, intervention and treatment. The commenter noted that three Institute of Medicine studies have recommended that at least one RN be on duty at all times. They state that 24-hour RN coverage is essential because the acuity level of LTC facility residents has increased dramatically since the federal law was passed and expert nursing skills are required to anticipate, identify and respond to changes in condition; ensure appropriate rehabilitation, and maximize the chances for a safe and timely discharge home. In addition, a resident's condition can destabilize or deteriorate at any time. When that occurs, the individual must be immediately assessed and a determination made about whether the resident needs to go to the hospital for treatment or whether he or she can be properly cared for in the LTC facility. Because physicians do not have to be on-site, registered nurses are often the only medical personnel in a LTC facility with the education and licensure to conduct the assessment required. The commenter noted that substantial evidence that RN staffing is a key element for safe and effective resident care in U.S. LTC facilities has grown substantially over the last 2 decades, typically using quality measures or

deficient practice from the CMS survey data and that higher levels of RN time are associated with positive outcomes, such as reduced unnecessary hospitalizations, lower antipsychotic use and other improved outcome measures (pressure ulcers, restraint use, cognitive decline; reduced incidences of catheterizations, urinary tract infections, and antibiotic use; and less decrease in function and weight loss). The commenter stated that only 11 percent of nursing facilities nationwide report to CMS that they do not have enough RNs on staff for 24-hour RN coverage, therefore it is reasonable to expect the remainder to do so. The commenter's calculation is based on 2012 CMS Expected Staffing Data, assuming, in part, that a minimum of four RNs (A DoN and an RN on each shift) would provide the necessary RN staffing.

Another commenter who advocated mandating a 24/7 RN stated that, as a result of SNF Value-based purchasing and because of the effect of RNs in decreasing unnecessary hospitalizations of LTC facility residents cited above, they anticipate that LTC facilities themselves will be seeking to employ RNs around-the-clock.

*Response:* We agree that sufficient staffing is necessary, along with the need for that staff to be competent in delivering the care that a resident requires. We also agree that all of these factors are associated with quality of care. However, we do not agree that we should establish minimum staffing ratios at this time. As discussed in the preamble to the proposed rule, this is a complex issue and we do not agree that a ''one size fits all'' approach is best. We have re-evaluated the literature and commenters concerns and remain convinced that additional data will be helpful in determining if and what such ratios should be. Our approach would require that facilities take into account the number of residents in the facility, those residents' acuity and diagnoses. We believe the added specificity of this approach precludes facilities from making staffing decisions based solely on fiscal considerations, without taking these other factors into account. We further believe that this approach can strengthen evaluation of staffing during the survey process. We also agree that RNs are a valuable resource in LTC facilities, however, we are not mandating a 24/7 RN presence in each facility at this time. We note that the current regulatory requirements parallel statutory requirements. While we would have the discretion to impose a more stringent requirement regarding RN presence, we do not have the discretion to eliminate the waiver option, as it is statutory. See sections 1819(b)(4)(C)(ii) and 1919(b)(4)(C)(ii) of the Act. While there are no current RN waivers in effect, such a mandate could result in an increase in such requests. We are also concerned that imposing such a requirement could negatively impact the development of innovative care options, particular in smaller, more home-like settings, for a subset of residents who might benefit from and be appropriate for such a setting. We are also concerned that, while the RN supply overall might be sufficient, geographic disparity in supply could make such a mandate particularly challenging in some rural and underserved areas. Finally, to the extent that facilities may already be moving in this direction, payroll based reporting, discussed previously in our responses, may give us a better picture of the extent to which increased RN staffing is occurring, although, at this time, we will still lack information on the extent to which this results in 24 hour coverage. We have noted elsewhere in our responses to comments that there are concerns about the validity of self-reported staffing data in accurately reflecting how a facility is staffed throughout the year. This, in concert with our inability to determine to what extent adequate RN hours equate to 24 hour RN coverage, impacted the assumptions we made regarding the number of facilities that would be impacted by imposing a 24/7 RN mandate. Thus our estimate of the number of facilities that would be required to hire additional RN staff is much higher than the commenters'.

We have reviewed the recommendations of the Institute of Medicine in its 2004 report ''Keeping Patients Safe: Transforming the work Environment of Nurses.'' That report reiterates prior recommendations for a mandatory RN presence in LTC facilities and mandatory minimum staffing requirements, although it does not recommend a specific ratio. The report states, in part, that

''Patient safety requires staff resources that are sufficient to prevent an inappropriately high rate of untoward events that could be avoided with adequate staffing levels. For such a standard to be reasonable, it must at least be based on the number of residents in the LTC facility and address NAs, who provide most of the care to LTC facility residents. Such minimum staffing standards are not a precise statement of how many staff are required to fully meet the needs of each specific group of residents on each unit, nor are they a quality improvement tool to optimize quality in each LTC facility. Rather, a minimum staffing level is one that avoids placing individual residents unnecessarily at risk because of insufficient numbers of staff to provide even the most basic care.''

The report discusses CMS's 2001 Report to Congress ''Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes—Phase II Final Report'' and states:

''With respect to the recommendation that DHHS specify staffing standards in regulations that would increase with the number of patients and be based on the findings and recommendations of the Phase II DHHS report to Congress on the appropriateness of minimum staffing ratios in nursing homes, the committee notes that the thresholds identified in that study above which no further benefit from staffing ratios could be identified are above the staffing levels of 75 to 90 percent of facilities, depending on the type of staff. However, a minimum standard set by DHHS need not approach the threshold level above which there is no further benefit. In fact, such a standard would go beyond the expectation for a minimum, which is intended to identify situations in which facilities unequivocally place residents at an unacceptable level of risk. The challenge is that there is no absolute minimum level of risk for untoward events that is considered acceptable.''

The IOM report further states:

''The study does not propose a specific minimum standard for RNs, licensed nurses, and NAs because agreement must first be reached about what is an unacceptable level of risk. However, data exist from this national study with which to determine the staffing levels for each type of staff that are associated with any level of risk for untoward events.''

Finally, the IOM report states:

''At the same time, a number of nursing organizations, policy experts, and HCOs [health care organizations] point out the limitations of staffing ratios. While they may help ensure a baseline level of staffing in HCOs that may be outliers, they are poor instruments for achieving optimal staffing. Depending on the skill mix and expertise of nursing staff and patient acuity, minimum ratios may still not provide the needed levels of safety. Moreover, counts of patients needed to calculate nurse staffing levels consistent with a ratio must be taken at a point or points in time. Yet patient admissions, transfers, and discharges are frequent; therefore, an adequate nurse-to-patient ratio at 7 a.m. may be inadequate at 10 a.m., and an organization that has satisfied a nurse-to-staffing ratio at one point in time may still have inadequate staffing at another point. Thus, while staffing ratios can help protect against the most egregious staffing deficiencies, HCOs will need to employ more sensitive approaches internally to fine-tune staffing levels.''

We include only a few portions of this report to highlight the complexity of

this issue and our concerns about determining a ''right'' number for any staffing ratio. CMS has begun mandatory, payroll-based collection of staffing information from long-term care facilities, to include registered nurses, licensed practical or vocational nurses, certified nursing assistants, or other types of medical personnel as specified by CMS, along with census data, data on agency and contract staff, and information on turnover, tenure and hours of care provided by each category of staff per resident day. We believe this information, once a sufficient amount is collected and analyzed, could greatly assist us in re-evaluating this issue. In addition, other elements of this regulation, such as QAPI, Infection Control, Compliance and Ethics, and Training, are also intended to put in place systemic process to prevent placing individual residents unnecessarily at risk.

*Comment:* One commenter was pleased that the proposed regulations require that facilities ''have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial wellbeing of each resident '' However, this commenter as well as other commenters expressed concern about the proposed mechanism for determining what constitutes ''sufficient staff,'' with the ''appropriate competencies and skills.'' The proposed regulations require the facility to conduct an assessment, at least annually, to determine the appropriate level and type of staffing needed. This proposal is of concern because it relies on the facility's own assessment of staffing needs without any enforcement mechanisms or safeguards to ensure that the facility is indeed objectively assessing resident needs, acuity, and other important factors and not unduly relying on other factors such as cost and convenience. The commenter felt that that this proposal requiring a ''facility assessment'' is not materially different from what nursing facilities currently do to determine staffing levels—a method which has produced serious staffing and quality deficiencies. Other commenters felt that the proposal was insufficient in its explanation of expectations. Other commenters were concerned that our proposal did not allow sufficient flexibility for facilities to determine how they staff nursing units. Some commenters stated that a facility's ability to care for residents should be based on outcomes of care, such as annual survey results, quality measures, and the 5-star rating system.

The commenter agreed with CMS that the regulations must not encourage facilities to set staffing levels based solely on regulatory minimum requirements and in lieu of actual resident needs and acuity levels of the residents they serve. They further agreed that the facility assessments should take into consideration all the factors set out in the proposed regulation in § 483.70(e) and that each facility should conduct this assessment itself. However, the commenter suggested that CMS require that the facility assessment be audited by a facility surveyor and that the surveyor be empowered to require, under threat of graduated monetary penalties, the facility to provide additional nursing resources if he or she disagrees with the facility's assessment. Lastly, the commenter believed that the facility should be required to seek and use input from the Long-Term Care Ombudsman, the resident and family groups, and family caregivers when conducting its assessment.

Another commenter noted that instead of establishing a minimum staffing standard or requiring 24-hour RN coverage, CMS proposed a competency-based staffing approach that stems in part from a facility assessment and stated that this assessment appeared to be put forth as the answer to requiring a specific number of staff or hours of nursing care. The commenter was concerned that this would not require facilities to do anything different than they have been doing and that this simply maintains the status quo. The commenter believed that the facility assessment could be useful in addition to a minimum staffing standard if revised to include staffing practices and used as a factor to consider in adjusting staffing levels upward based on resident needs.

*Response:* We appreciate the commenters concerns and we have re-reviewed the literature as well as additional information. There is no question that staffing and quality are associated, and we direct readers to our concerns about mandatory ratios in the previous response. As one of the commenter notes, the proposed facility assessment is in line with current industry practice. However, our approach would require that facilities document the assessment and take it into account, including the number of residents in the facility, and those residents' acuity and diagnoses, when making staffing decisions. Several commenters have noted that a primary driver of understaffing is that facilities make staffing decisions based solely on fiscal concerns. We believe the added specificity of this approach precludes facilities from making staffing decisions based solely on fiscal considerations without taking resident specific factors and needs into account. Further, the facility assessment is conducted at the facility level and it must be used in making staffing decisions, precluding staffing decisions from being made solely at a corporate level based on fiscal considerations and without taking facility- and resident-specific factors into consideration. We believe this approach provides facilities adequate flexibility while still requiring that there be sufficient staff to care for residents. As noted earlier, we also believe that this approach can strengthen evaluation of staffing during the survey process. We further address comments regarding the facility assessment in our discussion of comments received with respect to proposed § 483.70.

*Comment:* One commenter stated that, somewhere in the regulations, it is important to ensure that all facility staff, including non-permanent employees, be determined by the facility to be competent to provide care to the residents. The commenter stated that they have seen where the facility counts on the contract agency to determine competency and training, and this has not actually been completed in a timely manner. When a deficiency is cited, neither the facility nor contract agency wants to be held responsible for the resultant care that was provided to the residents. Regardless of whether the individual is a permanent facility employee or a contract employee, the facility should remain accountable for the competency of the individuals who are providing care to the residents. Language should be added to hold the facility is accountable to ensure that the contract staff have received the regular in-service education required every 12 months under § 483.35 (d)(7), otherwise there is no way to ensure these individuals meet their annual in-service education requirements. Many other commenters stated that facilities should not be accountable for ensuring the competency of contract personnel. Many of these commenters stated that the agency that employs the individual should be accountable for their employees' competency. One such commenter stated that they hire the agency, not the nurse or CNA.

*Response:* We agree that all staff providing care must have the skill sets and competencies to provide that care. Proposed § 483.35(a)(3) and (c) specifically require that licensed nurses and nurse aides, respectively, have the

competencies and skills necessary to provide care to residents in accordance with that resident's needs. These provisions are not conditioned on the manner by which the individual's services are obtained. Further, we establish in proposed § 483.95, training requirements for all staff. Please see our responses for that section for additional information. Furthermore, we re-designated but did not otherwise change the requirements for the use of outside resources, which requires that the facility obtain services under an agreement that specifies, in writing, that the facility assume responsibility for obtaining services that meet the professional standards and principles that apply to professionals providing such services and are timely. Depending on a facility's needs, contract staffing may be used infrequently, routinely, and for extended periods of time. A facility can require in its agreement with a staffing agency that the personnel the agency sends to fill staffing needs meet certain requirements. The facility could use mandatory training requirements as well as its facility assessment, past experience, and other knowledge of its staffing needs to determine what requirements it would expect the staffing agency to ensure personnel have met prior to being sent to the facility. However, when a contract individual reports for duty, the facility must ensure that the work assigned to that individual is appropriate for his or her competencies and skill sets.

*Comment:* One commenter recognized that nurses need many diverse skills, but felt the meaning of this proposed requirement is unclear. They asked whether we intended to require this of all of nursing in the aggregate, or every nurse individually. They asked whether we intended that each nurse have competencies for all the residents/patients under their care each day, or on the unit on which they work. The commenter felt that it was unclear about how surveyors would evaluate this requirement fairly and consistently, in order to judge a facility's compliance with this provision. The commenter recommended that § 483.35(a)(3) be revised to read: The facility must ensure that its licensed nurses collectively have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care. Other commenters stated that competency and skill set requirements were unnecessary, as these are ensured by education and licensure, and covered by requirements that care meet professional standards of practice.

A commenter also recommended that ''Proficiency of nurse aides'' should be revised to read: ''The facility must ensure that nurse aides have the basic skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.''

*Response:* The individual providing the care must have the skills and competencies to deliver the care that they are expected to provide to the resident, consistent with the individual's position and, when applicable, their scope of practice under state law. We recognize that education and licensure provide many foundational skill sets. There are many common competencies that every staff member or every member of a specific job position (such as nurse aide) need. We would expect those competencies to be identified through the facility assessment. We understand that not every staff member can have every competency for every resident and that an individual facility, based on the population it serves, may have some unique needs. It is not enough, however, that the staff, collectively, have the competencies and skill sets to provide the care. That could imply that the requirement is met so long as one member of the staff has the required training or knowledge, regardless of whether or not that staff member actually provides the care or is even present in the facility when the care is delivered. The facility must ensure that the individual providing care to a resident has the skills and competencies necessary to deliver that care. For example, if a particular resident is on contact isolation as a result of a medical diagnosis, every individual caring for that resident must know how to comply with those procedures. Similarly, if a resident requires the use of a specialized eating implement, the individual(s) responsible for assisting the resident to eat must know the proper use of the implement. If the individual has to obtain guidance for such use, such guidance must be timely. It would not be enough for one individual to have the knowledge if that knowledge was not actually used in caring for the resident.

*Comment:* One commenter felt that the language of proposed § 483.35(d)(2) was unclear and could be interpreted to mean that a facility could not have a temporary worker that did not meet the requirements but could have a permanent employee who did not meet the requirements.

*Response:* § 483.35(d)(1) addresses the use of nurse aides; paragraph (d)(2) establishes that facilities cannot avoid compliance with (d)(1) through the use of non-permanent employees. In context, this does not permit any employee to whom paragraph (d) applies to not meet the requirements. We are finalizing this provision as proposed.

*Comment:* A commenter stated that traditional in-service education has been largely supplanted by other approaches and may have marginal value in imparting skills and attitudes and in improving performance. Self-education, computer-based training, real-time coaching, mentoring, and other forms of education and training and coaching are often more productive. Furthermore, ''in-service education'' is not defined and lacks pertinent standards. The commenter recommended revising the wording of (d)(7) to reflect more flexible, efficient, effective, and modern approaches to the issue. Otherwise, regulatory compliance is limited by the inflexible specific requirement for ''in-service education.''

*Response:* ''Regular in-service education'' is required by sections 1819(b)(5)(E) and 1919(b)(5)(E) of the Act. ''In-service'' training is generally understood to be training intended for those actively engaged in the profession or activity concerned. We agree with that there are multiple ways of providing ongoing training that assures that individuals used as nurse aides are competent to perform services as nurse aides. We would encourage facilities to use the most efficient and effective training methods available to them to achieve their training objectives.

*Comment:* One commenter felt that the final regulation should clearly address a specific, replicable methodology for calculating nursing staff and assessing whether or not it is adequate to meet the needs of residents in each facility. The commenter urged CMS to examine whether the current methodology for the five-star rating system, which calculates expected staffing based on RUG values along with reported staffing levels, can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. Such an adaptation must be designed to incorporate the more robust payroll-based staffing data that will be in place as a requirement for all certified SNFs and NFs by July 2016. The commenter felt that a competency-based assessment could easily ask for a determination of whether or not the facility has 24-hour RN coverage, and whether all LPNs and CNAs have sufficient training to be able to communicate with and respond to the needs of individual residents who have difficulty communicating, notably individuals with dementia. A

competency assessment could also ask for further details about initial and in-service training, including whether all nursing staff understand ethics and compliance and QAPI standards well enough to use them. Further, a competency assessment could inquire about the composition of interdisciplinary teams, and whether these care teams record and take into account the treatment preferences and quality of life goals that residents express during care planning. The commenter stated that the importance of regulators having clearer yardsticks to understand what constitutes ''sufficient'' staffing in different facilities in order to ensure resident well-being cannot be overstated. Careful oversight by nursing staff serving residents is a core fiduciary responsibility of LTC facilities and the direct responsibility of the Administrator and the Director of Nursing (DoN). This responsibility must be understood to extend to the adequacy of training and the operational deployment of nursing staff—at all times, including night and weekend shifts, and during holidays—regardless of the business structure of the facility, and independent of any policies promulgated by individuals or entities that may be operationally and/or financially connected to a given LTC facility. To be useful, therefore, an annual facility assessment must be able to establish that its staffing will remain adequate throughout the year, both with regard to levels of total nurse staffing, and with respect to the responsibility that certain types of staff, for example, RNs and LPNs, have in overseeing the medical management of residents with regard to medications, falls prevention, development of pressure ulcers, readmission to hospitals and other key areas.

*Response:* We will consider the commenters' recommendation to examine whether the current methodology for the five-star rating system, which calculates expected staffing based on RUG values along with reported staffing levels, can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. Please see our discussion of § 483.70 for further discussion of the facility assessment requirement.

*Comment:* In advocating for mandatory staffing standards, some commenters addressed the high cost of poor care. One commenter noted that CMS itself has recognized these costs. The commenter further noted that nearly 25 years ago, the Senate Labor and Human Resources Subcommittee on Aging issued a report that addressed, and used the term, ''high cost of poor care''—that is, the costs that are incurred by the health care system when inadequate nurse staffing in LTC facilities leads to avoidable medical problems that the health care system spends money to try to correct. The report detailed several poor care outcomes, their causes, and their estimated costs, noting that the costs would be far higher in 2015 dollars and links avoidable hospitalizations to ''the insufficient number of adequately trained nursing staff.'' The commenter notes additional studies that further support this conclusion. The commenter also discussed the use of INTERACT (Interventions to Reduce Acute Care Transfers is a quality improvement program that focuses on the management of acute change in resident condition) to avoid inappropriate hospitalizations and to support hospitalization that is medically necessary. The commenter further stated that considerable research demonstrates that unnecessary and inappropriate hospitalizations can be avoided when nursing facilities have more health care professionals in place on a daily basis—physicians, physician assistants, and registered nurses. Finally, the commenter discussed other costs of insufficient staffing, such as staff injuries. Another commenter stated that the lack of a specific minimum staffing standard and 24-hour registered nurse coverage in the proposed regulations has been a major obstacle to quality care since the Nursing Home Reform Law was passed in 1987 and will continue to be until these standards are adopted. The commenter highlighted the relationship between staffing levels and quality and stated that CMS discounts the numerous studies that support the relationship between nursing staff and quality.

*Response:* We do not discount the relationship between staffing levels and quality. We disagree that this requires that we set minimum staffing ratios and that we know what that minimum staffing ratio should be. As discussed previously, we believe that there are concerns about utilizing a minimum staffing standard and we do not necessarily find that the 4.1 hours per resident day (hrpd) is the right standard for every facility. LTC facilities are varied in their structure and in their resident populations. Some facilities are Medicare-only SNFs that focus on short term rehabilitation services. Others are primarily Medicaid facilities that include primarily long-stay residents. Many are both. Some facilities specialize in dementia care. Some facilities have pediatric residents, young adult residents, or ventilator dependent residents. The care needs of each of these populations are different. Facilities range in size from the very small to the very large. The capabilities of these facilities are likely to be different. As noted above, we discuss our concerns with establishing a minimum staffing ratio in prior responses. As stated in the proposed rule, our intent is to require facilities to make thoughtful, informed staffing plans and decisions that are focused on meeting resident needs, including maintaining or improving resident function and quality of life.

*Comment:* One commenter stated that while they believe recommended minimum staffing requirements should be implemented when the revised rules go into effect, an alternative approach would be to phase-in the staffing standards incrementally over a 5 year period. A number of states, such as Florida and Illinois, have used an incremental phase-in period. This approach would give facilities ample time to increase staffing to the required levels.

*Response:* We are not finalizing a minimum staffing requirement at this time. We will consider a phased-in approach if we determine to impose minimum staffing standards through future rulemaking.

*Comment:* Several commenters stated that, despite industry claims to the contrary, they believe it is not necessary for CMS to increase Medicare and Medicaid LTC facility payment rates if CMS requires minimum staffing standards. One commenter noted that the actual facility-reported average RN staffing levels increased to 0.85 hours per resident day (hprd), LVN staffing increased to 0.83 hprd, and total staffing steadily increased to 4.15 hprd in 2015. Because the average LTC facility staffing is already 4.1 total hprd and 0.8 RN hprd, most homes should be able to meet these standards without an increase in reimbursement rates. The commenter felt that the for-profit chains who in general report lower staffing levels are in the best position to increase staffing without additional reimbursement.

*Response:* We thank the commenters for this information. We are aware of concerns that current, self-reported staffing data may not fully reflect a facility's staffing across time. We expect our understanding of how facilities are staffed on an ongoing basis to improve with the collection of payroll-based staffing data. Also, it is important to note that changes to these requirements

do not necessarily drive changes to Medicare or Medicaid payment rates.

*Comment:* Several commenters questioned the accuracy of the cost estimates CMS presented for the proposed rule. They believe that the salary figures appeared to be overly inflated and asked CMS to review its cost estimates. The commenters suggested that CMS use the BLS OES wage data that are specific to SNFs and felt that the 48 percent fringe benefit and overhead factor appeared overly generous. Finally, the commenters stated that it would be helpful for CMS to provide additional information on the justification and methodology for determining the benefit factor and what the specific elements of overhead costs are.

*Response:* We have reviewed our calculation and believe that we provide a good faith estimate of the cost of requiring 24/7 RN coverage. We note that the overhead percentage used in our calculations is based on guidance from the Office of Management and Budget. After eliminating facilities that already require a 24/7 RN, we estimate that there are 13,279 facilities that will likely need to 'staff-up.' We believe that ''staffing-up'' would entail hiring an additional one to four RN FTEs to cover an additional two shifts per day (14 eight hour shifts per week) in the 13,279 facilities that are not currently required to have a 24/7 RN presence. Given the 2015 mean annual wage of $62,440 for an RN working in a nursing care facility (*http://www.bls.gov/oes/current/oes291141.htm*), and assuming either 48 percent or 100 percent overhead, we estimate the burden of implementing such a mandate to be $92,411 to $124,880 per additional RN, for a total of between $1.2 and $6.6 billion in addition to the current estimated first year costs of the proposed rule. Particularly given existing concern that current self-reported staffing data may be inflated, we believe that payroll based staffing data will help us better estimate the burden.

One commenter suggested that we should use $42.82 hourly wage based on the BLS OES Median for NAICS 623100, inflated by 48 percent. If we used that number, assuming 40 hours per week for 52 weeks, we get an estimate of $1.1 to $4.7 billion for an additional one to four RNs at 13,279 facilities. Some commenters believe that we have over-estimated the number of facilities that would need to hire one or more additional RNs. One commenter believes that 89 percent of facilities, already meet or exceed four RN FTEs per day (1 DoN and 1 RN on each shift), based on a calculation of RN hours per resident day and currently reported staffing data. That would mean only 1,777 facilities would need additional RN staffing. Using this estimate and the $42.82 median hourly wage, the burden estimate is $158 to $633 million for one to four additional RN at 1,777 facilities. However, we believe this calculation significantly underestimates the number of facilities that would be required to hire additional RNs. We based our estimate on the number of facilities that are not currently required to have an RN 24/7.

*Comment:* Several commenters stated that, given the relationship between staffing and outcomes, increased staffing levels could save the Medicare and Medicaid programs billions of dollars, and cite studies demonstrating the possible cost savings. They noted that, while the trauma inflicted upon LTC facility residents and their loved ones from understaffing could not be easily categorized and calculated, the financial costs are quantifiable.

*Response:* We agree that improved staffing, as well as improvement as a result of several of our proposals, could result in savings to the Medicare and Medicaid programs. In developing our proposals, we considered possible cost savings from these proposals. Those cost savings were not included in our estimates as they were deemed to potentially be the aggregate result of more than one requirement or activity, as well as speculative in nature.

*Comment:* Some commenters are concerned that our requirements related to the DoN can be waived and note that the role of the DoN is critical to quality resident care. The commenter stated that the DoN is responsible for administrative, clinical, educational, staff and public relations; the core competencies include such skills as conducting root cause analysis, setting benchmarks, directing change, and mentoring and teaching and, with the increased acuity level and medical complexity of LTC facility residents, a DoN with the expertise, training and skills of a RN is necessary. The commenter recommends that we delete the waiver so the regulation reads: ''The facility must designate a registered nurse to serve as the director of nursing on a full time basis.''

*Response:* We agree that the position of DoN is very important and that an RN should fill this position. However, the waiver in question is established by statute and we do not have the discretion to eliminate it. We note that the waiver only applies to rural facilities where the supply of RNs is not sufficient, and only when specific conditions are met. Further, we note that no such waivers are currently in effect.

After consideration of the comments we received on the proposed rule, we are finalizing these provisions as proposed.

*N. Behavioral Health Services (§ 483.40)*

Currently, § 483.25 requires that each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. We proposed to add a new section § 483.40 to address this requirement as it relates to behavioral health services and include requirements for social workers. These provisions work in conjunction with other provisions we proposed, including those related to reducing the inappropriate use of psychotropic medications, to address the behavioral health care needs for residents.

We proposed at § 483.40(a) to require that the facility have sufficient direct care staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at proposed § 483.70(e). We proposed to specify in § 483.40(b) that, based on the comprehensive assessment of a resident, the facility must ensure that a resident who displays or is diagnosed with mental or psychosocial adjustment difficulty receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental health and psychosocial well-being. In addition, we proposed to specify that a resident whose assessment does not reveal or who does not have a diagnosis of a mental disorder or psychosocial adjustment difficulty will not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that the pattern was unavoidable. Furthermore, if rehabilitative services such as physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for a mental disorder and intellectual disability are required in the resident's comprehensive plan of care, the facility must provide the required

services, including specialized rehabilitation services as required in § 483.40(c)(1); or obtain the required services from an outside provider of specialized rehabilitative services in accordance with proposed § 483.65(a)(2).

General Comments

*Comment:* Some commenters were very supportive of our proposed requirements for behavioral health services, but noted that these requirements focused substantially on behavioral and psychiatric conditions. They supported the focus on sufficient direct care staff with the appropriate skills and competencies to provide the necessary care to residents with a mental disorder and cognitive impairment, including how to implement non-pharmacological interventions. Some commenters supported requiring facilities to provide social services to the residents and that all of the behavioral health services that are indicated in the resident's comprehensive plan of care must be provided by the facility.

*Response:* We thank the commenters for their support. We believe these proposals, which have been finalized in this rule, are essential for residents who need behavioral health services. We also agree that having a focus on behavioral health through having a separate section on behavioral health with a focus on, among other things, sufficient direct care staff with the appropriate skills and competencies and non-pharmacological interventions, emphasizes the importance of providing the behavioral health services residents need to obtain their highest practicable physical, mental, and psychosocial well-being. Facilities will be required to provide the behavioral health services indicated on the resident's comprehensive plan of care; however, § 483.65(a)(2) also allows for the facility to have these services provided by an outside source.

*Comment:* Some commenters were supportive of the proposed requirement for sufficient direct care staff with the appropriate skills and competencies to provide the necessary care to residents who need behavioral health services and for this to be determined by a facility assessment. However, the commenters were concerned that it was the facility itself that would conduct this assessment. Without any enforcement mechanism or safeguards to ensure that the facility is objectively assessing its residents' needs, acuity, and other important factors, the commenters were concerned that the assessment could be influenced or rely upon other factors, such as the cost or convenience to the facility. In addition, the commenters stated that this requirement was not materially different from what facilities currently do and that current practice has resulted in serious staffing and quality deficiencies. Some commenters proposed that we require the facility to seek out and use the input from outside sources and that a surveyor audit the facility assessment and impose monetary penalties if the auditor disagreed with the facility assessment.

*Response:* We understand the commenters' concerns about facilities performing their own facility assessment to determine staffing and other resource requirements and that the assessments could be based upon factors other than the care needs of the resident population, such as justifying their current staffing and other resources, as well as taking into consideration the facility's cost and convenience. However, we believe that facilities need the flexibility to determine the best way to perform their facility assessments to comply with this requirement. The facility can certainly perform this assessment itself or it may choose to have an outside entity perform the assessment. We believe that if a LTC facility does not objectively assess its resident population and resources, surveyors will be able to detect this during the survey, not only from reviewing the facility assessment but also from the LTC facility's compliance with the other requirements in this final rule. For further discussion on the facility assessment, please see the discussion for § 483.70(e) below.

*Comment:* Some commenters were very concerned about not having sufficient resources that would be needed to comply with these requirements. Some commenters noted the shortage of behavioral/mental health providers in their areas, especially qualified psychiatrists. Others noted that Medicaid per diem rates do not include any compensation for specialized behavioral health services. Other commenters were concerned they would have insufficient resources to obtain additional staff and provide the training, both initial training and continuing in-services, that would be required to comply with the requirements.

*Response:* We understand that there are concerns about how to comply with the requirements in this final rule. However, sub-regulatory guidance will be published for these requirements. This guidance should provide the detailed information that LTC facilities need to understand what is needed to comply with these requirements.

*Comment:* Some commenters believed that complying with the proposed requirements is unrealistic and problematic due to the high staff turnover in LTC facilities. A commenter noted that in 2012 there was a median turnover rate of 43.9 percent turnover for all employees and 50 percent or more for direct care RNs, and CNAs. The turnover rate for LPNs and LPNs was 36.4 percent.

*Response:* We acknowledge that the high turnover rates for staff in LTC facilities present a challenge. However, as discussed in other areas of this rule, we believe that these requirements will not only improve the quality of care and life for residents but also the quality of the work environment for the staff. We believe that over time this will result in lower turnover rates for staff and savings for LTC facilities.

*Comment:* Some commenters were supportive of the emphasis on behavioral health; however, they also recommended a more holistic approach to improve care for residents with behavioral and psychiatric impairments, including dementia. They noted that all psychiatric and behavioral disturbances have a significant medical and biological component. In addition, there were many reliable and reputable resources in medicine, neurology, psychiatry, and other disciplines that explain how health professionals, other than psychiatrists, should be able to properly assess, diagnose, and manage behavioral and psychiatric issues. They are concerned that these requirements would perpetuate ''silos'' of care, which is managing each body part or symptom by a particular discipline, which could undermine managing all of a resident's symptoms and conditions holistically. Some of the commenters believed that mental health professionals are not often needed and may actually be unhelpful for some residents. Some commenters did not believe that having consultants provide behavioral care is unlikely to improve vital staff and practitioner understanding and performance.

*Response:* We agree with the commenters that behavioral health issues have a medical and biological component and that healthcare, including the healthcare in LTC facilities, requires a holistic approach. We proposed and have finalized this section, not to elevate the treatment of mental disorders and emotional issues above physical health issues, but to ensure that assessment and treatment of behavioral health issues are viewed with the same importance as the physical and receive the resources necessary to provide appropriate

treatment to residents in need of behavioral health services. This is why we have also finalized requirements for assessments, personalized care plans, the involvement of an IDT, the involvement of the resident or their representative in the resident's care, as well as other requirements. We also agree with the commenters that behavioral health care can be provided by healthcare personnel other that psychiatrists. In this final rule, we have not required that the individuals who provide behavioral health care and services have specific degrees or certifications; however, the facility must have sufficient staff with the appropriate competencies and skill sets to provide nursing and related services to residents in need of behavioral health care and services.

*Comment:* Some commenters were concerned that the behavioral health section requirements appear to be implying that facilities would be responsible for ensuring that people with mental or emotional disorders maintain stable emotions and behaviors. They also believed that the proposed requirements appeared to imply that the facility would be held responsible if residents could not adjust or behave adequately in a social setting, or if they withdrew, got angry, or failed to interact well with others. However, commenters noted that many residents may have long-standing, and often misdiagnosed or inappropriately or inadequately managed, behavioral health problems prior to being admitted to a LTC facility. They asserted that this indicates how widespread the problem of inadequate behavioral health care is in our healthcare system.

*Response:* According to § 483.40, LTC facilities are responsible for providing each resident with the necessary behavioral health care and services for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with his or her comprehensive assessment and plan of care. No healthcare provider, including a LTC facility, can guarantee any particular result for its residents. In addition, an LTC facility can only be responsible for the care they provide and not the care the resident received prior to admission. However, they can, and are expected to, properly assess residents, develop plans of care, and provide residents with the appropriate behavioral health services that they need to attain or maintain their highest practicable physical, mental, and psychosocial well-being.

*Comment:* Some commenters stated that the requirements were increasingly mandating certain approaches and discouraging or prohibiting the use of others. Commenters believed there was an emphasis on non-pharmacological interventions over the judicious and appropriate use of medications. The commenters did not believe that the approach in the proposed rule was based upon sound clinical judgment. Some commenters were supportive of the efforts to reduce unnecessary anti-psychotic drug use in LTC facilities, but they also believed in the judicious use of medications for appropriate indications with adequate monitoring of efficacy and side effects. They were particularly concerned about what they perceived as an anti-medication orientation that was obsessive and counterproductive and could inhibit the appropriate use of necessary medications that can effectively and safely relieve symptoms such as distressing delusion, hallucinations, and self-harming behaviors. Commenters recommended the wording be changed to focus on objective support for all potentially useful interventions that could be used in the appropriate context after a clinically competent assessment has been performed.

*Response:* We appreciate the commenters concerns; however, these requirements neither mandate specific techniques or care nor do they require facilities to forego the use of any medically acceptable drugs or techniques. The requirements finalized in this rule regarding behavioral and non-pharmacological interventions, as well as those concerning psychotropic and anti-psychotic drugs in § 483.45, are all intended to encourage appropriate care for the residents. We disagree that these finalized requirements have an anti-medication orientation. The requirements regarding medications are intended to promote the safe and effective use of medications and discourage the inappropriate use of these medications. Non-pharmacological or behavioral interventions are required in an attempt to reduce or eliminate psychotropic medications, but only if these non-pharmacological methods are not clinically contraindicated for the resident.

*Comment:* Some commenters indicated that CMS failed to specify the elements of the facility assessment that would be required to determine the facility's direct care staff needs; the expectations CMS would have regarding how facilities would determine the competencies and skill sets necessary to provide behavioral health services; and whether facilities would need to ensure expanded access to outside professional behavioral health services, which are costly and already difficult to access in rural and geographically underserved areas. Numerous commenters recommended that we delay the behavioral health requirements due to their lack of specificity, especially what ''appropriate'' is, who will determine what the competencies should be, and who will determine if the staff meet the competencies.

*Response:* We have not provided specific instructions on how to conduct the facility assessment. We believe that each facility needs to have the flexibility to decide the best manner in which to conduct that assessment, as long as it addresses or includes the factors or items set forth in § 483.70(e). We understand that the commenters' concern about how to comply with the requirements in this final rule and how they will be surveyed. However, such specificity is not suitable for these requirements; this is more detailed information than is usually incorporated in the requirements and would likely need to be modified more frequently than the requirements. In addition, after this rule is published, sub-regulatory guidance on complying with these requirements will be published.

*Comment:* Some commenters recommended that we reverse the order of proposed § 483.40(b)(1) and (b)(2). They stated that the first statement is not expecting a resident who does not have behavioral health problem at admission to develop one, unless there is a medical reason specific to that individual that makes the problem unavoidable. This first statement would then be followed by the statement requiring a facility to provide appropriate care to a resident who needs the service.

*Response:* We do not believe it is necessary to reverse the requirements. Thus, we will finalize those requirements as proposed.

*Comment:* Some commenters supported our proposal that the facility have sufficient staff with ''the appropriate competencies and skill sets,'' but they believed that the behavioral needs of residents could not be met unless CMS also specified that each facility have staffing practices that include the number and types of staff, staffing assignments (such as rotating or consistent assignment), schedules, and systems that affect communication, teamwork, and participation. Commenters recommended specific language for such a provision.

*Response:* We agree with the commenters that staffing practices are important. Some staffing practices, such as consistent assignment, are also best

practices. We encourage LTC facilities to use best practices with staffing when it is feasible. However, we have not mandated the use of specific practices in these requirements because we believe that LTC facilities need the flexibility to ensure they have sufficient staffing for their residents.

*Comment:* Some commenters recommended that the final rule strengthen the requirements related to assessment of behavioral health and other psychosocial concerns. Commenters specifically recommended that the final rule require that there be a comprehensive psychosocial assessment and social history completed upon admission according to § 483.21(b), with the assessment portion updated annually or when significant changes in the resident's health or behavioral health occur. They also recommended that care plans be required to address psychosocial and behavioral needs identified by the IDT assessments, social histories, and applicable sections of the MDS and associated Care Area Assessments.

*Response:* According to § 483.21(b), LTC facilities must develop a comprehensive care plan, which among other things, must include measurable objectives and timetables to meet a resident's mental and psychosocial needs that are identified in the comprehensive assessment. This comprehensive care plan must be reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments. We believe that by complying with these requirements LTC facilities should be able to provide the behavioral health care their residents need.

*Comment:* Some commenters agreed that mental health care and services are integral to the goal of assuring the highest practicable well-being for residents; however, they also believed that any discussion of the existing requirements or proposals required consideration of the history, structure, and function of LTC facilities. Commenters were particularly concerned about the suggestion that LTC facilities are appropriate settings to care for seriously mentally ill residents or perhaps even being required to admit these residents and provide the specialized behavioral care and services these residents need. They noted that historically LTC facilities were not expected to admit residents that required specialized behavioral health services. They noted that residents with psychiatric illnesses are complex and require a thoughtful plan and that LTC facilities should not be expected to fill in the gaps in the behavioral health care system.

Commenters said that expectations regarding the mental health care that LTC facilities can provide must be balanced against these facilities' ability to provide those services and the possible ramifications for the residents with mental disorders and the remaining resident populations in those facilities. A serious unintended consequence could be frail, elderly residents with dementia being housed with residents with a serious mental disorder, which could result in a dangerous situation. Other commenters were concerned that they would be pressured to admit residents with serious, complex behavioral health needs that they could not meet.

*Response:* These requirements do not mandate that a LTC facility admit any resident with a serious mental disorder. However, if a resident does have behavioral health issues, the LTC facility is responsible for providing the appropriate care for that resident. As discussed in the proposed rule, by 2012, more than 48 percent of LTC facility residents were estimated to have some form of dementia, including Alzheimer's disease, and/or depression (80 FR 42202) Thus, residents requiring behavioral health services are already being cared for in LTC facilities.

*Comment:* Some commenters were confused about the intent of the behavioral health services requirements and what was expected of providers. They requested clarification and some recommended that CMS not finalize the proposed behavioral health requirements, but work with the state survey agencies and providers to address how residents with complex behavioral challenges can best be served.

*Response:* We understand that some of the requirements related to behavioral health services are new and will require time and resources to comply with the requirements. We will also be publishing sub-regulatory guidance to assist LTC facilities in complying with these requirements.

*Comment:* Some commenters were concerned that some of the proposed requirements regarding behavioral health services were inconsistent with a proper, objective assessment of a resident. They believe that instead of emphasizing sound clinical reasoning and problem solving the proposed requirements would encourage inflexible ''cookbook'' approaches that impeded adequate consideration of causes and treatment options. Commenters were concerned that the proposed regulations are primarily psychosocial and focuses on psychosocial interventions while largely ignoring or underemphasizing the reality of dementia as a neurological disorder and the benefits of competent medical assessment and diagnosis. In addition, some commenters were concerned that the proposed rule emphasized non-pharmacological interventions over pharmacological treatments. Commenters noted that competent and reputable sources, such as the World Health Organization (WHO) have emphasized the judicious use of medications in appropriate situation to produce remarkable improvement in the function and quality of life for individuals. They believe that amounts to an attempt to influence clinical practice that is unlikely to promote an improvement in the quality of care provided to residents.

*Response:* We disagree with the commenters. Person-centered care is a focus of these requirements. Each facility is responsible for assessing every resident and developing care plans upon admission and periodically thereafter in accordance with § 483.20 and § 483.21 for each resident. Section 483.45 ''Pharmacy services'' includes safeguards concerning specific types of medication; however, it does not require or prohibit the prescription or use of any medically acceptable medication for a resident. In addition, although behavioral or non-pharmacological interventions are required for residents on psychotropic medication in an effort to discontinue these drugs, this is only required if it is not clinically contraindicated for the resident (§ 483.45(e)(2)). Hence, there is no ''cookbook'' approach for the care for any resident. We have specifically addressed dementia below.

*Comment:* Some commenters were concerned about some of the language in § 483.40(a) and (a)(1). They were concerned about identifying specific conditions, especially the language concerning residents with a history of trauma and/or post-traumatic stress disorder. They do not believe that these conditions are neither more nor less relevant than other psychiatric and behavioral disorders. This could divert attention away from other disorders and problems that are equally important. Commenters provided recommendations on specific changes to the regulatory text.

*Response:* The inclusion of certain issues, such as ''history of trauma and/or post-traumatic stress disorder'' is not intended to exclude other types of disorders or problems. We believe that the remaining language in § 483.40(b)

clearly indicates that those requirements pertain to other behavioral health issues.

*Comment:* Some commenters recommended that the behavioral health requirements not be contained in a separate section. Instead, they recommended that these requirements be relocated into the quality of care requirements, under special services, since it appears to be the intent for these services for residents who have a mental disorder, psychosocial disorders, and trauma or post-traumatic stress disorders.

*Response:* In the previous requirements, the requirements related to behavioral health services were integrated throughout the requirements. However, we became aware of concerns that behavioral health services were either not always being addressed or not addressed to the extent required, in LTC facilities. We proposed, and are finalizing, these requirements in a separate section to emphasize the importance of behavioral health and ensure that LTC facilities address these issues (80 FR 42203).

Definitions

*Comment:* Some commenters were concerned about what care and services were encompassed within the behavioral health requirements. They recommended that there be a definition of behavioral health in the final rule.

*Response:* We agree with the commenters that there should be a definition of ''behavioral health'' in this final rule. LTC facilities are also the residence for residents. Hence, we believe there needs to be a holistic approach to behavioral health and that it should encompass a resident's mental, emotional, and physical well-being. We believe this holistic approach should also encompass prevention. Additionally, we do not want to limit the behavioral health requirements to residents who have been diagnosed with mental or substance use disorders. Therefore, we have inserted the following definition into the stem statement at § 483.40, ''Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.''

*Comment:* Some commenters were concerned about how ''direct care/direct access'' staff would be interpreted. Some commenters also recommended that the wording be changed to, ''[t]he facility must have sufficient staff who provide direct services to residents and who have the appropriate competencies and skills to provide nursing, social work, and other services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being . . .''

*Response:* We acknowledge that there could be some confusion concerning the use of ''direct care/direct access'' staff. Depending on the setting, this term could be interpreted as applying to virtually every staff member in the facility or more narrowly to nursing staff and any applicable therapist. We believe that ''sufficient staff who provide direct services to residents'' is more appropriate language and have finalized that language in § 483.40(a). Thus, the facility would be responsible for ensuring that every staff member that provided direct services to residents has the appropriate competencies and skill sets to provide nursing and other services. Those competencies and skill sets would depend upon the services the staff members were providing to the residents. However, we do not agree that ''social work'' needs to be specifically mentioned in this requirement. Although ''social work'' is very important, other services are also important to the residents. In addition, ''social work'' is clearly included in ''other services''.

Social Workers and Social Services

*Comment:* Some commenters noted that we proposed to move the requirement that the facility provide medically-related social services from the previous quality of life requirement at § 483.15(g), to § 483.40(d). Commenters said that this implies that medically-related social services were only for those with mental disorders or psychosocial adjustment difficulties, a history of trauma and/or post-traumatic stress disorder. They indicated that social workers also provide services that benefit all residents, such as contributing to ongoing care planning, facilitating transitions of care, and advocating for residents' rights and helping facilities. These commenters believed that many residents could benefit from the services of social workers, in addition to those residents that have behavioral health or mental health issues. Other commenters wanted to move the behavioral health requirements to a stand-alone section on Quality of Care and Quality of Life requirement section.

*Response:* We agree with the commenters and believe that this is already required. Section 483.40(d), both as proposed and finalized, requires the facility to provide medically-related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident. Thus, this requirement for medically-related social services goes to all of the facility's residents, not just those with identified behavioral or mental health issues.

*Comment:* Some commenters recommended that the requirement for medically-related social services be strengthened. They noted that the current requirement is for a full-time social worker in facilities with 120 or more beds; however, smaller facilities also need clinical social workers to assist residents and their families with concerns about care and rights. Commenters noted that while non-clinical social services staff are also important for helping arrange for and coordinate services not provided by the facility, discharge planning, and identifying ongoing care and services for residents who are moving out of facilities, they thought it was important for the staff providing medically-related social services to have clinical credentials. Some commenters recommended that LTC facilities be required to employ sufficient numbers of social workers who are professionally credentialed to provide clinical services to residents. Some commenters also noted that the current inability of social workers to bill Medicare Part B had created a barrier to these services.

*Response:* We agree with the commenters that residents in smaller facilities could also benefit from medically-related social services. However, the requirement that facilities with 120 or more beds must employ a full-time, qualified social worker is a statutory requirement (sections 1819(b)(7) and 1919(b)(7) of the Act). While we believe we have statutory authority to require facilities with fewer beds to employ full-time social workers, we did not propose changing this provision. We will retain these comments for consideration if there is future rulemaking concerning social workers or social work services.

*Comment:* Some commenters noted that proposed § 483.40(d), which reads, ''[t]he facility must provide medically-related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident.'' Commenters noted that ''physical'' was included in § 483.40 and § 483.40(a). They recommended that ''physical'' be inserted before ''mental''.

*Response:* We thank the commenters for pointing out that ''physical'' was left out of § 483.40(d). We have finalized that section so that the word ''physical'' is included.

*Comment:* Some commenters stated that residents had limited access to

clinical social workers and that this posed a significant barrier to a facility's ability to meet residents' mental and behavioral health needs as identified in proposed § 483.40. Commenters also stated that social work is essential to realize the goal of § 483.40(a). Clinical social workers have either a master's or doctoral degree in social work, at least two years of post-degree supervised experience in a clinical setting, and a state-issued clinical social worker license, certification, or registration. They also noted that the Health Resources and Services Administration (HRSA) recognizes social work as one of the five core mental health professions. Commenters noted that some LTC facilities do employ clinical social workers to provide social services to residents and that this staffing pattern can certainly contribute to staff identification and response to residents' mental and behavioral health concerns. Commenters discussed how reimbursement contributes to this lack of access. Specifically, they stated that psychotherapeutic diagnosis and treatment is not included in the services covered by the SNF Part A resource utilization group payment. They also noted that even if these services were included in the payment, many clinical social workers employed in a social services capacity would not have the time or flexibility to provide the mental health services some residents would require. In addition, many LTC facilities contract with Medicare-certified independent practitioners to provide mental and behavioral health services to LTC facility residents. However, at this time, clinical social workers are only reimbursable under Medicare Part B if the resident is not receiving SNF benefits under Medicare Part A. The commenters believe that it was the implementation of the requirements in the Balanced Budget Act of 1997 (Pub. L. 105–33), which bundled all social work services in the per-diem SNF payment (section 4432 of the BBA), failed to distinguish between medical social work services provided to all SNF residents and discretionary psychotherapeutic services provided by clinical social workers with specialized needs. They argued that this revocation of the clinical social workers ability to bill Medicare Part B for psychotherapeutic services to SNF residents contrasts with the privileges retained by psychiatrists and psychologists, whose services are not bundled in the SNF per-diem rate. They recommended that correcting this discrepancy would reduce costs to both the beneficiaries and the Medicare program by helping to prevent unnecessary transfers to the emergency department or psychiatric hospital, as well as to decrease avoidable re-hospitalizations related to mental and behavioral health.

*Response:* We agree with the commenters that social workers offer valuable services to residents. LTC facilities with less than 120 beds are not required to have a full-time social worker on staff. However, in this final rule, LTC facilities are required to have sufficient staff with the appropriate competencies and skill sets to provide the care needed by their residents. Thus, LTC facilities must ensure that their residents have the social services, including medically-related social services, they require. Policy governing billing and payment for the services of social workers is beyond the scope of this regulation.

Relationship to Other Requirements

*Comment:* Some commenters requested clarification on how the behavioral health services section requirements intersect with the current pre-admission screening and resident review (PASARR) process, particularly with respect to the Level II screening when it results in a finding that a resident would require specialized behavioral health services.

*Response:* According to § 483.40, LTC facilities are required to provide the necessary behavioral health care and services to residents for those residents to attain or maintain their highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

*Comment:* Some commenters were concerned about LTC facilities being confused with Institutions for Mental Diseases (IMDs) or Institutions for Individuals with Intellectual Disabilities (IIDs). The primary focus of the regulatory design for LTC facility was based on meeting the nursing and/or medical needs of residents. While the commenters noted that we have progressed to a more holistic, person-centered approach, LTC facilities continue to lack the capability in terms of specialized staffing, access to resources and specialized care, and the overall character of their population, to provide the appropriate care for residents with serious mental disorders or who require long-term and intensive psychotherapy. Commenters also pointed out that there is a provision for mental health services under the Medicaid program that prohibits federal financial participation (FFP) to centers for services rendered in LTC facilities that CMS finds qualify as an IMD. Commenters described the criteria used to determine if a facility is an IMD, including whether more than 50 percent of the residents need to be in an institution as a result of a mental disorder and an unusually large proportion of the staff has specialized psychiatric/psychological training.

*Response:* The requirements in § 483.40 Behavioral health, as well as the other requirements on staffing finalized in this rule, do not require any LTC facilities to admit any resident for whom the facility cannot provide appropriate care. According to the requirements in this final rule, facilities must perform a facility assessment, which includes both their resident population and the resources the facility needs to care for their residents. The facility must then provide those resources, including the sufficient number of staff with the appropriate competencies and skill sets, to care for their resident population. We are not requiring that LTC facilities admit residents with behavioral health needs that the facility cannot meet. However, the facility must provide the appropriate care for the residents it does have.

Dementia

*Comment:* Some commenters were very concerned about the proposed rule not having specific requirements that addressed dementia. Some noted that the word dementia was not even included in the behavioral health section; however, the preamble implies that the proposed regulation would apply to residents with diagnoses such as dementia and Behavioral and Psychological Symptoms of Dementia (BPSD). They insisted that nothing was more central to the purpose of LTC facilities than providing good care to individuals with dementia. Dementia is increasing among LTC facility residents and two-thirds of those dying with dementia are dying in LTC facilities. They also noted that consumers and advocates have said that the quality of care that is provided in LTC facilities to residents with dementia is frequently poor and these residents are often chemically restrained and deprived of needed care and not treated with dignity. These commenters believed that establishing standards for dementia care in LTC facilities is a necessity. Some of these commenters recommended that there be a separate section and new standards for dementia care. Other commenters recommended adding a requirement to § 483.40(b)(1) stating, ''[a] resident whose assessment reveals a history of or potential for dementia-related behavior receives appropriate

care and interventions to prevent or de-escalate dementia-related behaviors.'' Some commenters recommended that we incorporate into the requirements the guidance on dementia contained in the survey and certification letter, ''Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309—Quality of Care and F329—Unnecessary Drugs'' (S&C: 13–35–NH) that was published on May 24, 2013.

*Response:* We believe and intended that dementia be included in our requirements that address behavioral health. However, we understand the commenters' concerns regarding the lack of specific requirements concerning the care of residents with dementia. The survey and certification letter recommended by some of the commenters (S&C: 13–35–NH) does contain valuable guidance for LTC facilities concerning care for their residents with dementia. However, we did not propose specific requirements for the care of residents with dementia. We believe that this would require more research and discussion than we have completed at this time. However, we will retain these comments in case there is future rule-making concerning dementia. At this time, we can specifically include dementia as a condition that the facility must address. Thus, we have inserted at § 483.40(b)(3), the following, ''[a] resident who displays the signs of or is diagnosed with dementia, receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.''

*Comment:* Some commenters were concerned about the burden associated with these requirements. Some commenters were concerned about imposing additional reporting and documentation requirements. Others were concerned about whether facilities would need to ensure expanded access to outside professional behavioral health services, which are costly and already difficult to access in rural and geographically underserved areas. Some commenters also noted that facilities would incur potentially significant cost to provide required behavioral health training to their entire staff under the proposed § 483.95(i).

*Response:* We do not believe that the costs associated with the behavioral health services requirements are burdensome for LTC facilities. In the previous requirements, § 483.25 ''Quality of care,'' LTC facilities were already required to ensure that, ''[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.'' In addition, concerning mental and psychosocial functioning, facilities were already required to ''ensure that—(1) [a] resident who displays a mental disorder or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem; and (2) [a] resident whose assessment did not reveal a mental disorder or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable'' (former § 483.25(f)). Hence, LTC facilities should already be complying with many of the requirements in this rule and that should reduce the costs associated with complying with these requirements.

After considering the comments, we are finalizing as proposed, with the addition of the definition for ''behavioral health.''

*O. Pharmacy Services (§ 483.45)*

The LTC requirements regarding pharmacy services were located at § 483.60. We proposed to relocate these provisions to § 483.45. Section 483.60(c) required a pharmacist to perform a drug regimen review (DRR) for each resident at least once a month. At § 483.45(c)(2), we proposed that the pharmacist be required to review the resident's medical record concurrently with the DRR when: (1) The resident is new to the facility; (2) a prior resident returns or is transferred from a hospital or other facility; and (3) 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. The previous LTC requirements at § 483.25(l)(2) specifically identified antipsychotic drugs and provided specific safeguards for their use. We proposed to re-designate these requirements to § 483.45(e) and at § 483.45(c)(3) to expand the drugs to which § 483.45(e) applies to include psychotropic medications (anti-psychotic drugs are included in the definition of psychotropic drugs). We proposed to use the definition of psychotropic drug used in the November 2001 OIG report, ''Psychotropic Drug Use in Nursing Homes'' (OEI–02–00–00490), which is a drug that affects 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) anti-anxiety, (4) hypnotic, (5) opioid analgesic, and (6) any other drug that results in effects similar to the drugs listed above.

The previous LTC requirements also required the pharmacist who conducted the monthly DRR to report any irregularities to the attending physician and the director of nursing. The term ''irregularities'' was not previously defined in the regulation and no examples were given. We proposed at § 483.45(c)(4) to define ''irregularities'' as including, but not limited to, the use of any drug that meets the criteria set forth in proposed paragraph (d) for an unnecessary drug. In addition, previously the pharmacist performing the monthly DRR was required to report any ''irregularities'' to the attending physician and the facility's director of nursing, and that these reports must be acted upon.

We proposed that the medical director be added to the individuals who should be notified of irregularities identified by the pharmacist during the residents' DRRs. We also proposed that the pharmacist create a written report that is dated, and contains, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. To ensure that the reported irregularities are acted upon, we also proposed that the attending physician must document in the resident's medical record that he or she has reviewed the report of the identified irregularity and what, if any, action has been taken to address it. If there is to be no change in the medication for which an irregularity was identified, the attending physician should document his or her rationale in the resident's medical record.

The current description of ''unnecessary drugs'' and the specific requirements for antipsychotic drugs are set forth in § 483.25(l)(1) and (2), respectively, under the ''Quality of Care'' condition of participation. We proposed to relocate these requirements from § 483.25 ''Quality of Care'' to proposed § 483.45 ''Pharmacy services.''

In addition, we proposed at § 483.45(e)(3) that LTC facilities ensure that residents would not receive psychotropic drugs pursuant to a PRN order unless that medication was necessary to treat a diagnosed specific condition that was documented in the clinical record. In addition, at § 483.45(e)(4), we proposed that every PRN order for a psychotropic drug be limited to 48 hours and not be

continued beyond that time unless the resident's primary care provider, for example, his or her physician, documented the justification for this continuation in the resident's clinical record.

General Comments

*Comment:* Some commenters were generally supportive of the proposed requirements for pharmacy services. One commenter said the section strengthened the role of both the physician review and accountability in regards to psychotropic medications and added additional oversight by the pharmacists. One commenter believed CMS already had, and had used, its authority to enforce requirements concerning unnecessary drugs and inappropriate drug use.

*Response:* We thank these commenters for their support for the proposed requirements for pharmacy services. Although CMS already exercises its authority to regulate the use of unnecessary and inappropriate drugs, we believe that the requirements finalized in this rule will strengthen the protections for residents concerning pharmacy services and improve our oversight of the drugs used in LTC facilities.

*Comment:* Some commenters believed that our proposals were insufficient to protect residents from the inappropriate use of psychotropic medications or otherwise questioned the value of the proposals. Some commenters also recommended additional provisions, such as informed consent from the resident or resident representative prior to administering any psychotropic or anti-psychotic drug. Another commenter believed that LTC facility resources would be better spent on enforcing and reinforcing existing requirements, combined with an intensified focus on some of the key underlying reasons for problematic prescribing and use of medications (including medication-related problems during care transitions and acute changes of condition), regardless of the medication category or underlying medical condition.

*Response:* We believe the requirements finalized in this rule strengthen the protections for residents from the use of inappropriate drugs. For example, the finalized requirements for the monthly DRRs, which include a requirement that each resident's medical record be reviewed in conjunction with the monthly DRR, should result in more frequent and thorough reviews of residents' drug regimens. Please see the section on DRRs below for further explanation. The requirement to copy the facility's medical director on the report of irregularities, in addition to the attending physician and the facility's director of nursing, should result in medical directors becoming more aware of, if not involved in, the residents' medication management. Requiring the attending physician to document his or her review and action taken with respect to any identified irregularity should ensure that the irregularity is reviewed, and that medication errors and potential adverse events related to medications are minimized. Expanding the requirements for antipsychotic drugs to psychotropic drugs will expand protections for residents prescribed drugs that have an increased potential for being prescribed inappropriately or for reasons other than the resident's benefit, such as for the purpose of a chemical restraint.

*Comment:* One commenter disagreed with our proposals regarding pharmacy services because the proposals did not address the root cause of the medication issues in LTC facilities. The commenter stated that most medication management and related issues emanate from shortcomings in the care delivery process and clinical reasoning and diagnosis. They said that the proposed changes would only create another ''silo'' by reorganizing more requirements into the Pharmacy Services requirement. Since implementation is the primary challenge, the commenter stated that everyone's time and effort would be better spent in enforcing and reinforcing existing requirements, combined with an intensified focus on some of the key underlying reasons for problematic prescribing and use of medications (including medication-related problems during care transitions and acute changes of condition), regardless of the medication category or underlying medical conditions. They believe that the most effective approach would be to focus all providers and practitioners on a thorough evaluation of each resident to establish a clinically valid rationale for all current treatments, and to effectively use existing requirements and surveyor guidance to look for evidence of appropriate clinical care, documentation, and implementation.

*Response:* The ''Pharmacy Services'' requirements are a part of a comprehensive update of the long-term care requirements. As finalized, we believe all of the requirements in this rule, including the ''Pharmacy Services'' section, will work together to protect the residents' rights and improve the quality of care they receive in LTC facilities. For example, the pharmacist must do a medical record review when the resident is taking an antibiotic or any drug the facility's QAA committee has requested be included in the monthly DRR (42 CFR 483.45(c)(2)(iii)). Reviewing the medical record concurrently with the MAR or other list of current medications during the monthly DRR if the resident is taking an antibiotic supports the infection control program, especially the antibiotic stewardship program (§ 483.80(a)(3)). Since the QAA committee coordinates and evaluates QAPI activities under the QAPI program, the pharmacist reviewing the medical record for those residents taking a drug identified by the QAA committee also contributes to QAPI activities. Thus, the requirements finalized in this rule should work together to address the care delivery process and promote improved clinical care for the residents.

*Comment:* Some commenters were concerned that the pharmacy services requirements appeared to place the primary responsibility for medication management, especially for antipsychotic or psychotropic drugs, on the pharmacist. They argued that other disciplines, especially prescribers and nursing, have the primary accountability for the residents' drug regimens. One commenter also noted that while the consultant pharmacist and the IDT provide input to the prescriber, it is the prescriber, not the consultant pharmacist, who determines which medications are appropriate, based on the resident's clinical condition, goals of care, and the risks, benefits and alternatives to specific medications.

*Response:* It is the physician or the prescribing practitioner who is responsible for prescribing medication. Nurses also bear the responsibility for the medications they administer to residents. Hence, we disagree with commenter that the proposed requirements place the primary responsibility for medication management on the pharmacist. The pharmacist is performing a DRR designed to identify irregularities, which is within their scope of practice. When the pharmacist identifies an irregularity, he or she is identifying a medication that they believe presents an issue that needs to be addressed. However, it is not the pharmacist but the attending physician who would review the identified irregularity and the resident's medical record and then determine if there should be any change to that medication. Thus, the resident's medication regimen is the responsibility of the physician or the prescribing practitioner, not the pharmacist.

*Comment:* Some commenters were concerned that the proposed requirements were intended to have an overall chilling effect on the prescription of psychotropic drugs in LTC facilities. One commenter asserted that the proposed requirements established a default position that basically psychotropic drugs were not to be prescribed and, if a resident was on one of these drugs, the facility was to do everything it could to get the resident off the drug. This could result in anti-psychotic and other psychotropic medications not being prescribed even when they are appropriate and needed for the resident's health and for their benefit.

*Response:* As we said in the proposed rule, ''[w]e want to emphasize that the proposed requirements concerning psychotropic medications are not intended to have a chilling effect or in any manner discourage the prescription or use of any medication intended for the benefit of a resident who has been diagnosed [with] a specific condition that requires these medications. Our proposed requirements are intended to protect LTC facility residents from drugs that are not being prescribed for their benefit'' (80 FR 42204). In addition, as described below, we have not finalized all of the requirements as proposed. As discussed below in responses to comments, we have made modifications in this proposed rule in response to such comments. We do not believe that the requirements finalized in this rule are so burdensome that any practitioner should be discouraged from using any psychotropic medication when it is appropriate for the resident and is being prescribed for the resident's benefit.

*Comment:* Some commenters were concerned about reorganizing these requirements from the quality of care section to the pharmacy services section. They believed this created the impression that antipsychotic or other psychotropic drugs were not a matter for quality of care or a fundamental human right. They also expressed concerns about how this reorganization would affect the surveyor's ability to be able to extend surveys due to a finding of substandard care. Some commenters wanted the pharmacy requirements retained in the quality of care section. They believed that only requirements related to procedures, staff, credentials, and so forth should be included in the pharmacy services requirements. They were also concerned that it would create an undesirable ''silo''.

*Response:* We acknowledge that there will need to be changes in the survey process due to some of the changes encompassed in this final rule. However, any changes to the survey process will be managed through sub-regulatory guidance. We disagree with the commenters regarding the reorganization. As we explained in the proposed rule, we believed that there needed to be improvements in the overall readability and logical order of the requirements (80 FR 42178). We believe that the requirements in the pharmacy services sections should logically be grouped together and their new location makes them more accessible, especially to individuals who are not familiar with the requirements.

*Comment:* One commenter recommended that the pharmacy services section be re-written to specify the goal and purpose for the use of psychotropic medications. They suggested that we specify in the requirements that the goal of caring for individuals with cognitive impairment is to limit the use of psychotropic medications. They recommended that the classes of medications along with exceptions or drugs in those classes to which the requirements should not apply, be included in the sub-regulatory guidance.

*Response:* The goal or purpose of the requirements finalized in this rule is not to limit the overall amount of psychotropic drugs used by the facility or to supplant the judgment of a physician or other prescribing clinician concerning the use of psychotropic medications. As stated above, the purpose of these requirements is to ensure that residents receive psychotropic drugs only when these medications are appropriate and intended for the resident's benefit. These requirements are intended to decrease, and hopefully eliminate, inappropriate psychotropic drug use and the use of medications for reasons other than the resident's benefit.

Drug Regimen Reviews

*Comment:* Some commenters approved of the proposed requirements concerning drug regimen reviews (DRRs), especially the requirement for periodic review of residents' medical records and monthly reviews when the resident is taking certain medications or during transitions in care. One commenter believed that requiring a medical record review for residents taking drugs identified by the QAA Committee was a good idea. However, some commenters recommended that the requirements be strengthened by requiring the concurrent review of each resident's medical record during the monthly DRRs. Another commenter wanted to require that all residents have their medical records reviewed during the DRR at least quarterly, instead of every six months. Another commenter supported the proposed requirements for reviewing the medical record in conjunction with the DRR under the proposed circumstances; however, the commenter also noted their concern about polypharmacy. Some commenters even stated they believed that a DRR by definition implies review of the resident medical record. This would enable any issues with the resident's medications to be identified sooner.

*Response:* After reviewing the comments we received concerning the proposed requirement for the pharmacist to review residents' medical records in conjunction with the monthly DRR under certain specific circumstances, we agree with the commenters that the pharmacist should review each resident's medical record during every monthly DRR. We also agree with the commenter that expressed concern over the large number of drugs that many residents are being prescribed or polypharmacy. In addition, we agree that reviewing the medical records for all residents with each monthly DRR would likely identify irregularities sooner. Identifying irregularities sooner could assist in preventing adverse medication reactions and aid in earlier identification of medication issues. Requiring that the pharmacist review the medical record for each resident during his or her monthly DRR provides residents with protection from inappropriate drug use without being burdensome for the facility. Thus, we will not be making the commenters' recommended changes to require monthly or quarterly review of medical records in conjunction with the DRR, but modifying § 483.45(c)(2) by requiring that the monthly DRR include a review of the resident's medical record.

*Comment:* Some commenters were concerned about situations in which there is no action concerning an irregularity identified by the pharmacist during the DRR. Some commenters recommended a requirement for the pharmacist to report the irregularity and the lack of any action concerning that irregularity to an outside authority, such as the state's office of the long-term care ombudsman, state licensing authority, or CMS, if the pharmacist's believes that the irregularity detected requires action.

*Response:* While we appreciate the commenters' concerns for residents, we do not believe that it is appropriate to require pharmacists to report to an outside entity if they do not agree with the action or lack of action taken by the attending physician or other prescribing

practitioner. The attending physician is notified of the irregularity, as well as the facility's medical director and director or nursing. It is the attending physician's responsibility to review the identified irregularity and take any action, or no action, based upon his or her professional judgment. If there is no action and either the facility's medical director or DoN has questions or disagrees, we would expect that either or both of these individuals would follow-up with the attending physician. Unless specifically allowed under the relevant state law, it is outside the scope of practice for pharmacists to prescribe medication. The appropriate action to take after an irregularity is identified is the responsibility of the attending physician. However, we do believe that the resident's medical record should demonstrate that the attending physician has reviewed the identified irregularity and what, if any, action was taken. If no action was taken, the medical record should indicate why no action was appropriate. Thus, we have finalized § 483.45(c)(4)(iii) that requires the attending physician to document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been 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.

*Comment:* Some commenters wanted there to be more transparency with the monthly DRR process. They recommended that the report of irregularities become part of the resident's medical record. Another commenter wanted the resident or the resident's representative to be notified of the irregularity.

*Response:* According to the SOM, Appendix PP-Guidance to Surveyors for Long Term Care Facilities (Rev. 149, 10–09–15), the pharmacist's findings are part of each resident's active medical record. These findings should be maintained in the resident's medical record or in the facility where it is readily available for review. According to proposed § 483.10(f)(3), finalized at § 483.10(g)(2), the resident has the right to access any medical record that pertains to him or herself. Thus, the pharmacist's findings are already available to the resident or the resident's representative. However, we decline to require that the resident or their representative be notified of the pharmacist's findings. The irregularity identified by the pharmacist may require no action, updating or modifying documentation, or some other action that does not affect the quality of care for the resident. Unnecessary notifications could lead to confusion and anxiety for the resident. We believe that it is the responsibility of the attending physician to determine whether to notify the resident or their representative. In addition, each facility could also make that determination and address notification of the resident and the resident's representative in the policies and procedures for the DRR process that is now required at § 483.45(c)(5).

*Comment:* Some commenters expressed concerns over various aspects of the DRR. Some were concerned about the absence of timeframes concerning how much time the pharmacist should have after discovering an irregularity to submit a report of irregularities to the attending physician, medical director, and the director of nursing or how long the facility or attending physician has to take action on any identified irregularities. In addition, some commenters were concerned there were no requirements related to what a pharmacist should do if he or she believed the identified irregularity required urgent or emergency action to protect the resident. Some commenters also recommended that there be designated circumstances or triggers for an emergency review. One commenter proposed that the supervising or attending nurse should be able to request an emergency medical records review from the pharmacist for residents taking psychotropic drugs upon observation of adverse side effects, significant changes in the resident's condition, the absence of a diagnosis of a major mental disorder in the medical records, or the presence of a primary diagnosis of Alzheimer's Disease or another form of dementia. If the irregularity involved the inappropriate use of psychotropic drugs, the facility should be required to take immediate steps to gradually reduce the drug and implement behavioral intervention with the goal of discontinuing the use of the drug as soon as it is safe and practicable. Other commenters were concerned about the increased documentation required by physicians, especially in cases where physicians might have to repeatedly document rationales for the same medications for the same residents after a pharmacist noted the medication on the report of irregularities. These commenters recommended that accommodations be made in cases where there had been previous irregularities noted for the same medication for a particular resident and even provided specific language for the regulatory text. Other commenters recommended that the facilities have policies and procedures that cover different aspects of the DRR process.

*Response:* We agree with the commenters that LTC facilities should have policies and procedures concerning the monthly DRR, including appropriate time frames. We also agree that pharmacists should have a procedure to follow so that the appropriate individuals are notified if the pharmacist believes that an irregularity needs to be reviewed immediately due to the potential for harm to a resident. However, we do not believe that we should establish those time frames. We believe that each facility should establish policies and procedures that address the entire DRR process, especially the timeframes for various actions in the process and a procedure for a pharmacist to follow when he or she believes the irregularity must be addressed immediately due to the potential for harm to the resident. We disagree with the commenter that recommended that the attending or supervising nurse be able to request that the pharmacist perform an emergency DRR for a resident under certain circumstances or, if the drug in question is a psychotropic, institute gradual dose reductions (GDRs). The facility should have its own policies and procedures for the nurse if she or he is concerned about any medication order. We generally believe that the nurse, not the pharmacist, should be contacting the attending physician or the prescribing practitioner if there are any questions concerning the safety or appropriateness of a medication for a resident.

We also agree with the commenter that physicians should not be required to repeatedly document the same rationale in the resident's medical record, once a clinically acceptable rationale is already documented in the medical record for a specific medication. However, we believe that each facility should have the flexibility to determine the best manner in which to handle this situation. We encourage facilities to address this situation in their policies and procedures concerning the monthly DRR. Concerning the other recommendations, we believe that each facility needs the flexibility to determine how the monthly DRRs will be conducted and how the facility will comply with the requirements in this final rule. Thus, in this final rule we are adding a requirement at § 483.45(c)(5) that the facility must establish and maintain policies and procedures that addresses the monthly DRR, including but not limited to, timeframes for the various steps in the process and procedures a

pharmacist is to take when he or she believes immediate action is required due to potential harm to the resident.

*Comment:* One commenter disagreed with the amount of detail and specificity in the requirements for the DRR. They also did not believe the regulatory text was sufficiently flexible to accommodate likely changes related to medication usage without modification. One commenter stated that with the increasing adaptation of e-prescribing real time reviews will become more frequent. With these types of reviews, some of the pharmacy requirements will become outdated. They recommended more general language, such as that in the preamble. They suggested we amend § 483.45(c)(2) to read: ''[t]his review must occur on a regular basis including more frequent targeted reviews for medications that may be associated with an increase of adverse events or overutilization as well as when the resident experiences transitions in care or when requested by the facility.'' Written communication, they believed, did not allow for new and more effective methods of communication. By specifying specific elements, it would not provide for new data elements. Some commenters also argued that there was too much specificity concerning when the medical record review must be done in conjunction with the DRR.

*Response:* We do not believe that the preamble language cited by the commenter would be appropriate for the regulatory text. The regulatory text must be specific enough to inform the facility of what activities are necessary to comply with the requirement. While it may be appropriate under certain circumstances to use more general language such as that suggested by the commenter, we do not believe it is appropriate for the monthly DRR. The inappropriate use of drugs has the potential to be very dangerous for residents. We believe that there are specific times when the medical chart must be reviewed concurrently with the DRR to ensure a thorough review of the resident's drug regimen and provide the resident with protection from inappropriate drugs. We believe that the requirements are specific enough to clearly indicate what is necessary to comply with the requirement, but flexible enough to allow facilities to decide how to comply. Thus, we have finalized as proposed the requirements for when a pharmacist must review the resident's medical record in conjunction with the DRR and the report of irregularities.

*Comment:* One commenter was concerned about adding the facility's medical director to the list of individuals to whom the report of irregularities must be forwarded. The commenter noted that by increasing the number of persons the report must be forwarded to, it increased the likelihood of miscommunication and errors. Other commenters wanted the report forwarded to the appropriate prescribing practitioner, not just the attending physician.

*Response:* We believe that it is crucial that the facility's medical director be notified of any irregularities detected by the pharmacist in the monthly DRRs. The medical director is responsible for the medical care provided in the facility. In addition, as a physician, the medical director is in the best position to discuss the identified irregularity with the attending physician, especially if there are continuing concerns about the medication after the attending physician has reviewed and acted upon the identified irregularity. Concerning the report of irregularities, although the pharmacist is required to forward the report of irregularities to the attending physician and the facility's medical director and director of nursing, this does not preclude the facility from forwarding the report to any other individuals they believe is appropriate, such as a prescribing practitioner.

*Comment:* Some commenters were concerned about conflicts of interest between the facility and the pharmacists who are conducting the monthly DRR. These commenters wanted us to address the issue of independence for these consulting pharmacists.

*Response:* Requirements addressing the independence of the consulting pharmacist were not included in the proposed rule. Therefore, we will not address this issue in this final rule. However, we will consider these comments if there is any future rulemaking concerning this issue.

Definition of ''Psychotropic Drug''

*Comment:* Some commenters supported the proposed definition of ''psychotropic drugs.'' One commenter noted that use of inappropriate psychotropic medications is prevalent in nursing facilities. They indicated that psychotropic drugs are powerful and often given to sedate or control elderly people with behavioral challenges caused by dementia, rather than major mental disorders as defined at 42 CFR 483.102. Thus, these drugs are not being prescribed or administered in accordance with the safeguards set out in the current regulation.

*Response:* We thank the commenters for their support. We believe that the definition of ''psychotropic drug'' finalized in this rule will not only ensure additional scrutiny when prescribed, but will also enhance the protection for residents from inappropriate use of these and other medications not prescribed for the residents' benefit. However, based upon our review of the public comments, we have made some modifications to the definition as described below.

*Comment:* Several commenters stated that the proposed definition was so expansive as to make the use of psychotropic drugs unmanageable. The commenters indicated that the proposed definition would also include medications that do not warrant the resident protection safeguards and additional scrutiny required when a psychotropic drug is prescribed for a resident. One commenter recommended we use the term ''psychopharmacological medication'' instead of ''psychotropic drugs.'' One commenter said the new definition was unlikely to improve or correct process problems.

Some commenters were especially concerned about the last part of the definition, ''any other drug that results in effect similar to the drugs listed'' in the previous sections. They believed this was too expansive and included nearly all medications, such as drugs for seizures and Parkinson's disease, NSAIDs, beta-blockers, and eye drops for glaucoma. Another commenter also argued that the proposed definition would include commonly used drugs that do not merit additional scrutiny, such as Compazine, which is used for nausea. Another commenter recommended we define the classes of drugs, but provide exceptions in sub-regulatory guidance.

*Response:* After reviewing and analyzing the comments, we believe that the definition of psychotropic drugs should be modified. We share the commenters' concerns that the proposed definition for ''psychotropic drugs'' at § 483.45(c)(3) might include many drugs for which the additional requirements in this section would be superfluous and unnecessary. Hence, we have removed the last element in the proposed definition of ''psychotropic drug,'' specifically, ''(vi) Any other drug that result in effects similar to the drugs listed in paragraphs (c)(3)(i) through (v) of this section.'' We have also modified the language in § 483.45(c)(3) to read, ''[e]xamples of these drugs, include but are not limited to, drugs in the following categories . . .'' We modified this language to clarify that the definition includes drugs from the four identified categories (anti-psychotic, anti-depressant, anti-anxiety, and hypnotic)

and that CMS has the authority to add other drugs to the definition through sub-regulatory guidance.

*Comment:* Some commenters support the goal of reducing the use of unnecessary psychotropic medications in long-term care facilities, but were concerned that the proposed requirements, including the drugs included in the definition, were so extensive that it could result in under-treatment of pain and other distressing symptoms and reduce the efficacy of palliative care and the overall quality of life for the residents. They argued that individuals suffering from pain have the right to be informed of, choose, and receive effective pain and symptom evaluation, management, and ongoing monitoring as part of basic medical care, even if such pain and symptom management may result in analgesic tolerance, physical dependence, or as an unintended consequence, shorten the individual's life. They believe that the inclusion of both antidepressants and opioid analgesics in the definition of ''psychotropic drugs'' would inevitably cause LTC facilities to avoid the use of such interventions, because they would be scrutinized as closely as anti-psychotic drugs, which have too often been misused in long-term care settings. The proposed regulation could potentially cause not only under-treatment but also unnecessary hospitalizations due to necessary medication not being prescribed or lapses in prescriptions due to limitations on PRN prescriptions of psychotropic drugs. One commenter stated it would be difficult to survey facilities consistently, using that definition.

*Response:* We agree with the commenters that the proposed definition of ''psychotropic drug'' is too broad. We especially agree with the commenters that objected to including opioid analgesics in the definition. We are particularly concerned about the possibility that including opioid analgesics in the definition could result in negative consequences for pain management, especially since they are usually given PRN and there could be interruptions in the prescriptions due to the proposed limitation on PRN prescriptions. Therefore, we have removed the drug category of ''opioid analgesics'' from the finalized definition of ''psychotropic drug.'' Although we have not removed anti-depressants from the definition, we have made modifications to the PRN limitation that we believe addresses the commenters' concerns, which are discussed below.

Although we are not finalizing ''opioid analgesics'' in the definition of ''psychotropic drug,'' it is not our intention to in any way to either diminish the importance of these drugs in the alleviation of pain nor the serious consequences of their inappropriate use. Opioid abuse is a serious public health issue with devastating consequences. Currently, the United States is in the midst of a prescription opioid overdose epidemic. According to the Centers for Disease Control (CDC), in 2014, more than 28,000 people died from opioid overdose, and at least half of those deaths involved a prescription opioid. Many more became addicted to prescription and illegal opioids.[1] Overall, overdose deaths from opioids, including prescription opioids and heroin, have nearly quadrupled since 1999.[2] In response to this crisis, HHS has made addressing the opioid epidemic a top priority.

HHS continues to build upon current efforts to combat the opioid abuse epidemic, including continuing to help health professionals to make the most informed prescribing decisions by:

- Teaching medical professionals how and when to prescribe opioids by working with lawmakers on bipartisan legislation requiring specific training for safe opioid prescribing and establishing new opioid prescribing guidelines for chronic pain;
- Supporting data sharing for safe prescribing by facilitating prescription drug monitoring programs (PDMP) and health information technology integration and further adoption of electronic prescribing practices;
- Increasing investments in state-level prevention interventions, including PDMPs, to track opioid prescribing and support appropriate pain management.

In addition, HHS supports efforts that encourage the increased use of naloxone, which reverses potentially fatal overdoses caused by opioids, and expand the use of Medication-Assisted Treatment (MAT), which combines behavioral therapy and medications to treat substance use disorders. In addition, we strongly encourage prescribing practitioners to follow CDC guidelines for prescribing opioids for chronic pain. The CDC guidelines provide recommendations which focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. The CDC guidelines are available at the following Web site: *http://www.cdc.gov/drugoverdose/prescribing/guideline.html*. We note that additional information and guidance on the CDC guidelines, as well as guidance on how practitioners can help to combat opioid abuse, will be included in the sub-regulatory interpretive guidance, which will be available after the publication of this final rule.

We believe that the requirements we have finalized in this rule provide residents with the protections they need from the inappropriate use of drugs, including opioids. However, we will continue to assess the opioid epidemic and will consider whether to propose additional requirements for providers in future rulemaking.

*Comment:* One commenter said that good medical practice requires that all issues and conditions be viewed and managed in the proper context, and not as isolated conditions or risks. Singling out certain topics actually limits and reverses the current requirement, because it distracts attention from other equally or more important issues. Facilities learn only to address those medications that are on the radar screen, resulting in problematic use of many medications that are not under intense scrutiny.

*Response:* The pharmacy services requirement at § 483.45 in this final rule addresses all medications. Although any drug could be used inappropriately, we believe that certain medications, such as psychotropic drugs, do have more potential for inappropriate use. Such drugs also merit additional scrutiny for the protection of the residents. Hence, we are finalizing the requirements related to psychotropic drugs, as modified by this rule.

*Comment:* One commenter recommended that instead of the proposed definition of psychotropic drug and the PRN limitation, CMS should instead take steps to develop palliative care quality indicators focused on assuring that the care received is in accordance with resident and family priorities.

*Response:* We did not propose the development of palliative care quality indicators in the proposed rule. This comment is beyond the scope of this rule. However, we will keep this comment in mind if there is future rulemaking on this issue.

*Comment:* Some commenters stated that while psychotropic drugs are a problem in LTC facilities, they opposed including anti-psychotic drugs. They argued that combining anti-psychotic drugs into a new category called

[1] Centers for Disease Control and Prevention. *Increases in Drug and Opioid Overdose Deaths—United States, 2000–2014.* MMWR 2015; 64;1–5.

[2] CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at *http://wonder.cdc.gov*.

psychotropic drugs dilutes or takes attention away from anti-psychotic drugs, which are harmful and deadly when given to most LTC facility residents, who have dementia but no psychosis. There is less evidence that other psychotropic drugs are as frequently prescribed inappropriately or are as harmful for LTC facility residents. Some suggested that the current requirements for anti-psychotic drugs be maintained or expanded and that a separate section for psychotropic drugs be finalized. One commenter supported expanding the definition of drugs of concern, but also supported continued collection of data specific to anti-psychotics. Some expressed the belief that the proposed requirements actually diminished or reduced the focus on antipsychotic drugs.

*Response:* We do not believe that expanding the requirements that previously only applied to anti-psychotic drugs to all psychotropic drugs would diminish or dilute the attention given to antipsychotic drugs. Antipsychotic medications are included in the definition of ''psychotropic drugs,'' and are a focus for CMS. Since 2012, CMS has partnered with other federal and state agencies, LTC facilities, other providers, advocacy groups, and caregivers to form the ''National Partnership to Improve Dementia Care in Nursing Homes'' (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html*, accessed December 30, 2015). The initial focus of this partnership was to encourage reduction in the use of anti-psychotic medications. Since the launch of this initiative, there have been significant reductions in the use of anti-psychotic medications in LTC facilities. For specific information on the National Partnership to Improve Dementia Care in Nursing Homes, see their Web site that can be accessed at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html*. We also disagree with the commenter that other medications should not receive the same scrutiny as anti-psychotic drugs. However, we do agree that anti-psychotics do merit more scrutiny under some circumstances. Anti-psychotic drugs continue to be a particular concern for us due to the serious side effects, including death, to elderly residents. In response to comments, we have modified the general PRN limitation on psychotropics specifically with respect to anti-psychotic drugs, which is discussed below. We are finalizing the definition of ''psychotropic drugs'' to include four specific categories of drugs, including anti-psychotic drugs.

*Comment:* Some commenters expressed concern that the proposed pharmacy services requirements do not include sufficient protection against antipsychotic and psychotropic medications being used as chemical restraints. They noted that there are epidemic levels of chemical restraints in LTC facilities. They also expressed their belief that there was likely underreporting of the residents who were being given antipsychotic drugs, despite the significantly increased risk of death from these drugs. Some commenters recommended a new section, which would specifically address chemical restraints and the unnecessary use of psychotropic drugs and one commenter suggested the regulation be based on a proposed rule published in 1992 by HHS (''Medicare and Medicaid Programs: Omnibus Nursing Home Requirements'', 57 FR 4516, February 5, 1992). Some commenters also recommended that the final regulation establish a presumption that chemical restraints are harmful, require written informed consent before the use of psychotropic drugs, strengthen rather than diminish focus on misuse of anti-psychotic drugs, require physicians to both examine residents before prescribing antipsychotic drugs and justify that the potential benefits clearly outweigh the potential harmful effects. Another commenter expressed concerns about the current enforcement of the right to be free from chemical restraints by the state survey agencies and CMS. A commenter wanted to define ''chemical restraint'' as the unnecessary use of a psychotropic drug.

*Response:* Residents have the right to be free from chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms, as already specified in § 483.12. We do not believe that a separate section on chemical restraints is necessary. We also believe that the special requirements previously imposed on anti-psychotics should be applied to psychotropic medications to protect residents from inappropriate use, especially to ensure that these medications are not used as chemical restraints and are only used for the benefit of the resident. In addition, we do not believe that it would be appropriate to characterize the unnecessary use of a psychotropic drug as a chemical restraint. Concerning the proposed rule published by HHS in 1992, we reviewed that rule during our research for this proposed rule (80 FR 42168). We did not re-propose some of the requirements in the 1992 proposed rule because we believed they were too prescriptive. We do not agree that the unnecessary use of a psychotropic drug should be defined as a ''chemical restraint.'' Some psychotropic drugs could be used unnecessarily or have some other type of irregularity associated with their use, and this would still not be considered a chemical restraint. For example, a facility could fail to properly monitor a resident who is taking a psychotropic drug; however, if this is the only irregularity, its use would not qualify the drug as a chemical restraint.

Specific Requirements Related to Psychotropic Drugs

*Comment:* Some commenters were concerned about the requirement for gradual dose reductions (GDRs) and behavioral interventions for all psychotropic drugs. Commenters argued that GDRs are not appropriate for many residents on psychotropic drugs. The commenters argued that GDRs are not appropriate for, among others, residents with mental disorders who are stable on their current drug regimen, such as residents diagnosed with depression, schizophrenia or bi-polar disorder or residents with seizure disorders. Another commenter stated that the term ''behavioral interventions'' is dated and misleading. One commenter recommended a broader requirement that ''[n]ursing homes should be required to use individualized care, services, attention and environmental modifications that are directed specifically towards the elimination or modification of the symptoms and distress for which the drugs are prescribed.'' Another commenter questioned why the proposal assumed that any psychotropic drug started prior to admission to the LTC facility was appropriate and did not require the documentation but that all of them would need a GDR along with behavioral intervention, unless contraindicated.

*Response:* We agree with the commenters that GDRs are not appropriate for all residents taking psychotropic drugs. Based upon the comments, it is apparent there was confusion about this proposal. The requirements finalized in this rule are intended to reduce the inappropriate use of psychotropic drugs and the use of these drugs for reasons other than the resident's benefit. This is consistent

with one of the central themes of this final rule, which is person-centered care (see § 483.21). For many residents, psychotropic drugs are clearly appropriate to address a diagnosed disorder, necessary for their health, and prescribed for their benefit. For those residents taking psychotropic drugs, we expect that each resident would be evaluated by their attending physician to determine whether GDRs and behavioral interventions for a psychotropic drug are clinically contraindicated. If GDRs and behavioral interventions for a particular psychotropic drugs are clinically contraindicated, the physician should document that in the resident's medical record. Many of the examples provided by commenters would likely be determined to clinically contradict GDRs and behavioral interventions. For example, a resident who is taking an anti-anxiety or anti-depressant medication for a diagnosed condition and who was prescribed the medication for their benefit and who is stable would likely not need these interventions. Otherwise, we would expect that the attending physician, in conjunction with the IDT (§ 483.21((b)), to consider GDRs and behavioral interventions and institute a plan that is appropriate for that resident. For that reason, we are finalizing as proposed the requirement for GDRs for residents taking psychotropic drugs, ''unless clinically contraindicated'' (§ 483.45(e)(2)).

Concerning the recommendation that we not finalize the term ''behavioral interventions,'' we note that facilities may use any terminology they choose to describe these activities; however, we believe that behavioral interventions is a commonly used term that is universally understood. Thus, we have finalized this requirement using the term ''behavioral interventions.''

We disagree with the commenter that said our proposal assumed that any psychotropic drug prescribed prior to admission to the LTC facility was appropriate and did not require the same documentation. Section 483.45(e) requires that residents who have not used psychotropic drugs not be given those drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record, but that all resident who received psychotropic drugs receive GDRs and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs. This requirement does not assume that psychotropic drugs that were prescribed prior to admission are appropriate. It is intended to ensure that residents are not put on psychotropic drugs without there being a diagnosed and documented condition for which they are appropriate. Then, all residents who are on psychotropic drugs must then receive the GDRs or behavioral interventions, unless they are clinically contraindicated, as discussed above.

*Comment:* One commenter recommended that psychotropic drugs should only be administered to a resident after the facility obtained informed consent from the resident or their representative.

*Response:* We have finalized the requirement for comprehensive person-centered care planning, which requires that the participation of the resident and the resident's representative, to the extent practicable (§ 483.21(b)). The resident and their representative should be involved in the resident's care. We believe that requiring a separate informed consent solely for psychotropic drugs would be burdensome for the facilities and unnecessary. It could also interfere with the resident's care if the resident needs a psychotropic drug urgently.

*Comment:* One commenter recommended that we require that psychotropic medications be used for FDA-approved conditions without limitations. We understand this to mean that the commenter wants to have psychotropic medications used only for the conditions set out in the medication's FDA approval. Alternatively, they suggested we change the language to either define ''antipsychotic use in dementia'' or ''psychotropic in dementia to treat'' whatever condition or disorder the drug is intended to treat the resident.

*Response:* We do not believe that the additional language recommended by the commenter is necessary. In addition, restricting the ability of health care practitioners to prescribe medication for uses other than those that have received FDA approval could violate the prohibition against interference with the practice of medicine at section 1801 of the Act.

*Comment:* Some commenters were concerned about the effects these requirements could have on the facility. Another commenter was concerned that with such an increase in documentation requirements, some LTC facilities could unintentionally be out of compliance, with our requirements, resulting in a cascading sequence of penalties. The additional time and resources to correct any non-compliance would take away from resident care.

*Response:* We believe that the requirements in this final rule are reasonable and necessary. We also believe that these requirements are not overly burdensome for the LTC facilities. Additional sub-regulatory guidance to assist LTC facilities in complying with the requirements in this final rule will be provided after this final rule is published.

Limitations on PRN Prescriptions of Psychotropic Drugs

*Comment:* Many commenters were concerned about the 48 hour limitation on PRN prescriptions for psychotropic drugs. One commenter wanted to prohibit PRN orders for all anti-psychotic drugs. The commenter stated that physicians should not delegate the responsibility for PRN order for psychotropic drugs to the nursing staff. They believed that it was inappropriate to have the nursing staff determine when and for how long anti-psychotics and other psychoactive drugs were to be administered to a resident.

*Response:* Based upon our own experience with LTC facilities, as well as other comments, there are situations in which PRN prescriptions for psychotropic drugs are appropriate for residents. Some residents may require a therapeutic trial to determine if a particular medication addresses the diagnosed disorder and what the correct dosage should be. In addition, some residents may only require a psychotropic drug for intermittent symptoms. We are also concerned that prohibiting PRN prescriptions for psychotropic drugs could result in either overmedication from physicians prescribing these drugs on a specific schedule when a PRN order would be appropriate or under medication from physicians not prescribing drugs they believe are needed for the resident's health. In addition, we believe that it is appropriate, and within their scope of practice, for nurses to make decisions on when drugs prescribed via PRN orders should be administered, including psychotropic medications. We also believe that prohibiting PRN orders for psychotropic drugs could violate the Act's prohibition against interference with the practice of medicine at section 1801 of the Act. Thus, we will not prohibit the PRN prescription of psychotropic drugs.

*Comment:* Many commenters stated that the 48-hour limitation on PRN prescriptions for psychotropic drugs could result in serious unintended consequences. Some commenters argued that the 48-hour limitation could be difficult, if not impossible to comply with, especially in rural areas which may have limited access to physicians or other prescribers. Some commenters stated that the physicians or other health care practitioners who covered

their facilities, such as nurse practitioners, not only covered their facilities but also had their own private practices or covered other facilities. By increasing the burden to these providers, it could become more difficult to locate providers who would be willing to provide services in their facilities. Other facilities also noted having limited access to a physician or other health care practitioner who could renew a prescription for a psychotropic drug every 48 hours. Unless the physician was coming to the facility, the nurse would likely have to call the physician and get a verbal order to renew the prescription. Depending upon the number of these prescriptions, this could be time-consuming for both the nurse and the physician. This requirement also does not provide for the physician to assess the resident in person. If the prescription was renewed over the phone, there might be minimal, if any, assessment of the resident before the prescription would be renewed. Commenters indicated that the proposed requirements could also result in more frequent transfers to the emergency room due to interruptions in residents' drug regimens of essential drugs, such as could happen if the resident was on antipsychotic drugs or pain medication. Since it could require longer than 48 hours to assess a resident's response to some medication, such as during therapeutic trial or GDR, this proposed requirement could result in numerous renewals of the same prescription before the physician would have time to reasonably assess whether there should be any change in the prescription. In some cases, physicians might avoid this limitation in cases in which they believe it is not appropriate by writing the prescription for regular intervals when they would otherwise determine that a PRN prescription would be appropriate for a resident. Other commenters suggested a longer timeframe, such as 72 hours or 7 days. One commenter recommended at least 7 days and some commenters recommended CMS delete the limitation on PRN medications entirely. One commenter stated that the current surveyor guidance defines an acute psychiatric situation and allows use of psychopharmacological medications for up to a week before additional documentation is needed. One commenter suggested there be a requirement that facilities develop policies with the medical director and/or medical staff to define the review process for all PRN medications, including timing of the review and documentation expectations. Another commenter recommended an exception for residents who are expected to be in the facility for a short-term, since these residents are expected to return to their primary care providers upon discharge.

*Response:* We agree with the commenters that our proposal for a 48-hour limitation on PRN prescriptions for psychotropic drugs could result in unintended consequences that could be detrimental to the residents' health in some cases and might also be burdensome for some facilities. In addition, based on our experience with LTC facility residents and comments we received, there are cases in which it is appropriate for a particular drug to be given PRN for a prolonged period of time. For example, some residents could require anti-depressants or anti-anxiety medications long-term but only intermittently based upon the resident's symptoms. As described above, we believe that some of the commenters' concerns have been addressed by the modifications made to the definition of ''psychotropic drugs'' in this final rule, especially by not finalizing opioid analgesics as a category of drugs to be included. However, we continue to be concerned about PRN prescriptions. As we were conducting research for the proposed rule, we became aware of concerns about residents remaining on PRN prescriptions for prolonged periods of time when it might not be appropriate. Based upon comments, we now believe that a 48-hour limitation is overly restrictive and burdensome.

As finalized in this rule, all residents, including those on psychotropic drugs, will have their medical records reviewed by a pharmacist in conjunction with their monthly DRR. This requirement provides additional review, which we believe is beneficial; however, we are concerned that a resident that is, for instance, treated for 30 days with a psychotropic drug, especially on a PRN basis, could be receiving treatment that was inappropriate or detrimental. We proposed a 48-hour limitation on PRN orders of psychotropic drugs to address this concern. However, as noted above, many commenters disagreed with the 48-hour limitation. Some commenters recommended different limitations, such as a 72-hour or 7 day limitation on PRN prescriptions of psychotropic drugs. Another commenter suggested at least 7 days. We are concerned that the recommended 72-hour or 7 day limitation could be detrimental to some residents and still be burdensome for facilities that have limited access to physicians and other prescribing practitioners. When a facility has limited access to physicians and other prescribing practitioners, there could be an interruption in a resident receiving necessary medication due to a PRN prescription expiring before the prescribing practitioner could renew or write another prescription. This interruption could be detrimental to the resident. For example, as one commenter pointed out, an interruption in anti-anxiety medications could result in the resident experiencing withdrawal symptoms. Based on the limited access some facilities have to physicians and other prescribing practitioners and the potential for detrimental effects to residents from interruptions in their medication regimen, we believe the limitation on PRN prescriptions for psychotropic drugs should be longer and agree with the commenter that recommended at least a 7 day limitation. As finalized in this rule at § 483.45(c)(2) all residents will have a pharmacist reviewing their drug regimen monthly. However, a physician is only required to visit a resident at least once every 30 days for the first 90 days after the resident is admitted to the facility and every 60 days after that (42 CFR 483.70(c)). We believe that 30 days is too long for a resident to be on a psychotropic drug on a PRN basis without the physician or other prescriber having to evaluate whether the resident should continue on the subject drug according to the PRN order. Thus, we are establishing a 14-day limitation on psychotropic drugs. By establishing this 14-day limitation, each resident who is taking a psychotropic drug will have his or her prescription reviewed by the physician or prescribing practitioner every 14 days and also by a pharmacist every month. Since there was no previous limitation on PRN prescriptions for psychotropic or anti-psychotic drugs, this will provide residents receiving this type of medication on a PRN basis additional protections against unnecessary drugs, drugs with another type of irregularity, and drugs that might be prescribed for reasons other than the resident's own benefit. We also believe that a 14-day limitation on PRN prescriptions for psychotropic drugs should not be burdensome for facilities. Therefore, we have finalized a 14-day limitation on PRN prescriptions for psychotropic drugs, subject to the exceptions discussed below.

We are also aware that some residents might require psychotropic drugs on a PRN basis for prolonged periods of time. Thus, we have established an exception to this 14-day limitation. For psychotropic drugs that the attending physician believes a PRN prescription

for longer than 14 days is appropriate, the attending physician can extend the prescription beyond 14 days for the resident by documenting their rationale in the resident's medical record. However, we believe this exception would be inappropriate for anti-psychotic drugs. If the attending physician believes that the resident requires an anti-psychotic drug on a PRN basis for longer than 14 days, he or she will be required to write a new PRN prescription every 14 days after the resident has been evaluated. Detailed requirements for this evaluation will be developed in sub-regulatory guidance.

Concerning the recommendation that we require a facility to have policies and procedures regarding PRN prescriptions and the facility's review of these prescriptions, we disagree with the commenters. Facilities need to have the flexibility to determine the policies and procedures they require, consistent with this rule and other sub-regulatory guidance, to manage their facility. We believe that the requirements finalized in this rule are sufficient to provide the scrutiny psychotropic drug prescriptions require to protect residents. However, we encourage facilities to develop their own policies and procedures concerning PRN prescriptions for their facility.

Concerning an exception for short-term residents, we disagree with the commenter. All of the requirements in this final rule, as well as other requirements and sub-regulatory guidance, apply to all residents, regardless of the length of their stay in the facility. Short-term residents deserve the same quality of care and protection of their rights as any other resident in a facility.

*Comment:* One commenter recommended that LTC facilities be required to draft and complete an Antipsychotic Drug/Dementia Care Compliance Report for each resident taking an antipsychotic drug. The facility would be required to identify the resident's diagnoses, all attempted non-pharmaceutical interventions, consent, and recommendations for, and physician response to, consultant pharmacists' recommendations for gradual dose reductions. These reports would be signed by all members of the IDT, certifying compliance with all federal requirements. Surveyors would then review these as part of the annual survey or any relevant complaint survey.

*Response:* We believe that the requirements in this final rule provide the necessary scrutiny and protections residents need from inappropriate drug use. We also believe that requiring a separate report, especially with all the requirements suggested by the commenter, would be overly burdensome for some facilities. However, facilities themselves could choose to prepare such reports.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have added § 483.45(c)(5) to require LTC facilities to develop and maintain policies and procedures for the monthly DRR, which include but are not limited to, timeframes for the various steps in the process and procedures a pharmacist must take when he or she believes immediate action is required to protect the resident.
- We have modified the definition of a psychotropic drugs in § 483.45(c)(3) by removing paragraphs (v) and (vi).
- We have modified the limitation for PRN prescriptions of psychotropic drugs by extending the time for PRN prescription to 14 days by modifying § 483.45(e)(4).
- We have added a specific limitation on PRN prescriptions for anti-psychotic drugs by modifying § 483.45(e)(5).

*P. Laboratory, Radiology, and Other Diagnostic Services (§ 483.50)*

Currently, § 483.75(j) sets forth requirements regarding laboratory services and § 483.75(k) sets forth requirements for radiology and other diagnostic services that a facility must provide or obtain to meet the needs of its residents. These regulations are currently located in § 483.75 ''Administration,'' which largely focuses on the manner in which a facility must operate to provide quality care to its residents. Following the reorganization of subpart B, we proposed to relocate and re-designate both § 483.75(j) and § 483.75(k) to a new § 483.50 entitled, ''Laboratory, Radiology, and Other Diagnostic Services.'' This section includes all of the content from current § 483.75(j) and § 483.75(k) relocated to § 483.50(a) and § 483.50(b), respectively. We proposed to retain the existing requirements with some revisions, as discussed in detail below.

Current § 483.75(j)(a)(2)(i) and § 485.75(k)(2)(i), require that a facility must provide or obtain laboratory and radiology and other diagnostic services ''only when ordered by the attending physician.'' We proposed to clarify these requirements by removing the phrase, ''the attending physician'' and replacing it with ''a physician, a physician assistant, nurse practitioner, or clinical nurse specialist.'' The revised requirements were proposed to be located at § 483.50(a)(2)(i) and (b)(2)(i), respectively. Furthermore, we proposed to allow for these orders only if the practitioners were acting in accordance with state law, including scope of practice laws and facility policy.

Additionally, current § 483.75(j)(2)(ii) and (k)(2)(ii) require that facilities ''promptly notify the attending physician of the findings'' once laboratory results have been obtained. We proposed to allow increased flexibility under this requirement to provide that other practitioners have the ability to receive laboratory and radiology and other diagnostic results if these practitioners ordered the tests. Specifically, we proposed to revise § 483.50(a)(2)(ii) to permit that the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist to be notified of laboratory results. In addition, we proposed in § 483.50(a)(2)(ii) to clarify that the laboratory would have to promptly notify the ordering professional if results fell outside of clinical reference or expected ''normal'' ranges, unless the orders for the test or the facility's policies and procedures required otherwise.

*Comment:* Commenters supported the proposal to clarify that a physician assistant, nurse practitioner, or clinical nurse specialist could order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope of practice laws. Commenters noted that this revision aligned with the literature that supports better quality with the use of non-physician practitioners and is consistent with state licensure laws. Commenters also supported the proposal to allow other practitioners to receive laboratory, radiology, and other diagnostic results if these practitioners ordered the tests. Commenters noted that this revision would help to provide results in a timelier manner and improve care to the resident.

*Response:* We appreciate the feedback and support from commenters. We agree and believe that this revision will ultimately increase access to care and also reduce some of the burden on facilities.

*Comment:* Some commenters opposed our proposal at § 483.50(a)(2)(ii) to clarify that the laboratory would have to promptly notify the ordering professional if results fell outside of clinical reference or expected ''normal'' ranges; the commenters were skeptical that the policy would improve the notification process. Commenters noted that the term ''promptly'' is not defined, and used multiple times throughout the regulation with varying timeframes. Commenters also did not believe there

was a need to notify practitioners of results that fell outside of the clinical reference range. Specifically, the commenters indicated that the proposed language was too broad, did not provide enough flexibility, and stated that the revision would actually increase unnecessary notification of practitioners and result in unnecessary repeat testing. One commenter recommended revising the language to require that practitioners be notified when results fall outside a ''critical value'' because this term is defined by laboratories and would avoid unnecessary calls when a result was outside the clinical reference, but not critical and trending in the right direction. Another commenter noted that many abnormal lab values are not necessarily associated with any medical problems, nor do they require immediate intervention. The commenter recommended removing the phrase ''lab values that fall outside of normal range'' and revising the language to require facilities to develop a policy and procedure for notifying the ordering practitioner of test results in a timely manner to assure that results requiring intervention or new orders are addressed. Another commenter also recommended replacing the term ''promptly'' with ''timely''.

In contrast, some commenters indicated that facilities should be urged to notify practitioners of abnormal results as soon as possible and recommended that the term ''promptly'' be replaced with ''immediately''. Commenters noted that the standard of practice for nurses is to notify practitioners immediately of results that fall outside of clinical reference ranges regardless of facility policy or physician order. One commenter recommended further that the language be revised to remove the flexibility allowing notification to be based on facility policy or procedure. One commenter recommended that facilities also be required to notify the resident and their representative when they notify the practitioner of test results.

*Response:* We appreciate the commenters' feedback, but disagree that the proposed language will increase unnecessary notifications of practitioners. In the proposed rule we indicated that the proposal would revise existing language at § 483.75(k)(2)(ii) which stated that facilities must ''promptly notify the attending physician of the findings''. We believe that by specifying that the ordering practitioner be notified of the results, many ''unnecessary'' notifications will be eliminated by ensuring that results are received by the individual who requested the information. We also disagree that the proposed language is too broad and does not provide flexibility. The proposed language provides that notification of the ordering physician should align with facility policy and procedure. It is also common practice for health care settings to establish procedures for determining normal/abnormal lab values. Therefore, in situations that may provide an abnormal result, but do not warrant an emergency response or repeat test, facilities have the flexibility to address these situations in their policies and determine how notification should take place. In addition, we note that the interpretative guidance to this final rule may also provide more detailed information regarding how a facility may choose to establish guidelines for promptly notifying practitioners of test results.

We do not believe that facilities should notify the resident and their representative of results when they notify the practitioner. As commenters have indicated, there are many aspects of a person's care and medical condition to balance when reviewing the results of laboratory tests. We believe that it would be inappropriate to prematurely notify a resident of results before a practitioner responsible for the resident's care has had an opportunity to assess the results. This action could cause unnecessary anguish or result in the delivery of improper information to the resident and their representative.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal without modification.

*Q. Dental Services (§ 483.55)*

Under the reorganization of subpart B, requirements regarding dental services remain at § 483.55. In the proposed rule, we indicated that section 1862(a)(12) of the Act states, in part, that Medicare does not cover dental services such as the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. Medicaid state plans, by contrast, vary in their coverage of dental services. However, both sections 1819(b)(4)(A)(vi) and 1919(b)(4)(A)(vi) of the Act include requirements related to the provision of dental services. Currently, § 483.55 requires that facilities assist residents in obtaining appropriate dental services at the resident's expense for SNF residents and as covered under the state plan for NF residents.

We proposed limited changes to update and clarify this section. First, we proposed to add a new § 483.55(a)(3) to clarify that a facility may not charge a resident for the loss of or damage to dentures when the loss or damage is the responsibility of the facility. Second, we proposed to re-designate existing § 483.55(a)(3) as § 483.55(a)(4) and revise § 483.55(a)(4) by adding the phrase ''or if requested'' to clarify that if a resident asks for assistance in scheduling a dental appointment, the facility would be required to provide the assistance. Third, we proposed to modify the section by adding language at new § 483.55(a)(4)(ii) and § 483.55(a)(5) regarding transportation and referrals for dental services. Finally, we proposed to re-designate § 483.55(a)(4) as § 483.55(a)(5) and would require that referral for dental services occur in 3 business days or less from the time the loss or damage to dentures is identified unless the facility can provide documentation of extenuating circumstances that resulted in the delay. We also proposed to make the same changes at § 483.55(b)(2) and § 483.55(b)(3) to apply to nursing facilities and add a new § 483.55(b)(4) to require that facilities assist residents to apply for reimbursement of dental services as an incurred medical expense under the state plan as appropriate.

*Comment:* Several commenters recommended we include stronger requirements for dental care and oral hygiene, as good dental care and oral hygiene can result in cost savings.

*Response:* We agree that dental care and oral hygiene are important. In the proposed rule we discuss the importance of dental care and oral hygiene (80 FR 42197). We have included requirements related to oral hygiene at finalized § 483.25(a)(2), which requires that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. With respect to dental care, as noted in the proposed rule, 80 FR 42205, pursuant to section 1862(a)(12) of the Act, Medicare does not cover many dental services. Medicaid states plans vary widely in providing dental services. In keeping with these limitations, we address facility responsibilities related to assisting residents in obtaining dental services in § 483.55. We did not propose to change existing regulations at 42 CFR 483.55(a)(1)and (2) and (b)(1), which require facilities to provide or obtain dental services to meet the needs of each resident.

*Comment:* One commenter suggested we explicitly recognize dental hygienists.

*Response:* We thank the commenter for this suggestion, but decline to incorporate it at this time. We proposed and are finalizing changing references to

a ''dentist's office'' to ''dental services'' in order to recognize that dental care may be provided in dental clinics, dentals schools, or even on site. These requirements are broad enough to encompass dental services provided by a dental hygienist working within their scope of practice under state law.

*Comment:* Some commenters stated that obtaining dental services for residents is difficult due to difficulty finding providers, limitations in Medicaid coverage, and resident preferences regarding dental care. Some commenters felt existing regulations already address dental concerns and our proposed revisions were unnecessary.

*Response:* We thank the commenters for their information. A resident or, when applicable, their representative, has the right to determine what dental care they will consent to, just as they have the right to request or refuse treatment as specified in § 483.10. Medicaid coverage of dental services is outside the scope of this regulation. We would expect a facility to document extenuating circumstances that delay obtaining necessary dental care. We disagree that our proposed revisions are unnecessary. Our proposed revisions address areas where we are aware problems have occurred or where we are aware of opportunities to improve access to care. We note that other commenters have suggested that these revisions are useful and that we do not go far enough in ensuring adequate resident protections in this area.

*Comment:* One commenter recommended we modify proposed § 483.55(a)(3) and § 483.55(b)(4) by adding ''A facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility . . .''

*Response:* We agree that adding this statement adds clarity and have modified these provisions to state that the facility must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility.

*Comment:* Commenters expressed concern that facility policies for lost or damaged dentures would be written in order to absolve the facility of any responsibility. One commenter stated that this would allow a facility to develop a policy that would allow staff to damage the resident's property and not replace it and this would affect the resident's ability to consume meals. Other commenters stated that the facility should not be held financially responsible when residents throw away, damage, or lose dentures or when the loss is a result of a resident's actions or failure to abide by facility policies.

*Response:* As noted above, we have modified the proposed requirement to state that the facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility. We do not believe a blanket policy of facility non-responsibility would meet the modified requirement. In addition, proposed § 483.15(a)(2)(iii) prohibits facilities from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. We have also modified the provision to require that the facility not only document extenuating circumstances that cause a delay in making a referral for dental services, but also require that the facility document efforts to ensure that the resident is able to eat and drink adequately while awaiting the dental services. We believe that the cumulative effect of these provisions address the commenters' concerns. We defer additional discussion to sub-regulatory guidance.

*Comment:* Some commenters objected to the three day time frame for making a referral for dental services to replace lost or damaged dentures, stating that it was unreasonable. One commenter asked that we clarify that the 3-day time frame applied to the referral, not to obtaining repaired or replaced dentures. One commenter suggested that 5 to 7 business days would be a more appropriate time-frame for requiring a facility to make a referral.

*Response:* The three-day time frame is to make the referral, not to complete the dental appointment, or obtain repaired or replaced dentures. We continue to believe that such a time frame is necessary to ensure prompt referrals and minimize avoidable delays, but understand that there may be circumstances that prevent a timely referral. Extenuating circumstances could include issues such as the resident's preferred provider's office not being open or the need to obtain an insurance pre-authorization. Facilities would be expected to document such circumstances.

*Comment:* One commenter suggested the focus should be on ensuring that residents could eat and drink adequately while awaiting dental services.

*Response:* We agree and have added this to the regulatory requirement. However, we do not believe that this should be in lieu of documenting extenuating circumstances and maintain our proposed requirement that facilities document extenuating circumstances that lead to delayed referrals.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We are adding a requirement at § 483.55(a)(3) and (b)(4) that the facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility.
- We are adding a requirement at § 483.55(a)(5) and (b)(3) that the facility must document what they did to ensure that the resident could eat and drink adequately while awaiting dental services.

*R. Food and Nutrition Services (§ 483.60)*

We proposed the revisions described below in an effort to improve the nutritional status of LTC facility residents. In the proposed rule, we included a detailed discussion regarding dietary standards for residents of LTC facilities. We encourage readers to refer to the proposed rule for this discussion.

We proposed to re-designate existing § 483.35 ''Dietary Services'' as new § 483.60 ''Food and Nutrition Services'' and revise the introductory language to include taking resident preferences into consideration. We proposed to revise § 483.60(a) to require that the facility employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population.

In § 483.60(a)(1) we proposed to retain the requirement that a facility employ a qualified dietitian on a full-time, part-time or consultant basis and update the requirements to be considered a qualified dietitian. We also proposed to require minimum qualifications for dietitians working in SNFs or NFs. We proposed to require that a qualified dietitian must either be registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics, or be recognized (licensed or certified) by the state in which the SNF or NF operates as a dietitian or clinically qualified nutrition professionals. We also proposed to allow up to 5 years after the effective date of the regulation for dietitians hired or contracted prior to the effective dates of the revised regulations to meet these requirements.

In re-designated § 483.60(a)(2), we proposed to continue to require that, if a qualified dietitian or other clinically qualified nutrition professional was not employed full-time, the facility would have to designate a person to serve as the director of food and nutrition

services who would receive frequently scheduled consultation from a qualified dietitian. We proposed to require that the director of food and nutrition services, if hired or designated after the effective date of these regulations, would have to be a certified dietary manager or certified food service manager as evidenced by meeting national certification standards for a certified dietary manager such as those by the Association of Nutrition and Foodservice Professionals (ANFP), or for a certified food manager such as those by the International Food Service Executives Association or the Food Management Professional certification through the National Restaurant Association. If already serving as a director of food and nutrition service on the effective date without one of these certifications, the individual must obtain a certification no later than 5 years after the effective date of the rule. Alternatively, we proposed that the director of food and nutrition services could also meet the proposed requirement through specialized education or training in food service management and safety resulting in an associate's or higher degree in hospitality or food service management. Finally, we proposed that the director of food and nutrition services could meet our proposed requirement if he or she met applicable state requirements to be a food service manager or dietary manager.

In § 483.60(a)(4), we proposed to require that the facility provide sufficient support personnel with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and a facility assessment that includes the number, acuity and diagnoses of the facility's resident population.

We proposed a new § 483.60(b) to specify that a member of food and nutrition services also participate in the IDT. At § 483.60(c)(1), we proposed to change ''Recommended Dietary Allowances'' to ''established national guidelines or industry standards.'' We also proposed to add a new § 483.60(c)(4) to require that menus reflect the religious, cultural, and ethnic needs of the residents, as well as input received from residents or resident groups.

At § 483.60(d), we proposed minor revisions to incorporate the addition of drinks, to clarify that ''proper'' meant both safe and appetizing, to include consideration of allergies, intolerances, and preferences in preparing food, and to ensure that water and other dietary liquids are available to residents and provided, consistent with resident needs and preferences.

At new § 483.60(e) ''Therapeutic diets,'' we proposed to retain the requirement in current § 483.35(e) that therapeutic diets be prescribed by the attending physician. However, we proposed to add a new § 483.60(e)(2) to allow the attending physician to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by state law.

We proposed to modify § 483.35(f) in re-designated § 483.60(f) regarding frequency of meals. Specifically, we proposed to modify the requirement that facilities provide and residents receive three meals per day at regular times by adding language to clarify that meals should be served at times in accordance with resident needs, preferences, requests and the plan of care. We further proposed to eliminate the requirement that there be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a substantial bedtime snack is provided. Instead, we decided to focus on when residents prefer to eat and on ensuring that meal service is provided to meet residents' clinical and nutritional needs. We proposed to require that the facility provide suitable, nourishing alternative meals and snacks for each resident who want to eat at non-traditional times or outside of the facility's scheduled meal service times, in accordance with their respective plans of care. We indicated in the proposed rule that ''suitable, nourishing alternative meals'' would mean that when a resident missed a meal or snack, an alternative of comparable nutritive value to the missed meal or snack would be provided.

We proposed to re-designate existing § 483.35(g) as new § 483.60(g) and revise it to require that the facility provide not only adaptive eating equipment and utensils for residents who need these devices but also provide the appropriate staff assistance to ensure that these residents can use the assistive devices when consuming meals and snacks.

We proposed to re-designate existing § 483.35(h) as new § 483.60(h) and retain, with some revisions, provisions for paid feeding assistants, as set out in the 2003 final rule (68 FR 55528). Section 483.35(h)(2)(ii) currently requires that, in an emergency, a paid feeding assistant must call a supervisory nurse for help ''on the resident call system.'' We proposed to eliminate the reference to the resident call system. We also proposed to have the IDT make the determination of whether a paid feeding assistant would be appropriate for a resident.

We proposed to clarify in new § 483.60(i)(1)(i) that facilities could procure food directly from local producers, farmers or growers, in accordance with state and local laws or regulations. We further proposed to clarify in new § 483.60(i)(1)(ii) that this provision would not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and handling practices, such as the use of pesticides in accordance with manufacturers' instructions. Consistent with § 483.70(b), we proposed to specify in § 483.60(i)(2) that facilities would be required to store, prepare, distribute, and serve food in accordance with professional standards for food service safety. We proposed to add a new § 483.60(i)(3) to require a facility to have a policy in place regarding use and storage of foods brought to residents by visitors to ensure safe and sanitary handling.

*Comment:* One commenter suggested that we reference the new Dining Practice Standards agreed to by 12 national standard setting organizations.

*Response:* We thank the commenter. We mentioned in the preamble to the proposed rule an August 2011 report by the Pioneer Network Food and Dining Clinical Standards Task Force but did not provide the location of that resource. We would encourage facilities and practitioners to read the report. It is available at *http://www.pioneernetwork.net/Providers/DiningPracticeStandards/.*

Pioneer Network also has a ''how to'' resource called the ''Dining Standards Toolkit'' that may assist LTC facilities in their efforts to understand and meet the updated requirements. In addition, CMS produced a video related to these standards. The video can also assist LTC facilities in their efforts to understand and meet the updated requirements. The video is available at *http://surveyortraining.cms.hhs.gov/pubs/VideoInformation.aspx?id=1101&cid=0CMSNEWDINPRSTAN.*

*Comment:* Some commenters felt that our proposed requirement that the facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e) was subjective and not specific enough. Some

commenters felt that the term ''sufficient'' was unclear and impossible to objectively measure. One commenter requested that we define ''support personnel'' or ''support staff''.

*Response:* Our proposal specifically requires that a facility have a dietitian, a food service manager in facilities that do not have a full-time dietitian, and enough support staff with the appropriate competencies and skills to carry out the functions of the food and nutrition service. Facilities have widely varying populations, and census. Thus, we would expect a facility to use the newly required facility assessment to determine both the competencies and skills that are required to effectively carry out the functions of the food and nutrition services, as well as the number of support staff that are needed. Given the potential diversity of each facility, we continue to believe that a ''one-size-fits-all'' approach to food and nutrition services serves neither the residents nor the facility. A facility should have some flexibility to determine how to best meet its resident's needs in the area. Furthermore, a facility should be able to articulate how it made its staffing decisions and how various factors, including the facility assessment and resident-specific needs, are incorporated into that decision making.

We note that the term ''sufficient support personnel'' is an existing term in the current requirements for long-term care facilities. It is defined in current sub-regulatory guidance as 'enough staff to prepare and serve palatable, attractive, nutritionally adequate meals at proper temperatures and appropriate times and support proper sanitary techniques being utilized.'' It would include any staff in addition to the qualified dietitian or other clinically qualified nutrition professional and the food service manager that are needed to carry out the functions of the food and nutrition service and meet the requirements of this section. We disagree that the term ''sufficient'' is unclear and impossible to objectively measure. ''Sufficient'' staff would be mean an adequate number, or enough staff, who have the skills and knowledge to safely and effectively deliver the care that residents need and that is the responsibility of the food and nutrition service. Direct observation and interview questions can be used to determine if residents are receiving the food and nutrition services they require, in accordance with his or her plan of care, in a safe, timely, and effective manner. Factors such as timely meal service, food that is served at an appropriate temperature and in an appetizing form, available assistance for residents who require assistance to eat a meal, as well as resident-specific issues such as unintended weight loss and dehydration may all be indicators considered when determining if a facility has sufficient staffing. We believe that surveyor training on these requirements and questions such as those identified above will allow surveyors to make evidence-based decisions about whether or not a facility has or does not have sufficient staffing.

*Comment:* One commenter suggested not referring to 'alternative' or 'substitute' meals, but instead refer to choices and options and ''at times of the resident's choosing.''

*Response:* We agree and have revised the language at § 483.60(d)(5).

*Comment:* One commenter recommended that we modify our proposal for therapeutic diets to allow the attending physician or that physician's covering physician to delegate the task a prescribing a resident's diet, including a therapeutic diet, to a registered or licensed dietitian to the extent allowed by state law.

*Response:* Please see our discussion regarding section § 483.30(f). We are retaining the existing regulatory language which states that the attending physician must prescribe a therapeutic diet and we are finalizing our proposal, with some modification, to allow the attending physician to delegate this task to a qualified dietitian or other clinically qualified nutrition professional. We note that the qualified professional to whom the task is delegated must not only be acting within their scope of practice under state law, they must also be under the supervision of the physician.

*Comment:* One commenter did not support our proposal to allow an attending physician to delegate the task of writing dietary orders to a qualified dietitian or other nutrition professional acting within the scope of state law. The commenter acknowledged that it has been a real challenge through the years of getting physicians to fulfill their responsibilities in this aspect of care but believed that there are alternatives to our proposal and that it is not in the interest of resident to put a blanket authorization in regulation with its potential for misuse to the detriment of the residents. Finally, the commenter stated that the development of protocols to allocate responsibility to those of other disciplines should be done on a facility level based on knowledge of staff capabilities and close oversight of who is allowed to write orders in consultation with a medical practitioner.

*Response:* As we discussed earlier, our proposal is intended to improve responsiveness to a resident's needs and is implemented at the discretion of the physician. It does not allow a physician to shift all authority to either a dietitian or a therapist, as the qualified professional to whom the task is delegated must not only be acting within their scope of practice under state law, they must also be under the supervision of the physician. As one commenter noted, our proposal provides for both oversight and accountability. Given the limited time that many commenters have stated physicians spend in the facility, we believe that in appropriate circumstances, this flexibility will benefit both the physician and the resident. Furthermore, nothing in this rule precludes a facility from implementing many of the alternatives suggested by the commenter, such as more detailed assessments of resident appetite and weight issues, better communications to the attending physicians, facility use of reliable and comprehensive references on nutrition, and facility adoption of protocols based on reputable references and resources. We agree that facilities should be knowledgeable of staff capabilities and would expect an attending physician who chooses to delegate responsibility for writing any order would also be knowledgeable about the capabilities of the staff to whom responsibility is being delegated, particularly since the attending physician remains accountable.

*Comment:* One commenter suggested we change the term ''skill sets'' to ''skills'' as the terms are synonymous.

*Response:* We thank the commenter for their suggestion, however, we have retained the language as proposed as we do not believe that this change would substantially improve the clarity or intent of the provision.

*Comment:* One commenter urged us to make a more straightforward statement in the final rule that each resident, unless medically contraindicated, must be afforded a choice of foods at all times. One commenter suggested we more specifically address pureed foods. Another suggested that we change the language at § 483.60(f)(3) that currently states that ''Suitable, nourishing meals and snacks must be available for residents who want to eat at non-traditional times or outside of scheduled meal times, in accordance with the plan of care'' to eliminate ''in accordance with the plan of care'', as resident requests to dine outside of mealtime should not be required to be

documented on the plan of care, unless nutrition is a concern and is being monitored for specific reasons. Other commenters objected to this requirement on the basis that it would require extended kitchen hours.

*Response:* We believe our proposal, as written, addresses the concerns implicated in the commenters' statements. We agree that a resident's request to eat outside of mealtime does not necessarily need to be documented in the plan of care, nor should a resident be able to eat outside of meal time only if it is required by the plan of care. However, where nutrition is a concern and being monitored for a specific reasons, or where there are dietary restrictions necessitated by a resident's medical condition(s), the provision of such snacks and meals must be consistent with the plan of care. We have modified the regulatory language to state ''Suitable, nourishing meals and snacks must be provided for residents who want to eat at non-traditional times or outside of scheduled meal times, consistent with the plan of care'' to focus on residents actually receiving these snacks or meal options, rather than focusing on the availability of such options. As discussed in the proposed rule, this requirement is not intended to require the availability of a 24-hour-a-day full service food operation (80 FR 42208), but rather accommodate residents who cannot or choose not to eat at a scheduled mealtime.

*Comment:* Some commenters supported our proposed revisions to the food and nutrition requirements. One commenter stated that they expect the proposed rules will improve the quality of life and health outcomes for residents in LTC facilities.

*Response:* We thank these commenters. The intent of our proposals is, ultimately, to improve the quality of life and the health outcomes for LTC facility residents. We understand that residents may have varying and unique dietary and hydration needs. We also appreciate the commenters support for our proposals that require that facilities incorporate resident preferences in decisions about food and beverages as well as the need to acknowledge cultural and ethnic diversity in menus and the requirement to provide meals at times in accordance with resident needs, preferences, requests, and the plan of care.

*Comment:* Some commenters objected to our requirement that menus reflect the religious, cultural, and ethnic needs of the residents, as well as input received from residents and resident groups. The commenters felt that this meant that every facility would have to meet all religious dietary requirements for multiple faiths and that this was not achievable. One commenter suggested that we add ''to the extent possible'' to the requirement.

*Response:* This requirement does not mandate that every facility be able to provide every possible religious, cultural, or ethnic diet. However, a facility should consider these factors with respect to the population it serves, as well as input from residents and resident groups, when developing its menus. We have clarified this provision to state that menus should ''reflect, based on a facility's reasonable efforts, the religious, cultural and ethnic needs of the resident population, as well as input received from residents and resident groups;'' and defer additional discussion to sub-regulatory guidance.

*Comment:* One commenter objected to the inclusion of the term ''industry standards'' with regard to menus. One suggested we retain only the term ''national guidelines.'' The commenter expressed concern that ''industry standards'' could allow for poor quality foods.

*Response:* We agree that including ''or industry standards'' could allow for menus that don't meet national guidelines and therefore have eliminated the term ''industry standards.''

*Comment:* One commenter suggested that in paragraph § 483.60(c)(1) after ''in accordance with established national guidelines or industry standards'' we add ''in accordance to the individual per his or her comprehensive assessment and care plan. The commenter is concerned that many kitchen staff mistakenly think that they must offer the dietary guideline amounts, ignoring a resident's preferences such as smaller portions, as bigger portions may overwhelm some individuals. Another commenter suggested we make proposed § 483.60(c)(7) stronger by revising it to read: '' The comprehensive assessment and care plan support resident choice and preference for larger or smaller portions''. The commenter asked that we make clearer that residents decide what they want to eat. They wanted to clarify that no resident should be made to eat or to believe that they should eat a certain amount of food, which is what happens when menus are built upon generic ''recommended dietary allowances.''

*Response:* We agree that an individual's preference for smaller portions or who are overwhelmed by large portions should have that preference or need accommodated. However, the section in question refers to the menu that is prepared for the facility as a whole, not how each meal is provided to the resident. We believe that the provisions as proposed require appropriate menu development at the facility level, but also clearly allow, and in fact require, that meals meet individual needs and accommodate resident preferences. Specifically, § 483.60(c)(7), as finalized, states that nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices and § 483.60(d)(4) requires that each resident receive food that accommodates resident allergies, intolerances, and preferences. We would defer additional specificity, such as choice of portion size, to sub-regulatory guidance.

*Comment:* Commenters requested that we eliminate paid feeding assistants. One commenter is concerned that feeding assistants have little training and are ill-equipped to help residents who may have swallowing difficulties or resist being fed. The commenter suggests such assistants need training and skills that CNAs have and that assigning such tasks to CNAs would promote continuity of care and support the CNA's relationship with the resident. Another commenter asked that we change the title to ''dining assistant.''

*Response:* We did not propose to eliminate the role of paid feeding assistants and do not have the benefit of public comment on such a proposal. The requirements for paid feeding assistants were issued in 2003 in response to demonstration programs that evaluated supplementing LTC facility staffing with this role in order to address a recognized problem that most LTC facility residents needing mealtime assistance did not receive enough feeding assistance to ensure adequate nutrition and hydration. A follow-up study by Abt Associates, Inc. in 2007 did not support concerns that paid feeding assistants would be poorly trained or that they would replace existing nurse aides or used for additional resident assistance. The study did raise a concern regarding facilities identification of residents who were assigned a paid feeding assistant. We proposed a requirement that the IDT identify residents who were appropriate for this program that assessment should be reflected in the comprehensive care plan. This would assist in ensuring that resident selection for paid feeding assistance is appropriate. We believe we would need to pursue notice and comment rule-making to eliminate this role. Further, we believe we need to further investigate the need to do so and

the implications of doing so. We will evaluate the concerns raised and consider this issue for inclusion in future rule-making.

*Comment:* Some commenters supported the proposed requirements' enhanced focus on resident preferences, assessment and care planning in this section, including incorporating resident preferences, recognizing residents' religious, ethnic, and cultural diversity, flexible meal times, the addition of 'drinks, including water and other liquids, and the inclusion of a member of food and nutrition services on the IDT. Another commenter strongly supported our proposed requirements in § 483.60(i)(1) to allow food to be obtained from local producers or grown on-site, subject to some safety requirements and to clarify that the requirements do not preclude residents from consuming foods not procured by the facility (that is, food brought in by visitors).

*Response:* We appreciate the commenters' support. We agree that these efforts will improve facility responsiveness to the unique needs and preferences of residents while ensuring residents a greater sense of participation in their care.

*Comment:* One commenter suggested that instead of requiring specific educational requirements for the director of food services or any other position, we require that a member of the food and nutrition services management team include a person credentialed in the manner we have proposed. The commenter stated that there are many highly capable professionals with many years of food service experience without specific credentials who may nonetheless be competent within a long-term care environment. Another commenter suggested that our requirements for a food service manager were ''woefully inadequate'' specifically citing the fact that we included a degree in hospitality as an option.

*Response:* Effective management and oversight of the food and nutrition service is critical to the safety and well-being of all residents of a nursing facility. Therefore, it is important that there are standards for the individuals who will lead this service. However, we agree that there are many highly capable professionals with many years of food service experience without specific credentials who may nonetheless be highly competent within a long-term care environment. It is for this reason that we have allowed sufficient time to meet the new requirements. With regard to our requirements for food service managers, we have modified the option of a degree in hospitality. Based on the comment that a degree in hospitality was a ''woefully inadequate'' qualification, we conducted additional research, and determined that not all hospitality degree programs specifically require food service management. However, based on our research, food service management/restaurant management is a common aspect of hospitality degree programs. Therefore, rather than eliminate a hospitality degree as an qualifying option for facilities, we have clarified to specify that, in order to qualify based on a degree in hospitality, the individual must have included food service management/restaurant management in their degree program.

*Comment:* Some commenters supported our proposed definition of 'qualified dietitian' but recommended refinements. Other commenters opposed our definition of 'qualified dietitian,' asserting that the proposed change would weaken professional standards and enable unqualified practitioners without the necessary training or skills to oversee facilities' food and nutrition services. They suggested that we define ''qualified dietitian'' consistent with the definition of ''registered dietitian or nutrition professional'' set out at section 1861(vv)(2) of the Act.

*Response:* We based our proposal for the definition of a ''qualified dietitian'' in part on our experience in allowing hospitals to grant specific nutritional ordering privileges to qualified professionals. We discussed our rationale in the final rule ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II; published on May 12, 2014 (79 FR 27106).

Section 1861(v)(2) of the Act defines a ''registered dietitian or nutrition professional'' as an individual who holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose, who has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed; or, in the case of an individual in a state that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes. The definition of a ''registered dietitian or nutrition professional'' at § 410.134 is closely aligned with this statutory definition, adding only that, in a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the degree and practice requirements specified by the statute. Section 483.94(e) of our rules defines a qualified dietitian as ''an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.'' We note that, according to the Academy of Nutrition and Dietetics, the credential ''registered dietitian nutritionist'' (RDN) is synonymous with ''registered dietitian'' (RD) and the two credentials have identical meaning and legal trademark definitions.

We have reviewed state requirements for licensure or certification of dietitians and nutrition professionals and find those requirements, with a few exceptions, generally include, at a minimum, similar education and experience requirements to those forth by the statute and currently reflected in § 410.134. Many also require an examination and/or defer to the national examination provided by the Commission on Dietetic Registration for qualification as a Registered Dietitian. A few states do not require or offer licensure or certification. One state repealed such requirements in 2014. In those states, our proposed definition would require that qualified dietitians or nutrition professionals must be a RD in the state they are providing services. However, we agree that there could be states whose licensure requirements are less than the statutory requirement and we cannot predict future changes in state licensure requirements. Therefore, in order to better align our definition with section 1861(v)(2) of the Act, we have removed our proposed definition and provide that a qualified dietitian or other clinically qualified nutrition professional is one who: Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; has completed at least 900 hours of supervised dietetics practice under the

supervision of a registered dietitian or nutrition professional; and is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or has a bachelors' degree or higher and has completed at least 900 hours of dietetics practice.

*Comment:* Some commenters assert that 5 years is too long to allow for facilities to come into compliance with the proposed qualifications for dietitians and food service managers. Some commenters suggest 2 years as an alternative.

*Response:* We appreciate the commenters concerns and considered shorter timeframes. However, as another commenter noted, there are many highly capable professionals with many years of food service experience without specific credentials who may nonetheless be highly competent within a long-term care environment. We do not want to penalize such professionals and want to ensure that they have sufficient time to meet the new requirements and remain an asset to their facility.

*Comment:* Some commenters objected to the alternative qualifications for a food service manager and suggest that the food service manager must be a certified dietary manager who has obtained a ServSafe® certification. A number of commenters expressed concern about the existing supply of certified dietary managers. These commenters recommended we allow 6 to 18 months after the effective date of this final rule for facilities to hire new food service managers and give them time to complete the requirements to become a certified dietary managers.

*Response:* We note that there are currently no regulatory requirements for a food service manager. The ServSafe® manager certification requires training in the importance of food safety, good personal hygiene, time and temperature control, preventing cross-contamination, cleaning and sanitizing, safe food preparation, receiving and storing food, methods of thawing, cooking, cooling and reheating food, HACCP (Hazard Analysis and Critical Control Points), food safety regulations, and more. These are important topics. However, while ServSafe® manager certification is one way to ensure that food service managers are current in this knowledge, it is not the only way to ensure this. We have chosen to allow some flexibility in this regard. Given commenters' concerns regarding a potential workforce shortage of certified dietary managers, we agree it is reasonable to allow facilities 12 months from the effective date of this rule for a food service manager hired after the effective date of this rule to meet the updated qualifications.

*Comment:* We received a number of comments both supporting and objecting to our proposal to eliminate the requirement that there be no more than 14 hours between meals. Those who object felt that our objective was not person-centered care, as we stated in the preamble, but rather an intent to limit the existing regulatory requirement that facilities ensure that appropriate food is available and provided to residents at reasonable times. These commenters saw no reason not to retain the current requirement and recommended doing so. Other commenters felt that our proposal would allow facilities to tailor their food service programs to the needs and desires of its residents and patients and would improve the resident's environment and quality of life.

*Response:* The intent of our proposal was, as some commenters noted, to give facilities some flexibility and to focus their efforts on meeting the residents' needs and preferences. The proposal required that the facility provide three meals a day at ''regular times comparable to the community or in accordance with the resident needs, preferences, requests, and plan of care'' and that suitable and nourishing alternative meals and snack *must* (emphasis added) be available for residents who want to eat at non-traditional times or outside of scheduled meal service times. We believe these requirements, in combination with other requirements, including the requirements for food and drink in paragraph (d), ensure that each resident will receive adequate nutrition and will have in say in both what he or she eats and when. However, the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span, does not conflict with the proposed requirement and may prevent diminished availability of meal service. Therefore, we will not finalize our proposal to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.

*Comment:* Some commenters objected to our requirement that facilities establish a policy regarding use and storage of foods brought to residents by visitors to ensure safe and sanitary handling. These commenters felt they were not capable of policing this and that it was inappropriate to ask them to, but at the same time felt that foods from visitors were an enhancement to resident enjoyment.

*Response:* We were deliberately flexible in establishing this requirement, to allow facilities to determine how to best balance resident enjoyment of such treats and food safety. For example, some facilities may have the capacity to provide refrigeration space for residents, while others will not. We continue to believe that having a policy which residents and visitors are aware of is an important safeguard.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified our definition of ''qualified dietitian or other clinically qualified nutrition professional'' at § 483.60(a)(1) to more closely align with statutory requirements.
- Director of Food and Nutrition Services: We have modified § 483.60(a)(2)(i)(D) to specify that the hospitality degree must include food service or restaurant management.
- Menus and Nutritional Adequacy: We have deleted the term ''industry standards'' from our proposal at § 483.60(c)(1) that menus must meet the nutritional needs of residents in accordance with established national guidelines. We also clarified that menus must reflect, based on a facility's reasonable efforts, the religious, cultural and ethnic needs of the resident population, as well as input received from residents and resident groups.
- Food and Drink: At 483.60(d)(5), we have replaced the terms ''substitutes'' and ''alternative'' with the terms ''options'' and ''different meal choice.''
- We have withdrawn our proposal at (f)(2) to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.

*S. Specialized Rehabilitative Services (§ 483.65)*

Current regulations at § 483.45 set forth the services that a facility must provide if a resident needs specialized rehabilitative services including, but not

limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for a mental disorder. Following the reorganization of part 483 subpart B, we proposed to relocate these existing provisions to § 483.65 with minor revisions. We proposed at re-designated § 483.65(a) to specifically add respiratory therapy to the list of specialized rehabilitative services. The addition of this service explicitly requires facilities to provide or obtain these services when necessary and meet the needs of residents facing respiratory issues. However, this addition did not change coverage policy regarding respiratory therapy. At § 483.65(a)(2), we proposed to clarify that when it is necessary for facilities to obtain these services from an outside source, the provider would have to be a certified Medicare and/or Medicaid provider.

Secondly, we proposed to clarify the meaning of specialized rehabilitative services in relation to PASARR. We proposed to add in § 483.65 a cross reference to the PASARR regulations at § 483.120(c) which set out the mental health or intellectual disability services a nursing facility must provide to all residents who need these services. In addition, we proposed to correct a typographical error deleting the redundant ''mental health'' before ''rehabilitative services for a mental disorder and intellectual disability''.

*Comment:* Many commenters supported the inclusion of respiratory therapy in the list of specialized rehabilitative services. One commenter suggested that recreational therapy also be added since recreational therapy is recorded in the MDS 3.0 for LTC facilities under Section O.

*Response:* We appreciate the feedback and support from commenters. We have chosen not to add recreational therapy to the list of specialized rehabilitative services at § 483.65 because at this time we do not believe that we have the evidence as to the efficacy of such therapy to support the addition.

*Comment:* One commenter indicated that it is unclear whether the proposed rule requires that respiratory therapy services be provided by a respiratory therapist. The commenter notes that it would be nearly impossible to find enough respiratory therapists to provide the services and noted further that a nurse with appropriate training could provide necessary respiratory services in most instances. Commenters requested that a regulatory definition of ''respiratory therapy'' and a clear discussion of the scope of respiratory therapy services that must be provided be included in the final rule. In addition, commenters noted that the final rule should include a discussion of the qualifications necessary for individuals to furnish these services to help providers better understand how to meet these requirements.

*Response:* All specialized rehabilitative services are considered facility services and are included within the scope of facility services. Therefore, the facility must provide the necessary respiratory therapy services for all residents who need them, so that the needs of the resident are met and support the resident in attaining or maintaining their highest practicable physical, mental, and psychosocial well-being. In addition, the regulation requires that these services be provided in accordance with the resident's comprehensive assessment and plan of care. Regulations at § 483.70(f) discuss staff qualifications and specify that the facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of the requirements for LTC facilities. This would include those services related to specialized rehabilitative services, including respiratory therapy. In addition, the regulations at § 483.70(f) require that professional staff must be licensed, certified, or registered in accordance with applicable state laws.

*Comment:* One commenter indicated concern regarding the difficulty smaller and more rural facilities may face when providing very complex respiratory therapy services such as mechanical ventilation. The commenter noted that it would be reasonable to permit facilities some flexibility in how the needs of these residents are met and requested that we include provisions describing what complex respiratory services could be excluded from those services the facility must provide. The commenter noted that rehabilitation agencies provide services that may be furnished in a home environment that is similar to a SNF, such as an assisted living facility or independent senior living residence and recommended that the regulations be revised to allow the appropriate flexibility for SNFs that is consistent with that permitted in other Medicare outpatient therapy provider settings.

*Response:* We appreciate the commenter's feedback and understand that there are challenges that smaller and rural facilities may face when trying to obtain access to care and services for their residents. However, facilities must be able to provide, directly or under arrangement, the necessary care that their residents require. We urge facilities to use the facility assessment that was proposed at § 483.70(e) as a tool for appropriately assessing the resources necessary for providing care to its residents. Facilities should use this assessment to make decisions about their direct care staff needs as well as their capabilities to provide services to the residents in their facility.

*Comment:* One commenter disagreed with our proposal to clarify that when it was necessary to obtain specialized rehabilitative services from an outside source, the provider would have to be a certified Medicare and/or Medicaid provider. The commenter noted that this revision limits access to providers and recommends that facilities continue to be permitted to obtain necessary services from a qualified therapy professional that is appropriately licensed or certified to practice in the state in which services are being furnished. The commenter recommended that services obtained from an outside resource should only be restricted to a provider who was not excluded from federally funded health care programs including Medicare and/or Medicaid.

*Response:* We appreciate the commenter's feedback and have given much consideration to the implications that this revision may have on access to providers of specialized rehabilitative services. Our goal is to ensure that all LTC residents receive services from qualified professionals. Therefore, in an effort to balance the need to assure the safety of LTC residents against the concerns of facilities regarding obtaining access to providers, we have withdrawn our proposal at § 483.65(a)(2) to require that an outside resource must be a Medicare or Medicaid provider. Instead we are revising the requirement to indicate that services obtained from an outside resource must come from a provider that is not excluded from any federally funded health care program. We believe that this revision supports our intent to assure that LTC facility residents receive services from outside resources that are both professional and safe, while maintaining the access to providers.

*Comment:* Some commenters indicated that the use of the term ''specialized rehabilitative services'' should be revised to ''rehabilitative services and devices'' to be consistent with a CMS regulation entitled, ''Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2016'' (80 FR 75487). Commenters noted further that the final rule should adopt a definition of ''rehabilitative services'' that includes explicit recognition and coverage of devices. Commenters noted that the

definition of ''rehabilitative devices'' should also include durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In addition, commenters recommended that rehabilitative devices should be covered whether or not they are considered part of the SNF per diem rate or separately billable to the Medicare program.

*Response:* We disagree with commenters and believe that the term ''specialized rehabilitative services'' is appropriately used in the LTC setting. Sections 1819(b)(4)(A) and 1919(b)(4)(A) of the Act specifically use the term ''specialized rehabilitative services'' when discussing the provision of services that a facility must provide, directly or under arrangement, to the extent needed by residents to fulfill all plans of care. The CMS regulation discussed by commenters (''Patient Protection and Affordable Care Act; CMS Notice of Benefit and Payment Parameters for 2016'' (80 FR 75487)) applies to private insurance under the Affordable Care Act and does not have an impact on long-term care facilities that participate in the Medicare and Medicaid program. In addition, the coverage of rehabilitative devices under the Medicare program falls outside the scope of this regulation.

*Comment:* A few commenters also recommended that the regulation be revised to ensure compliance with the decision in *Jimmo* v. *Sebelius,* which indicated that Medicare coverage for skilled services should not be denied based on the absence of potential for improvement or restoration. Commenters indicated that residents should not have to show improvement for rehabilitative services to be determined as reasonable and necessary.

*Response:* We thank the commenters for highlighting the importance of the decision in *Jimmo* v. *Sebelius.* However, the *Jimmo* v. *Sebelius* settlement agreement did not modify or expand the existing eligibility requirements for receiving Medicare coverage and does not fall into the scope of this regulation. We note that CMS committed to conducting a number of activities in response to the settlement agreement to ensure that the existing Medicare policy is clear and that Medicare claims are adjudicated consistently and appropriately. Specifically, CMS planned to engage in the review of claims determinations, update program manuals, and educate contractors, adjudicators, and providers and suppliers on the policy clarifications. Readers may refer to the CMS Web site at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/SNFPPS/downloads/jimmo-factsheet.pdf* for a fact sheet regarding the *Jimmo* v. *Sebelius* settlement agreement.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- At § 483.65(a)(2), we are removing the requirement for outside resources to be Medicare and/or Medicaid providers of specialized rehabilitative services. We have clarified that the outside resource must be a provider of specialized rehabilitative services that is not excluded from participating in any federal or state health care programs pursuant to sections 1128 and 1156 of the Act.

*T. Outpatient Rehabilitative Services (§ 483.67)*

We proposed to add a new § 483.67 ''Outpatient Rehabilitative Services'' to address facilities that choose to provide outpatient rehabilitative therapy services to individuals that do not reside in the facility. Currently, the provision of outpatient rehabilitative services for non-residents is not addressed by the requirements for LTC care facilities. We noted that § 483.65 ''Specialized Rehabilitative Services'' sets forth the requirements that a facility must meet when providing rehabilitative therapy services to residents who reside in their facility.

We proposed to require facilities that provide outpatient rehabilitative therapy services to meet requirements similar to those already established for hospitals. Specifically, we proposed to require in new § 483.67 that if the facility provides outpatient rehabilitation, physical therapy, occupational therapy, audiology, or speech-language pathology services, the services must meet the needs of the patients in accordance with acceptable standards of practice and the facility must meet certain requirements. At § 483.67(a), we proposed that the organization of the service must be appropriate to the scope of the services offered. At § 483.67(b), we proposed to require that the facility assign one or more individuals to be responsible for outpatient rehabilitative services and that the individual responsible for the outpatient rehabilitative services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services. We also proposed to require that the facility must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered. In addition, we proposed to require that physical therapy, occupational therapy, speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in part 484 of this chapter. At § 483.68(c), we proposed to require that services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under state law and that all rehabilitation services orders and progress notes must be documented in the patient's clinical record in accordance with the requirements at § 483.70(i). Finally, we proposed to require that the provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

*Comment:* The majority of commenters indicated support for the addition of the requirements regarding facilities that provide outpatient rehabilitative services. Commenters noted that there has been inconsistent interpretation regarding how SNFs can furnish outpatient therapy services to non-residents and that steps towards standardization are needed. While a few of the commenters indicated that the new section provides adequate guidance for those facilities offering these services, other commenters raised concerns that the proposed requirements need further clarification and revision.

Specifically, one commenter raised the issue of SNFs that provide outpatient rehabilitative services to non-residents at a location outside of the facility. The commenter requested that the regulations address SNFs that may furnish outpatient rehabilitative services in locations other than the facility and allow flexibility in how these services are provided. The commenter urged CMS to revise the regulations so that they are consistent with requirements imposed for other Medicare outpatient therapy providers. The commenter indicated that the outpatient therapy services furnished by SNFs resemble the delivery of services furnished through outpatient rehabilitation providers described under 42 CFR part 485 subpart H (referred to in the comment as rehabilitation agencies) and not those services furnished through outpatient hospital departments. The commenter noted that unlike a hospital, rehabilitation agencies may also provide outpatient therapy services to individuals in a home environment, such as to residents of independent senior living and assisted living

residents. In addition, the commenter noted a CMS memo from April 3, 2015 entitled ''Clarification of Requirements for Off-Premises Activities and Approval of Extension Locations for Providers of Outpatient Physical Therapy and Speech-Language Pathology Services and Off-Premises Activities'' (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-33.pdf*). The commenter requested that the provisions addressed in this memo regarding off-premise treatment activities be added as requirements for SNFs.

A few commenters also recommended that the requirements be revised to ensure compliance with the decision in *Jimmo* v. *Sebelius,* which indicated that Medicare coverage for skilled services should not be denied based on the absence of potential for improvement or restoration. Commenters indicated that residents should not have to show improvement for rehabilitative services to be determined as reasonable and necessary. Also, a commenter raised concerns regarding inconsistences between the proposed requirements and Medicare Part B outpatient therapy payment policy. Lastly, commenters requested that the regulatory section be updated to replace the term ''patient'' with ''resident''.

*Response:* We appreciate the in depth feedback from commenters. Through our proposal, we intended to establish requirements for outpatient rehabilitative services provided to non-residents in the LTC facility to ensure that these services meet health and safety standards. We were informed that a number of facilities provide rehabilitative services on an outpatient basis and that these services may be paid for under Medicare Part B. We want to ensure that our requirements are fully and clearly developed in an effort to provide clarity to facilities and safety to those individuals that are receiving services. After carefully considering all of the comments we received, reviewing the comprehensive regulations for outpatient therapy providers found in part 485, and the CMS guidance regarding off-premise treatment activities recommended by commenters (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-33.pdf*); we believe that the practice of some LTC facilities providing outpatient rehabilitative services presents several additional complex issues that were not carefully and thoroughly considered during the development of the proposed regulations. Therefore, we have decided against finalizing the proposed requirements for outpatient rehabilitative services. We believe that it is necessary to study the issue further and consider proposals for future rulemaking.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modification:

- We have withdrawn this proposed section in its entirety.

*U. Administration (§ 483.70)*

Relocation of Existing Requirements

We proposed to re-designate current § 483.75 ''Administration'' as § 483.70. At § 483.75(c), we proposed to replace the term ''handicap'' with the term ''disability''and to add a reference to the HIPAA Privacy, Security, and Breach Notification Rules, 45 CFR parts 160 and 164. In addition, we proposed to clarify that violations of other HHS regulations, as determined by the agency or entity with enforcement authority for those regulations, may result in a finding by CMS of non-compliance with the requirements of § 483.70(c).

We proposed to re-designate and revise existing § 483.75(e) and (f), provisions regarding nurse aides, to § 483.35 ''Nursing Services'' or § 483.95 ''Training'', as discussed under these sections.

We proposed to create new section § 483.50 ''Laboratory, radiology, and other diagnostic services'' and relocate and revise existing paragraphs, § 483.75(j) ''laboratory services'' and § 483.75(k) ''radiology and other diagnostic services'', to the new section. In addition, we proposed to retain the provisions in existing § 483.75(g), (h) and (i) unchanged and re-designate them as proposed § 483.70 (f), (g), and (h).

We did not receive any comments in response to these proposals and are finalizing as proposed except that we have added a reference to 45 CFR part 92 in the list of regulations that facilities are required to comply with, based on a comment received with regards to § 483.12.

Governing Body § 483.70(d)

At § 483.70(d)(2)(i) we proposed to delete the phrase ''where licensing is required'' since all states participating in the Medicaid program are required to license nursing home administrators under section 1908 of the Act. We proposed to add a new § 483.70(d)(2)(iii) to specify that the LTC facility administrator would report to and be accountable to the governing body. We also proposed to add a new § 483.70(d)(3) to specify that the governing body is responsible and accountable for the QAPI program, in accordance with proposed § 483.75(f).

*Comment:* One commenter pointed out that deleting the phrase ''where licensing is required'' could result in confusion in states where state law allows administrators of hospitals which have a distinct part SNF not to be certified as LTC facility administrators.

*Response:* We agree and withdraw this proposal.

*Comment:* Some commenters supported the proposed changes to § 483.70(d)(2)(iii), which would require that the LTC facility administrator report to and be accountable to the governing body.

*Response:* We thank the commenters. We believe this change will ultimately benefit LTC facility residents.

*Comment:* One commenter was concerned about the proposed requirement at § 483.70(d)(2)(iii) for the LTC facility administrator to report to and be accountable to the governing body. The commenter stated that, while they understand and appreciate the need for the governing body to be kept apprised of the operations and management of the facility, they do not support a regulatory requirement prescribing that the facility administrator report to and be directly accountable to the governing body. The commenter stated that many not-for-profit organizations have management structures that include a Chief Executive Officer (CEO) who is not the administrator of record of the LTC facility. Under the bylaws and governance structure of these organizations, the CEO is directly accountable to the board of directors and responsible for hiring and supervising the facility administrator and other executive staff. Requiring the administrator to report to and be directly accountable to the governing body in these circumstances would supplant the governance policies of these organizations and undermine the relationship of the CEO to the board of directors. The commenter recommended that this requirement be eliminated in its entirety. Alternatively, the commenter suggested the requirement could be modified to require that the organization's senior management keep the governing body apprised of the operations and management of the facility, while leaving it up to the organization to designate the individual

who would be responsible for this function.

*Response:* As the commenter noted, we believe that it is important for the governing body to be kept apprised of the operations and management of the facility. Under current regulation, the governing body is already responsible for appointing the administrator who is responsible for the operations and management of the facility. The proposed provision would add that the administrator reports to and is accountable to the governing body. The new provision does not specify ''directly'' and thus we believe that a governing body may appoint a designee, such as a CEO, to directly interface with an Administrator. However, the use of a designee does not change the Administrator's accountability to the governing body nor the governing body's responsibility to know and respond to concerns with the operation and management of the facility.

*Comment:* One commenter stated that they appreciate that CMS would make the administrator report to and accountable to the governing body. They note that while this may be implied, the proposed specificity clarifies this point. Given the governing body's responsibility for implementing the management and operations of the facility, the commenter agrees with CMS that the administrator must keep the governing body informed and knowledgeable about these issues. The commenter also supports the governing body also being responsible and accountable for the facility's QAPI. This program cannot be successful unless the facility leadership is involved.

*Response:* We agree. As noted above, we believe it is important that the governing body be kept apprised of the operations and management of the facility. Furthermore, should the governing body appoint an intermediary such as a CEO, the use of such an intermediary does not change the Administrator's accountability to the governing body nor the governing body's responsibility to know and respond to concerns with the operation and management of the facility.

Facility Assessment (§ 483.70(e))

We proposed a new § 483.70(e) to establish a new requirement for an annual facility assessment. We proposed to require that the facility assessment address or include:

- The facility's resident population, including the number of residents, the facility's resident capacity, the care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, and overall acuity that are present within that population.
- The staff competencies that are necessary to provide the level and types of care needed for the resident population.
- The physical environment, equipment, and services that are necessary to care for this population.
- Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.
- The facility's resources, including but not limited to buildings and other physical structures and vehicles; medical and non-medical equipment.
- The services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies.
- Personnel, including managers, employed and contracted staff, and volunteers, as well as their education and/or training and any competencies related to resident care.
- Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility both during normal operations and emergencies.
- Health information technology resources, such as systems for electronically managing patient medical records and electronically sharing information with other organizations.

General Comments

*Comment:* Some commenters did not believe that the proposed requirement for a facility assessment would be a significant change from what is currently required. Commenters pointed to language in the proposed rule, where we first said, that the requirement for a facility assessment was ''a central feature'' of our revisions and that ''[t]his is similar to existing common business practices for strategic planning and capital budget planning'' (80 FR 42210). Commenters said that authorizing a practice that is already common does not appear to be a significant change. The current requirements already require resident-centered and specific care plans designed to attain and maintain the resident's highest practicable physical, mental, and psychosocial well-being. LTC facilities already use multiple sources of data, including the items listed in the proposed rule, in various ways to make operational decisions, including the number of staff and skills that staff need to provide care to the residents. Some commenters also noted that the current requirement to determine staffing levels was already producing serious staffing and quality deficiencies and did not see where the proposed changes would make any appreciable difference. They also said the reason for this assessment was completely unclear.

*Response:* Based on our experience with LTC facilities, we believe that there is already some assessment of the resident population and the resources that would be required to care for that population. However, we do not believe that all facilities perform as thorough an assessment of their resident population or the facility's resources as is required by § 483.70(e). In addition, we do not believe that most facilities have a formal process that is documented. We believe that the requirement for a facility assessment that must address the factors identified in § 483.70(e)(1) through (3) will enable each LTC facility to thoroughly assess their resident population and the resources that are needed to provide the care they need. It will also enable the facility to determine the resources it has so that it can determine what resources it needs to competently care for its resident population. By having the facility assessment documented, it will also provide a record for staff and management in the future to understand the reasoning for decisions that were made on staffing and other resources. It will also provide a reference point for assessment when deficiencies are noted or when adverse events occur.

*Comment:* Some commenters were very supportive of the requirement for a facility assessment, but wanted us to also require that self-assessment plans include individual crisis plans for residents who may develop dementia-related or other behavioral crisis.

*Response:* We understand the commenters concern for residents who have or may develop dementia-related or other behavioral crisis. As proposed and now finalized in this rule, § 483.70(e) requires that facilities must, among other things, 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 and this assessment must address or include the care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity; and other pertinent facts that are present within that population. Hence, LTC facilities must already consider the care that is needed for those residents who already have dementia-related or other behavioral crises or could develop these during an emergency. We have not required a specific methodology for LTC facilities to perform their facility assessments because we believe that

facilities need the flexibility to decide how they will conduct their assessments. Thus, we will not require that individual crisis plans be included; however, each facility must address the needs of all residents, including those who have or may develop dementia-related or other behavioral crises both during day-to-day operations and emergencies.

Facility Assessment Methodology

*Comment:* Some commenters were supportive of LTC facilities conducting their own facility assessment and taking into consideration the factors set out in the proposed rule at § 483.70(e). However, they were concerned about the facility being able to rely on its own assessment without there being any enforcement mechanisms or safeguards to ensure that the facility was objectively assessing its residents' needs, acuity, and other important factors and not relying unduly on other factors, such as costs or convenience. Some commenters were concerned that LTC facilities would simply produce assessments that indicated that their current staffing and other resources were sufficient to care for their resident population. Commenters recommended that facility assessments be validated in some manner.

*Response:* We understand the commenters' concerns; however, we believe that in complying with the requirements finalized in this rule as set forth in § 483.70(e), LTC facilities will have to conduct and document a thorough assessment and analysis of their resident population, staff and staff competencies, and resources to determine not only the resources they currently have but also the resources they need to obtain in order to care for their resident population competently. We will also be developing sub-regulatory guidance that will provide more information on how to comply with this requirement. If any LTC facility simply writes up a facility assessment to justify the resources it currently has, we believe that will be evident in the facility assessment, as well as in their performance on surveys.

*Comment:* Some commenters were concerned about having the facility assessment developed by the LTC facility without requiring input from other sources. They recommended that the facility be required to seek and use input from the state's Office of the Long-Term Ombudsman, the resident and family groups, and family caretakers when conducting its assessment. However, other commenters believed that the facility assessment should be considered proprietary and that the facilities should not be required to either include input from sources outside the facility or share the assessment with them.

*Response:* While we encourage LTC facilities to seek out and consider input from multiple sources, including residents, residents' representatives, families, and advocates, including the state Office of the Long Term Care Ombudsman, we disagree with the commenters that this should be required. As stated in the proposed rule, we encourage LTC facilities to seek input from multiple sources; however, ''[w]e believe the facility should have the flexibility to determine when and from whom a facility would seek input and how to incorporate that information into their assessment'' (80 FR 42210 through 42211). We believe that each facility needs the flexibility to decide the best way to comply with this requirement. This is also the reason we have not required any specific methodology for facilities to use for the facility assessment.

*Comment:* Some commenters believed that the level of detail in facility assessment requirement was unreasonable, complex, and would be extremely burdensome for the LTC facilities. However, other commenters were concerned about the lack of specificity for the facility assessment requirement. They said it was unclear what these assessments would look like or which staff members should be involved. Some commenters noted that there was insufficient information in the preamble and the regulatory text to evaluate the requirement for a facility assessment. Commenters were particularly concerned that this inevitable lack of consistency in methodology would result in the results not being comparable. Thus, the facility assessments would not provide any valid comparisons or provide any precedent over time sufficient to be beneficial for LTC facilities, advocates, regulators, surveyors, or researchers. Commenters also questioned whether these assessments could fail to comport with the OBRA '87 requirement that every facility have adequate staff in place to ensure that residents can achieve their maximum well-being.

*Response:* We understand that the commenters have concerns and questions about what would be needed to comply with the requirement for a facility assessment. In proposed § 483.70(e), we only included the elements that we believe are essential for a facility to assess and analyze its resident population and resources so that it can competently determine the resources it needs to care for its resident population. As we said in the proposed rule, ''[t]his facility-wide assessment would determine what resources a facility would need to care for its residents competently during both day-to-day operations and emergencies'' (80 FR 42210). Thus, we believe that the basic elements for the assessment are included and do not believe that the requirements are unreasonable, complex, and would be extremely burdensome. As we indicated earlier, we believe that facilities are already performing some type of assessment, although it may not be as formal or documented. In addition, after this final rule is effective, additional sub-regulatory guidance will be published or disseminated to provide further detail on how to comply with these requirements.

We acknowledge that there will likely be some variation in how LTC facilities will conduct and document their facility assessments. However, due to the significant variations in the types of LTC facilities, resident populations, and resources among the LTC facility facilities, we believe that the facilities need the flexibility to determine the best way for each facility to comply with this requirement. As to consistency among the facility assessments, we believe that the accuracy of the assessments is more important. However, over time we believe that some consistency will likely develop due to facilities sharing what has worked best for them with other facilities and their associations. In addition, if a facility complies with the requirements for the facility assessment finalized in this rule, we believe that facilities will be able to determine what constitutes sufficient staff for their facility, which would be in compliance with the requirement in OBRA '87 for sufficient staffing.

Annual and Other Updates

*Comment:* Some commenters were concerned that facilities may potentially need to update their assessments frequently, such as every time their resident-mix changes, they hire new staff or a DoN, conduct any remodeling, etc. This continuous, or at least frequent, need to update the facility assessment could distract LTC facilities from improving resident care.

*Response:* We do not believe that the facility assessment will need to be updated as frequently as the commenters suggest. We understand that the resident-mix may change frequently. However, the care that needs to be provided for the resident populations should not change that frequently. Once the facility completes its assessment, changes in its resident

population should not necessitate a change in the facility assessment unless the facility begins admitting residents that require substantially different care. For example, when a facility does its initial assessment, it might not have any morbidly obese residents who require special bariatric equipment, such as a bariatric wheelchair and walker. However, in the future, if the facility wants to admit morbidly obese residents who require that equipment, it would need to identify the care needs for morbidly obese residents, update the facility assessment, ensure that its staff have the relevant competencies, and obtain the other required resources. As long as the facility assessment encompasses the care and resources needed by the residents, admitting new residents with the same needs should not require an update of the facility assessment. Likewise, hiring new staff or a DoN or even remodeling should not require an update of the facility assessment, unless these are actions that the facility assessment indicated the facility needed to do. In that case, it should only require notation that the facility has taken the actions to satisfy a need the facility assessment identified.

*Comment:* Some commenters questioned the requirement to perform the facility assessment annually. They said that appropriate staffing levels and the competencies that are required to care for their resident population change much more frequently than annually. Commenters said that the annual assessment must be able to establish that its staffing will remain adequate throughout the year, both with regard to levels of total nurse staffing, and with respect to the responsibility that certain types of staff, for example, registered nurses, licensed practical nurse, have in overseeing the medical management of residents with regard to medications, falls prevention, development of pressure ulcers, readmission to hospitals, and other key areas.

*Response:* We believe that an annual assessment is needed to ensure that there have not been any substantial changes that will require the facility to update its facility assessment. The annual assessment is a minimum requirement. LTC facilities should update their facility assessment whenever they believe it is appropriate.

Number of Assessments

*Comment:* Some commenters stated that a single facility assessment was insufficient. Some commenters said that the facility assessment requirement, as a single process, did not appear to serve long-range planning needs and, simultaneously, the changing day-to-day needs of a facility for staffing and other services, such as food and nutrition, rehabilitation, and housekeeping. Some commenters argued for two different assessments. One facility assessment would be limited to the day-to-day needs for the facility and another that would address emergency planning, strategic planning, and capital budget planning. Other commenters offered specific language for this type of requirement, with separate subsections: One for an annual strategic planning and capital budget assessment and another for a bi-weekly staffing and day-to-day operations assessment. For the bi-weekly staff and day-to-day operation assessment, commenters also recommended the individuals they believed should be involved in that assessment and that this assessment must also address emergencies.

*Response:* The requirement for a facility assessment as finalized in this rule and set forth in § 483.70(e) is a minimum requirement. If facilities choose to conduct another assessment or expand the facility assessment to include long-range planning needs or any other needs, it is free to do so as long as it complies with the minimum requirements in this final rule. We have not required the involvement of specific LTC facility personnel because we believe that the facility should have the flexibility to determine the appropriate individuals who should be involved in the facility assessment.

Use of Facility Assessment

*Comment:* Some commenters stated that each LTC facility is a unique organization with its own values, goals, experiences, and other factors that drive how it operates. The commenters were concerned that the requirement for the facility assessment could result in organizational decisions and approaches being specifically directed or managed by CMS, which is contrary to the spirit of QAPI whereby the organizations operations should be shaped by the staff, residents, governing body, and other parties. However, other commenters wanted the facility assessment audited by a facility surveyor and that the surveyor be empowered to require, under threat of graduated monetary penalties, that the facility provide additional nursing resources if the surveyor disagrees with the facility's assessment.

*Response:* The requirement for the facility assessment is intended to ensure that LTC facilities have appropriately assessed their resident population and determined the resources, including staff and their competencies, to competently care for their residents. The facility assessment will be performed and documented by the facility and not by CMS or any other entity. LTC facilities must comply with the long term care requirements; however, we have endeavored to allow for as much flexibility as possible for facilities to decide the best way for their facility to comply with these requirements. We also believe that the facility assessment could be very useful tool for QAPI, especially when assessing the facility's performance on the elements they are required to include in the assessment.

Implementation

*Comment:* Some commenters said that there was no discussion on implementation of the findings in the facility assessment. They recommended including language that requires the facility to implement the competent staffing and resources determined necessary to care for the residents based on the results of the facility assessment.

*Response:* There are many sections in this final rule, as in the proposed rule, that requires that the facility assessment be used to determine the resources the facility needs to devote to certain activities. For example, § 483.35 requires that the facility have the appropriate staff with the appropriate competencies and skill sets for the resident population in accordance with the facility assessment. Section § 483.40(a) requires that the facility have sufficient direct care staff with the appropriate competencies and skills sets in behavioral health for the residents in accordance with the facility assessment. Facilities must also establish and maintain their infection prevention and control programs based upon the facility assessment as set forth in § 483.80(a)(1). In addition, we encourage facilities to use their facility assessment in any other activities that affect their resident population. We believe these requirements are sufficient to require facilities to use their facility assessments so we will not include the recommended specific language.

Alternatives

*Comment:* Some commenters recommended that the proposal for the facility assessment not be finalized and that CMS form a stakeholder workgroup that could explore the potential use of ''facility assessments'' and unintended consequences or outcomes, as well as possible alternate approaches. Commenters wanted CMS to provide clarification on what it envisions for a facility assessment; provide evidence for the value of proposing a requirement for this facility assessment; and provide

evidence-based models of facility assessment and process. Other commenters questioned what evidence we had that supported the validity of this requirement.

*Response:* As discussed above, we believe that LTC facilities already perform some type of assessment to determine staffing and other resources they will need to care for their resident population. For example, previous § 483.30 ''Nursing services,'' required facilities to provide ''sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.'' Also, previous § 483.15 ''Quality of life,'' required facilities to ''care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.'' The Veterans Administration is also using facility assessments in its strategy to improve its health care delivery system (''Restoring Trust in VA Health Care,'' 271 New Eng. J. Med. 295 (2014), accessed on Westlaw (2014 WLNR 20261329) on July 26, 2016). We believe that these requirements are necessary to ensure that the facility competently cares for its resident population by appropriately assessing its resident population and resources. The requirement includes specific elements that each facility must address that relate to its resident population, staff, and the resources the facility needs to care for its residents. It provides for not only a process but also provides a valuable tool for facilities to use for planning for and improving care. We do not believe that a stakeholder group is necessary prior to implementing the requirement for a facility assessment; however, we are always willing to review any information or comments that any member of the public wishes to send to us and will consider that information if there is any relevant future rulemaking.

*Comment:* Some commenters did not want the requirement for a facility assessment finalized because they believed that the outcomes for residents under the existing requirements should stand as evidence of the adequacy of the facility's assessment. These commenters questioned the need to require LTC facilities to spend precious time documenting a facility-wide assessment that surveyors will use to interpret whether the facility has sufficient staff. The more appropriate way to assess allocation of resources is to assess whether or how the facility has met the individual needs of each resident rather than require another documentation endeavor.

*Response:* The requirement for a facility assessment addresses different issues that the requirements for person-centered care for residents. In the facility assessment, LTC facilities should be proactive in assessing and analyzing the needs for the entire resident population. Individual care plans would certainly be a valuable resource in performing the facility assessment; however, the care plan would address the specific needs for a single resident. The facility assessment must address the care needed for all of the residents, as well as the resources needed to provide that care competently.

*Comment:* Commenters urged that CMS examine whether the current methodology for the five-star system, which calculates expected staffing based on RUG values along with reported staffing levels, could be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. An adaptation of this system must also be designed to incorporate the more robust payroll-based staffing data that will be in place as a requirement for all certified SNFs and NFs by July 2016.

*Response:* As discussed above, we will consider the commenters recommendation to examine whether the current methodology for the five-star rating system, which calculates expected staffing based on RUG values along with reported staffing levels, can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments. In addition, we will also be reviewing the payroll-based staffing data that we will be receiving starting this year. However, proposals to use either of the above suggested methods would have to be developed. We will consider these recommendations if there is future rulemaking concerning the facility assessment or staffing.

Surveys/Surveyors

*Comment:* Other commenters were concerned about how the facility's management might use the facility assessment or how surveyors would use the facility assessment in assessing a facility's compliance with various requirements. The general requirement for a facility assessment invites a tremendous amount of subjectivity into the survey process when surveyors already have requirements and other sub-regulatory guidance to determine whether there is non-compliance during a survey.

*Response:* We understand the commenters' concern about how the facility assessment will be used by the facility and the surveyors. Facilities are required to use the facility assessment in determining how they need to comply with several requirements in this rule. However, facilities may also choose to use their assessments for other purposes. Concerning the surveyors, further guidance will be published or disseminated by CMS after this rule is published to provide additional information on what constitutes compliance with the requirements set forth in this final rule.

Medical Records (§ 483.70(i))

We proposed to re-designate existing § 483.75(l) as § 483.70(i) and to amend it to better conform to the requirements of the HIPAA Privacy, Security, and Breach Notification rules at 45 CFR parts 160 and 164. We also proposed minor revisions in it to clarify that the medical record must contain the resident's comprehensive plan of care and physician's and other licensed professional's progress notes. We noted in the proposed rule that existing paragraph (m) will be removed and revised pursuant to a separate proposed rule, ''Medicare and Medicaid Programs: Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers'' (78 FR 79081, December 27, 2013).

*Comment:* One commenter was concerned about proposed § 483.70(e)(2)(i) using the term ''medical records,'' rather than the term in the current § 483.75(l), which is ''clinical records.'' The commenter stated that the term ''clinical records'' appears to be broader than ''medical records'' and states that CMS offered no reason for the change. The commenter suggested CMS retain the current term ''clinical records.''

*Response:* We believe the commenter is referring to proposed § 483.70(i), which addresses medical records rather than § 483.70(e), which addresses facility assessment. In the preamble to the proposed rule, we noted that we proposed to establish requirements that mirror some of those found in the HIPAA Privacy Rule (45 CFR part 160, and subparts A and E of part 164). We did not specifically state that our change to the term 'medical record' was related to achieving consistency with the HIPAA rules, but that was the impetus for the change. The HIPAA rules in 45 CFR part 164 use the term 'medical record' rather than 'clinical record'. We regard the terms as synonymous.

*Comment:* One commenter suggested that we further clarify that the

comprehensive care plan and services provided includes records documenting activities of daily living care and services, bathing and skin inspections, and nutrition and fluid intake and output records.

*Response:* We thank the commenter for their suggestion. We proposed that the medical record must include, in addition to the comprehensive care plan and services provided and other existing requirements, the reports of diagnostic testing and the progress notes of licensed personnel. We expect that this will address some of the commenters concern. However, we will consider further expanding this requirement in future rule-making, which would give us the opportunity to obtain further feedback on this issue.

*Comment:* CMS proposed to incorporate, without change, the current requirements for medical directors, current § 483.75(i). The commenter was concerned that, too often, the medical director also serves as the attending physician for most of the facility's residents. The dual roles of medical director and attending physician make it impossible for the medical director to perform the medical director's specific regulatory functions—implementing resident care policies and coordinating medical care in the facility. The medical director cannot ''oversee'' the care he or she is providing to residents as attending physician. The commenter encouraged CMS to address this issue in final regulations. The commenter stated that, although there may be a need, in some limited instances, for medical directors to serve as residents' attending physicians, CMS needs to strengthen the regulatory standards for medical direction so that medical directors can, in fact, perform their critical management functions. The commenter suggested that, for example, CMS could mandate specific minimum numbers of hours per week or per month for medical direction functions; require certification for medical directors; limit medical directors from serving as medical director in more than two facilities; and prohibit medical directors from serving as the residents' attending physicians (with a limited exceptions process).

*Response:* We thank the commenter for these suggestions. As noted by the commenter, we did not propose any changes to this provision, but are re-designating it as § 483.70(h). We defer to sub-regulatory guidance for further discussion of the medical director's specific functions pertaining to resident care policies and coordinating medical care in the facility. In addition, while we are not addressing them in this final rule, we will continue to evaluate both the situation where the medical director is fulfilling the attending physician role and the oversight role and the need for additional standards for medical direction. We will consider addressing these concerns in future rule-making.

Transfer Agreement (§ 483.70(j))

In § 483.70(j), ''Transfer Agreement, ''we proposed to modify the current language at § 483.75(n) to allow a practitioner other than the attending physician to determine that a hospital transfer is medically appropriate in an emergency situation, consistent with state law and facility policy. We further proposed to specify here that the information exchange required by existing paragraph § 483.75(n)(1)(ii) be modified to require that the exchanged information include, at a minimum, the information we proposed to require under new paragraph § 483.15(b)(2)(iii)(B). We proposed to incorporate existing § 483.75(o), assessment and quality assurance, into proposed § 483.75(c).

*Comment:* Some commenters indicated support for our proposal to allow a practitioner other than the attending physician to determine that a hospital transfer is medically appropriate in an emergency situation, consistent with state law and facility policy.

*Response:* We thank the commenters. We believe this change will ultimately benefit LTC facility residents.

*Discussion of § 483.70(l), (m), and (o)*

Provisions on disclosure of ownership, facility closure-administrator, facility closure, and hospice services were proposed to be re-designated as paragraphs § 483.70(k), (l), (m), and (o) respectively, and the cross-reference in (m) updated, but otherwise unchanged. We proposed to address training of paid feeding assistants in § 483.95 ''Training requirements.''

*Comment:* One commenter stated that they believe that § 483.70(l) is an adequate statement of a requirement for facilities to be judicious about hospitalizing and re-hospitalizing people. The commenter further stated that the additional structural requirements proposed elsewhere in the proposed regulations related to hospital transfers are warranted or that they will somehow correct what are essentially process problems due to diverse causes.

*Response:* We address the commenters concerns about additional structural requirements related to transfer in our response to comments on proposed § 483.15. Section 483.70(l) applies to requirements for the facility administrator in the event of a facility closure.

*Comment:* A few commenters recommended we add notice and timing requirements related to facility closure, including notice to facility staff and any union representation.

*Response:* Timing and notice requirements for facility closures are specified in final § 483.70(l). We did not propose any changes, other than re-designation, to the requirements associated with facility closure. We will consider the commenters' suggestions for future rule-making.

*Comment:* One commenter was concerned that § 483.70(o)(1)(ii) enabled LTC facilities to ''not arrange for the provision of hospice services at the facility through an agreement with a Medicare-certified hospice.'' The commenter stated that they understand that a resident cannot use both the SNF and hospice benefits at once and that SNF discharge may be needed for a resident to access hospice. However, the commenter feels this situation does not seem to be the intent of the requirement. Moreover, the commenter is concerned that, although a facility may assist the resident in transferring to a facility that will arrange for the provision of hospice services, as stated in the requirement, such a transfer disrupts a resident's care at a critical juncture. Care cannot be person centered, and a LTC facility cannot be considered a resident's home, if the resident is not able to access the services of a Medicare-certified hospice. The commenter urges CMS to delete subsection (o)(1)(ii).

*Response:* We respectfully decline. While we understand the commenter's concern, such a change is outside the scope of this final rule, as we did not propose any changes to our hospice provisions and have not had the opportunity to obtain public feedback on this issue. We would need to carefully consider the implications for both hospice providers and long-term care facilities of mandating, without exception, that long-term care facilities contract for hospice services. There may be instances where an appropriate hospice provider is not available to the facility or there are other reasons that the facility is unable or unwilling to enter into a contractual relationship with a hospice provider or the hospice provider is unwilling or unable to enter into a contract with the facility. We would need to consider these issues carefully before mandating that nursing facilities contract for hospice services.

Binding Arbitration Agreements (§ 483.70(n))

We proposed in § 483.70(n) to require facilities that ask residents to accept binding arbitration to resolve disputes between the facility and the resident to meet certain criteria. We proposed that the facility be required to explain the agreement to the resident in a form, manner and language that he or she understands and have the resident acknowledge that he or she understands the agreement. The agreement could not contain any language that prohibited or discouraged the resident or any other person from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health department employees, or representatives of the Office of the State Long-Term Care Ombudsman, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action, in accordance with proposed § 483.11(i). If a facility utilized an arbitration agreement, such facility would be required to inform the resident, at a minimum, that the resident was waiving his or her right to judicial relief for any potential cause of action covered by the agreement. The agreement could only be entered into by the resident voluntarily and would have to provide for the selection of a neutral arbitrator and a venue convenient to both parties, the resident and the facility. We indicated in the proposed rule that any agreement for binding arbitration could not be contained within any other agreement or paperwork addressing any other issues. It would have to be a separate agreement in which the resident made an affirmative choice to either accept or reject binding arbitration for disputes between the resident and the facility. We also proposed to specify that the guardians or representatives could not consent to an agreement for binding arbitration on the resident's behalf unless that individual was allowed to do so under state law, all of the other requirements in this section were met, and the individual acting on behalf of the resident had no financial interest in the facility. In addition, in the proposed rule, we solicited comments on whether binding arbitration agreements should be prohibited entirely.

We received a significant number of public comments concerning this proposal. The commenters from the LTC facility industry overwhelmingly wanted us to withdraw our proposal. Other commenters, including members of the public, advocates, and members of the legal community, predominantly wanted a prohibition on ''pre-dispute'' arbitration agreements (that is, agreements made before any dispute had arisen). Some commenters believed that arbitration should not be allowed in LTC facilities under any circumstances. We also received numerous items of congressional correspondence concerning arbitration agreements. One letter signed by 34 senators urged CMS to ban pre-dispute arbitration clauses; another letter from three members of the House of Representatives argued that CMS lacked the authority to ban these agreements and, even CMS did have the authority, the agency should not prohibit them. Another senator urged us to seriously consider the concerns surrounding pre-dispute arbitration agreements and their consequences to residents. The senator noted that individuals seeking long-term care, many of whom are elderly or disabled, are basing their decisions on the cost of care and proximity to their loved ones, and that it would be difficult for these individuals to fully understand the gravity of contract terms and their legal rights to concerning potential future disputes between themselves and the facilities. This senator also noted that due to the limited grounds for appeal, it was imperative that both parties understand the terms of the agreement, especially in the long-term care setting, where individuals and their families are making choices that profoundly impact the health and safety of their loved ones.

In addition, we received a letter signed by 16 state attorneys-general stating that pre-dispute arbitration agreements were harmful to residents in LTC facilities and should be prohibited. Other commenters were concerned about particular aspects surrounding arbitration, such as: The conflict of interest in having the LTC facility explain and ask the resident to sign the agreement; the coercive nature of having the resident sign the agreement during the admission process, before any dispute has arisen; the arbitration process not actually being conducted by a neutral arbitrator or in a neutral environment; the costs of arbitration to the residents; and the secrecy of the entire arbitration process. Other commenters were not only against our proposed requirements but opposed any regulation concerning arbitration, including a ban on arbitration agreements. A summary of the comments and our responses are set forth below. We have grouped the discussion into issue areas raised by commenters.

Statutory Authority To Regulate Arbitration Agreements

*Comment:* Some commenters argued that the federal government, through the Federal Arbitration Act (FAA) (9 U.S.C.A. § 1 *et seq.*) favors arbitration and requires that arbitration agreements be enforced unless there are grounds that exist at law or in equity for the revocation of any contract, such as enforcing the agreement would be unconscionable (9 U.S.C.A. § 2). They also pointed out that both Congress and the courts have repeatedly refused to regulate arbitration agreements between LTC facilities and their residents. They noted that Congress had failed to pass five different bills to regulate arbitration agreements in LTC facilities during [time period].[1] Commenters also cited the Supreme Court's per curiam ruling in *Marmet Health Care Center, Inc.* v. *Brown* (132 S.Ct.1201, 1203 (2012)), which addressed on appeal a decision of the Supreme Court of Appeals of West Virginia. The West Virginia court had held that all predispute arbitration agreements pertaining to claims alleging personal injury or wrongful death were unenforceable in accordance with West Virginia's public policy. The Supreme Court reversed the decision, holding that ''[w]hen state law prohibits outright the arbitration of a particular type of claim, the analysis is straightforward: The conflicting rule is displaced by the FAA.'' *Id.* at 1203 (quotations omitted).

The commenters also pointed to cases in which courts rejected various federal agencies' attempts to prohibit the enforcement of arbitration agreements. The commenters argued that when Congress intends to give an agency authority to prohibit or impose conditions on the use of arbitration agreements it does so with unambiguous statutory language, and it did not do so in the Social Security Act. They also argued that there was no language in the Act that gave the Secretary statutory authority to interfere in commerce, and that Congress had in face expressed its opposition to such actions in creating the International Court of Arbitration of the International Chambers of Commerce (ICC) and the Federal Trade Commission (FTC). They argued that prohibiting the use of or regulating arbitration was contrary to legal policy and tradition favoring contract formation.

[1] *See* Fairness in Nursing Home Arbitration Act of 2012, H.R. 6351, 112th Cong.; Fairness in Nursing Home Arbitration Act of 2009, H.R. 1237, 111th Cong.; Fairness in Nursing Home Arbitration Act, S. 512, 111th Cong.(2009); Fairness in Nursing Home Arbitration Act of 2008, H.R. 6126, 110th Cong.; Fairness in Nursing Home Arbitration Act, S. 2838, 110th Cong. (2008).

In addition, they claimed that a previous survey and certification memorandum issued by CMS acknowledged that these agreements were between the facility and resident. They noted that former HHS Secretary Mike Leavitt had sent a letter dated July 29, 2008 addressed to the House Judiciary Committee, a letter that officially opposed the ''Fairness in Nursing Home Arbitration Act of 2008'' that would have amended the FAA to render pre-dispute binding arbitration agreements between LTC facilities and their residents unenforceable.

Some commenters pointed out that, in addition to the FAA, courts have upheld arbitration in many industries, and that many contracts in the health care field including but not limited to admissions contracts for LTC facilities, are on a take-it-or-leave it basis. Others argued that arbitration had been successfully used in LTC facilities for years and that further regulation was not necessary.

*Response:* We disagree with the commenters' assertions that CMS lacks authority to issue regulations concerning arbitration agreements contained in LTC facility admissions contracts.

First, we note that the plain language of the FAA applies only to existing arbitration agreements voluntarily made between private parties; it does not compel or require the use of arbitration between private parties.[2] Because it does not prescribe circumstances in which arbitration agreements must be used, it does not impinge on federal agencies' rights to issue regulations regulating the conditions of adoption of such agreements, assuming that the Secretary otherwise has proper statutory authority. Consequently, we believe that the proper focus of this discussion is only on whether these rules have been properly issued under the Act and the procedural requirements of the Administrative Procedure Act. The proposed and final regulation would have no legal effect on the enforceability of existing pre-dispute arbitration agreements between LTC facilities and patients, and therefore we believe that the terms of the FAA are not implicated. ''('' [W]hen two statutes are capable of co-existence . . . it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'' (citation omitted)).'' *Morris* v. *Ernst & Young LLP,* ____ F.3d ____ (9th Cir., August 22, 2016) (2016 WL 4433080 at *8).

We are finalizing this rule, which will prohibit facilities' use of pre-dispute arbitration agreements, as a requirement for participation in the Medicare and Medicaid programs. Under sections 1102(a) and 1871 of the Social Security Act, the Secretary of Health and Human Services Section is authorized to issue such rules as may be necessary to the efficient administration of the functions of the Department. Section 1866 of the Act requires all Medicare providers and suppliers to agree to certain conditions in order to participate in the Medicare program. Likewise, section 1902(a)(27) of the Act requires that Medicaid providers meet all the requirements set out in the Medicaid provider agreement; and section 1902(a)(28) of the Act requires that States ensure that Medicaid nursing facilities meet all provisions of section 1919(b)–(d) of the Act (governing requirements for Medicaid nursing facilities).

The Department regularly requires providers and suppliers of health care items and services to forgo certain rights they might otherwise have with respect to Medicare and Medicaid patients, such as the right to pursue the patient for payment when the patient has no way of knowing that services are not covered by Medicare (See Section 1879 of the Act); requirements that LTC facilities give Medicare beneficiaries written advanced notifications of non-covered services (See Skilled Nursing Facility Advance Beneficiary Notice (SNFABN) Form CMS–10055, accessed at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS019508.html*, on September 19, 2016), limitation on the rights of insurers to market alternative products while potential Medicare advantage customers are placed on hold (or to upsell products to Medicare Advantage and Medicare Prescription Drug Plans (See Medicare Marketing Guidelines, accessed at *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf*, on September 19, 2016), specific limitations on the rights to provide patients with promotional information, including a prohibition on marketing Medicare Advantage and Part D insurance plans to Medicare beneficiaries residing in long-term care facilities (including LTC facilities, assisted living facilities, board and care homes, etc.) without first receiving a specific request from the beneficiary (See Medicare Marketing Guidelines issued June 10, 2016, located at *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf*, accessed on September 19, 2016), and so on. These rules mandating that suppliers of health care items and services forgo contractual and other commercial rights they might otherwise have with respect to Medicare and Medicaid patients, evince a Congressional and administrative understanding that business arrangements with Medicare and Medicaid patients are not typical commercial contracts where both parties engage in arms-length bargaining. Given the unique circumstances of the LTC admissions process, coupled with the clear interest that Medicare and Medicaid have in protecting beneficiaries, a prohibition on the use of pre-dispute arbitration agreements is not by its nature outside the permissible realm of conditions a facility must meet if it wishes to receive payment under the Medicare and Medicaid programs.

In addition to the statutory authority of the Secretary to set general practice parameters for payment under Medicare and Medicaid, the Secretary, under the explicit authority of Congress, is charged with protecting the health, safety and welfare of LTC facility residents pursuant to specifically enumerated standards set out in sections 1819 and 1919 of the Act. In addition, Congress granted the Secretary explicit authority under sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to require LTC facilities to ''meet such other requirements relating to the health, safety, and well-being[3] of residents or relating to the physical facilities thereof as the Secretary may find necessary.'' As set out below, there is significant evidence that pre-dispute arbitration agreements have a deleterious impact on the quality of care for Medicare and Medicaid patients, which clearly warrants our regulatory response.

In addition, sections 1819(c)(1)(A) and 1919(c)(1)(A) of the Act create a host of specified rights for LTC facility residents, including, but not limited to, free choice, confidentiality, privacy, and the expression of grievances. These sections also include a broad grant authorizing the Secretary to establish ''any other right'' (sections 1819(c)(1)(A)(xi) and 1919(c)(1)(A)(xi) of the Act) as she may deem necessary. Based on the comments received in

[2] The applicable provision of the FAA reads, in its entirety: ''A written provision in any maritime transaction or a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.'' 9 U.S.C. 2.

[3] We note that section 1919(d)(4)(B) of the Act omits ''well-being''.

response to this rulemaking, we are convinced that requiring residents to sign pre-dispute arbitration agreements is fundamentally unfair because, among other things, it is almost impossible for residents or their decision-makers to give fully informed and voluntary consent to arbitration before a dispute has arisen. We believe that LTC residents should have a right to access the court system if a dispute with a facility arises, and that any agreement to arbitrate a claim should be knowing and voluntary.

With respect to the Supreme Court's opinion in *Marmet,* we believe the decision to be inapposite, because the matter under consideration involves the enforceability of an already-existing pre-dispute arbitration clause. As noted above, the rule we are issuing does not affect already-existing arbitration clauses, but prohibits Medicare-and Medicaid-participating LTC facilities from using them in the future, as a condition of participating in these programs. While we share the same public policy concerns about already-existing arbitration agreements, we are only addressing agreements reached after the effective date of this rule. Likewise, *Compucredit Corp.* v. *Greenwood,* 565 U.S. ____ 132 S.Ct. 665 (2012), a case involving consumer credit, considered whether a provision of the Credit Repair Organizations Act (15 U.S.C. 1679c(a)) (CROA) created a right to sue which would have the effect of rendering any arbitration clause unenforceable. The Supreme Court's opinion held that the statutory language of CROA failed to create an explicit right to have recourse to the courts that superseded the public policy concerns of the FAA. Because the case involved the interpretation of CROA's language, we do not believe it to create any meaningful restriction on the Secretary's statutory authority to prohibit facilities' future use of pre-dispute arbitration clauses as a condition of participation in Medicare and Medicaid.

Concerning the survey and certification letter previously published by CMS, we do not believe the requirements in this final rule contradict that letter. Any agreement for binding arbitration is clearly between a facility and a resident, and this rule does not in any way prohibit the use of post-dispute arbitration agreements. The requirements in this final rule only ensure that the residents receive basic protections in signing an agreement for arbitration. Since facilities will only be able to approach residents to request them to sign an agreement for binding arbitration after a dispute has arisen, residents and their representatives will have the information necessary to make an informed decision, and should also be able to negotiate specific terms. Former HHS Secretary Leavitt's letter, dated July 29, 2008 addressed to the House Judiciary Committee, officially opposedthe Fainess in Nursing Home Arbitration Act of 2008, which would have amended the FAA to render pre-dispute binding arbitration agreements between LTC facilities and their residents unenforceable. Again, we see no contradiction between the Secretary's letter and this final rule. The requirements in this rule do not prohibit arbitration between facilities and residents. After a dispute arises, facilities and residents could enter into agreements for binding arbitration and settle a dispute in arbitration. Our rule also does not affect any arbitration agreements signed before the effective date of the rule. Moreover, it does not purport to preempt or otherwise supersede arbitration agreements made after the effective date. We have only prohibited pre-dispute binding arbitration agreements between facilities and residents as a condition of participation in Medicare and Medicaid. If a facility wishes to continue to utilize pre-dispute agreements, it is free to continue in business without Medicare or Medicaid residents.

We agree with the commenters that arbitration is clearly favored in the Federal courts and has been used in many industries, including the healthcare industry, successfully for years. As discussed in detail below, however, some of the key organizations whose members conduct nursing home arbitrations (including the American Bar Association, the American Health Lawyers Association, and the American Arbitration Association) have expressed concerns about the fairness of pre-dispute arbitration clauses in the LTC context. Thus, while the FAA contains a policy encouraging arbitration, it also recognizes that there may be situations where enforcing an arbitration agreement is improper. For example, the FAA's saving clause permits agreements to arbitrate to be invalidated by certain defenses, such as ''fraud, duress, or unconscionability,'' but not by defenses that apply only to arbitration.

We recognize that an argument could be made that Medicare and Medicaid beneficiaries can assert in Court the FAA's saving clause if they believe that a pre-dispute arbitration agreement should not be enforced. However, the comments we have received have confirmed our conclusion that predispute arbitration clauses are, by their very nature, unconscionable. As one commenter noted, it is virtually impossible for a resident or their surrogate decision-maker to give fully informed or voluntary consent to such arbitration provisions. That same commenter also noted that refusing to agree to the arbitration clause, in most cases, means that care will be denied. Furthermore, Medicare and Medicaid beneficiaries are aged or disabled and ill. Many beneficiaries lack the resources to litigate a malpractice claim, much less an initial claim seeking to invalidate an arbitration clause. Rather than requiring Medicare and Medicaid beneficiaries to incur the additional fees, expense, and delay that would be the direct cost of opposing a motion to enforce arbitration, we have concluded that this is precisely the type of situation envisioned by the Congressional grant of authority contained in sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act authorizing the Secretary to establish ''such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.''

There is a significant differential in bargaining power between LTC facility residents and LTC facilities. LTC agreements are often made when the would-be resident is physically and possibly mentally impaired, and is encountering such a facility for the first time. In many cases, geographic and financial restrictions severely limit the choices available to a LTC resident and his/her family. LTC facilities are also, in many cases, the resident's residence. These facilities not only provide skilled nursing care, but also everything else a resident needs. Many of these residents may reside there for a prolonged period of time, some for the rest of their lives. Because of the wide array of services provided and the length of time the resident and his/her family may have interactions with the LTC facility, disputes over medical treatment, personal safety, treatment of residents, and quality of services provided are likely to occur. Given the unique circumstances of LTC facilities, we have concluded that it is unconscionable for LTC facilities to demand, as a condition of admission, that residents or their representatives sign a pre-dispute agreement for binding arbitration that covers any type of disputes between the parties for the duration of the resident's entire stay, which could be for many years.

*Comment:* Some commenters stated that the proposed requirements concerning arbitration agreements violate the Non-Delegation and the Separation of Powers Doctrines (*See* Black's Law Dictionary, 7th ed., West

Group, MN (1999)). The Delegation Doctrine states that an agency may only act within the authority granted to it by Congress in the enacting legislation. The Separations of Powers Doctrine states that governmental authority is divided between the three branches of government—the legislative, executive, and judicial—each has its own duties and the other branches should not encroach on its duties. According to these commenters, CMS, is quasi-executive and quasi-legislative. It is not part of the judicial branch and has no authority to act in a quasi-judicial function. They argue that the attempt to regulate arbitration amounts to interference in private contracts, which is contrary to legal policy and tradition favoring contract formation.

*Response:* As discussed above, the Secretary has statutory authority to promulgate regulations for the residents' health, safety, and well-being and administer the programs under the Act. In addition, the Secretary has the authority to create specified rights for LTC facility residents, including, but not limited to, free choice, confidentiality, privacy, and grievances. Sections 1819(c)(1)(A)(xi) and 1919(c)(1)(A)(xi) of the Act also grant the Secretary authority to establish any other rights for residents. Thus, the Secretary, in this final rule, is acting well within her statutory authority, particularly given the concerns raised by commenters over the unfairness of pre-dispute arbitration and the harm these agreements cause LTC facility residents. In addition, these requirements do not decide the validity of existing arbitration agreements, but establish protections for LTC facility residents prospectively by prohibiting pre-dispute binding arbitration agreements and establishing requirements for post-dispute agreements entered into after the provision's effective date. Insofar as the commenters are going beyond this to question the Secretary's right to issue legislative rules in general, we believe the Secretary's authority under the Social Security Act, authorizing her to promulgate legislative rules under the Administrative Procedure Act (5 U.S.C. 553) that protect the well-being of Medicare and Medicaid beneficiaries, is a matter of settled law.

Residents' Health, Safety, and Well-Being

*Comment:* Some commenters acknowledged that the Secretary had authority to promulgate regulations for the health and safety of LTC facility residents; however, they indicated that our concerns about these agreements being detrimental to the residents' health and safety were theoretical and the proposals were not ''necessary.'' They also indicated that they were not aware of any incidents in which residents or their families were precluded from expressing quality-of-care concerns with governmental officials. In contrast, other commenters stated that they believed that some facilities use pre-dispute binding arbitration agreements to avoid responsibility for providing poor or substandard care to their residents. Some commenters believed that residents who did not sign pre-dispute binding arbitration agreements received better care than the residents who did sign these agreements. Many commenters expressed their belief that the proposed requirements did not go far enough to protect residents' rights. Most of these commenters wanted to ban arbitration agreements, especially pre-dispute arbitration agreements. However, some of the commenters said that post-dispute binding arbitration agreements should be allowed.

*Response:* In addition to reviewing the comments received, we conducted a literature review and also reviewed court opinions involving arbitration in LTC facilities. Many the articles we reviewed provided evidence that pre-dispute arbitration agreements were detrimental to the health and safety of LTC facility residents (*See, e.g.,* Tripp, Lisa, ''A Senior Moment: The Executive Branch Solution to the Problem of Binding Arbitration Agreements in LTC facilities Admission Contracts'', *Campbell Law Review Sym. 2009,* 31 Campbell L.Rev. 157 (2009); Tripp, Lisa, ''Arbitration Agreements Used by LTC facilities: An Empirical Study and Critique of AT&T Mobility v. Concepcion'', 35 *Am. J. Trial Advoc. 87* (2011); and Bagby, K. and Souza, S., ''Ending Unfair Arbitration: Fighting Against the Enforcement of Arbitration Agreements in Long-Term Care Contracts'', 29 *J. Contemp. Health L. & Pol'y (2013)*). These articles discuss, among other things, the unequal bargaining power between the resident and the LTC facilities; inadequate explanations of the arbitration agreement; the inappropriateness of presenting the agreement upon admission, an extremely stressful time for the residents and their families; negative incentives on staffing and care as a result of not having the threat of a substantial jury verdict for sub-standard care; and the unfairness of the arbitration process for the resident. Bagby and Souza note that ''oftentimes, only after a nursing facility's negligence has caused a resident severe injury or death, does the resident or family member discover that, upon admission to the nursing facility or during their stay, the resident became bound to settle disputes in arbitration, ostensibly giving up the resident's constitutional right to a jury trial.'' (29 J. Contemp. Health L. & Pol'y 183). Tripp notes that ''residents of nursing homes are frail and elderly people who are completely dependent on the facility and its employees for their safety and health. Thus, many residents and their families would not oppose the arbitration provision because they are fearful of antagonizing the facility'' (31 Campbell L.Rev. 157, p. 5). Tripp further notes that, ''with so many operators selecting pre-dispute binding arbitration, this may have the effect of forcing some vulnerable elders suffering serious injury or even death to adjudicate their claims outside of the public court system with all of its safeguards, and into private arbitration without those protections'' (35 AM. J. Trial Advoc. 89).

Additionally, a number of commenters stated that arbitration clauses have a detrimental effect on patient safety. One commenter, a healthcare provider who had previously treated LTC facility residents, stated that they had personally witnessed resident neglect and attributed it to facilities believing that they were immune to any legal consequences for their mistreatment because of the likelihood that they would prevail in binding arbitration. Another commenter, a large association of lawyers, asserted that permitting pre-dispute arbitration clauses creates an unnecessary shield that protects facilities. Other commenters stated that binding arbitration clauses generally cover all claims, including claims involving serious bodily harm and death, and allow facilities to escape accountability for neglect and abuse. We believe we have ample basis between the published research and the statements of commenters to support the connection between the use of pre-dispute arbitration clauses and the health and safety of LTC facility residents.

*Comment:* Some commenters stated that proposed § 483.70(n)(4), regarding communication with outside parties, was unnecessary because proposed § 483.11(i) contained similar provisions. Proposed section 483.70(n)(4) would require that the binding arbitration agreement could not contain any language that prohibited or discouraged the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other

federal and state health department employees; and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k).

*Response:* Although the two requirements are similar, they are not identical. Proposed § 483.11(i), which is being moved but otherwise finalized as proposed, states that facilities must not prohibit or in any way discourage a resident from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal and state health department employees, including representatives of the Office of the State Long-Term Care Ombudsman and the protection and advocacy system, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action. However, § 483.70(n)(4) specifically addresses the arbitration agreement and applies both to the resident and anyone else who would like to, or chooses to, communicate with outside authorities. We wished to ensure that pre-dispute arbitration agreements could not be used to in any way prohibit or discourage anyone from contacting or communicating with outside authorities, while § 483.10(k) simply addresses the resident's right to contact outside entities. We believe both requirements are necessary to protect residents' rights and have finalized both of these requirements in this rule.

Arbitration as an Appropriate Forum

*Comment:* Some commenters believed that the proposed rule suggested that the arbitration proposals were being proposed due to recent changes in the business practices of LTC facilities, especially an increased prevalence of binding arbitration agreements in these facilities. These commenters stated that LTC facilities have been using these agreements for many years. These commenters also noted that residents can still obtain judicial review of an arbitration decision if the agreement was entered into as a result of corruption, fraud, or undue means or that an arbitrator was guilty of misconduct or exceeded his or her powers. They also pointed out that these agreements only establish the forum in which legal claims will be heard and not that residents are denied an opportunity to bring them. However, other commenters pointed out that the differences between arbitration and litigation did result in disadvantages to residents in addition to the lack of judicial review, such as, lack of choice of arbitrators, the venue for the arbitration, and limitations on discovery and damages, such as punitive damages, which might have been available if the dispute were settled in a court. Another commenter, a national association whose members included several groups dedicated to the protection of senior citizens and consumer rights, argued that these pre-dispute binding arbitration agreements and the associated disadvantages they have for residents actually deter many residents from pursuing claims and result in claim suppression.

*Response:* Although arbitration has been an alternative dispute resolution strategy that has been in use for many years, based upon the comments we have received, as well as our literature review, it appears to us that the use of arbitration agreements has increased in LTC facilities in recent years (Tripp, Lisa. ''A Senior Moment: The Executive Branch Solution to the Problem of Binding Arbitration Agreements in LTC facilities Admission Contracts.'' *Campbell Law Review Sym. 2009* 31 Campbell L. Rev. 157 (2009); and Schleppenback, John R., ''Something Old, Something New: Recent Developments in the Enforceability of Agreements to Arbitrate Disputes Between LTC facilities and Their Residents'', 22 Elder L.J. 141 (2014)). A number of commenters to this rulemaking also stated that there has been a marked increase in the use of binding arbitration agreements by LTC facilities in recent years. For example, one commenter, a large organization of attorneys, referenced a *Wall Street Journal* article that noted that LTC facilities became some of the biggest converts to binding arbitration after sustaining some very large jury awards in the 1990s (Nathan Koppel, ''LTC facilities, in Bid to Cut Costs, Prod Patients to Forgo Lawsuits'' *Wall Street Journal,* April 11, 2008, available at *http://www.wsj.com/articles/SB120786025242805879*, accessed August 3, 2016). The *Wall Street Journal* article also stated that attorneys that litigate on both sides of LTC facility-resident disputes agreed that arbitration in LTC facilities was quickly becoming the rule rather than the exception in these cases.

We disagree with the commenters who suggest that arbitration is merely a change of the forum and therefore, inconsequential. Arbitration changes the manner in which a dispute will be resolved by, among other things, waiving the right to a jury trial, and providing only limited grounds to appeal the arbitrator's decision. Some commenters noted that arbitration can be very expensive for the resident, with some agreements requiring the resident to bear some of the costs of the arbitration, and the limited discovery generally allowed puts the resident at a distinct disadvantage. However, due to contingency agreements with attorneys and the public funding of the court system, residents have a possibility of litigating a dispute with the LTC facility for little or no money. As noted, by entering into an arbitration agreement, both parties are waiving their right to a jury trial. There is no public forum and the arbitrator's decision will not usually be publically available, whereas a court decision would be a matter of public record. We believe that a public knowledge about a dispute and a public record of a decision are vitally important for checking the worst abuses of non-compliant LTC facilities.

We also disagree with the implication that judicial review of an arbitrator's decision is adequate protection for beneficiaries. A resident cannot usually challenge an arbitrator's decision even if it is based on a mistake in the applicable law for the issue in dispute. In addition, even when there are grounds under the applicable state law to overturn the arbitrator's decision, this requires additional judicial proceedings, which adds additional time and expense to the litigation.

We are also concerned about the possibility of claim suppression. If a resident or their representative does not believe that arbitration is a fair process, they may not pursue a claim despite its merit; the secretive nature of the process and decision only adds to the public perception that the forum may be biased against the resident. However, we believe that the requirements being finalized in this rule should mitigate some of commenters' concerns about claim suppression.

*Comment:* One commenter pointed out that other Medicare and Medicaid healthcare providers use arbitration agreements. This commenter also stated that there was no factual or legal justification for imposing requirements for arbitration agreements on LTC facilities and not on these other providers.

*Response:* We believe that the concerns about pre-dispute binding arbitration are applicable to any resident that signs one as a condition of receiving services, regardless of provider or supplier type. However, we have decided to make LTC facilities our first priority because many of the residents spend an extended period of time in these facilities, and as noted, these facilities often serve as the resident's residence. A number of commenters agreed with our conclusions. Whether arbitration

agreements should be prohibited for other providers and supplier types is beyond the scope of this rule. However, we will retain this comment for review in case there is future rulemaking in this area.

*Comment:* One commenter made a Freedom of Information Act (FOIA) request asking for the comments that raised our concerns about arbitration agreements in LTC facilities. They noted that CMS' response was that there was only one document and that was a three-year old letter that had been submitted by a national organization for trial attorneys. The commenter stated that the letter contained an inaccurate portrayal of the use of arbitration agreements in LTC facilities.

*Response:* We understand that the commenter may have different views from those expressed in the letter that raised the issue of arbitration agreements in LTC facilities. However, our proposed requirements for arbitration agreements were not based solely upon that letter. We performed a literature search and reviewed judicial decisions that involved arbitration agreements in LTC facilities. We also received input from healthcare providers with experience working in or surveying LTC facilities. Thus, our proposed requirements were based upon multiple sources of information, not just the letter described by the commenter. Moreover, as noted, we have received nearly a thousand comments on our proposal and reviewed substantial amounts of information supporting many different points of view.

*Comment:* Many commenters argued that arbitration was beneficial for residents and their families as well as facilities. Disputes could be resolved more quickly and with less animosity and expense than litigation. Some commenters also argued that prohibiting these agreements would only benefit lawyers, result in protracted litigation, increase costs to the facilities, and increase the burden on an already overwhelmed court system. This would also result in resources for resident care being diverted for litigation. Other commenters argued that prohibiting arbitration could be detrimental to residents. If a dispute was not worth a sufficient amount of money, the resident or their representative might not be able to obtain a lawyer, which could result in the resident not being able to address the dispute with the facility. Some commenters discussed how arbitration agreements may include a prohibition against the individual pursing a class action. A class action arbitration or lawsuit may be the only opportunity an individual may realistically have to pursue their claim. If they could not join a class action, they could be effectively denied any avenue of redress for the dispute. Other commenters were concerned that we had not sufficiently assessed not only the costs of these proposals but also the real life, practical implications of these proposals within the long-term care community and the daily practice within this community. Other commenters disagreed with these arguments. Some argued that there could still be protracted litigation even within the context of pre-dispute arbitration agreements; and noted that arbitration could be very expensive for the resident.

*Response:* There are both advantages and disadvantages associated with both pre-dispute arbitration agreements and arbitration itself. As finalized in this rule, residents and their representatives have the option of signing an agreement for binding arbitration with the facility after a dispute arises. In addition, residents can also use the facility's grievance process, as set forth at § 483.10(j). However, arbitration agreements, particularly pre-dispute agreements provided to residents on a ''take-it-or-leave-it'' basis, present opportunities for facilities to include terms that undercut commenters' contention that arbitration is a neutral process that works to the benefit of both parties. A report of the American Bar Association noted, ''[c]lauses frequently specify that the provider can select the arbitration service and the location of the arbitration. Some include caps on damages, even for tragic and possibly preventable deaths. Moreover, some clauses or arbitration procedures restrict the discovery process–limiting the number of investigative interviews or the exchange of documents. 'This could prevent an aggrieved consumer's lawyer from deposing all possible employees who might have witnessed an incident at a nursing home and gaining access to relevant records,' whereas the facility has the records and personnel at its disposal (Sturgeon, J., ''Nursing Homes Use Arbitration As a Shield,'' The Roanoke Times, Aug. 24, 2006). The resident may have to pay substantial fees for the arbitration.'' (American Bar Association, Commission on Law and Aging, Policy on LTC facility Arbitration Agreements 111B, page 4, February 16, 2009, at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, accessed on September 15, 2016). By contrast, this final rule will allow residents to avail themselves of the benefits of arbitration once a dispute has arisen and the resident and/or his/her representatives can determine whether it may be an advantageous forum for them.

Concerning class actions, we share the commenters' concerns about residents possibly not being able to pursue their claims. However, since we did not propose to address matters relating to class actions in our proposed rule, we are unable to address them in this final rule. We also note that to date, litigation against LTC facilities has involved primarily malpractice claims, which tend to be individual-specific. Because class actions against LTC facilities remain rare, we believe that it is not yet clear that there is a problem that would require additional regulation. We will retain these comments and concerns about protection of class-action litigation and consider for future rulemaking.

*Comment:* Some commenters pointed out the lawyers in their areas are already aggressively advertising for LTC facility litigation. Another commenter noted that some residents and/or their families are already dispositionally angry before they even arrive at the facility and may find fault with the facility despite the provision of quality care. Other commenters noted that depending upon the jurisdiction and the aggressiveness of the attorney, jury verdicts could be excessive; however, an arbitrator who is an impartial and experienced profession should be able to look at the dispute and make a rational decision. Some commenters noted that an important factor in determining liability insurance premiums was whether a facility used pre-dispute arbitration agreements and that prohibiting these agreements could result in a substantial increase in LTC facilities' insurance premiums. Other commenters expressed their concern that prohibiting pre-dispute binding arbitration agreements could result in a substantial increase in the cost of business without any commensurate quality in care. It would increase the amount of frivolous lawsuits because arbitration was effective in deterring those claims due to the lower damages generally awarded by an arbitrator. In addition, attorney fees are generally much lower in arbitration. This could result in costs becoming prohibitive and force some LTC facilities to close.

*Response:* We agree with the commenters that arbitration offers advantages to both parties. We also realize that settling disputes in court might take longer and result in more costs to facilities. However, a resident or their representative's choice to engage in arbitration to settle a dispute should be informed and voluntary. This final rule does not prohibit binding

arbitration, only the use of pre-dispute binding arbitration agreements. Once a dispute arises between a resident and the facility, the parties can enter into an agreement for binding arbitration subject to the requirements in this rule. No resident, resident representative, or facility is being denied the opportunity to engage in arbitration to settle a dispute, and this rule has no effect on the enforceability of arbitration agreements in general.

*Comment:* Some commenters have argued that CMS should not be interfering with a matter that is a private contract between the parties. They noted that some states have already passed legislation concerning arbitration. This legislation may directly concern arbitration, arbitration in LTC facilities, or tort reform. Commenters argued that these issues should be left to the states.

*Response:* We disagree with the commenter's contention that LTC services are a private contractual matter between two independent parties. Unlike traditional arms-length commercial contracts that are, for the most part, business arrangements between two private individuals, the Medicare and Medicaid programs have a significant interest in both the services being delivered as well as the well-being of the beneficiary. In many cases, Medicare and Medicaid are the sole payors for the services. This is why, for example, Congress has required that the Secretary create a wide assortment of rules and regulations relating to quality of care and the delivery of services in the LTC context.

Furthermore, because the Congress has expressed an clear interest in protecting the rights of Medicare and Medicaid beneficiaries in LTC facilities, it has granted the Secretary statutory authority to establish rights for residents (sections 1819(c)(1)(A)(xi) and 1919(c)(1)(A)(xi) of the Act) and to protect the health, safety and well-being of residents in LTC facilities (sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act). Because of overriding Congressional mandate that the Secretary protect the health and welfare of LTC residents, we believe that a federal uniform response is both necessary and appropriate.

When, How Arbitration Agreement Is Reached

Commenters noted that residents or their representatives are typically asked to sign arbitration agreements during the admission process, and that the pre-dispute arbitration agreement is one clause in a contract comprising many pages. Since no dispute had yet occurred, the resident or their representative could not fully understand the rights they were waiving or how any future dispute would be handled. They might also not understand or be thinking about the possible problems that could occur during their stay, including substandard care that could result in serious injury or even death. It is also highly unlikely they would have consulted a lawyer about the agreement. Commenters noted that admission to a LTC facility is usually an extremely stressful time for the resident and his or her family. The resident may have a serious injury, surgery, or illness, is being removed from their usual living arrangements, and is being admitted to a facility for an indeterminate period of time.

One commenter noted that one state, Georgia, has a statute that states, concerning medical malpractice claims, ''no agreement to arbitrate shall be enforceable unless the agreement was made subsequent to the alleged malpractice and after a dispute or controversy has occurred and unless the claimant is represented by an attorney at law at the time the agreement is entered into'' (Ga. Code Ann., § 9–9–62).

Some commenters pointed out that in the state of Mississippi this proposal could result in neither the resident nor a healthcare surrogate being able to sign an agreement to arbitrate disputes with the facility. Miss. Code Ann. § 41–41–211 allows for a healthcare surrogate to make healthcare decisions for another person if that individual's primary care physician determines that he or she lacks capacity and no agent or guardian has been appointed or the agent or guardian is not reasonably available. Commenters also cited a court case, *Mississippi Care Center of Greenville, LLC. et al.* v. *Nancy Hinyub,* 975 So.2d 211 (Miss. 2008) (*Hinyub*), a case in which the Mississippi Supreme Court held that a health care surrogate could not bind a party to arbitration unless the arbitration provision was an essential part of the consideration for the receipt of ''health care.'' The commenters noted that after *Hinyub,* Mississippi LTC facilities now require patients or their surrogates to sign pre-dispute arbitration agreements as a condition of admission and receipt of services. Some commenters noted that a facility's explaining an arbitration clause to a resident could be viewed as providing legal advice and therefore the unlicensed practice of law.

*Response:* When a resident or his or her representative signs an agreement for binding arbitration, he or she is waiving the right to go to court and have a dispute decided by a judge and jury. We believe that any waiver of this right should be voluntary and informed. Would-be residents are often presented a ''take-it-or-leave-it'' contract under circumstances where meaningful or informed consent for pre-dispute arbitration is often lacking. Thus, we believe that voluntary post-dispute arbitration agreements are the best way to balance the policy favoring arbitration with the need to protect beneficiaries from unfairly waiving their rights to a jury trial. While we support the public policy behind the Georgia statute referenced by the commenter, we acknowledge that this provision was determined to have been preempted by the Federal Arbitration Act (*see Triad Health Management of Georgia, LLC, III* v. *Johnson,* 298 Ga. App. 204, 679 SE.2nd 785 (2009) and suggests that leaving this policy to the discretion of states may not be an effective strategy. Consequently, this case, like others, illustrates the necessity of prohibiting pre-dispute arbitration agreements.[4] With respect to the decision in *Hinyub,* we note that this rule will effectively moot the holding in this case, since LTC facilities will no longer be able to assert that pre-dispute binding arbitration agreement was an element of consideration in the admissions contract. To the extent that *Hinyub* would be applicable to surrogates' power to bind the resident to a post-dispute arbitration agreement meeting our requirements, we defer to state law on this matter.

*Comment:* A few commenters were concerned about the requirement in proposed § 483.70(n)(5)(iii) that indicated that another individual could sign the agreement for binding arbitration if, among other things, that individual had no interest in the facility. Commenters pointed out that some residents might have next-of-kin or representatives that work for the facility or are otherwise associated with, or have an interest in, the facility. This proposed requirement could result in representatives that might want to sign the agreement, but would be prohibited from doing so.

*Response:* We understand that, in some circumstances, this could mean that a particular representative for a resident would not be able to sign an agreement for binding arbitration. However, we continue to believe that individuals who have a financial or employment interest in a facility have

[4] According to the complaint in *Triad,* ''as a proximate result of Triad's negligence, Johnson's father, Matthew Johnson, developed bed sores, which led to his development of sepsis and his subsequent hospitalization, illness, and death.'' 298 Ga. App. At 204.

an inherent conflict of interest and must not sign an agreement for binding arbitration for another person. We believe that the resident's family would be able to find an individual not associated with the facility for such purposes. In any case, the rare occasion when the representative of the patient also has a financial interest in the facility will not prevent us from implementing a provision that generally protects residents against conflicts of interest.

Unequal Bargaining Power

*Comment:* Commenters noted that facilities would likely have experience with arbitrations, but not residents. The facility usually decides, and sometimes names in the arbitration agreement, how the arbitrator will be chosen and where the arbitration will be held. Some commenters argued that the arbitrator has a financial incentive to be favorable to the facility. It is unlikely that the resident will need to hire an arbitrator in the future; however, facilities are likely be involved in future arbitrations. Hence, the arbitrator will want facilities to select them for future arbitrations. Other commenters said that this potential bias could be addressed by educating residents and their representatives about local arbitrators. Other commenters believed that no regulation could overcome the problems with arbitration in LTC facilities, such as the facility's superior bargaining power, the risk that the resident or their representative will not fully understand the agreement, that signing the agreement would inherently be coerced, unfair, or unconscionable, and the inherent conflict of interest of having the facility explain the agreement (the potential future adversary in any dispute). Some commenters noted that facility may imply that the agreements were not voluntary such that the resident or their representative may not believe they have a choice on whether to sign it. As previously noted, arbitration agreements are often just one paragraph of an admissions package that generally that is quite extensive. The arbitration agreement may be a clause within another document or otherwise does not stand out. Thus, the resident or their representative may not even realize they are signing an arbitration agreement. The agreement may not be sufficiently explained so that the resident or their representative fully understands the rights they are waiving or the arbitration process. The facility employee admitting the resident may not even fully understand the agreement.

*Response:* We agree with those commenters that asserted that there is unequal bargaining power between the residents and their representatives and the facilities. The resident's immediate need for nursing care and lack of experience with arbitration means that residents are unlikely to ask for time to seek legal advice concerning the agreement for binding arbitration. We believe that this unequal bargaining power cannot be alleviated with the protections we initially proposed. Thus, in this final rule, in response to a significant volume of public comment, we are prohibiting the use of pre-dispute binding arbitration agreements between residents and the facilities. After a dispute arises, residents or their representatives will have the time to seek legal advice, if they choose to, and evaluate the option to arbitrate the dispute with the facility.

Three major legal or arbitration associations have made policy statements against pre-dispute binding arbitration agreements. In 2009, the American Bar Association (ABA) issued a policy statement that opposed the use of mandatory, binding, pre-dispute arbitration agreements between a long-term care facility and a resident or a person acting for the resident. That policy statement also indicated that the ABA supported enactment of federal regulations that would, among other things, invalidate such arbitration agreements (American Bar Association, Commission on Law and Aging, Policy on LTC facility Arbitration Agreements 11B, February 16, 2009, at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, accessed on August 3, 2016). The American Health Lawyers Association's Alternative Dispute Resolution Services Rules of Procedure for Arbitration, revised in May 2012, indicated that their ADR service would administer a ''consumer health care liability claim'' only if ''all of the parties agreed in writing to arbitrate the claim after the injury has occurred'' or arbitration is order by a judge (file:///G:/DIQS/LTC%20Facilities/Regulations/Resources/AHLA%20Arbitration%20Procedures%20May%2031,%202012.pdf, citation added). (A later revision to the statement did not include this prohibition, but did include requirements to ensure, among other things, that a pre-dispute arbitration agreement was voluntary, could not be a condition for obtaining care, and included a right to revoke the agreement within 10 days after being signed.) (*https://www.healthlawyers.org/dr/SiteAssets/Lists/drsaccordion/EditForm/Rules%20Effective%20April%207.pdf*, accessed on August 3, 2016). In addition, in 2003, the American Arbitration Association issued a Healthcare Policy Statement that said ''it would not administer healthcare arbitrations between individual patients and healthcare service providers that relate to medical services, such as negligence and medical malpractice disputes, unless all parties agreed to submit the matter to arbitration after the dispute arose'' (file:///C:/Users/PI47/Downloads/HC%20Policy%20Statement.pdf, accessed August 3, 2016).

After a dispute arises and residents or their representatives have the opportunity to seek legal counsel and review their options, we believe they can make a rational and informed decision about arbitration. Thus, while the bargaining power between LTC facilities and residents will undoubtedly never be equal, we believe that the requirements finalized in this rule will provide residents with the protections they need to preserve their rights, while still preserving the option of arbitration if both parties decide to arbitrate a dispute.

Confidentiality of Arbitration Process and Decisions

*Comment:* Several commenters indicated that the arbitration process is usually confidential and secretive. Most, arbitration agreements have confidentiality clauses that prohibit both parties from discussing the dispute and what happens during the arbitration process, including the decision, with outside parties. Some of the commenters were concerned that arbitration regarding disputes involving abuse and neglect shields facilities from having their poor quality or dangerous conditions exposed to the public and prevented judges who would hear the case if it were decided in court from making findings of fact and conclusions of law that would influence future nursing facility conduct. One commenter stated that not only did arbitration and its secrecy result in substandard care for residents but also that facilities had incentives to, and did, provide better care to residents who did not sign the pre-dispute arbitration agreements. Other commenters asked how CMS would be able to survey facilities for compliance with arbitration requirements.

*Response:* We agree that the secrecy surrounding the arbitration process is a substantial concern. We are also concerned that the arbitration process, especially the secrecy it involves, could

result in some facilities evading responsibility for substandard care. We are finalizing the proposed requirement at § 483.70(n)(4) that the agreement cannot contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials. When any dispute involves any allegations that relate to our long-term care requirements, especially the health care provided by the facility or instances of abuse or neglect, we believe it is necessary for the protection of the health and safety of residents that federal, state, and local health and regulatory officials have access to the relevant information and be able to conduct an investigation as appropriate. Anything that could interfere with federal, state, or local health and regulatory officials or LTC advocates from learning of, or restricting the investigation of, instances of substandard care or other serious instances affects the health and safety of residents. When a surveyor discovers substandard care or another violation of the LTC facility requirements of participation and cites the facility with a deficiency, the surveyor would cite the deficiency on a Form CMS–2567, which is filed with both the state surveyor agency and CMS. This form is available to the public and can be accessed on the LTC Facility Compare Web site at *https://www.medicare.gov/nursinghomecompare/search.html*. Concerning CMS' ability to survey for compliance with the requirements in this final rule, we have also inserted a requirement that when the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee. This will provide surveyors and CMS the opportunity to learn how often and under what circumstances arbitration is occurring at a facility, as well as the outcomes of any arbitrations. In addition, CMS will be publishing sub-regulatory guidance for surveyors concerning the requirements. Although arbitration proceedings will not have the potential publicity of a trial, arbitrations in LTC facilities will no longer be confidential and secret. CMS will be monitoring the use of arbitration in LTC facilities through the survey process, not only through the normally scheduled surveys but also through the complaint process.

General Comments

*Comment:* Some commenters argued that it was inconsistent for CMS to describe the problems associated with the use of binding arbitration agreements but nonetheless authorize their use in LTC facilities. Some commenters also believed the proposed arbitration requirements were inconsistent with other proposed requirements in the proposed rule. Specifically, commenters noted that § 483.15(a)(2)(iii), which prohibits facilities from requesting or requiring residents ''to waive potential facility liability for losses of personal property'' could be deemed to be at cross-purposes with binding arbitration. In addition, the commenters noted that proposed § 483.10 confirms the residents' rights to exercise rights as citizens or residents of the United States.

*Response:* We agree with the commenters that indiscriminate use of arbitration agreements in LTC facility contracts can create a risk of improperly insulating facilities from liability or loss of property, and they, likewise, create a risk of residents unwittingly waiving their rights. We also recognize, however, there are legal and policy reasons supporting post-dispute arbitration. We believe a balance be struck between protecting residents' rights and conducting arbitration when appropriate. We do not believe that the requirements identified by the commenters are inconsistent with the arbitration requirements. In cases where residents or their representatives sign arbitration agreements, they still have the right to pursue claims for losses of personal property. However, the dispute would be handled through arbitration, rather than in court. Section 483.10, which confirms the residents' rights to exercise their rights as citizens or residents of the United States, is also consistent with the arbitration requirements. The arbitration requirements in no way denigrate the residents' rights as citizens or residents of the United States. We will continue to monitor arbitration agreements to ensure that residents' rights are, in fact, protected.

*Comment:* Some commenters argued that our proposed requirements concerning arbitration were inconsistent with the positions taken by the legal community and other federal agencies. One commenter said that one legal scholar has called on the Department of Health and Human Services to declare arbitration agreements by LTC facilities unconscionable and to ''prohibit federal funding of LTC facilities that use them'' (citing Lisa Tripp's ''A Senior Moment''). They pointed to the 2009 Midyear Meeting of the American Bar Association, in which the House of Delegates adopted Resolution 111B, which was introduced by the ABA Commission on Law and Aging and co-sponsored by the Section of Dispute Resolution. The Resolution, which became official policy of the ABA, ''supports the enactment of federal, state, and territorial legislation and regulations that oppose the use of mandatory, binding, pre-dispute arbitration agreements between a long-term care facility and a resident of such facility or person acting on behalf of such resident'' accessed at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, on September 19, 2016). In addition, the commenters discussed an initiative of the Consumer Financial Protection Bureau (CFPB), which initiated rulemaking on arbitration agreements, and, in March 2015, issued a Congressionally-mandated report, which found that arbitration agreements limit consumer relief in disputes. Some commenters pointed to examples in which arbitration was specifically prohibited for specific types of claims. For example, commenters cited a 2009 amendment to the Department of Defense Appropriations Act, which imposed a restriction on the ability of certain DOD contractors and subcontractors to enter into or enforce mandatory arbitration agreements with their employees in cases of discrimination or sexual assault (Section 8116, Pub. L. 111–118 December 19, 2009). According to the commenters, since its passage, the amendment has been successfully implemented by the Department of Defense, the government's largest federal contracting agency. (*See* 48 CFR 252.222–7006 Restrictions on the Use of Mandatory Arbitration Agreements). Another example was from 2014, when President Obama issued an Executive Order (E.O.) aimed at ensuring safe workplaces and fair pay for American workers. Among its protections, the E.O. mandates that companies with federal contracts of $1 million or more cannot require their employees to enter into pre-dispute arbitration agreements for any disputes arising out of Title VII of the Civil Rights Act or from torts related to sexual assault or harassment. E.O. 13673, Section 6, 79 FR 45309 (July 31, 2014).

*Response:* While we recognize that some members of the legal community and other federal agencies may have taken different approaches to this issue,

each situation is different, and the legal and policy issues are unique to each particular agency and program. While some commenters have requested that we ban all arbitration, we have determined, at this point, to implement a policy that strikes a balance between banning arbitration in all situations and allowing unfettered use of arbitration clauses with no restrictions on their terms or usage. We are aware of attempts to regulate arbitration taken by these agencies, and we are also aware of the positions taken by some groups against arbitration and pre-dispute arbitration agreements. The regulations finalized in this rule prohibit pre-dispute binding arbitration agreement and are intended to protect residents from many of the problems identified by critics of arbitration. We also note that many groups do not call for an outright ban on arbitration in LTC facility contracts but, rather, encouraged us to add limits on arbitration agreements. For example, as noted above, the American Bar Association's comments stated that, while arbitration can be a viable means of resolving LTC facility resident-facility disputes, it is only appropriate after the dispute has arisen and each party knows the contours and seriousness of the claims. See the ABA's Position Statement 111B at *http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf*, accessed on August 1, 2016. The other requirements finalized in this rule also work to protect the rights of the residents and prohibit many of the unfair practices that have been identified by the commenters. We will continue to monitor this issue in order to ensure that the requirements implemented by these regulations adequately protect resident' rights and, if we determine that they do not, we may revisit the issue of banning arbitration or adding additional protections for residents.

*Comment:* Some commenters pointed out that the proposed requirements could adversely affect residents' legal positions in litigation regarding the enforceability of arbitration agreements in general. Facilities could use their compliance with the requirements to argue that the resident or their representative fully understood the agreement and voluntarily choose to sign the agreement. The requirements could also be interpreted as in some way condoning or authorizing binding arbitration agreements in facilities. It could make it more difficult for residents to challenge the arbitration.

*Response:* These regulations are not meant to limit or provide standards for courts to use in determining if an arbitration agreement should be enforced in, for example, a motion to compel arbitration. These requirements are minimum requirements for ensuring fairness for LTC facility residents. By addressing these agreements in this rule, we are not condoning them, but simply acknowledging that they are used by LTC facilities. The requirements will provide residents with the minimum protections they need and we intend that these rules will allow residents to make an informed and voluntary choice. With respect to the litigation posture of parties that might have wished to challenge a facility's motion to compel arbitration under our proposed rule, we believe that this concern has been mooted by our decision to prohibit the use of pre-dispute arbitration agreements entirely. Insofar as a party would wish to challenge a post-dispute arbitration agreement, we believe the existing jurisprudence interpreting the FAA would be applicable under such circumstances.

*Comment:* Commenters disagreed with our contention that the proposed requirements ensured that residents and their representatives would be offered a ''voluntary'' choice concerning binding arbitration. The commenters stated that both arbitration and mediation are alternatives to litigation and options for alternative dispute resolution (ADR). If arbitration is the only ADR option offered to residents and their representatives, it is a forced substitute rather than an alternative that is voluntarily and knowingly entered into by the parties.

*Response:* We agree that ADR consists of multiple options in addition to arbitration. However, we are only addressing arbitration in this rule. Rules regarding mediation are not within the scope of this rulemaking.

*Comment:* Some commenters cited *Hinyub* for the proposition that it is permissible for LTC facilities to require residents or their surrogates to sign arbitration agreements as a condition of admission and receipt of services. Commenters claim that, if these agreements were not part of the admissions contracts, there may be no one to sign them, which would deny the resident the option to choose arbitration, which would be a violation of the FAA.

*Response:* Although the commenters cite *Hinyub* as support for the legality of mandatory arbitration agreements under Mississippi law, to the contrary, this case illustrates the Secretary's concerns about the fundamental fairness of making arbitration agreements a mandatory condition for admission to a LTC facility. The dispute in *Hinyub* included, among other things, claims against a LTC facility and others for malpractice, negligence, fraud, breach of fiduciary duty, and wrongful death. The response of Mississippi's LTC facilities to require arbitration agreements as an organic part of the agreement, illustrates our underlying concerns about the incentives such agreements provide to deliver substandard care. Under our final rule, Mississippi LTC facilities that require new residents to agree to pre-dispute arbitration as a condition of admission will not be deemed to be in compliance with our requirements and will be subject to termination.

*Comment:* One commenter recommended that any regulations concerning arbitration be delayed. The commenter believed that there was insufficient evidence of what problems, if any, existed with arbitration in LTC facilities. The commenter noted that Congress has considered various pieces of legislation concerning this issue and not passed any of them; this demonstrates that the issues are not well understood or no optimal solution has yet to be determined. They recommended that CMS not finalize any requirements concerning arbitration until Congress has more fully explored this issue and determined what, if any, actions are appropriate.

*Response:* We disagree with the commenter. In response to the proposed rule, we received almost 1,000 comments about our proposed arbitration requirements. In addition, we believe that our review of case law and the literature, including law review articles, amply demonstrates the importance of the issues surrounding arbitration in LTC facilities. Because we believe that further monitoring of the effects of this rule are necessary, we are requiring that LTC facilities retain a copy of the signed agreement for post-dispute binding arbitration and the arbitrator's final decision for 5 years to that it can be inspected by CMS or its designee upon request. This will enable us to gather information on arbitrations that have taken place in LTC facilities to determine if the requirements finalized in this rule are providing the protections resident need.

We also note that although no specific legislation has passed, Congress has not been silent on this issue. Several hearings have been held on this issue, and there is a voluminous legislative record evidencing the need for action on this matter. We also note that there is broad support for protecting residents of LTC facilities. For instance, in a Joint Hearing of the Senate Judiciary Subcommittee on Antitrust, Competition, and Consumer Rights and

the Special Committee on Aging, Sen. Gordon Smith (R–OR) stated, ''The Federal Arbitration Act was enacted in 1925 as a means to ensure a framework for the enforcement and to determine the validity of arbitration agreements. . . . Today, however, we are talking about a particularly vulnerable population. And when we talk about such populations, we must ensure an additional level of scrutiny to guarantee that their rights are protected, as they may not be in a position to protect themselves.'' (Senate Special Committee on Aging, ''S. 2838, the Fairness in Nursing Home Arbitration Act'', 110th Congress, June 18, 2008, accessed at *http://www.aging.senate.gov/hearings/s2838-the-fairness-in-nursing-home-arbitration-act* September 15, 2016).

*Comment:* One commenter, an association of elected officials, believed that it was important that consumers be informed of the potential impact of binding arbitration agreements on LTC facility residents. They suggested that HHS develop a public information campaign concerning these agreements and tools to assist consumers to understand the implications of these agreements and how they would affect their rights as consumers.

*Response:* We understand and appreciate the commenter's concern that consumers, especially facility residents and their representatives, be informed about binding arbitration agreements, their implications, and how they affect consumer rights. However, such a campaign is beyond the scope of this rule.

Final Decision

We are adding a requirement to proposed § 483.70(n) to provide that Medicare and Medicaid-participating LTC facilities can no longer enter into pre-dispute binding arbitration agreements with their residents or their representatives. We are retaining the proposed requirements and specifying at paragraph (n) that they will apply if a facility chooses to ask a resident to sign a post-dispute arbitration agreement. We have also revised proposed § 483.70(n)(3) to provide that an LTC facility cannot require the resident to sign a post-dispute arbitration agreement as a condition of the resident's continuing to stay at the facility. Finally, to address commenters' concerns regarding the confidentiality of the arbitration process and its negative effects on patient health and safety, we have added a new paragraph (n)(2)(vi) to provide that when the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee. Although the arbitration proceedings themselves could still be confidential, this requirement will enable us to evaluate whether agreements for binding arbitration and the impact of arbitration in the long-term care industry is having desired effects for both the residents and the facilities.

We emphasize that this final rule does not prohibit all arbitration agreements between residents and the LTC facilities in which they reside, and does not have any effect on existing arbitration agreements or render them unenforceable. It has no effect on LTC facilities that do not participate in the Medicare or Medicaid programs. It does not create any new standard for determining whether an arbitration agreement is unconscionable. It only affects Medicare and Medicaid LTC facilities insofar as they wish to ask their residents if they wish to voluntarily enter into arbitration. After a dispute arises, the resident and the LTC facility may voluntarily enter into a binding arbitration agreement if both parties agree and comply with the relevant requirements set forth in § 483.70(n) of this final rule.

Social Worker (§ 483.70(p))

We proposed to relocate the requirement for and qualifications of a social worker from the current § 483.15(g)(3) to § 483.70(p). In addition, there is a list of human services fields from which a bachelor's degree could provide the minimum educational requirement for a social worker. We proposed to add ''gerontology'' to that list of human services fields.

*Comment:* Commenters were very supportive of and expressed their belief in the importance of social workers in LTC facilities. Some commenters were very concerned about the qualifications for social workers in LTC facilities, especially the education that is required. Some commenters disagreed with allowing individuals with bachelor's degree in a human services field other than social work, which is a human services field, to work as social workers in LTC facilities and believed that the minimum requirement for a social worker in a LTC facility should be a bachelor's in social work. Other commenters wanted a bachelor's or master's degree in social work as a minimum education requirement and that the degree be from a program accredited by the Council On Social Work Education (CSWE). Other commenters' objected to using the title of ''social worker'' for anyone who does not have a bachelor's (BSW), master's (MSW) or doctorate in social work. Commenters pointed out that individuals with a bachelor's in a human services field do not have the same education as social workers. Social workers, at both the bachelor's and master's degree levels, receive training in interviewing and psychosocial assessment, care planning, and intervention. Individuals with other human services degrees may not be adequately prepared to identify and address psychosocial issues. In addition, some commenters specifically disagreed with the proposed addition of ''gerontology'' to the examples of human services degrees that could qualify someone as a social worker. Commenters noted that CSWE-accredited programs provided competency-based education that integrates and applies knowledge, skills, and values and are based on nine competencies and that these competencies are congruent with the competency based emphasis in the proposed rule. They also noted that these programs provide for field placements that are under the supervision of professional social workers. They noted their concerns about CMS recognizing degrees in psychology, rehabilitation counseling, sociology, special education, and other ''human services'' as sufficient preparation for LTC facility social work. They were also concerned with the de-professionalization of LTC facility social work and cited to a study that indicated that 20 percent of social services director did not have even a bachelor's degree and only 50 percent held a bachelor's in social work. Commenters also noted that the educational preparation for BSWs and MSWs prepares individuals to fulfill the requirements in the proposed rule, such as, promoting quality of care and quality of life for all residents (§ 483.25), advocating for residents' rights and helping facilities uphold those rights (§ 483.10), preventing and addressing abuse, neglect, and exploitation of older adults and other LTC facility residents (§ 483.12), and facilitating transitions of care and discharge planning (§ 483.15 and § 483.20). Commenters also pointed to other areas that professional social workers were well-equipped to perform in the facility, such as, strengthening communication among residents, families, and facility staff; facilitating financial and medical decision making, including advance care planning; and providing individual, family, and group education and counseling related to

illness, disability, treatment, interpersonal relationships, grief, loss, dying, and death. Commenters also agreed with the one year of supervised social work experience in a health care setting working directly with individuals.

*Response:* We understand the commenters' concern for the qualifications for social workers in LTC facilities. However, pursuant to sections 1819(b)(7) and 1919(b)(7) of the Act, for skilled nursing facilities and nursing facilities, respectively, with 120 or more beds, the facility must have a full-time social worker with at least a bachelor's degree in social work or similar professional qualifications employed to provide or assure the provision of social services. This is a statutory requirement. Thus, we cannot remove the requirement that an individual with similar professional qualifications can provide or assure the provision of social services. Individuals with a bachelor's degree in a human services field, including but not limited to, sociology, special education, rehabilitation counseling, and psychology can be qualified social workers under the current requirements for long-term care facilities. We believe that LTC facilities need the flexibility to hire individuals who are qualified and have the competencies and skill sets to perform the jobs they are hired to do. According to this final rule, LTC facilities must conduct a facility assessment, which assesses, among other factors, the care required by the resident population and the staff competencies necessary to care for that resident population (§ 483.70(e)), and, must have sufficient direct care/direct assess staff with the appropriate competencies and skills to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident (§ 483.40(a)). If the LTC facility does employ an individual with a human services degree as a social worker, that individual must have the competencies and skill sets to perform the duties and responsibilities the LTC facility determines are needed for the social worker position in their facility. Thus, we are finalizing the social worker qualifications at § 483.70(p) as proposed, with ''gerontology'' as an example of a human services field that an individual with a bachelor's degree could qualify as a social worker in a LTC facility.

*Comment:* Some commenters wanted to delete the exemption for a full-time social worker in LTC facilities with 120 or fewer beds and require that all LTC facilities, regardless of size, be required to employ a full-time social worker. Other commenters recommended a ratio of one full-time equivalent (FTE) social worker for the first 50 residents and one FTE social worker for up to an addition 12 residents. Commenters noted that this is the ratio proposed by the National Nursing Home Social Work Network's Policy Committee. They believe that all LTC facility residents need the services of social workers because of their importance in ensuring residents' quality of care and quality of life and that there must be a sufficient number of social workers in each facility. Commenters also noted that the new requirements in the Mandatory Data Set (MDS) increased the social workers' workload and has already affected the quantity and quality of psychosocial services they can provide and the launch of MDS 3.0 will increase that workload. In addition, some commenters argued that the 120-bed rule was incompatible with the current and proposed requirements to provide person-centered care.

*Response:* As discussed above, the requirement for one full-time social worker for LTC facilities with more than 120 beds is statutory (sections 1819(b)(7) and 1919(b)(7) of the Act). One of the focuses of this final rule is person-centered care (see § 483.21 ''Comprehensive person-centered care planning''). Social services are essential; however, the requirements for social workers will vary depending up the needs of the resident population, as well as the staff and the facility itself. Smaller LTC facilities might not need a full-time social worker. Larger LTC facilities or facilities with residents with complex needs might require either more than one full-time social worker or more staff to assist the social worker. As discussed above, the facility assessment performed by the LTC facility should identify the social services the resident population requires (§ 483.70(e)). The LTC facility should then determine how to ensure that those social services are provided. Hence, we will be finalizing the requirement for the social worker as proposed.

*Comment:* Commenters noted that some LTC facilities might decide to hire social services staff to fulfill administrative function, such as completing financial paperwork, or meeting some of the residents' needs, such as arranging appointments or locating lost items. The commenters wanted these individuals to be called ''social services assistants'' and not be counted as ''qualified social workers,'' especially for any minimum staffing ratio.

*Response:* As discussed above, we are finalizing the qualifications for a ''qualified social worker'' as proposed. Hence, the facility may refer to anyone who meets those qualification as a ''qualified social worker'' regardless of the duties and responsibilities they are assigned. In addition, as discussed above, we will not be establishing any minimum staffing ratios for LTC facilities, including ratios for social workers.

*Comment:* Some commenters stated that social work practitioners with more experience providing quality psychosocial care could provide consultation to BSWs and MSWs, especially those with little experience, to ensure that residents receive high-quality psychosocial care. The commenters recommended that LTC facilities provide expert social work consultation to social work directors. This consultation should address practice, administrative, and organizational issues along with program planning and professional development. A consultant could also provide consultation to the facility administration and staff concerning program planning, policy development, and priority setting related to social work services; case consultation concerning the psychosocial needs of residents and their families; and in-service education on selected topics.

*Response:* We agree with the commenters that many LTC facilities and their residents could benefit from consultation with an expert in social work. However, we do not believe that we should require that consultation in this final rule. As discussed above, LTC facilities must perform a facility assessment and determine what resources it needs to care for its residents. LTC facilities need the flexibility to not only assess the needs of the resident population but determine how to satisfy those needs. When a LTC facility determines that it is deficient in the social services it needs to provide its residents, and perhaps the staff or facility itself, then we would encourage them to obtain consultation concerning social services. However, we will not require that consultation.

*Comment:* Some commenters acknowledged that some facilities had reported difficulties in locating an adequate number of BSWs or MSWs. These commenters offered some suggestions on how LTC facilities could recruit and retain BSWs and MSWs. These suggestions included partnering with social work degree programs, chapters in social work associations, and state associations that are concerned about the care provided by

LTC facilities to recruit social workers. Commenters also believed that LTC facilities could enhance their recruiting and retention of social workers by making their jobs more appealing and noted some of the challenges social workers encounter in LTC facilities, such as low wages, large caseloads, professional isolation, and assigned tasks being below their skill level. Commenters also recommended that CMS provide extra resources to support social worker recruitment and retention efforts for LTC facilities, especially for frontier and rural areas.

*Response:* We appreciate the commenters' suggestions. We encourage LTC facilities to consider these suggestions for recruiting and retaining social workers. However, requiring LTC facilities to follow these suggestions will not be included in this final rule. In addition, providing more resources is beyond the scope of this rule. LTC facilities are expected to comply with these requirements within the funding that is provided.

Mandatory Submission of Staffing Information Based on Payroll Data in a Uniform Format (§ 483.70(q))

Finally, we indicated that in the proposed rule entitled ''Medicare and Medicaid Programs; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016, SNF Value-Based Purchasing Program, SNF Quality Reporting Program, and Staffing Data Collection'' (CMS–1622–P) (80 FR 22044), published on April 20, 2015, at § 483.75(u), we proposed to require that facilities submit staffing information based on payroll data in a uniform format. Section 6106 of the Affordable Care Act of 2010 (Pub. L. 111–148, March 23, 2010) added a new section 1128I to the Act that requires a facility to electronically submit to the Secretary direct care staffing information, including information for agency and contract staff, based on payroll and other verifiable and auditable data in a uniform format according to specifications established by the Secretary. We proposed to re-designate § 483.75(u) (as set out in the April 20, 2015 proposed rule at 80 FR 22044) to § 483.70(q). We note that the proposed rule was finalized on August 4, 2015 (see 80 FR 46389) and we are finalizing the re-designation of the requirement in the final rule at § 483.75(u) to § 483.70(q) in this final rule.

As a result of comments received, we are finalizing this section as proposed, with the following revisions:

- We have added 45 CFR part 92 to the regulations specifically referenced in § 483.70(c) ''Relationship to other HHS regulations.''
- We have withdrawn our proposal to delete the phrase ''where licensing is required'' from § 483.70(d)(2)(i).
- In § 483.70(n), we have modified paragraph (1) to prohibit the use of pre-dispute agreements for binding arbitration between any resident or their representative and the facility and allow post-dispute agreements for binding arbitration, if the facility complies with the requirements in this section.

*V. Quality Assurance and Performance Improvement (QAPI) (§ 483.75)*

Section 6102 of the Affordable Care Act amended the Act by adding new section 1128I. Subsection (c) of section 1128I of the Act requires that the Secretary establish and implement a QAPI program requirement for all SNFs and NFs, including those that are part of a multi-unit chain of facilities. Under the QAPI provision, the Secretary must establish standards relating to facilities' QAPI program and provide technical assistance to facilities on the development of best practices in order to meet these standards. No later than 1 year after the date on which the standards are issued, a facility must submit to the Secretary a plan for the facility to meet these standards and implement the best practices, including a description of how it would coordinate the implementation of the plan with quality assessment and assurance activities currently conducted under sections 1819(b)(1)(B) and 1919(b)(1)(B) of the Act. In accordance with the QAPI provisions of the Affordable Care Act, we proposed to establish these standards.

Current regulations at § 483.75(o) require a facility to maintain a quality assessment and assurance (QAA) committee, consisting of the director of nursing services, a physician designated by the facility, and at least three other members of the facility staff. The QAA committee must meet at least quarterly and identify quality deficiencies and develop and implement plans of action to correct the deficiencies. The facility is only required to disclose records of the QAA committee if the disclosure is related to the compliance of the committee with the regulatory requirements. We proposed to retain the substance of the existing QAA requirements at § 483.75(o) and pursuant to the requirements of the Affordable Care Act, we proposed a revised § 483.75 entitled, ''Quality Assurance and Performance Improvement.''

At § 483.75(a), we proposed to require that a facility develop, implement, and maintain an effective, comprehensive, data-driven QAPI program, reflected in its QAPI plan, that focuses on systems of care, outcomes, and services for residents and staff. The QAPI program would be designed to monitor and evaluate performance of all services and programs of the facility, including services provided under contract or arrangement. We proposed that the facility's governing body, or designated persons functioning as a governing body, would ensure that the QAPI program is defined, implemented, and maintained and addresses identified priorities. Therefore, we proposed at § 483.75(a)(1) that the facility maintain documentation and demonstrate evidence of its QAPI program. This would include, but would not be limited to, the QAPI plan. We proposed at § 483.75(a)(2) that the facility would be required to submit the QAPI plan to the State Agency or federal surveyor, as the agent of the Secretary, at the first annual recertification survey 1 year after the effective date of these regulations. In addition, we proposed at § 483.75(a)(3), based on the Secretary's authority at sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act to establish other requirements relating to the health and safety of residents, to require that the facility present the QAPI plan to the State Agency surveyor at each annual recertification survey and upon request to the State Agency or federal surveyor at any other survey and to CMS upon request. Further, we proposed at § 483.75(a)(4), to require the facility to present its documentation and evidence of an ongoing QAPI program upon request of a State Agency, federal surveyor, or CMS. The State Agency, pursuant to its agreement with the Secretary under section 1864 (a) of the Act, would consider such plan in making its certification recommendation and providing evidence to the CMS Regional Office for a compliance determination.

At § 483.75(b), we proposed requirements for the design and scope of the QAPI program. We proposed to require that the facility design its QAPI program to be ongoing, comprehensive and address the full range of care and services provided by the facility. When implemented, the QAPI program would be required to address all systems of care and management practices and always include clinical care, quality of life, and resident choice. It would also require LTC facilities to utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have

been shown to be predictive of desired outcomes for residents of a facility and reflect the complexities, unique care, and services that the facility provides.

We proposed at § 483.75(c) to establish requirements for QAPI program feedback, data systems and monitoring. We proposed at new § 483.75(c)(1) that, as part of its QAPI process, the facility must maintain effective systems to obtain and use feedback and input from direct care/direct access workers, other staff, and residents, resident representatives and families to identify opportunities for improvement. At § 483.75(c)(2), we proposed to require that the systems, governed by appropriate policies and procedures, also include how the facility would identify, collect, and use data from all departments, including how the information would be used to identify high risk, high volume or problem-prone areas. At § 483.75(c)(3), we proposed to require that the policies and procedures include a description of the methodology and frequency for developing, monitoring, and evaluating performance indicators. Finally, at § 483.75(c)(4), we proposed to require that the system, policies and procedures include the process for identification, reporting, analysis, and prevention of adverse events and potential adverse events or near misses. We indicated in the proposed rule that this would include methods by which the facility obtains information on adverse events and potential adverse events from residents, family and direct care/direct access staff, and how the facility addresses and investigates the adverse event or potential adverse event and provides feedback to those same individuals.

We proposed to establish a new § 483.75(d) to address QAPI program systematic analysis and systemic action. We proposed in § 483.75(d)(1) to require that the facility take actions aimed at performance improvement and, after implementing those actions, to measure the success of those actions and to track performance to ensure that the improvements are sustained. We further proposed to require in § 483.75(d)(2), that the facility develop policies describing how they would use a systematic approach (such as, root cause analysis, reverse tracer methodology, and health care failure mode and effects analysis, for example) to determine underlying causes of problems impacting larger systems.

At § 483.75(e), we proposed to establish requirements for program activities. Specifically, we proposed to require at § 483.75(e)(1) through (3) that the facility establish priorities for performance improvement activities that focus on patient safety; coordination of care; autonomy; choice; and high risk, high volume, and/or problem-prone areas identified as a result of the facility assessment as specified in § 483.70(e). We proposed to require that performance improvement activities track medical errors and adverse resident events, analyze their causes, and implement preventative actions and mechanisms that include feedback and learning throughout the facility. Finally, we proposed to require that the QAPI program activities include Performance Improvement Projects (PIPs). Under the proposal, the facility is required to conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources. We proposed that each facility be required to implement at least one project annually that focused on a high risk or problem prone area identified through the required data collection and analysis.

Finally, at § 483.75(f), we proposed to require that the facility ensure, through the governing body or executive leadership, that an ongoing QAPI program would be defined, implemented, and sustained during transitions in leadership and staffing and that the QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed. Furthermore, we proposed that the governing body or executive leadership would have to ensure that the QAPI program identified and prioritized problems and opportunities based on performance indicator data; resident and staff input that reflected organizational processes, functions, and services provided to residents; that corrective actions addressed gaps in systems, and were evaluated for effectiveness; and that clear expectations were set around safety, quality, rights, choice, and respect.

We proposed to re-designate § 483.75(o) as § 483.75(g). At § 483.75(g)(1), we proposed revisions to clarify that the QAA committee membership requirements would be a minimum requirement. We also proposed the requirement that the Infection Control and Prevention Officer (ICPO) would participate in the quality assessment and assurance committee.

At § 483.75(g)(2), we proposed that the quality assessment and assurance committee would report to the facility's governing body, or designated persons functioning as a governing body, regarding its activities, including implementation of the QAPI program required under new § 483.75(a) through (f). We further proposed that the committee would coordinate and evaluate activities under the QAPI program, including performance improvement projects, and that the committee would review and analyze data collected under the QAPI program as well as data from pharmacists resulting from monthly drug regimen reviews and the resulting reports as specified in § 483.45(c)(4).

We proposed to add a new § 483.75(h) to address disclosure of information. We proposed to re-designate existing § 483.75(o)(3) as § 483.75(h)(1) and add a new § 483.75(h)(2) to clarify that facilities, in order to demonstrate compliance with the requirements of this section, may be required to disclose or provide access to certain QAPI information. Specifically, we proposed to require, to the extent necessary to demonstrate compliance with the requirements of this section, access to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; documentation demonstrating the development, implementation, and evaluation of corrective actions or process improvement activities; and other documentation considered necessary by a state or federal surveyor in assessing compliance. We further proposed to re-designate § 483.75(o)(4) as § 483.75(i).

In the proposed rule we included a discussion regarding technical assistance, materials, and resources available to LTC facilities on the development of best practices relating to QAPI (80 FR 42168, July 16, 2015). We encourage readers to review that discussion and take advantage of the tools available.

*Comment:* Many commenters stated that they generally support QAPI in facilities. One commenter stated that they were pleased that we have proposed standards for QAPI.

*Response:* Thank you. These standards build on our experience requiring QAPI for other providers and, importantly, on the knowledge gained during the CMS QAPI demonstration project in LTC facilities. We believe facilities are familiar with the principles we are using and expect that some facilities have or are in the process of developing QAPI programs using the materials developed during the project and now available through the CMS Web site.

*Comment:* Some commenters felt that mandating QAPI in facilities was unnecessary due to current voluntary

activities in hospitals and managed care, including quality improvement efforts to reduce unnecessary re-hospitalizations, and value-based purchasing.

*Response:* We disagree. Effective QAPI programs are critical to improving the quality of life, and quality of care and services delivered in facilities. Furthermore, QAPI in LTC facilities is mandated by Section 6102 (c) of the Affordable Act and CMS does not have any discretion to not implement the provision.

*Comment:* One commenter requested that we not use the word ''program'' to encourage facilities to make QAPI part of the everyday life and operations of the facilities.

*Response:* We thank the commenter and agree that QAPI should be part of the everyday life and operations of the home; however, the statute specifically refers to the ''QAPI program'' and, for clarity and consistency, we have chosen to remain consistent with statutory language.

*Comment:* One commenter supported our focus on ''high-risk, high-volume, or problem-prone areas'' and suggested we not include a list of areas that each facility must address. If we were to provide such a list, the commenter suggests that inclusion of topics addressing psychosocial well-being, mental and behavioral health, and quality of life are crucial. They specifically note that a positive approach that focuses on improving long-term residents' everyday experience, promotion of short-term residents' decision making, and improving palliative and end of life care would be particularly useful. One commenter stated that ''each organization should be able to determine their own areas of focus based on the collection of data, trends, and comparable benchmarks vs arbitrary mandates.''

*Response:* We are not adding a specific list of QAPI topics or required performance improvement projects at this time. We want to allow facilities the flexibility to determine what issues should be prioritized for their QAPI program based on the needs of the facility and its residents. If we decide to require specific topics or performance improvement projects in the future, we will consider the topics suggested by the commenter as well as other comments we may have received.

*Comment:* One commenter felt that the proposed requirements exceeded our authority, and suggested that we withdraw our proposal and replace it with the statutory language. Some commenters felt that the proposed requirements are very detailed, too prescriptive, and significantly exceed the requirements for other providers. One commenter believes that the number of system areas that must be minimally included is too large. Some commenters expressed general concern that our proposed QAPI provisions lack specific requirements or stated that additional guidance is necessary. One commenter suggested regional sharing of program development, training, program evaluation and other resources.

Some commenters suggested that we allow a 5 year implementation period during which the facility would show progress in its implementation process during the annual standard survey, while other commenters suggested a 2 to 3 year phase-in for the QAPI provisions.

*Response:* We appreciate the commenters concerns regarding both the need for sufficient specificity to meet requirements and sufficient flexibility. We have worked to achieve a balance between specificity and flexibility in recognition of the wide diversity that exists among LTC facilities. We have re-evaluated our proposal to determine if we can be less prescriptive in some areas, and have modified our language accordingly. For example, we have eliminated the specific methodologies listed in proposed § 483.75(d)(2)(i), as these may be more appropriate in sub-regulatory guidance. We do not agree that we have exceeded our authority and should include only the statutory language as suggested.

In addition, we have received many comments regarding the overall implementation of this rule and address that issue in section II.B. Implementation. With regard specifically to QAPI, we note that the statute requires at 1128I(c)(1) of the Act that the QAPI plan be submitted to the Secretary not later than one year after the date on which the requirements are issued. We have modified our regulatory provision to mirror the statutory language. We would expect facilities to show their efforts to effectuate the QAPI plan, on an ongoing basis thereafter, with no fixed start or end date.

QAPI is intended to be a continuous part of the everyday life and operations of the home. We note that facilities have been expecting these regulations for a number of years, since publication of the Affordable Care Act in 2010. In developing our proposal, we relied heavily on the experiences gained in the CMS QAPI demonstration project which was conducted from Sept 2011 through Sept 2013. Resources and tools were developed as a result of that pilot, were rolled out on June 7, 2013 (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-37.pdf*) and remain available on the CMS Web site (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html*). In addition, QIOs are currently using these tools in their work with LTC facilities and additional resources are under development. We would encourage facilities to share best practices and other resources as they develop their QAPI programs. Furthermore, this proposal, while tailored to long-term care facilities, is consistent with our requirements (Conditions of Participation and Conditions for Coverage) for QAPI for other providers, such as community mental health centers (§ 485.917), end stage renal disease facilities (§ 494.110), hospitals (§ 482.21), hospices (§ 418.58), organ procurement organizations (§ 486.348), and transplant centers (§ 482.96) as well as proposed requirements for home health agencies (79 FR 61164).

*Comment:* One commenter supports the concept of an effective QAPI program, but feels we have over-emphasized data and outcomes and do not adequately acknowledge the qualitative processes such as clinical reasoning, correct diagnoses, and the nuances of selecting individualized treatments that are the foundation of high-quality results. They further state that any requirements about QAPI programs should focus attention on improving processes and practices, including those related to both clinical and nonclinical decision making, reasoning, and problem solving. The commenter is concerned that excessive emphasis on data and results distracts attention from improving the basis for those results, that available quality measures and data only represent a small part of the many aspects of quality care, and that aggregate results may not faithfully reflect the quality of the overall care of individual residents. The commenter suggests language to strike a better balance between looking at data and focusing on practices and processes that need optimized regardless of the data. The commenter also suggests that the QAPI requirements specifically include case review.

*Response:* We believe that our focus on outcomes is appropriate. We agree that QAPI should focus on improving processes and practices, and believe that data is a necessary element in doing so. Data is used to identify problems in processes and practices and to set goals related to improving those processes and practices. It is then used to validate that a change is successful in improving

that process or practice and subsequently to monitor that the change is sustained. Using data involves critical reasoning and analytical thinking; these are not mutually exclusive. We agree that case review is one tool that can be used to identify problems and collect data. We would defer specificity regarding such tools to sub-regulatory guidance.

*Comment:* One commenter suggests we use the term ''information'' instead of ''data.'' They note that ''information'' includes data as well as other knowledge, whereas data could exclude other information.

*Response:* We agree that information other than data may be useful in the QAPI process, but we also believe that data-facts, measurements, and statistics collected for analysis and planning are an integral part of the QAPI process. Rather than substitute one term for the other, we have, where appropriate, used both.

*Comment:* One commenter believes the regulations should be more flexible with regard to performance improvement projects (PIP) and that the proposal is overly prescriptive. The commenter notes that there are many performance project activities that would not be considered a PIP but are activities that could be built into everyday activities and real-time problem solving. They state that the PIP requirement is problematic and these regulations need a better balance of diverse methods including qualitative reasoning and real-time problem solving.

Another commenter suggested that each facility be required to have at least three PIPs in place at a time, reflecting different areas of concern and at least one reflecting residents' rights and quality of life. The commenter further suggests that a facility cited with immediate jeopardy deficiency(ies) be required to initiate a PIP in the area where the immediate jeopardy was cited.

One commenter suggests that CMS develop and annually update a list of a dozen mandatory PIPs reflecting issues that CMS has identified as significant quality of care and quality of life issues. Each facility would then be required to choose at least one PIP from that list annually.

*Response:* The comments regarding the PIP requirements reflect opinions advocating for both less and more specificity in our PIP requirements. One of the critical elements of QAPI is to give facilities the flexibility to use QAPI to best meet their own needs. In order to give facilities this flexibility, we believe that a less prescriptive approach to PIPs is appropriate. However, this flexibility must occur in the context of a QAPI program that addresses the full range of care and services provided by the facility. Accordingly, we limited our proposal to require only one PIP annually, and declined to establish mandatory PIPs at this time.

We agree that not all improvement activities are PIPs and believe that our proposed regulatory language is inclusive of these activities. (See § 483.75(e)). In addition, we have reviewed our proposals and, where appropriate, have expanded our references to PIPs to include other improvement activities. While we agree that areas in which an immediate jeopardy deficiency is cited require immediate action, we are not certain that a PIP will always be an appropriate response, and therefore have not adopted this recommendation at this time.

*Comment:* One commenter stated that they were pleased that the medical director or his or her designee is specifically listed as a member of the QAA committee. They support medical director and other medical practitioner involvement in the development and assessment of the QAPI program.

*Response:* Thank you. We agree that medical director involvement in QAPI is an important leadership element. We also believe that the involvement of other medical practitioners can contribute to the success of a QAPI program.

*Comment:* Some commenters suggested that we needed to ensure resident, resident representative, and staff participation in the QAPI program. The commenters raised concerns and suggested additional language that would address resident, resident representative, and staff involvement in the QAPI program.

*Response:* Our proposed requirements include obtaining and using feedback and input from staff, residents and resident representatives. We are finalizing this particular requirement as proposed.

*Comment:* Some commenters recommend adding staffing and worker safety elements to the QAPI requirements.

*Response:* The QAPI program is required to address the full range of care and services provided by the facility. This would include staffing as well as a number of other areas. We defer additional specificity to sub-regulatory guidance. While facilities could certainly include worker safety in their QAPI processes, we have not specifically included worker safety in this regulation as we believe worker safety is more appropriately the purview of other federal agencies such as HRSA and OSHA.

*Comment:* One commenter suggested that we require effective collaboration training for members of the QAA committee.

*Response:* We agree that effective collaboration training could be useful for members of a QAA committee, as well as individuals in other positions. However, we do not mandate any specific trainings for QAA committee members and do not believe that we should mandate this specific training for all QAA committee members. There are many trainings that could be equally beneficial, and some that might be a greater priority, based on prior training and experience of the members of the QAA committee. We will defer such decisions to the facility.

*Comment:* One commenter recommended that we require a contracted consultant pharmacist sit on the Quality Assessment and Assurance Committee. The commenter stated that adverse medication events, including medication errors, remain a serious problem in LTC facilities.

*Response:* We appreciate the commenters' suggestion, but, while we would agree that this would be a good practice, we are not adopting this recommendation at this time. As part of the update of these requirements, we have updated our requirements related to pharmacy services and mandated adverse event monitoring as a part of the QAPI program. We believe that these requirements will help reduce adverse medication events. Mandatory membership on the Quality Assessment and Assurance Committee reflects a minimum standard and facilities can add members based on the needs and priorities of the facility.

*Comment:* Several commenters supported our proposed requirements regarding disclosure of QAPI information to demonstrate compliance with the requirements for the QAPI program. One commenter stated that they believed it would improve facility compliance with the requirements and would assist in federal and state oversight. Another stated that the purpose of the quality assurance provisions is to ensure that LTC facilities identify and act on information about neglect, abuse, and other adverse events, not that they be able to hide this information by making it part of a QAPI record. Another asked that we clarify that documents and reports used or relied on by QAPI are not confidential and that non-disclosure applies only to minutes, internal working papers, or statements of conclusions of QAPI and

QAA. They further stated that we should clarify that records and materials submitted to the QAA committee for review are not confidential solely because they are used or reviewed by the QAA committee. Others stated that the QAPI plan should be made available to residents, resident representatives, and staff.

Other commenters objected to our proposed provisions regarding information disclosure to demonstrate compliance with the QAPI requirements. One commenter stated that this requirement could be misconstrued. Several suggested that these requirements could have a chilling effect on advancing QAPI efforts and should be deleted or substantially modified. Several commenters felt that the proposed rules for QAPI would discourage open and honest evaluation of areas of concern without fear of negative consequences. A number of commenters were concerned that disclosing quality assurance records to surveyors would expose providers to increased risk of sanctions and litigation. One commenter stated that surveyors should not have broad access to facilities' QAPI data or deliberations. Another commenter stated that they believe that the proposed regulations exceed the statutory authority granted to CMS. The commenter stated that we have significantly expanded upon the statutory mandate by requiring a ''laundry list'' of requirements related to the QAPI program, including requiring the disclosure of, or potentially requiring a facility provide access to, a plethora of QAPI-related documents and records. They further stated that proposed 42 CFR 483.75(a)(4), requiring facilities to present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with the requirements to a State Agency, Federal surveyor, or CMS upon request exceeds the permissibly required disclosures under the statute. One commenter stated that these provisions are contrary to state law. Finally, they believed that proposed § 483.75(h) is internally inconsistent.

*Response:* We thank those commenters who support our proposal regarding the need to provide documentation demonstrating compliance with the QAPI requirements. We have attempted to strike an appropriate balance between concerns about inappropriate use of QAPI materials and our obligation to provide effective oversight of Medicare and Medicaid participating facilities.

We do not agree with commenters who believe that we have exceeded our authority in establishing these requirements. Under section 1128I(c) of the Act, as added by section 6102 of the ACA, Congress required the Secretary to establish and implement a quality assurance and performance improvement program for facilities. The Secretary is also required to set forth standards for QAPI and provide technical assistance to develop best practices for facilities to meet those standards. The expectation that facilities will implement a QAPI program that meets those standards is clear, and facilities must be able to demonstrate that they have implemented their QAPI plan and have an effective, ongoing QAPI program. The standards, the best practices, and the tools to support facilities as they implement their plan to meets those standards were developed in the course of the QAPI demonstration project conducted by CMS. We also consider our experiences with requiring QAPI programs from other providers such as community mental health centers (§ 485.917), end stage renal disease facilities (§ 494.110), hospitals (§ 482.21), hospices (§ 418.58), organ procurement organizations (§ 486.348), and transplant centers (§ 482.96) as well as proposed requirements for home health agencies (79 FR 61164).

QAPI is intended to be one aspect of a LTC facility's operations that helps to maintain and protect the health and safety of the residents of the facility. Section 1819(f)(1) of the Act states that it is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care in skilled nursing facilities under Title XVIII, and the enforcement of such requirements, are adequate to protect the health, safety welfare, and right of residents and to promote the effective and efficient use of public moneys. Therefore, we have an obligation to ensure that the QAPI plan becomes more than a paper exercise. To that end, we proposed requirements that would demonstrate that a facility has not only written a plan that meet the established standards, but has actually implemented that plan. In our proposed requirements, we stated that the facility must present its QAPI plan at its annual recertification (or in the case of a new facility, during its initial certification) after the effective date of this regulation and at every annual survey thereafter, as well as during other surveys or upon our request. We included this ongoing requirement because we understand that a QAPI plan will need to be updated and modified as a facility implements it and learns from the QAPI program. We proposed that the facility would have to present documentation and evidence of its ongoing QAPI implementation to reflect the ongoing nature of the QAPI program.

It is not our intent that a facility lose existing protections for QAA documents, including those established under state law, nor do we intend to create a punitive environment or increase litigation. At the same time, we cannot ignore our obligation to ensure that facilities implement their QAPI plan, and continue to modify and implement that plan over time. What we require is satisfactory evidence that a facility is implementing its QAPI plan and maintaining an ongoing QAPI program. We further articulated in the proposed rule what sort of evidence and documentation we believe may be necessary to demonstrate compliance. We retain the proposed requirement, as required by statute, that a State or the Secretary may not require disclosure of a QAA committee's records except insofar as such disclosure is related to the compliance of such committee with the requirements of the statute. Clearly, this requirement recognizes that, in some cases, such records will be necessary to evaluate compliance. However, much information relating to the implementation of the QAPI plan could be available outside of the QAA committee's records. Further, we do not believe that every document, piece of information, or data reviewed or generated in the course of implementing QAPI is a ''record of the QAA committee.''

We also retain the proposed requirement that ''Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanction.'' This requirement is not new; however, it now also includes QAPI activities. As is currently the case, surveyors are instructed not to cite as a deficiency for a requirement other than the QAPI requirements a concern that would not have been identified but for a review of QAPI materials for the purpose of determining compliance with the QAPI regulations. That said, nothing in this section would preclude a surveyor from citing a concern that is identified based on a review of materials or on observations separate and apart from an assessment of QAPI compliance. Excluding such a concern simply and only because it has also been identified by the QAPI program would be irresponsible of CMS. We understand that the ability to discern when and how a deficiency is identified is of concern to facilities. We have and will continue to educate surveyors on the parameters of this provision and the need to not

inappropriately request or use QAPI documentation.

With regard to concerns about increased litigation, we reiterate that our purpose is neither to inappropriately make documents public nor to expose facilities to litigation risk. In fact, section 1106 of the Act specifically states that, for health programs established by titles XVIII and XIX, reports (including program validation survey reports and other formal evaluations of the performance of providers of services) made public by the Secretary or the State Agency shall not identify individual patients, individual health care practitioners, or other individuals. Our obligation to conduct effective oversight is not waived in the face of litigation fears. We have attempted in these regulations to establish an appropriate balance between ensuring that QAPI can be conducted in an open, non-punitive environment and ensuring that we can provide effective oversight of requirements necessary to protect the health and safety of LTC facility residents. We have re-evaluated our proposed language and made some modifications in order to be less prescriptive and duplicative. In order to address the commenters concerns about internal consistency and overreach, we have moved the language regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated, as potentially overbroad, proposed paragraph (iii) which stated ''other documentation considered necessary by a State or Federal surveyor in assessing compliance.'' We are finalizing as proposed the requirement that facilities must provide documentation and information that demonstrates that they are effectively implementing their QAPI plan, on an ongoing basis, and surveyors must have sufficient information to evaluate if a facility is in compliance with the requirements of this section.

*Comment:* One commenter supported our proposed QAPI provisions and stated that QAPI must be among the services disclosed to residents on the notice of services. The commenter suggested that there be some method for a resident to ''trigger'' a QAPI performance improvement project (PIP).

*Response:* Our requirements include obtaining and using feedback and input from staff, residents and resident representatives. While not all such input would trigger a PIP, it is important that it be included in the facility's assessment of concerns and priorities.

*Comment:* One commenter asked if using programs such as Abaqis or PCC are sufficient to meet the QAPI regulation.

*Response:* Programs such as PointClickCare and Abaqis may assist facilities to meet the QAPI requirements, but using them is neither necessary nor sufficient for compliance. Facilities must evaluate their use of such tools and ensure that they comply with the QAPI requirements.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified paragraph (a)(2) to mirror the statutory language to indicate that the facility must present its QAPI plan to the State Survey Agency not later than one year after the date the regulation is issued.
- We have added the term ''information'' in paragraphs (c)(2) and (f)(4).
- In paragraph (e)(3), we have referenced performance improvement activities in the context of our PIP requirement.
- We eliminated the parenthetical examples in paragraph (d)(2)(i)
- We have moved the language in proposed § 483.75(h)(2) regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated proposed paragraph (iii) which stated ''other documentation considered necessary by a State or Federal surveyor in assessing compliance.''

*W. Infection Control (§ 483.80)*

As part of our overall reorganization of these regulations, we proposed to re-designate the provisions under existing § 483.65 as § 483.80. We proposed to modify the introductory language to include infection prevention as well as control and to clarify that the program must help prevent the development and transmission of communicable diseases as well as infections. We proposed to revise paragraph (a) to read ''Infection prevention and control program'' (IPCP) and add new § 483.80(a)(1), (2) and (3) to specify the elements of the IPCP. We proposed to require that the program must follow accepted national standards, be based upon the facility assessment conducted according to § 483.70(e) and include, at a minimum, 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 a contractual arrangement. We proposed to require the facility to have written standards, policies, and procedures for the IPCP, including but not limited to, a system of surveillance designed to identify possible communicable disease or infections before it can spread to other persons in the facility; reporting requirements for possible incidents of communicable disease or infections; standard and transmission-based precautions to be followed to prevent spread of infections; circumstances in which generally, isolation should be used for a resident; the circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if the contact is likely to transmit the disease; and the hand hygiene procedures to be followed by all staff as indicated by accepted professional practice. We also proposed that the facility be required to train staff related to the IPCP as specified in § 483.95.

We proposed that the facility's IPCP must also include an antibiotic stewardship program that includes antibiotic use protocols and systems for monitoring antibiotic use and recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

We further proposed to add a new paragraph (b) to require that the facility designate an infection prevention and control officer (IPCO) who is responsible for the IPCP and who has received specialized training in infection prevention and control. We proposed that the IPCP be a major responsibility for the individual assigned as the facility's IPCO. We proposed to require that the IPCO be a healthcare professional with specialized training in infection prevention and control beyond their initial professional degree. At § 483.80(c), we proposed to require that the IPCO be a member of the facility's Quality Assessment and Assurance (QAA) committee.

We proposed to eliminate the exception that is currently located at § 483.25(v), which provides that, based on an assessment and practitioner recommendation, a second pneumococcal immunization could be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

We proposed to add a new § 483.80(f) to require that the facility review its IPCP annually and update the program as necessary. We also proposed to relocate the requirements for influenza and pneumococcal immunizations from the current § 483.25(n) to § 483.80(d). The language in § 483.80(d) is identical to the current § 483.25(n), except that

we proposed using the term ''resident representative'' instead of ''legal representative.'' Finally, we proposed moving the requirement concerning linens from the current § 483.65(c) to the proposed § 483.80(e).

Infection Prevention and Control Program (IPCP)

*Comment:* Many commenters agreed that infection control is very important for residents in LTC facilities and commended CMS for proposing to significantly enhance the infection control requirements given the physical harm and financial cost of HAIs. One commenter said the proposed measures are an important step forward.

*Response:* We would like to thank the commenters for their support. We agree that infection control is very important for residents, as well the staff and other individuals who work or visit the facility. We believe the requirements that are finalized in this rule will contribute to the reduction in HAIs, which should result in a reduction in physical harm to residents and others, as well as a decrease in the associated health care costs.

*Comment:* One commenter expressed a concern that the infection control efforts could not be effective without adequate numbers of consistently assigned, well-trained and well-supervised direct care nursing staff. Nurses and nursing assistants are essential for infection control prevention, detection and intervention. The commenter recommended a minimum staffing standard of at least 4.1 hours of direct care nursing per resident day, 24-hour registered nurse coverage for the facility, and staffing practices to promote successful infection prevention.

*Response:* We agree with the commenter that for the infection control requirements finalized in this rule to be effective, the facility would need a sufficient number of trained and supervised direct care nursing staff. However, we disagree that this final rule should establish a minimum staffing standard for LTC facilities. In this final rule, each facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for it residents competently during both day-to-day operations and emergencies (§ 483.70(e)). That assessment must include, among other things, the resident population and the care required by that population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present in that population, as well as the staff competencies that are necessary to provide the level and types of care needed by that population. This assessment must then be used to determine what is the number of sufficient nursing staff and the competencies and skill sets the nursing and related staff must have to care for their resident population (§ 483.35). Based on these requirements, as well as the infection control requirements finalized in this rule, each facility will need to determine the resources it needs to devote to its infection control program.

*Comment:* Commenters recommended that the guidelines from the Centers for Disease Control and Prevention be inserted into § 483.80(a)(1), so that it reads, ''staffing practices, and following accepted national standards including, but not limited to guidelines from the Centers for Disease Control and Prevention; . . .''

*Response:* We disagree with the commenters. We believe that facilities need the flexibility to determine which national standard they are going to follow. We also believe it is appropriate for the different types of national standards that are acceptable to CMS to be included in the sub-regulatory guidance for this rule. Although we are not requiring that LTC facilities follow the CDC guidelines, we agree with the commenters that the CDC is an excellent resource for guidelines, as well as other information on infection control, and encourage LTC facilities to consider the CDC guidelines. For example, the CDC has a Web site for information on infection control in LTC facilities, ''New CDC Infection Control Web site for Nursing Homes and Assisted Living,'' (*http://www.leadingage.org/Infection_Control_Website.aspx*). Other organizations also have information available on their Web sites, such as The Society of Healthcare Epidemiology of America (SHEA) (*http://www.shea-online.org/*), Infectious Diseases Society of America (IDSA) (*https://www.idsociety.org/Index.aspx*), and the Association for Professionals in Infection Control and Epidemiology (APIC) (*http://www.apic.org/*).

CDC and CMS are also exploring opportunities to develop and implement infection prevention and control training specific for LTC facility clinical personnel. We expect that this would provide training on a variety of infection control topics relevant for LTC facility staff developing and sustaining an IPCP. We expect that any training would be widely available for all providers, surveyors, and other partners. We are also exploring opportunities for continued education, dissemination of promising practices, and ensuring that new infection prevention and control guidance and information for LTC facility staff can be shared widely. CMS is pleased to be collaborating with CDC on this type of comprehensive training for providers. CMS has previously developed specific surveyor training on infection control topics in 2014 and 2015. CMS is also exploring processes for reviewing infection prevention and control practices in the context of transitions of care. Please see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-05.pdf* for additional information about that pilot.''

*Comment:* One commenter stated that the detail in the scope and components in the infection control program went well beyond what is required in the hospital CoPs. They noted that hospitals are a setting with much greater risk of infections and individuals at higher risk of adverse events from infections. They recommended adopting more general language similar to that used in the hospitals CoPs and specify the details in interpretive guidance that should be developed in partnership with stakeholders. They noted that referring to the goal and purpose of the infection control program along with following national standards allows the goal and intent to be accomplished. This affords the providers greater flexibility and creativity in how to achieve the goals also provides CMS flexibility to provide additional suggested approaches in interpretative guidance. They also noted that modifying and updating the guidance as new and better practices are identified over time is preferable to the long and arduous formal rulemaking process to update the requirements.

*Response:* We disagree with the commenters. As we discussed in the proposed rule, it is estimated that there are between 1.6 and 3.8 million HAIs in LTC facilities annually (80 FR 42215). These infections result in an estimated 150,000 hospitalizations; 388,000 deaths; and healthcare costs between $673 million to $2 billion. In addition, residents may be more susceptible than individuals in other types of healthcare facilities due to malnutrition, dehydration, comorbidities, or functional impairments, such as urinary and fecal incontinence, or medications that diminish immunity or mobility. Also, due to the length of their stays, there is more opportunity for exposure to infectious agents from the socialization between residents. This clearly indicates that infection prevention and control is a critical issue for LTC facility residents. In addition,

due to transfers between hospitals and LTC facilities, infection control in LTC facilities directly affects hospitals as well. The LTC facility resident with an infection today maybe the patient that the hospital must treat tomorrow when he or she arrives in the hospital's ED.

Concerning the level of detail in the infection control requirements, we disagree with the commenter. Hospitals and LTC facilities are different types of facilities. LTC facility residents generally stay much longer than patients in hospitals and generally require care for chronic conditions instead of acute illnesses, injuries, or surgeries. In addition, there must be sufficient detail in the regulatory text so that LTC facilities know what will be needed to be in compliance with requirements. We believe there is sufficient detail in the infection control requirements so that LTC facilities and the public understand what is expected for compliance. We also note that CMS published a proposed rule on June 16, 2016 entitled, ''Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility and Improvement in Patient Care (CMS–3295–P) (81 FR 39448). These proposed regulations update and add specificity to the infection prevention and control requirements for hospitals.

Concerning the commenter's recommendation that referring to the goal and purpose of the infection control program along with following national standards allows the goal and intent to be accomplished. We do not believe this is needed in the regulatory text. However, further direction will be provided in sub-regulatory guidance. Concerning the use of interpretative guidance, sub-regulatory guidance for this final rule will be developed and published as soon as possible. That guidance will contain more specific direction for long-term care facilities, surveyors, and others concerning compliance with these regulatory requirements. Thus, we believe that the level of detail in the infection prevention and control requirements in this final rule are appropriate and ensure that LTC facilities are aware of what is required to comply with these requirements.

*Comment:* One commenter was concerned about the specificity of the language in the infection control comments. They recommended specific language changes to remove much of the detail in this section and suggested using ''should'' instead of ''must'' to allow more flexibility for both the providers and CMS when legitimate exceptions are identified or new and better practices are identified.

*Response:* We disagree with the commenter. While the commenter is correct that the use of ''should'' would convey more flexibility, that is not the purpose of these requirements. This final rule contains requirements for LTC facilities, not suggestions. LTC facilities must be in compliance with these requirements. In addition, further guidance will be provided through sub-regulatory guidance. As practices change in the future, we would appreciate comments from the commenter, as well as any other individuals, on any recommended changes to these requirements.

*Comment:* One commenter supports the efforts to address antibiotic stewardship; however, they noted that the problem is not isolated to LTC facilities. For example, hospital emergency departments (EDs) will usually obtain a urine analysis on residents who are sent to the ED. Over 50 percent of these tests will show asymptomatic bacteria which would not meet the Society for Healthcare Epidemiology of America (SHEA) criteria for giving antibiotics. However, the ED frequently starts the resident on antibiotics before the resident returns to the facility. In addition, a State Survey Agency will cite a facility for an adverse event when the LTC facility does not begin an antibiotic based upon an asymptomatic urinalysis but the resident later develops an infection. The commenter noted that this has occurred across the country over the past several years as providers have attempted to follow the SHEA criteria. If the proposed requirements are finalized as proposed, the commenter requested that language be added that indicates that providers will not be cited if an infection develops when the provider has followed nationally accepted guidelines for antibiotic use, such as SHEA. The commenter recommended that the hospital CoPs also be modified to prevent citation for an adverse event under these circumstances.

*Response:* We agree with the commenter that antibiotic stewardship is not an issue for LTC facilities alone and as noted above, we have published a proposed rule with requirements for antibiotic stewardship programs for hospitals (81 FR 39454 through 39459). However, it is crucial that LTC facilities establish an infection prevention and control program that contains an antibiotic stewardship program. As we discussed in the proposed rule, antibiotic resistance has become a national concern and both the inappropriate and even appropriate use of antibiotics contribute to this problem (80 FR 42215). In addition, LTC facilities are part of the overall healthcare system. With the growth in the short term resident population, more residents with complex healthcare issues are coming from the hospital into the LTC facility. Residents with infections in the LTC facility may become patients in the hospitals ED. In addition, residents also may go to other healthcare facilities for care, such as ambulatory surgical centers (ASCs) and dialysis centers. Therefore, the facility's IPCP, and its antibiotic stewardship program, also affects other facilities and individuals throughout the healthcare system. Therefore, we are finalizing the requirement for LTC facilities to establish and maintain an IPCP, which must include, among other things, an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

Regarding the commenter's concern about being cited by a surveyor for following national standards and modification of the hospital CoPs, we will be working on developing sub-regulatory guidance and training for the surveyors that should address situations that the commenter described.

*Comment:* One commenter expressed concerns about § 483.80(a)(2)(iv), which requires ''(2) [w]ritten standards, policies and procedures, which must include, but not limited to: . . . (iv) [w]hen isolation should be used for a resident.'' The commenter said they had heard directly from residents, families and ombudsmen about situations where facilities have barred all visitors from accessing residents for a significant period of time due to the outbreak of certain infectious viruses among residents and/or facility staff. The commenter noted that the practice of facilities restricting visitation as part of an infection control protocol has been regularly reported in the news. The commenter noted that the current interpretive guidelines already recognize the potential adverse psychological impact on residents when instituting any precautions to control outbreaks. According to the guidelines, ''because of the potential negative impact that a resident may experience as a result of the implementation of special precautions, the facility is challenged to promote the individual resident's rights and well-being while trying to prevent and control the spread of infections,'' and it is appropriate for facilities to ''use the least restrictive approach'' to infection control while adequately protecting the residents and others.'' The commenter recommended that the language from the interpretive guidelines be inserted in the rule to strike a balance between protecting the

health of the residents and their psychological well-being. They recommended the following language, ''[t]he facility must isolate infected residents only to the degree needed to isolate the infecting organism. The method used must be the least restrictive possible:''

*Response:* We agree with the commenter that isolation should only be used when necessary to control the spread of infections and should be the least restrictive as possible to the resident. The current interpretative guidelines contain language about using the least restrictive approach possible that adequately protects both the resident and others and that maintaining isolation longer than necessary my adversely affect the resident's psychosocial well-being, We also agree that there should be more detailed requirements for isolation in the regulatory text. Thus, in this final rule we have modified the text of § 483.80(a)(2)(iv) to read: ''When and how isolation should be used for a resident, including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) that the type and duration of the isolation should be the least restrictive possible for the resident under the circumstances.''

Infection Prevention and Control Officer (IPCO)/Infection Preventionist (IP)

*Comment:* Some commenters were concerned about the requirement for an IPCO. They question whether the requirement was even viable, particularly in areas that already lack adequate numbers of registered nurses. They indicated that for many locations, particularly rural areas, individuals with this expertise are simply not available. The commenter also expressed concern that the requirement was mandating structure instead of focusing on process expectations, which left little to no opportunity to accomplish the objectives of infection prevention and control through means other than those prescribed by the structure-related regulation.

*Response:* We disagree with the commenters. We do not believe that requiring an IPCO is unrealistic. We believe it is necessary to have one or more individuals responsible for the infection control program in each facility. However, as discussed below, we have modified this requirement based upon other comments.

*Comment:* Some commenters recommended that the requirement for the IPCO, allow two or more individuals to be responsible for the IPCP. Another commenter noted that the director of nursing (DoN) is often the part-time infection prevention and control officer for the facility. When the DoN is unavailable because he or she is on vacation or busy with other responsibilities, there is no one to address the infection prevention and control responsibilities. The commenter recommended that we not allow the DoN to be the primary IP.

*Response:* After reviewing the comments, we agree that LTC facilities should have the flexibility to determine if more than one individual should be designated to be responsible for the facility's IPCP. We also believe that LTC facilities should ensure coverage whenever the designated IP(s) is unavailable. However, we disagree with the commenter that recommended that we prohibit the DoN from being an IP. We believe that each facility should have the flexibility to determine how their facility should comply with the requirements in this final rule, including which individuals should be designated as the IP(s). Therefore, we have modified the requirements at proposed § 483.80(b) to allow for more than one individual to be responsible for the IPCP and be the designated IP.

*Comment:* Some commenters argued that the requirement for the IPCO was inconsistent with our assertion in the proposed rule, ''[w]e considered prescriptive approaches, such as requiring specific numbers and types of staff . . .'', but instead decided on a ''competency-based approach.'' The commenters recommended that a more reasonable approach that would be to provide detailed standards for the infection control activities and procedures, and then allow LTC facilities to make the determination as to whether the individual responsible for this function possesses the competency and expertise to function effectively in the role to accomplish the defined processes.

*Response:* We disagree with the commenters. The language referenced by the commenters in the proposed rule (80 FR 42175) is located under our discussion of the facility assessment and competency based approach taken in the proposed rule and finalized in this rule. It pertains to the approach we have taken towards staffing. We noted in the proposed rule that we wanted to ensure that our requirements would ''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'' (80 FR 42175). However, regardless of the facility assessment, each LTC facility must have an IPCP. As we said in the proposed rule, ''[w]hile all staff should be responsible for infection prevention and control, we agree with the SHEA/APIC guidelines that establish that an effective IPCP should have a designated IPCO for whom implementation and management of the IPCP is a major responsibility'' (80 FR 42216). As discussed above, we are not finalizing ''major'' to describe the IP's responsibility due to the burden it would impose on nursing facilities. However, we continue to believe that it is essential at least one individual be designated the IP for each LTC facility. In addition, we have modified this final rule so that LTC facilities can designate more than one individual as an ICPO. Thus, requiring that at least one individual be responsible for the IPCP is consistent with the facility assessment and competency-based approach in this final rule.

*Comment:* Commenters disagreed with using the term ''officer'' for the infection prevention and control officer (IPCO). The commenter said that officer was ill-defined and its rationale is unclear. The commenter recommended that the term ''coordinator'' or infection prevention and control coordinator (IPCC).

*Response:* We understand that different terms are used to identify the individual or individuals who are responsible for the facility's infection control program. For example, in Appendix A-Survey Protocol, Regulation and Interpretive Guidance for Hospitals, (Rev.151,11–20–15), it states that the individual(s) ''responsible for the infection control program may be called a hospital epidemiologists (HEs),'' ''infection control professionals (ICPs)'' or ''infection preventionists (IPs).'' In the Appendix PP-Guidance to Surveyors for Long Term Care Facilities in the SOM, accessed on January 28, 2016), the interpretative guidelines refer to an ''infection Preventionist (IP)'' or an ''infection control professional (ICP)''. Regardless of the title used by the facility, we are referring to the individual who is responsible for the facility's IPCP. However, to prevent any confusion, we have modified this final rule to use the term ''infection preventionist'' or IP. Therefore, there must be at least one individual who is responsible for the facility's infection control program.

*Comment:* Some commenters were concerned about the qualifications for the ICP. Some commenters asked who would be included in the term ''clinician'' and asked that it be defined. Other commenters were concerned about the requirement that the IPCO

(now IP) to have specialized training in infection prevention and control beyond their initial professional degree. One commenter noted that APIC provides specialized training in infection prevention and control and also provides the opportunity for individuals to become certified. Some were unsure what training would qualify, while others believed it would difficult for facilities to find qualified staff with this training or get the training for their staff due to availability or cost.

*Response:* We understand that there is a substantial amount of concern and confusion about the qualifications for the IP. We also understand that many LTC facilities currently have individuals who are responsible for infection control who might not qualify under the proposed requirements, but who have been performing their duties exceptionally well. These individuals may have obtained their knowledge through training at the facility or other experience. Thus, we have modified the requirements to allow for flexibility and for individuals with a broader range of experience to be a qualified IP. Specifically, we have removed the term ''clinician'' and instead provide at § 483.80(b) that the IP's primary professional training must be in nursing, medical technology, microbiology, or epidemiology, or other related field and that IPs can be qualified by education, training, experience or certification.

*Comment:* Commenters supported the requirement for a LTC facility to designate an IP for whom the IPCP is their major responsibility and who serves as a member for the facility's QAA committee. However, other commenters argued that it is unrealistic to specify that the IPCP must be a ''major responsibility'' for the IP and that this requirement was unclear. The commenter said that this could easily be interpreted as 0.50 FTE or more. This lack of clarity will lead to confusion and inconsistencies for providers and surveyors, resulting in technical misunderstandings that will undermine the intent of the requirement. One commenter pointed out that the hospital CoPs do not require the IPCP as a major responsibility of the IP or require the IP to have specialized training in infection prevention and control. The commenter recommended that the word ''major'' not be finalized. If the requirement is finalized, the meanings of ''major responsibility'' and ''specialized training'' should be clarified. However, other commenters wanted the requirement strengthened by changing ''major'' to ''primary'' responsibility.

*Response:* Depending upon the facility, we understand that there is a substantial variation in the amount resources required for the IPCP, especially the amount of time the IP needs to devote to those responsibilities. For some facilities, especially small and rural LTC facilities, it may not be feasible or even necessary to have one staff person devote a substantial amount of their time to the IPCP or have it be their primary responsibility. Hence, we have modified the requirement for the IP by removing the language at § 483.80(b) indicating the IPCP must be a major responsibility for the IP. However, we expect that each facility will review their facility assessment they conducted according to § 483.70(e) to determine the resources it needs for its IPCP and ensure that those resources are provided for the IPCP to be effective. In addition, we are finalizing the requirement that the IP work at the facility at least part-time.

*Comment:* One commenter questioned whether the reference in proposed § 483.80(a)(1) to § 483.75(e) should be § 483.70(e).

*Response:* We would like to thank the commenter for pointing out this discrepancy in the reference. Yes, the reference should be to § 483.70(e). We have inserted the correct reference to that section in this final rule.

Influenza and Pneumococcal Immunizations

*Comment:* Some commenters disagreed with many of the requirements related to influenza and pneumococcal immunizations. They noted, among other things, that no justification had been provided for a different process for immunizations in LTC facilities as compared to other healthcare facilities and that it was unclear why these particular vaccines should have these detailed requirements when other vaccines may have higher side effects. They also noted that the requirements did not recognize electronic medical records (EMRs). They noted that specifying the date ranges is not consistent with good public health practices and that the level of detail makes it more difficult to modify or update standards. The commenter recommended that most of the section be removed and that the facility should be required to develop policies and procedures to ensure that all residents and employees with direct patient care contact be offered and receive the influenza vaccine, unless they decline, per CDC guidance and that all residents be offered and receive the pneumococcal vaccine, unless they decline, per CDC guidance. Other commenters expressed concerns about the recommended dates for immunizations since this may change or vary in different regions. The commenter saw no valid reason to be so prescriptive about the exact date range and stated that doing so may make the regulations obsolete in the future. One commenter agreed with informing residents and/or their representatives about influenza and pneumococcal immunizations. However, since it is impossible to identify or judge whether they were sufficiently ''educated,'' the commenter recommended that the wording be changed.

*Response:* We disagree with the commenters. As we explained in the proposed rule, we reorganized the requirements for influenza and pneumococcal immunizations for their previous location at § 483.25(n) to where it is now finalized, § 483.80(d). With few exceptions, it is the identical requirement. We eliminated the exception that was set out at § 483.25(v), which provided that based on an assessment and practitioner recommendation, a second pneumococcal immunization could be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization because this was no longer the standard of care (80 FR 42216). We replaced the term ''legal representative'' with ''resident's representative'' because we believe it is a broader term and encompasses individuals whom the resident has personally identified as their representative (80 FR 42216 through 42217). We believe that reorganizing this requirement to the infection control requirement was appropriate. According to the CDC, a vaccine is a product that stimulates the immune system to produce immunity to a specific disease (Immunization: The Basics, located at *http://www.cdc.gov/vaccines/vac-gen/imz-basics.htm, accessed on January 26, 2016*). Based upon our experience with LTC facilities, these immunizations are generally given by nursing personnel. Therefore, we believe that the infection control section is the most appropriate place for the requirements related to influenza and pneumococcal immunizations.

Concerning the other comments on requirements for the pneumonia and pneumococcal immunizations, we did not propose any changes to these requirements. Influenza and pneumococcal immunizations are crucial for the resident populations. Due to the higher morbidity and mortality rates, we believe it is crucial that these immunizations be offered to the resident

population. Thus, we believe it is appropriate to specifically address these immunizations in these requirements. We also believe that the details, including dates and documentation, are also necessary to ensure appropriate immunizations for the residents. Although EHRs are not specifically addressed in this requirement, we do discuss health IT in other sections of this final rule. We expect that LTC facilities that use EHRs will include documentation concerning immunizations in those EHRs, as LTC facilities that use paper charts are expected to include the immunization documentation in the paper record. We have decided to retain the wording about ''education'' in the requirement. We believe further details concerning this requirement are best addressed in sub-regulatory guidance, which we will be producing for this final rule after it is published.

Implementation

*Comment:* One commenter recommended that LTC facilities be allowed a minimum of two and up to three years to meet the requirements for a healthcare professional with additional training to serve as an IP and that there be a waiver process when the facility can not comply when due diligence has been followed but such a person is not available. They also recommend a minimum of two years and up to three years for a LTC facility to fully develop and implement the IPCP.

*Response:* We understand that for some facilities, especially the smaller and rural LTC facilities, coming into compliance with the infection control requirements in this final rule may require an extended period of time. We are finalizing a phased in delay of the implementation date for these requirements. We refer readers to Section II. B for a detailed discussion regarding the implementation deadline for these specific requirements.

Costs

*Comment:* Commenters pointed out that the proposed infection control requirements, especially those concerning the IP, are unnecessary and will increase costs.

*Response:* We agree that coming into compliance with the infection control requirements in this final rule will require additional resources for many facilities. However, we have modified the requirements for the IP, now the infection control professional or ICP, which we believe will decrease the burden associated with this provision and address many of the commenters' concerns related to increased costs.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified § 483.80(a)(1) by changing the reference from § 483.75(e) to § 483.70(e).
- We have modified § 483.80(a)(2)(iv) by inserting after, ''[w]hen and how isolation should be used for a resident,'' the following language, ''including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and a requirement that the isolation should be the least restrictive possible for the resident under the circumstances.''
- We have modified § 483.80(b) to change the infection prevention and control officer (IPCO) to an infection preventionist (IP).
- We have modified § 483.80(b) to allow LTC facilities to designate more than one IP.
- We have modified § 483.80(b)(1) and (2) to establish that IPs 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.
- We have modified § 483.80(b) by removing the requirement that the IPCP be a major responsibility for the IP.

*X. Compliance and Ethics Program (§ 483.85)*

As noted previously, section 6102 of the Affordable Care Act amended the Act by adding new section 1128I. Subsection 1128I(b) of the Act requires the operating organizations for SNFs and NFs to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care consistent with regulations developed by the Secretary. In the proposed rule we included a robust discussion regarding several industry-specific guidance documents on compliance issued by the DHHS OIG. In addition, we also included a detailed discussion regarding a September 23, 2010 proposed rule entitled, ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,'' in the **Federal Register** (75 FR 58204), to which we received feedback through public comment regarding compliance program requirements that are required by both sections 6102 and 6401(a) of the Affordable Care Act. We encourage readers to review the proposed rule for this background information.

Proposed § 483.85(a) and § 483.85(b)

At § 483.85(a), we proposed to define the terms ''compliance and ethics program,'' ''high-level personnel'', and ''operating organization.'' We proposed to define ''compliance and ethics program'' to mean with respect to a facility, a program of the operating organization that has been reasonably designed, implemented, and enforced so that it is effective in preventing and detecting criminal, civil, and administrative violations under the Act, and in promoting quality of care; and includes, at a minimum, the required components specified in § 483.85(c). We did not propose using the term ''managing employee'' that is contained in the current LTC facility requirements, but rather proposed to retain the use of the term ''high-level personnel'', which is used in the Affordable Care Act. We proposed to define ''high-level personnel'' as individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization. We indicated that the individuals considered ''high-level personnel'' will differ according to each operating organization's structure. However, some examples include, but are not limited to, the following: (1) A director; (2) an executive officer; (3) an individual in charge of a major business or functional unit; and (4) an individual with a substantial ownership interest as defined in section 1124(a)(3) of the Act in the operating organization.

We also proposed to define ''operating organization'' to mean the individual(s) or entity that operates a facility. Section 1128I(b)(1) of the Act defines an ''operating organization'' as ''the entity that operates the facility.'' Although many LTC facilities are part of corporate chains, there are still some LTC facilities that are owned by an individual or a small group of individuals. Therefore, we proposed to add ''individual(s)'' to the definition to make it clear that all LTC facilities, regardless of their legal structure, are required to comply with these requirements.

In § 483.85(b), we proposed that the operating organization for each facility must have in operation a compliance and ethics program (as defined in § 483.85(a)) that meets the requirements of this section beginning on the date

that is one year after the rule's effective date.

Proposed § 483.85(c)

In § 483.85(c), we proposed that the operating organization for each facility be required to develop, implement, and maintain an effective compliance and ethics program that contains at a minimum several components. First, at § 485.85(c)(1) we proposed that the operating organization must establish written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Second at § 483.85(c)(2), we proposed that the operating organization must assign specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization (proposed § 483.85(c)(2)). At § 483.85(c)(2), we proposed that the program must include provisions ensuring that the specific individuals designated with oversight responsibility in proposed § 483.85(c)(2) have sufficient resources and authority to assure compliance with these standards, policies, and procedures.

Next at § 483.85(c)(4), we proposed that the operating organization is required to use due care not to delegate discretionary authority to individuals whom the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, or administrative violations under the Act.

We also proposed at § 483.85(c)(5) that the operating organization be required to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff including individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training or orientation programs, and/or dissemination of information that explained in a practical manner what was required under the program.

Next at § 483.85(c)(6), we proposed that the compliance program must ensure that reasonable steps were being taken to achieve compliance with the program's standards, policies, and procedures, such as utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retaliation, and having a process for ensuring the integrity of any reported data. We also proposed at § 483.85(c)(6) that the operating organization be required to enforce consistently the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the appropriate party identified in the operating organization's compliance and ethics program. We proposed that an operating organization is required to consistently enforce its standards and procedures through appropriate disciplinary mechanisms.

Lastly, at § 483.85(c)(8) we proposed that after an operating organization detected a violation, it must ensure that all reasonable steps identified in its program were taken to respond appropriately to the violation and, to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act. We noted in the proposed rule that in sections 1128I(b)(3)(F) and (G) of the Act, which correspond to § 483.85(c)(7) and (8), the term ''offense,'' is used instead of ''violation'' and that the previously described components are mandatory for all of the SNF and NF operating organizations' compliance and ethics programs.

Proposed § 483.85(d)

At § 483.85(d), we proposed to require operating organizations that operate five or more facilities to designate a compliance officer, and require that such individuals be designated as high-level personnel of the operating organizations with the overall responsibility to oversee the compliance and ethics program. In addition, the designated compliance officer must report directly to the governing body for the operating organization. We also proposed that all operating organizations designate a compliance and ethics program contact.

In addition at § 483.85(d), we proposed that operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

- A mandatory annual training program on the operating organization's compliance and ethics program (§ 483.85(d)(1)).
- A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility (§ 483.85(d)(2)).
- Designated compliance liaisons located at each of the operating organization's facilities (§ 483.95(d)(3)).

Proposed § 483.85(e)

Lastly, at § 483.85(e), we proposed that the operating organization for each facility must review its compliance and ethics program annually, and revise its program, as needed to reflect changes in all applicable laws or regulations and within its organization and facilities to improve its performance in deterring, reducing, and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care.

General Comments

*Comment:* Some commenters were very supportive of the proposed requirements for compliance and ethics programs, especially the components that are required for all facilities. Some commenters also appreciated the recognition of the different levels of resources that were available to smaller and larger operating organizations to develop, implement, and maintain compliance and ethics programs.

*Response:* We thank the commenters for their support. We do recognize that there would be varying levels of resources available to smaller and larger organizations. Although the requirements for compliance and ethics programs finalized in this rule go to all operating organizations. with additional requirements for those with five or more

facilities, we would expect that all operating organizations would also use the facility assessment they developed according to § 483.70(e) in developing and maintaining their programs. For example, the operating organization must provide, among other things, sufficient resources to reasonably assure compliance with the program's standards, policies, and procedures (§ 483.85(c)(3)). In addition, operating organizations must also take steps to effectively communicate the standards, policies, and procedures of its program to its entire staff, individuals providing services under contractual arrangements; and volunteers, consistent with their expected roles (§ 483.85(c)(5)). This can be accomplished by mandatory training, orientation programs, or disseminating information that explains in a practical manner what is required under the operating organization's program (§ 483.95(f)). Operating organizations should use the facility assessment to determine the resources they need to devote to their compliance and ethics programs to reasonably assure compliance with the requirements finalized in this rule.

*Comment:* Some commenters supported the proposed requirements, but also recommended certain individuals who they believed should be involved in developing and maintaining the facility's compliance and ethics program. Some commenters said that professional social workers, who are guided by the National Association of Social Work (NASW) *Code of Ethics* (2008), would be well equipped to contribute to and help to lead such programs.

*Response:* We appreciate the commenters support for the proposed requirements. We also agree that social workers could play an important role in compliance and ethics programs. However, not all LTC facilities are required to have a full-time social worker on staff so we cannot require that a social worker be involved in developing, implementing, and maintaining these programs. We also believe that each facility needs the flexibility to determine how it will comply with the requirements finalized in this final rule, including choosing the individuals who will be involved in compliance and ethics programs.

*Comment:* Some commenters noted there were definitions for some terms used in proposed § 483.85, including ''compliance and ethics program'', ''high-level personnel'', and ''operating organization''; however, there was no definition for ''reasonable'' or ''reasonably''. They also noted that CMS did ask for comments on how to evaluate ''reasonableness'' in the proposed rule (80 FR 42221). The commenters supported our statement that ''reasonableness'' may depend on the applicable facts and circumstances. Some commenters also recommended that the term ''reasonable'' be defined and that we use the Black's Law Dictionary definition of ''reasonable person'' as it is often used in other areas of the law, such as, an ordinary person who exercises care while avoiding extremes of boldness and carefulness.

*Response:* We do believe that reasonableness depends upon the applicable facts and circumstances surrounding any particular situation. As stated in the July 16, 2015 proposed rule (80 FR 42168), the terms ''reasonable'' and ''reasonably'' were used in the section 6102 of the ACA and consequently used in proposed § 483.85(c)(1), (6), and (8). We did not propose a definition of these terms in the proposed rule, but did state that ''[w]e would appreciate comments on how to evaluate the reasonableness of the design, implementation, and enforcement of an operating organization's compliance and ethics program and how to determine the reasonableness of the steps an operating organization has taken to achieve compliance with its standards and the steps an operating organization should take in response to offenses and prevent similar occurrences (80 FR 42221). We will not be finalizing a definition of ''reasonable'' or ''reasonably'' in this rule. However, we will be publishing further sub-regulatory guidance on how to determine reasonableness for these requirements''.

*Comment:* Some commenters were concerned about including contractual staff and volunteers in some of the requirements. Specifically, proposed § 483.85(c)(1), (5), and (6) that state that LTC facilities must establish ''disciplinary standards,'' communicate ''the standards, policies, procedures . . . includ[ing] . . . mandatory participation in training or orientation programs and/or dissemination of information,'' and ''ensure that reasonable steps were being taken to achieve compliance'' by the facility's staff, and ''individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.'' They argued that it would not be a good use of the facility's time and resources and that some LTC facilities could find it burdensome to train and orient contractor staff and volunteers to their compliance and ethics program. It should be the contractor that it responsible for training the contract staff and the LTC facility should only be responsible for orienting the contract staff to the nuances in their program. In addition, they argued that training for these individuals could be inconsistent with the best practices that are currently in place for LTC facilities, which is to educate contractors or volunteers about the facility's compliance program, seven core elements of an effective compliance program, code of conduct, reporting processes (hot line numbers and other alternative reporting mechanisms) and correction processes by furnishing written materials to contractors or volunteers to review and having them attest to reviewing the materials. The contracting agency should be discussing compliance and ethics matters with their employees and this is often covered in their contracts with the LTC facilities. It should be understood that the LTC facility would be responsible for orienting contractual staff to the individual nuances of the compliance and ethics program for the facility. The commenters recommended that LTC facilities not be required to provide full training and education to volunteers and contractor agency personnel but that the facilities be required to provide these individuals with an overview of their programs.

*Response:* For any operating organization's compliance and ethics program to be effective, it is crucial that all of the organization's staff, including those who are providing services under contract, and volunteers, consistent with their roles, need to understand the standards, policies and procedures for that program. If these individuals do not understand the program's requirements and their responsibilities under that program, they will not be able to comply appropriately and that will severely reduce, or perhaps eliminate, the effectiveness of the program. Operating organizations with four or less facilities ''must effectively communicate'' to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. It could be formal training, but they could also comply with this requirement through dissemination of materials, as the commenters noted above. For operating organizations with five or more facilities, annual training is required. However, these requirements do not specify how the training or dissemination of information is to be performed. Further, as set forth in § 483.95, it states that ''[a] facility must determine the amount and types of

training necessary based on a facility assessment as specified at § 483.70(e).'' We believe that each operating organization needs to have the flexibility to determine the best way for each of them to comply with this requirement and this final rule provides them that flexibility to determine what kind of dissemination of information or training they need to provide. In addition, it is the training or dissemination of the information that is crucial. For example, the operating organization could choose to arrange with the contractor to have the contractor provide the required training or dissemination of information for the compliance and ethics program as some commenters indicated happens today.

*Comment:* Some commenters recommended that LTC facilities be required to integrate the information from the compliance program into the facility's QAPI program. The commenters believed that compliance must be coordinated into the current ongoing activities so that the primary focus remains on doing the right thing in the right way routinely, and on proper clinical reasoning and problem solving, with regulatory and legal compliance always kept in mind but not as a separate or predominant activity. They were concerned that an excessive or separate focus on compliance could potentially result in clinically questionable activities in the name of ''compliance'' that could be inconsistent with desirable care approaches.

*Response:* We agree that the information and data obtained through the facility's compliance and ethics program should be integrated into the facility's QAPI program. However, the QAPI requirements finalized in this rule already provide for this integration. The facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility and must address, among other things, all of the systems of care and management practices (§ 483.75(b)(1)). In addition, each facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring (§ 483.75(c)). Also, the QAA committee must regularly review and analyze data and act on available data to make improvements (§ 483.75(g)((2)(iii)). Thus, LTC facilities should be integrating the information and data they collect or arises out of their compliance and ethics programs into their QAPI program.

The requirements for compliance and ethics and the QAPI programs should work together or be coordinated to not only ensure compliance with the requirements in this final rule but also improvements in the quality of care provided to the residents. Also, we do not believe this will result in an excessive or separate focus on compliance or result in negative consequences to the residents, staff, or facility.

Additional Requirements for Operating Organizations With Five or More Facilities

*Comment:* Some commenters were concerned that our proposal for additional requirements for operating organizations with five or more facilities was imposing additional requirements on certain operating organizations based upon an arbitrary number of facilities. Some commenters recommended that only operating organizations with 15 or more facilities be required to comply with the additional requirements.

*Response:* We proposed additional requirements for operating organizations with five or more facilities, because section 1128I(b)(2)(B) of the Act, as added by section 6102 of the ACA (Pub. L. 111–148 (2010), states that ''with respect to specific elements or formality of a program, in the case of an organization that operates 5 or more facilities, vary with the size of the organization.'' Since the statutory language specifically indicates that the compliance and ethics programs for operating organizations with five or more facilities should be a more formal program or have more elements, we will be not finalize § 483.85(d) to apply to operating organizations with 15 or more facilities. Hence, we have finalized that section so that the additional requirements apply to operating organizations that have five or more facilities.

*Comment:* Other commenters were very supportive of the proposed additional requirements for operating organizations with five or more facilities as set forth in § 483.85(d): Mandatory annual training programs on the operating organizations' compliance and ethics programs that meet the requirements set forth in § 483.95(f); designated compliance officers for whom their operating organization's compliance and ethics program is a major responsibility; and designated compliance liaisons located at each of the operating organization's facilities.'' These commenters recommended that all operating organizations, regardless of size, be required to comply with these additional requirements.

*Response:* We appreciate the commenters support for these additional requirements. However, in developing requirements, we must balance the necessity of the requirement for the health and safety of the residents with the burden of that requirement to the operating organization. We believe that the additional requirements are necessary for larger operating organizations to develop and maintain effective compliance and ethics programs. Larger organizations will generally be caring for more residents and have more locations for which they are responsible. We believe this requires that the larger operating organizations have a compliance officer. Since that compliance officer will be responsible for the organization's program at five or more facilities, we believe he or she will need someone at each facility, the compliance liaison, to assist them with the program at each facility. In addition, considering the number of facilities, we believe this requires annual training to ensure that all staff, including those who are providing services under a contract and volunteers, consistent with their roles, are knowledgeable about the operating organization's program and how they are expected to comply with its standards, policies, and procedures. For operating organizations with four or fewer facilities, we believe they can develop and maintain a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act as required by section 1128I(b)(1) of the Act without the additional requirements for larger operating organizations. However, we would encourage operating organizations with four or fewer facilities to incorporate these additional elements if their facility assessments indicate that they are necessary to ensure that their compliance and ethics programs are effective. Thus, we will not be extending the addition requirements set forth in § 483.85(d) to all operating organizations.

*Comment:* Some commenters were concerned about the requirement for designated compliance liaisons at each facility for operating organizations with five or more facilities (§ 483.85(d)(3)). They did not believe it was good policy to appoint someone at each facility who does not have the critical experience, education, or knowledge of a compliance officer. It is also not feasible to expect that each facility could hire someone with the background or expertise to be a compliance officer in the operating organization's compliance and ethics program.

*Response:* Compliance liaisons are not compliance officers. In the proposed rule, we did not define ''designated compliance liaison'' but stated that

''[w]e would expect that operating organizations would develop a description for these positions and the duties and responsibilities these individuals would have in the operating organization's compliance and ethics program . . . [a]t a minimum, these liaisons should be responsible for assisting the compliance officer with his or her duties under the operating organization's program at their individual facilities'' (80 FR 42220). We believe that each operating organization needs the flexibility to determine what the qualifications, duties, and responsibilities that these compliance and ethics program liaisons should have in their organization. Thus, it is the operating organization with five or more facilities that will develop its own definition for the position of ''designated compliance liaison'' and determine the qualifications, duties, and responsibilities for the individuals in this position.

*Comment:* Some commenters noted that compliance officers could not to be subordinate to the general counsel (GC), chief financial officer (CFO) or chief operating officer (COO) in proposed § 483.85(d)(2). They were very supportive and noted that in many large organizations the GC is the compliance officer and is often the best qualified to address potential legal violations and other areas of concern. In addition, the commenters noted that in many mid-sized organizations the GC, CFO, or COO is the compliance officer because the organization cannot financially support a full-time compliance officer. Some commenters recommended that we insert a sentence that specifically indicates that the GC, CFO, or COO may serve as the compliance officer. Other commenters recommended that the compliance officer also not be subordinate to the facility's chief executive officer (CEO) or the administrator.

*Response:* We agree with the commenters that it is very important that the compliance officer not be subordinate to certain individuals in the operating organization. We agree that the compliance officer should also not be subordinate to an administrator; however, we believe that the compliance officer would be within the operating organization's staff and not located at an individual facility to avoid any interference or influence of the compliance officer by an administer. We do not agree that the compliance officer could not be subordinate to the CEO, who is generally the highest ranking officer in an operating organization. For these reasons, we did not propose that the compliance officer could not be subordinate to the CEO or an administrator. The compliance officer must be able to communicate with the governing body without being subject to any coercion or intimidation. This is why we proposed § 483.85(d)(2) that states that the compliance officer must be able to report directly to the governing body. Thus, we have finalized § 483.85(d)(2) as proposed. We believe any further detail on who can and cannot serve as the compliance officer should be provided in the sub-regulatory guidance for this requirement. We refer facilities to additional guidance the OIG has published for nursing home compliance programs, ''OIG Supplemental Compliance Program Guidance for Nursing Facilities'' (73 Fr 56832) (*https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf*).

Implementation and Costs

*Comment:* Some commenters were concerned about the 1-year timeframe for implementation of the compliance and ethics programs. Commenters wanted at least 2 years for LTC facilities to develop their compliance and ethics programs. They based the 2 years on both the statutory language in ACA that stated that the Secretary had 2 years to promulgate regulations for compliance and ethics programs and to allow adequate time to change and adjust current compliance and ethics programs allow adequate time to change and adjust current processes and procedures and to reconfigure facility budgets.

*Response:* We appreciate the commenters' concerns about the implementation of the requirements for compliance and ethics programs. We are finalizing a phased in delay of the implementation dates for this final rule. We refer readers to Section II.B. for a detailed discussion regarding the implementation deadlines for these requirements. The estimated costs for complying with these requirements are discussed in sections V. Collection of Information Requirements and VI. Regulatory Impact Analysis (RIA).

*Comment:* Some commenters believed that the requirements for the compliance and ethics program were unduly prescriptive and costly and could impose an unnecessarily onerous burden on some LTC facilities. However, some of these commenters also indicated that a major organization for long-term care facilities had already been educating its membership on the requirements in ACA for compliance and ethics program in LTC facilities and had educational tools on its Web site.

*Response:* Section 6102 of the ACA mandated compliance and ethics programs in LTC facilities. Hence, these are not discretionary requirements. In developing these regulations, we have established the requirements contained in the ACA and have been mindful of the burden which will be required to comply with these requirements. In finalizing these requirements, we strived to avoid not only any unnecessary burden but also to provide maximum flexibility for operating organizations to comply with the requirements established in ACA.

Surveys

*Comment:* Some commenters were concerned about how the LTC facilities would be surveyed for the compliance and ethics program requirements. Some commenters wanted a tangible observational process established for the surveyors, which would validate that facilities are providing compliance and ethics policies and procedures to the staff and that governing bodies are implementing those policies and procedures.

*Response:* We understand that commenters have concerns about how surveyors would determine compliance with these requirements. As discussed above, we will be developing and publishing or disseminating sub-regulatory guidance, including interpretative guidelines (IGs), before surveyors begin to survey LTC facilities for these requirements. That guidance will provide the detailed information surveyors need to determine compliance with these requirements.

After consideration of the comments we received on the proposed rule, we are finalizing the requirements as proposed.

*Y. Physical Environment (§ 483.90)*

In the proposed rule we indicated that the facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public. Many of these provisions relate to Life Safety Code (LSC) requirements. We recently published a final rule which adopts many provisions of the 2012 LSC ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,'' (81 FR 26871, May 4, 2016). As part of our comprehensive review and restructuring, we re-designate the existing provisions of § 483.70 as new § 483.90; however, the language in existing § 483.70(a) ''Life safety from fire'' and § 483.70(b) ''Emergency power'' are unchanged, including new provisions related to the requirement that long term care

facilities have automatic sprinkler systems added by the final rule ''Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, Part II'' published in the **Federal Register** on May 12, 2014 (79 FR 27106).

In § 483.90(c) ''Space and equipment'', we proposed to add the resident's individual assessment, including preferences and choices, as an element to consider in addition to the resident's plan of care when considering the space and equipment requirements of the facility. We proposed to eliminate the word ''essential'' from § 483.90(c)(2) (re-designated from § 483.70(c)(2)). In addition, we proposed to add a new § 483.90(c)(3) to specifically require that facilities conduct regular inspections of all bed frames, mattresses, and bed rails and to ensure that bed rails are compatible with the bed frame and mattress.

Currently, in existing § 483.70(d), the regulations allow for bedrooms that accommodate up to four residents. We proposed to require at § 483.90(d)(1)(i) that bedrooms in facilities accommodate not more than two residents unless the facility is currently certified to participate in Medicare and/or Medicaid or has received approval of construction or reconstruction plans by state and local authorities prior to the effective date of this regulation. We indicated in the proposed rule that reconstruction means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified. We also proposed to require that the bed size and height be not only convenient for the resident's needs, but also safe.

Section 483.70(e) currently requires that each bedroom be equipped with or located near toilet and bathing facilities. We proposed at § 483.90(e) to add the requirement that, for facilities that receive approval of construction or reconstruction plans by state and local authorities or are newly certified to participate in Medicare and/or Medicaid after the effective date of this rule, each resident room must have its own bathroom equipped with at least a toilet, sink and shower. In addition, we proposed that if a facility undergoes reconstruction, each resident room in the reconstructed space must have its own bathroom equipped with at least a toilet, sink and shower. We indicated in the proposed rule that reconstruction means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified.

At § 483.90(f) (proposed to be re-designated from § 483.70(f)), a resident call system is required. We proposed to revise this revision and require that the facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from the resident's bedside, toilet and bathing facilities.

At § 483.90(g) (proposed to be re-designated from § 483.70(g)) we address dining and activity rooms and include a requirement to designate non-smoking areas. We proposed to eliminate the language ''with non-smoking areas identified''.

We also proposed to add a new paragraph at § 483.90(h)(5) to require facilities to establish policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety, including but not limited to non-smoking residents.

*Comment:* One commenter asked that we adopt the 2012 Life Safety Code.

*Response:* This concern has been addressed through separate rule-making. As noted above, we published the final rule, ''Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities,'' which would adopt many provisions of the 2012 LSC on May 4, 2016 (81 FR 26871).

*Comment:* Some commenters recommended that CMS consider adopting the ''Guidelines for Design and Construction of Residential Health Care and Support Facilities,'' produced by the Facilities Guidelines Institute, in addition to and in the same manner as we currently adopt the Life Safety Code.

*Response:* We thank the commenters for their suggestion. We will evaluate this suggestion further and consider it for future rulemaking.

*Comment:* Some commenters disagreed with our proposed requirement regarding bed rails. One stated that their facility already had a process in place and this would require an additional inspection that would take away from their ability to complete other maintenance tasks. Another stated that our requirements were inadequate given the risks posed by bed rails, citing concerns about the availability of manufacturer information and guidance. One commenter recommended strengthening our requirements including adding additional detailed requirements, especially to safeguard against entrapment.

*Response:* We agree that resident safety in important when considering the use of bed rails. However, detailed guidance regarding the use of bed rails is more appropriate in interpretive guidance. As noted in the proposed rule, additional resources are available at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default.htm.* If a facility already conducts regular inspections of all bed frames, mattresses, and bed rails, no new process would be required as long as the requirements at § 483.25(n) and § 483.90(c) were met. If a facility was unable to identify a manufacturer and access manufacturer information and guidance for bed rails that they used, they would not be meeting requirements to follow the manufacturers' recommendations and specifications for installing and maintaining bed rails set forth in § 483.25(n)(4).

*Comment:* Several commenters supported our proposal to limit the number of residents in a room to two. Many suggested that the requirements do not go far enough. Several suggested that this requirement should apply to all facilities, not just newly constructed, certified, or renovated. Others suggested that private rooms should be the standard, with a few double rooms to accommodate couples or those desiring a roommate. A few commenters objected to the requirement. Some commenters stated that this requirement was burdensome and would discourage new construction and renovation. Some commenters felt that this requirement should apply to new construction only and were concerned about the definition of reconstruction. One commenter stated that their facility had large rooms and putting an occupancy limit on all rooms regardless of considering the size of the rooms would be unreasonable.

*Response:* We have taken into account all of the comments received, both supportive comments and those pointing out concerns with our proposal to limit room occupancy only in newly constructed, reconstructed, or newly certified facilities and considered multiple alternatives. We believe that semi-private rooms are far more supportive of privacy and dignity. We recognize that for many residents, a private room would be ideal. However, for others, a spouse or other roommate is desirable. We note that many states have physical environment requirements that exceed our requirements. These requirements vary widely, but many states include a

requirement for no more than two beds per resident room or establish a minimum percentage of rooms that must be private or semi-private. Individual facilities can choose to offer private rooms as well. However, as these regulations apply to every Medicare- and Medicaid- certified facility, we must also consider the potential for our requirements to discourage innovation, new construction, or reconstruction and to negatively impact access to care. Therefore, at this time, we believe our proposal represents an appropriate balance among the concerns voiced and we are finalizing this requirement as proposed. With regard to the definition of reconstruction, we have stated that this means that the facility undergoes reconfiguration of the space such that the space is not permitted to be occupied, or the entire building or an entire occupancy within the building, such as a wing of the building, is modified. We would clarify that, for reconstruction, the requirement applies to the reconstructed area, so that where reconstruction involves a limited area within a building, we would not expect the entire building to upgrade to the new requirements. This should not deter facilities from making needed renovations. We defer additional discussion to sub-regulatory guidance.

*Comment:* One commenter noted that residents benefit from being outdoors, not just in the facility. The commenter suggested that CMS should establish goals that help pave the way to more universal standards for facilities that are person-centered in all aspect, including physical environment that recognizes the needs of residents for privacy, dignity and personal choice and included should look to models such as Green House® to ''borrow'' as appropriate. Another commenter recommended that we include a requirement that the facility provide sufficient outdoor space that is accessible to residents and where residents can sit and move around as independently as possible.

*Response:* We thank the commenter for their suggestions. We agree that some residents may benefit from access to outdoor spaces. Such access, of course, must be balanced with safety and supervision concerns, which may vary significantly across resident populations. In addition, such requirements would need to be equally applicable to all long-term care facilities, whether urban, suburban, or rural, or small, medium, and large. We are aware of the Green House® and other models and will continue to evaluate these models and new innovations, including requirements for outdoor space, and consider their application in future rule-making.

*Comment:* A couple of commenters asked that we consider using terms other than ''toilet facilities'' or other terms that reflect an institutional mindset.

*Response:* We appreciate the comment and have modified language at § 483.90(e).

*Comment:* Several commenters objected to our proposal to include a shower, in addition to a toilet and sink, in rooms that are renovated, or newly constructed or certified after the effective date of the final regulation. A number of commenters suggested that not only would such showers be under-utilized, they would present a safety hazard. Some commenters raised, in particular, safety concerns related to residents with dementia having unsupervised access to a shower. One referred to a shower as ''costly, wasted space'' and another stated that ''it has been our experience . . . that current showers in private rooms go unused.'' Some commenters suggested this requirement should not apply to facilities being renovated, as this would discourage needed upgrades to facilities. A commenter suggested that building configuration and existing spaces would not be conducive to adding showers, given other square footage and code requirements applicable to resident spaces. Further, showers in these rooms would need to be of substantial size to accommodate specialized equipment when necessary, resulting in reduced living space for the resident. Some commenters suggested that construction costs may make this prohibitive for many companies to build new facilities, resulting in reduced construction at a time when additional facilities may be needed due to demographic factors or that such costs would create a disincentive to update and modernize resident rooms. Other commenters supported the inclusion of a shower for each resident room, stating that this would eliminate residents needing to go down the hall to a common bathing room. Another suggested that portable showers could serve the intended purpose but avoid some of the concerns that have been raised.

*Response:* We have taken into account all of the comments received, both supportive comments and those pointing out concerns with our proposal. We considered suggestions to require facilities to install safety features or special monitoring in bathrooms. We acknowledge concerns about safety as well as the disincentive for facility upgrades that our proposal could create, particularly in light of space requirements for a safe, effective shower. Given these concerns, at this time, we have decided to modify the proposed requirement at § 483.90(e) to require that resident rooms have a toilet and sink in facilities that receive approval of construction plans by state and local authorities or are newly certified to participate in Medicare and/or Medicaid after the effective date of this rule. Facilities continue to have the option to exceed our requirements, in keeping with the health, safety and quality of life of its residents.

*Comment:* Several commenters supported our proposal to require that each resident room must have its own commode and sink. Some commenters objected to our requirement that each room must have its own commode and sink. Several commenters stated that existing facilities are likely not to have adequate space to accommodate this requirement and believed that this would prevent facilities for undertaking renovations. One commenter asked if a bathroom shared between two resident rooms would be permissible.

*Response:* Our requirement states that each resident room must have its own bathroom. A shared bathroom would not meet this requirement. We have considered commenters concerns about cost and the lack of available space to add additional bathrooms deterring upgrades to existing facilities and have revised this requirement to apply only to facilities that receive approval of construction from State and local authorities or are newly certified after the effective date of this rule. Furthermore, we believe removing the requirement for each bathroom to include a shower substantially reduces the burden, both financial and in terms of space, that this requirement imposes on facilities subject to the heightened requirement.

*Comment:* One commenter asked that it be made clear that ''newly certified'' does not include facilities where there has been a change of ownership. Other commenters echoed similar concerns about certification after change of ownership.

*Response:* When facilities change ownership, the new owners have the option of accepting the existing provider agreement. In this case, the facility would not be ''newly certified.'' However, when a new owner does not accept the existing provider agreement, the facility does require a ''new certification'' and these requirements would apply. We considered explicitly exempting all changes of ownership from this requirement, however, there is the potential for significant abuse of

such an exemption and we believe that to do so is not appropriate.

*Comment:* One commenter objected to our inclusion of smoking cessation in proposed paragraph (h)(5). The commenter stated that while smoking cessation is a noble cause, it should not be required in every center's policies, particularly if a facility has adopted a policy for non-smoking. They further stated that smoking cessation programs are appropriate for some facilities but not for all. Finally, the commenter stated that the requirement, as written, was confusing and should also reference electronic cigarettes. Another commenter stated that smoking should not be considered a resident right and that accommodating smoking takes CNAs away from caring for residents.

*Response:* We appreciate the commenter's thoughtful suggestions. We have revised the provision to remove the reference to smoking cessation, and improve clarity. We did not at this time add electronic cigarettes, but will evaluate whether or not electronic cigarettes should be included in this provision in the future. We agree that a smoking cessation program may not be appropriate for some facilities, such as those facilities that are ''smoke-free.'' However, even ''smoke-free'' facilities may admit residents who smoke. Smoking cessation support should be offered to residents who smoke and addressed in their person centered plan of care. Smoking is not addressed as a resident right; rather, we require that facilities have policies and procedures to safeguard residents, whether smoking or non-smoking, if and where smoking occurs.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- We have modified our proposal at § 483.90(e) to require that, for facilities that receive approval of construction or are newly certified after the effective date of this final rule, each resident room must have its own bathroom with at least a commode and a sink.
- We have modified our proposal at § 483.90(h)(5) to state that facilities must establish policies in accordance with applicable Federal, State, and local laws and regulations regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

*Z. Training Requirements (§ 483.95)*

We proposed to add a new § 483.95 to subpart B which sets forth training requirements. We proposed that a facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. We also proposed that a facility be required to determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e).

We proposed at § 483.95(a) to include effective communications as a required training topic for direct care personnel. We did not propose to require a specific amount of time, specific communications topics, or specific training mechanisms to meet this requirement. We proposed at § 483.95(b) to require that facilities train staff members on the rights of the resident and the responsibilities of a LTC facility to properly care for its residents as set forth at § 483.10 and § 483.11, respectively. At § 483.95(c) we proposed to require that a facility provide training to its staff on the freedom from abuse, neglect, and exploitation requirements found in § 483.12. We proposed to specify that facilities must provide training to their staff that at a minimum educates staff on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property and procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.

At § 485.95(d), we proposed to require that a facility must provide mandatory QAPI training to its staff that outline the elements and goals of the facility's QAPI program. At § 483.95(e) we proposed to require LTC facilities to include staff training as part of their efforts to prevent and control infection. It would be the facility's responsibility to ensure that their staff was effectively educated on the facility's infection control policies and procedures.

At § 483.95(f)(1), we proposed that the operating organization for each facility must include as part of their compliance and ethics program training for staff that outlines the standards, policies, and procedures. We did not specify how a facility should develop this training; however we indicated in the proposed rule that the training must explain in a practical manner the requirements under the compliance and ethics program. In addition, at § 483.95(f)(2) we proposed to require that if the operating organization operates five or more facilities, it must include mandatory training annually.

Section 6121 of the Affordable Care Act added sections 1819(f)(2)(A)(i)(1) and 1919(f)(2)(A)(i)(1) of the Act. These sections require all NAs to receive on-going training in both dementia management and patient abuse prevention training, ''if the Secretary determines appropriate.'' We proposed to amend the LTC requirements by requiring that the current mandatory on-going training requirements for NAs include dementia management and resident abuse training.

We also proposed to relocate the training requirements for NAs at § 483.75(e)(8) to § 483.95(g). Specifically, we proposed to re-designate existing § 483.75(e)(8)(i), (ii), and (iii) to § 483.95(g)(1), (3), and (4), respectively. At § 483.95(g)(2), we proposed to add the new requirement that the 12 hours of annual in-service training for NAs must include dementia management and abuse prevention training. Also, at § 483.95(g)(3), we proposed to add to the existing requirement that the in-service training address areas of weakness as determined by a facility's assessment at § 483.70(e). In addition, current regulations at § 483.75(q) require facilities to only employ as a paid feeding assistant those individuals who have successfully completed a state approved training program, as specified in § 483.160. We proposed to relocate this provision without change to proposed § 483.95(h).

Lastly, we proposed at § 483.95(i) to require that facilities provide behavioral health training to its entire staff, based on the facility assessment at § 483.70(e). As required at § 483.70(e), we proposed that the facility be responsible for using their facility assessment to determine the behavioral health related needs of their residents. Then the facility must ensure that their staff is provided with behavioral health training that correlates with the needs of their residents.

*Comment:* Many commenters applauded the addition of the training section and the inclusion of the various required topics of training. Commenters noted that all trainings should be conducted in an environment that encourages participation and open discussion with the freedom to ask questions.

*Response:* We appreciate the feedback from commenters. We believe that requiring facilities to develop, implement, and maintain an effective training program for staff will help to prepare staff and improve outcomes. In addition, we believe that appropriately training staff can improve resident safety, create a more person-centered environment, and reduce the number of adverse events or other resident complications. We agree that training activities should encourage participation and allow for open dialogue among participants in order to

be productive. We encourage facilities to allow for this type of interaction and anticipate that the interpretive guidance to this regulation will further provide ideas and best practices for how to implement these training requirements.

*Comment:* While commenters supported the training topics named in the proposed rule, many commenters provided suggestions for additional topics to be required for all facility staff members who provide services directly to residents. Suggested topics included advance care planning, cultural competence, end-of-life care, geriatrics and gerontology, working with young and middle-aged adults, grief and loss, interdisciplinary collaboration, person-centered care, specialized rehabilitative therapy, and intellectual disability. In addition, one commenter recommended that the training section be expanded to require training on additional CMS requirements, such as resident choice and quality of life and care. One commenter indicated that staff should be educated on the aging process and have an understanding of how human beings change as they grow older.

*Response:* We appreciate the feedback from commenters. Given the volume of the proposed requirements and the concerns raised by commenters regarding the time needed to implement all of the requirements, we believe it would be overly burdensome to increase the number of required training topics at this time. We will continue to evaluate each of the suggested topics raised by commenters and consider them for future rulemaking. In addition, we note that while the regulations require specific training topics, facilities have the flexibility to add more topics to their training programs, in accordance with their facility assessments.

*Comment:* A couple of commenters recommended that the requirement for communication training specifically address the content that should be discussed in the training. One of the commenters recommended that the content specifically address individuals with dementia, individuals who are non-verbal, and individuals with hearing and/or vision impairments. Another commenter indicated that the requirement for communication training should specify the number of hours required for the training. One commenter indicated that the regulations should specifically require staff to pass exams as part of their training program.

*Response:* We appreciate the recommendations from commenters, but ultimately we recognize that training needs are likely to change over time. We believe that it is necessary for facilities to have the flexibility to determine, based on its internal facility assessment and competencies and skill sets needed for employees, how to structure training to meet its specific needs. To ensure that the training provided is facility specific and most beneficial to the residents receiving care in the facility, we believe that it is best not to limit the training requirements to too many specifics. We expect that the surveyor guidance associated with this final rule will provide facilities with additional guidance for how to meet these requirements. In addition we encourage readers to refer to the proposed rule discussion (80 FR 42222) for resources available for providing effective communication training including the Agency for Healthcare Research and Quality's (AHRQ) Team STEPPS Long Term Care communication training for front line staff in LTC facilities (*http://www.ahrq.gov/qual/ptsafetyltc/index.html*).

*Comment:* Many commenters recommended that caring for residents with dementia should be highlighted as a training topic for all nurse staffing personnel, not just nurse aides. Commenters noted that there are an overwhelming number of individuals with a diagnosis of Alzheimer's or another dementia-related illness in LTC facilities and the use of interdisciplinary teams to deliver care is on the rise. One commenter indicated that simple ideas such as sensory stimulation be used for communicating with an individual who has dementia and that this type of care does not need to be the province of just one type of staff who is caring for the individual. Another commenter noted the CMS ''Hand in Hand'' curriculum (*http://www.cms-handinhandtoolkit.info/*) as an excellent resource and highlighted a report developed by the Dementia Action Alliance entitled, ''Living Fully with Dementia: Words Matter'' (*http://daanow.org/living-fully-with-dementia-words-matter/*) as an additional resource for interested parties.

*Response:* Given the encouragement from commenters to extend dementia management training beyond just NAs, we have revised our proposal in this final rule. We agree that expanding the requirement for dementia management training to all staff will only further improve the care that is provided. Therefore, at § 483.95(c) we are adding a provision to require that all new and existing staff, individuals providing services under a contractual arrangement, and volunteers receive dementia management and abuse prevention training, consistent with their roles in the facility. We are not proposing that facilities develop a separate training from that required for nurse aides and given that the dementia management training will already be developed, it will not be overly burdensome for facilities to expand the training to all staff. In addition, we encourage facilities to utilize the free training materials available to facilities, such as the CMS ''Hand in Hand'' curriculum as well as the additional resources highlighted by commenters.

*Comment:* One commenter recommended that the term dementia management be replaced with ''appropriate care of residents living with dementia'' to be more person-centered.

*Response:* We appreciate the recommendation; however, dementia management is the language used in the Affordable Care Act and at this time we are using the same term for consistency.

*Comment:* One commenter indicated that all or part of the abuse, neglect, and exploitation training should be performed by an individual or agency that is not associated with the LTC facility.

*Response:* The regulations do not specify that a member of the facility has to conduct the training activities and facilities have the flexibility to work with outside entities to provide the training. We encourage facilities to leverage any resources available to assist with developing and implementing their training program.

*Comment:* One commenter recommended that all staff be required to receive an orientation to the LTC facility within their first two weeks of employment that includes training in at least residents' rights, aging, dementia, abuse reporting requirements, emergency procedures, and the policies of the LTC facility.

*Response:* We agree that new staff members should also receive training and have specified at § 483.95 that training must be provided to both new and existing staff. As discussed in a previous comment, we believe it would be burdensome to require additional training topics at this time.

*Comment:* One commenter recommended that all staff be required to be certified as nursing assistants. The commenter indicated that all staff should be able to assist residents with all activities of daily living without having to wait for a CNA.

*Response:* We agree that all staff should be able to assist residents with activities of daily living. However, we do not believe that having this capability is dependent on being a nursing assistant and therefore do not believe that it is necessary to require all

staff to be certified as nursing assistants. Instead we believe that facilities should assess their resident population including, among other things, the care required by the resident population considering the overall acuity that are present within the population. We proposed at § 483.70(e) to require facilities to conduct an annual facility assessment that addresses the staff competencies that are necessary to provide the level and types of care needed for the resident population. We believe that facilities will be able to use this information to appropriately staff their facilities and provide residents with the care and attention that they need.

*Comment:* One commenter recommended that those facilities with residents diagnosed with dementia should be required to conduct an annual assessment of all direct care staff that includes observation, to ensure that staff are providing adequate dementia care and abuse prevention. The commenter recommends further that for those staff members who exhibit caregiver stress, the facility should be required to have a plan in place to identify and support these individuals.

*Response:* The in-service training requirement for nurse aides specifies that the training must be no less than 12 hours per year. Therefore, following the implementation of this final rule nurse aides who provide direct care to residents will be re-trained in dementia management, as proposed at § 483.95(g)(2), at least annually. In addition, we note that in response to comments in this final rule we are expanding the requirement for dementia management and abuse prevention training to all direct care staff. As discussed previously, by direct care staff we are referring to those individuals who, through interpersonal contact with residents or resident care management, provide care and services to allow residents to attain or maintain the highest practicable physical, mental, and psychosocial well-being. While we appreciate that recommendation to provide staff members with support for caregiver stress, we believe that it would be overly burdensome to place this additional responsibility on facilities. We encourage those facilities that are capable to consider developing some type of employee assistance program that can be utilized by those staff members that may be exhibiting caregiver stress.

*Comment:* One commenter disliked the use of the phrase ''dementia management'' and suggested the use of the phrase ''dementia care'' indicating that this phrase is more person-centered.

*Response:* We appreciate the commenter's feedback, however dementia management is the phrase used in the statute and at this time we are aligning the terminology in our regulation with that of the statute for consistency.

*Comment:* A few commenters recommended increasing the number of on-going in-service training hours for nurse aides. Commenters provided various recommendations for the number of hours increased from 12 to 24 hours. Another commenter recommended that CMS evaluate the current in-service training provided to nurse aides in order to determine a minimum requirement for hours to enhance the continued competency of staff.

*Response:* We appreciate the feedback from commenters and agree that additional consideration should be given to increasing the number of in-service training hours required for nurse aides. We will continue to review the commenters and as recommended by commenters, review the current in-service training for nurse aides in order to determine a minimum number of training hours that will help to enhance the continued competency of staff.

*Comment:* One commenter recommended that the in-service training for nurse aides be expanded to include training in end-of-life care, teamwork, and problem solving. Another commenter recommended that nurse aides should also be trained to recognize situations where licensed nursing staff are needed and how to initiate immediate contact with them.

*Response:* We appreciate the feedback from commenters and believe that their concerns are already covered in the regulations. We proposed at § 483.95(a) to include effective communications as a required training topic for direct care personnel, which includes NAs. We believe that effective communication is important for reducing unnecessary hospitalizations as well as for improving a resident's overall quality of life and quality of care.

*Comment:* One commenter questioned whether employees of the LTC facility must develop the training materials. The commenter indicated that many facilities use consultants or contractors to develop training. In addition, a commenter indicated that the proposed rule did not clearly define the type of training that volunteers should receive. Also, the commenter indicated that the requirement for facilities to train all individuals under a contractual arrangement is unreasonable.

*Response:* Facilities have the flexibility to determine the materials to use for providing training and determining the appropriate individuals to be responsible for providing the training. In the proposed rule we indicated that training should be provided for new and existing staff, individuals providing services under a contractual arrangement, and volunteers consistent with their expected roles. We do not agree that requiring individuals under a contractual arrangement be trained is unreasonable. Facilities have a responsibility to ensure that the individuals they employ, whether directly or under contract, have their appropriate competencies and capabilities to provide services in their facility.

*Comment:* Commenters indicated concern regarding the financial and administrative burdens associated with requiring expansive training requirements. Commenters noted that it is already challenging to address the currently imposed training requirements. Also, commenters indicated that facilities need the flexibility to determine how to training staff on the proposed training topics. One commenter recommended that the proposed training topics be evaluated by a workgroup comprised of both CMS and providers and that any new training topics be implemented based on a 5 year phased-in schedule.

*Response:* We did not propose a specific training mechanism to meet the training requirements, therefore facilities have the flexibility to determine how to appropriately train staff. Given the overall comprehensive revision to the LTC requirements we are finalizing a phased in implementation schedule for this regulation. We defer readers to section II.B. Implementation for a detailed discussion regarding the implementation timeline for the training requirements, as well as the other requirements finalized in the rule.

*Comment:* One commenter noted that there are many ways to provide training such as computer based training, self-directed learning, mentoring and coaching.

*Response:* We appreciate the feedback from commenters and agree that there are many effective training mechanisms available to facilities to meet the training requirements including those recommended by the commenter.

After consideration of the comments we received on the proposed rule, we are finalizing our proposal with the following modifications:

- Adding a new requirement at § 483.95(c)(3) to require that staff

receive dementia management and abuse prevention training.

**III. Provisions of the Final Regulations**

In this final rule, we are adopting the provisions of the July 16, 2015 proposed rule with the following revisions:

- In § 483.5, we are revising the definition of ''abuse'' to ''the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. Willful, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.''
- In § 483.5, we are revising the definition of ''exploitation'' to ''taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.''
- In § 483.5, we are adding ''registered respiratory therapist or certified respiratory therapy technician'' to the definition of ''licensed health professional.''
- In § 483.5, we are adding a definition of ''mistreatment'' and define it as ''inappropriate treatment or exploitation of a resident.''
- In § 483.5, we are revising the definition of ''neglect'' to ''the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish or emotional distress.''
- In § 483.5, we are revising the definition of ''resident representative'' to (in accordance with 45 CFR 1324.1), ''(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications; (3) Legal representative, as used in section 712 of the Older Americans Act; or (4) The court-appointed guardian or conservator of a resident. (5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.''
- In § 483.10, we have consolidated proposed § 483.10 and proposed § 483.11 into § 483.10, ''Resident rights'' and removed or updated all cross-references as appropriate.
- In § 483.10, we have replaced the term ''verbal'' with ''oral'' throughout this entire section.
- In § 483.10, we have moved introductory language from proposed § 483.10 and proposed § 483.11, as well as § 483.11(a)(2) to § 483.10(a) ''Resident Rights.''
- In § 483.10, we have consolidated proposed § 483.10(a)(1) through (5), and proposed § 483.11(a)(1), and (a)(3) through (5) into § 483.10(b), ''Exercise of rights.''
- In § 483.10, we have revised § 483.10(b)(3) to incorporate previously existing language clarifying that the provision applies to residents who have not been adjudged incompetent by a State court.
- In § 483.10, we have revised § 483.10(b)(7)(i) to clarify that, in the case of a limited guardianship, a facility does not defer all decision making to a guardian, when a court's determination does not require it.
- In § 483.10, we have consolidated proposed § 483.10(b) and proposed § 483.11(b) into § 483.10(c), ''Planning and implementing care.''
- In § 483.10, we have changed the term '' disciplines'' to ''the type of care giver or professional'' at § 483.10(c)(4).
- In § 483.10, we have clarified in § 483.10(c)(5) that the physician or other practitioner or professional informs the resident of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options.
- In § 483.10, we have consolidated § 483.10(b)(6) and § 483.11(b)(2) into § 483.10(c)(7) which now states ''The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.''
- In § 483.10, we have withdrawn proposed § 483.10(c)(2) to require that physician's meet facility credentialing requirements and consolidated § 483.10(c)(1) and (3), and § 483.11(c)(1) through (3) at § 483.10(d).
- In § 483.10, we have redesignated § 483.10(d) as § 483.10(e), revised paragraph (6) to specify that the resident has a right to receive written notice, including the reason for the change before the resident's room or roommate in the facility is changed and added a new paragraph (7)(iii) to clarify that a room change cannot be solely for the convenience of staff.
- In § 483.10, we have consolidated proposed § 483.10(e) and proposed § 483.11(d) at § 483.10(f), Self-determination.
- In § 483.10, we have added ''and other applicable provisions of this Part'' to § 483.10(f)(1).
- In § 483.10, we have consolidated § 483.10(e)(3) and § 483.11(d)(1) at § 483.10(f)(4), clarified that the resident's right to deny visitation is ''when applicable,'' clarified that a facility must have written policies and procedures for visitation that includes restrictions, when such limitation may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation, and clarified that the facility must inform each resident not only of any limitation, but also to whom the restrictions apply.
- In § 483.10, we have added at § 483.10(f)(5)(i) that a facility must take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.
- In § 483.10, we have added at paragraph (f)(5)(ii) ''or other guests'' to the list of individuals who may only attend a resident or family group meeting at the group's invitation.
- In § 483.10, we have consolidated proposed § 483.10(e)(8) and § 483.11(d)(4) into § 483.10(f)(9).
- In § 483.10, we have consolidated proposed § 483.10(e)(9) and § 483.11(d)(5) into § 483.10(f)(10).
- In § 483.10, we have changed ''may'' to ''must'' in § 483.10(f)(11)(i).
- In § 483.10, we have changed ''health care provider'' to ''physician, physician assistant, nurse practitioner, or clinical nurse specialist'' in § 483.10(f)(11)(ii)(L)(1).
- In § 483.10, we have consolidated proposed § 483.10(f) and (h) and § 483.11(e) into § 483.10(g).
- In § 483.10, we revised proposed § 483.10(g)(2) to include both personal and medical records.
- In § 483.10, we revised § 483.10(g)(2)(ii) to remove the requirement that a resident must inspect a medical record prior to requesting to purchase a copy.

• In § 483.10, we updated § 483.10(g)(3) to exclude from its requirements documents specified in (g)(2) and (g)(11). This reflects that we do not require facilities to translate or summarize personal and medical records and survey reports.

• In § 483.10, we added ''State Survey Agency'' to § 483.10(g)(4)(ii) and added ''any suspected violation of state or federal nursing facility regulations'' to paragraph (g)(4)(vi).

• In § 483.10, we added ''requests for information regarding returning to the community'' to paragraph (g)(5)(ii).

• In § 483.10, we require at paragraph (g)(9)(iii) that electronic communications under this section must comply with state and federal law.

• In § 483.10, we have revised § 483.10(g)(11) to reflect the stricter standard imposed by the statutory language in section 1919(c)(8) of the Act and to better reflect both sections 1819(d) and 1919(d) of the Act, retaining the addition of availability of any plan of correction in effect with respect to facility, as proposed, and including the requirements that the notice of availability of such reports are prominent and accessible to the public and shall not make available identifying information about complainants or residents.

• In § 483.10, we have revised paragraph (g)(18)(v) to specify that any admission contract, whether the facility requires it or not, must not conflict with the requirements of these regulations.

• In § 483.10, we have consolidated proposed § 483.10(g) and § 483.11(f) into § 483.10(h), consolidating duplicative language in § 483.10(g)(2) and § 483.11(f)(1)(ii), consolidating proposed § 483.11(f)(1) and (f)(1)(i) into § 483.10(h)(2), and deleting § 483.11(f)(2) as an unnecessary cross-reference.

• In § 483.10, we have consolidated proposed § 483.10(i) and § 483.11(g) into § 483.10(i) ''Safe environment''.

• In § 483.10, we have added a new § 483.10(i)(1)(ii) to require that the facility exercise reasonable care for the protection of the resident's property from loss or theft.

• In § 483.10, we have consolidated proposed § 483.10(j) and § 483.11(h) into § 483.10(k).

• In § 483.10, we have revised § 483.10(j)(1) by adding ''the behavior of staff and of other residents; and other concerns regarding their LTC facility stay'' to the statement regarding what grievances may include.

• In § 483.10, we finalize, as proposed, § 483.11(i) at § 483.10(k).

• In § 483.12, we revised paragraphs (a)(3)(i), (ii), and (iii) to include ''exploitation.''

• In § 483.12(a)(3)(iii) we have revised the paragraph to read ''. . . Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, . . .''

• In § 483.12, we revised paragraph (b)(5)(i)(B) to read ''Each covered individual shall report immediately, but not later than 2 hours. . .''

• In § 483.12, we corrected paragraph (c)(4) to read ''Report the results of all investigations to the administrator or his or her designated representative and . . .''

• In § 483.15, we have withdrawn our proposal to rename § 483.15, ''Transitions of Care'' and add introductory language, and retain the current title ''Admission, transfer, and discharge rights'' without the introductory language.

• In § 483.15, we correct references to ''clinical record'' to ''medical record.''

• In § 483.15, we revised paragraph (a)(6) to require that a facility disclose and provide to a resident or potential resident, prior to admission, notice of special characteristics or service limitations of the facility.

• In § 483.15, we re-designated proposed paragraph (b)(1) as paragraph (b), and added a cross—reference to the definition of transfer and discharge in § 483.5 and a cross—reference to resident rights at § 483.10(a)(2).

• In § 483.15, we re-designated proposed (b) ''Transfer and discharge'' as (c), and renumbered paragraphs (c)(1)(ii) through (iii) to (c)(1)(i) through (ii).

• In § 483.15(c)(1)(i)(E), we have revised the provision to state that non-payment applies if the resident does not submit the necessary paperwork for third-party payment or after the third-party payor denies the claim and the resident refuses to pay for his or her stay.

• In § 483.15, we have clarified that paragraph (c)(1)(ii) applies unless the failure to transfer or discharge would endanger the health or safety of the resident or other individuals in the facility. In the event that failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility, the facility must document what danger the failure to transfer would pose.

• In § 483.15, we revised paragraph (c)(2)(ii) to clarify that the term ''documentation'' refers to the documentation specified in paragraph (2)(i).

• In § 483.15, we revised paragraph (c)(2)(iii) to reflect a more flexible list of elements to be documented in the resident's clinical record and communicated to the receiving health care institution or provider. The documentation must include: Contact information of the practitioner responsible for the care of the resident, resident representative information including contact information, advance directive information, all special instructions or precautions for ongoing care, as appropriate, the resident's comprehensive care plan goals, and all other necessary information, including a copy of the residents discharge summary, consistent with § 483.21(c)(2) as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

• In § 483.15, we removed the requirement for resident consent in paragraph (c)(3).

• In § 483.15, we revised paragraph (c)(5)(iii) to remove the phrase ''expected to be.''

• In § 483.15, we revised paragraph (c)(5)(iv) to require the discharge notice to include a statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request; and expanded paragraphs (vi) and (vii) to include individuals with related disabilities.

• In § 483.15, we revised paragraph (c)(8) by removing ''of the residents or other responsible parties.''

• In § 483.15, we revised ''readmissions'' to ''returns'' in paragraphs (d) and (e).

• In § 483.15, we revised proposed paragraph (c)(3) as paragraph (e). Paragraph (e)(1) is revised to state that ''a facility must establish . . .'' and (e)(1)(i)(B) is revised to read ''Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services'' and revised proposed paragraph (c)(3)(ii) as (e)(2)(ii) to state that if the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

• In § 483.20 we have removed the reference to ''direct access staff'' at paragraph (b)(1)(xviii).

• In § 483.21, we have clarified that the facility must implement the baseline care plan at paragraph (a).

• In § 483.21 we have added a requirement for facilities to provide residents and their representatives with a summary of their baseline care plan.

• In § 483.21, we have clarified that the facility must implement the comprehensive person-centered care plan at paragraph (b).

• In § 483.21, we have replaced the word ''timetables'' with ''timeframe'' at paragraph (b)(1).

• In § 483.21 we have removed the requirement at paragraph (b)(2)(E) for a social worker to participate on the IDT.

• In § 483.21 we have added at paragraph (c)(1) that a facility must develop and implement a discharge planning process that is consistent with the discharge rights set forth at § 483.15(b) as applicable. We have also removed the reference to ''post-SNF care'' to clarify that the discharge planning process applies to both SNFs and NFs.

• In § 483.21 we have removed the language ''his or her family'' at paragraph (c)(2)(iv) and replaced it with ''the resident representative (s).''In § 483.24, we have established § 483.24, ''Quality of life'', which contains proposed § 483.35(a), (b), and (c) re-designated as § 483.24(a), (b), and (c), respectively, and revised the introductory language to clarify that quality of life applies to all care and services provided to facility residents.

• In § 483.24, we have added an introductory statement to new paragraph § 483.24(b)

• In § 483.24, paragraph (b)(2), we have added the word ''walking.''

• In § 483.24, we have added ''related physician orders'' to paragraph (a)(3) regarding the provision of basic life support.

• In § 483.25, we have revised the title to read ''Quality of care,'' eliminated the modifier ''special care issues,'' revised the introductory to clarify that quality of care applies to all care and services provided by the facility, and re-designated proposed § 483.25(d)(3) through (5) as § 483.25(a) through (c), proposed § 483.25(d)(6) through (9) as § 483.25(e) through (h), proposed § 483.25(10) as § 483.25(d), and proposed § 483.25(d)(11) through (15) as § 483.25(i) through (m), respectively.

• In § 483.25, we removed paragraph (d)(1) relating to restraints and relocated the provision to § 483.12(a)(2).

• In § 483.25, we have re-designated proposed paragraph (2) bed rails as paragraph § 483.25(n), added an appropriateness qualifier to the regulatory text and reworded the provision about the bed's dimension for clarity.

• In § 483.25, we have re-designated paragraph (d)(6)(ii)(C) as (e)(2)(iii) and revised it to state ''restore continence to the extent possible.''

• In § 483.25, we have added language to § 483.25(f), (h), (i), (j), (k), and (l) to require that care be provided consistent with professional standards of practice applicable to that care as well as the comprehensive person-centered care plan, and the residents' goals and preferences.

• In § 483.25(g)(1), we have eliminated the reference to protein levels as a nutritional parameter and add reference to electrolyte balance.

• In § 483.30, we have withdrawn proposed § 483.30(e) and withdrawn our proposal to re-designate paragraphs (e) and (f) as paragraphs (f) and (g).

• In § 483.30, we have modified the regulatory text at § 483.30(e)(2) and § 483.30(e)(3), respectively, to specify that it is the attending physician who has the authority to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of writing dietary orders, and to delegate to a qualified therapist the task of writing therapy orders, to the extent that these professionals are permitted to perform these tasks under state law.

• In § 483.45, we have add paragraph (c)(5) to require LTC facilities to develop and maintain policies and procedures for the monthly DRR, which include but are not limited to, timeframes for the various steps in the process and procedures a pharmacist must take when he or she believes immediate action is required to protect the resident.

• In § 483.45(c)(3), we have modified the definition of ''psychotropic drugs'' by removing paragraphs (v) and (vi).

• In § 483.45(e)(4), we have modified the limitation for PRN prescriptions of psychotropic drugs by extending the time for PRN prescriptions to 14 days.

• In § 483.45(e)(5), we have added a specific limitation of 14 days for PRN prescriptions for anti-psychotic drugs.

• In § 483.55 Dental Services, we have modified proposed paragraphs (a)(3) and (a)(5) relating to dental services in SNFs and proposed paragraphs (b)(3) and (b)(4) to specify that both SNFs and NFs must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility and must document what they did to ensure that the resident could eat and drink adequately while awaiting dental services.

• In § 483.60, we have modified our definition of qualified dietitian or other clinically qualified nutrition professional at § 483.60(a)(1) to more closely align with statutory requirements.

• In § 483.60, we have clarified that an associate's or higher degree in hospitality must include food service or restaurant management in order to be accepted as an option for food services managers' qualifications in paragraph (2)(i)(D).

• In § 483.60, in paragraph (c)(1), we deleted the term ''industry standards'' from our proposal that menus must meet the nutritional needs of residents in accordance with established national guidelines.

• In § 483.60, in paragraph (d)(5), we have replaced the terms ''substitutes'' and ''alternative'' with the terms ''options'' and ''different meal choice.''

• In § 483.60, in paragraph (f)(2), we have withdrawn our proposal to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.

• In § 483.65 we are removing the requirement at paragraph (a)(2) for outside resources to be Medicare and/or Medicaid providers of specialized rehabilitative services.

• In § 483.67, outpatient rehabilitative services, we are removing this section in its entirety.

• In § 483.70, we have added 45 CFR part 92 to the regulations specifically referenced in § 483.70(c) ''Relationship to other HHS regulations.''

• In § 483.70(d), we have withdrawn our proposal to delete the phrase ''where licensing is required'' from § 483.70(d)(2)(i).

• In § 483.70(n), we have modified paragraph (1) to prohibit the use of pre-dispute agreements for binding arbitration between any resident or their representative and the facility and allow post-dispute agreements for binding arbitration, if the facility complies with the requirements in this section.

• In § 483.75, we have modified paragraph (a)(2) to mirror the statutory language to indicate that the facility must present its QAPI plan to the State Survey Agency surveyor not later than one year after the date the regulation is issued.

• In § 483.75, we have moved the language at paragraphs (h)(2)(i) and (ii) regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated proposed paragraph (h)(2)(iii) which stated ''other documentation considered necessary by a State or Federal surveyor in assessing compliance.''

• In § 483.75, we have added the term ''information'' in paragraphs (c)(2) and (f)(4).

• In § 483.75, we eliminated the parenthetical examples in paragraph (d)(2)(i).

• In § 483.75, in paragraph (e)(3), we have referenced performance improvement activities in the context of our PIP requirement.

• In § 483.80, we have modified paragraph (a)(1) by changing the reference from § 483.75(e) to § 483.70(e).

• In § 483.80, we have modified paragraph (a)(2)(iv) by inserting after, ''[w]hen and how isolation should be used for a resident,'' the following language, ''including but not limited to, (A) the type and duration of the isolation depending upon the infectious agent or organism involved, and (B) a requirement that the isolation should be the least restrictive possible for the resident under the circumstances.''

• In § 483.80, we have modified paragraph (b) to change the infection prevention and control officer (IPCO) to an infection preventionist (IP).

• In § 483.80, we have modified paragraph (b) to allow LTC facilities to designate more than one IP.

• In § 483.80, we have modified paragraphs (b) to establish that IPs must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field; be qualified by education, training, experience or certification; work at least part-time at the facility; and have completed specialized training in infection prevention and control.

• In 483.80, we have modified paragraph (b) by removing the requirement that the IPCP be a major responsibility for the IP.

• In § 483.90, we have modified our proposal at paragraph (e) to require that, for facilities that receive approval of construction or are newly certified after the effective date of this final rule, each resident room must have its own bathroom with at least a commode and a sink.

• In § 483.90, we have modified our proposal at paragraph (h)(5) to state that facilities must establish policies in accordance with applicable federal, state, and local laws and regulations regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

• In § 483.95 we have added a new requirement at paragraph (c)(3) that all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, receive dementia management and abuse prevention training consistent with their expected roles.

• Throughout the regulation, we have removed references to ''direct access'' staff, workers, or personnel.

Technical Corrections

In addition to the substantive revisions listed above we have also identified a few technical errors that were inadvertently made in the proposed. We identify the errors below and have made the corrections in the regulatory text.

• We have made conforming changes to revise cross-references to part 483 in title 42 found in § 488.301, § 489.52, and § 489.55 that were inadvertently not included in the proposed rule.

• We have modified the term ''mental illness'' by changing it to ''mental disorder'' throughout this rule to be consistent with current terminology.

## IV. Long-Term Care Facilities Crosswalk

The table below shows the cross-references between the current sections to the proposed. We also note that we have made conforming changes that would revise any cross-references to part 483 in title 42 that change due to the reorganization of subpart B in this final rule.

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.1 | Basis and Scope<br>(a) | Revised | § 483.1. |
| § 483.5(a)–(c) | (a) *Facility defined*<br>(b) *Distinct part*<br>(c) *Composite distinct part* | Re-designated | § 483.5 in alphabetical order. |
| § 483.5(d) | (d) *Common area* | Re-designated & revised | § 483.5 in alphabetical order. |
| § 483.5(e) | (e) *Fully sprinklered*<br>(f) *Major modification* | Re-designated | § 483.5 in alphabetical order. |
| § 483.10 | Resident rights | Revised | § 483.10. |
| § 483.10(a)(1) | (a) *Exercise of rights* | No change | § 483.10(b)(2). |
| § 483.10(a)(2) | (a) *Exercise of rights* | Revised | § 483.10(b)(2). |
| § 483.10(a)(3) | | Re-designated and revised | § 483.10(b)(7). |
| § 483.10(a)(4) | | Re-designated and revised | § 483.10(b)(3). |
| § 483.10(b)(1) | (b) *Notice of rights and services* | Re-designated & revised | § 483.10(g)(16). |
| § 483.10(b)(2) | | Re-designated & revised | § 483.10(g)(2). |
| § 483.10(b)(3) | | Re-designated | § 483.10(c)(1). |
| § 483.10(b)(4) | | Revised | § 483.10(c)(6). |
| § 483.10(b)(5) | | Re-designated & revised | § 483.10(g)(17). |
| § 483.10(b)(6) | | Re-designated & revised | § 483.10(g)(18). |
| § 483.10(b)(7) | | Re-designated & revised | § 483.10(g)(4)(i). |
| § 483.10(b)(8) | | Re-designated & revised | § 483.10(g)(5)(i)–(v). |
| § 483.10(b)(9) | | Re-designated & revised | § 483.10(d)(3). |
| § 483.10(b)(10) | | Re-designated & revised | § 483.10(g)(13). |
| § 483.10(b)(11) | | Re-designated & revised | § 483.10(g)(14). |
| § 483.10(b)(12) | | Re-designated | § 483.10(g)(15). |
| § 483.10(c)(1) | (c) *Protection of resident funds* | Re-designated & revised | § 483.10(f)(10), § 483.10(f)(10)(i). |
| § 483.10(c)(2) | | Re-designated | § 483.10(f)(10)(i). |
| § 483.10(c)(3) | | Re-designated & revised | § 483.10(f)(10)(ii). |
| § 483.10(c)(4) | | Re-designated | § 483.10(f)(10)(B)(iii)(A). |
| § 483.10(c)(5) | | Re-designated | § 483.10(f)(10)(B)(iv). |
| § 483.10(c)(6) | | Re-designated & revised | § 483.10(f)(10)(B)(v). |

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.10(c)(7) | | Re-designated | § 483.10(f)(10)(B)(vi). |
| § 483.10(c)(8) | | Re-designated & revised | § 483.10(f)(11). |
| § 483.10(d) | (d) *Free choice* | Re-designated & revised | § 483.10(d). |
| § 483.10(d)(1) | | Re-designated & revised | § 483.10(d). |
| § 483.10(d)(2) | | Re-designated & revised | § 483.10(c). |
| § 483.10(d)(3) | | Re-designated & revised | § 483.10(b)(7)(iii), § 483.10(c)(2). |
| § 483.10(e) | (e) *Privacy and confidentiality* | Re-designated & revised | § 483.10(h). |
| § 483.10(e)(1) | | Re-designated | § 483.10(h)(1). |
| § 483.10(e)(2) | | Re-designated & revised | § 483.10(h)(3)(i). |
| § 483.10(e)(3) | | Re-designated & revised | § 483.10(h)(3)(i). |
| § 483.10(e)(3)(i) | | Re-designated & revised | § 483.10(h)(3)(i). |
| § 483.10(e)(3)(ii) | | Re-designated & revised | § 483.10(h)(3)(i). |
| § 483.10(f) | (f) *Grievances* | Re-designated & revised | § 483.10(j). |
| § 483.10(f)(1) | | Re-designated & revised | § 483.10(j)(1). |
| § 483.10(f)(2) | | Re-designated & revised | § 483.10(j)(2). |
| § 483.10(g) | (g) *Examination of survey results* | Re-designated | § 483.10(g)(10). |
| § 483.10(g)(1) | | Re-designated & revised | § 483.10(g)(10)(i), § 483.10(g)(11)(ii). |
| § 483.10(g)(2) | | Re-designated | § 483.10(g)(10)(ii). |
| § 483.10(h) | (h) *Work* | Re-designated & revised | § 483.10(f)(9). |
| § 483.10(h)(1) | | Re-designated & revised | § 483.10(f)(9). |
| § 483.10(h)(2) | | Re-designated & revised | § 483.10(f)(9), § 483.10(f)(9). |
| § 483.10(h)(2)(i)–(iv) | | Re-designated | § 483.10(f)(9)(i)–(iv). |
| § 483.10(i) | (i) *Mail* | Re-designated & revised | § 483.10(h) &. |
| § 483.10(i)(1) | | Re-designated & revised | § 483.10(h)(2), § 483.10(h)(2). |
| § 483.10(i)(2) | | Re-designated & revised | § 483.10(g)(8)(ii), § 483.10(g)(8)(ii). |
| § 483.10(j)(1) | (j) *Access and visitation rights* | Re-designated & revised | § 483.10(f)(4), § 483.10(f)(4). |
| § 483.10(j)(1)(i)–(vi) | | Re-designated & revised | § 483.10(f)(4)(i)(A)–(F). |
| § 483.10(j)(1)(vii) | | Re-designated & revised | § 483.10(f)(4)(ii). |
| § 483.10(j)(1)(viii) | | Re-designated & revised | § 483.10(f)(4)(iii). |
| § 483.10(j)(2) | | Re-designated | § 483.10(f)(4)(iv). |
| § 483.10(j)(3) | | Re-designated & revised | § 483.10(h)(3)(ii). |
| § 483.10(k) | (k) *Telephone* | Re-designated & revised | § 483.10(g)(6). |
| § 483.10(l) | (l) *Personal property* | Re-designated & revised | § 483.10(e)(2). |
| § 483.10(m) | (m) *Married couples* | Re-designated | § 483.10(e)(4). |
| § 483.10(n) | (n) *Self-Administration of Drugs* | Re-designated & revised | § 483.10(c)(7). |
| § 483.10(o)(1)–(2) | (o) *Refusal of certain transfers* | Re-designated & revised | § 483.10(e )(7)(i)–(ii), 483.10(e)(7)(i)–(ii). |
| § 483.12(a) | Admission, transfer and discharge rights (a) *Transfer and discharge.* | Re-designated & revised | § 483.15(c). |
| § 483.12(a)(1) | (1) *Definition:* | Re-designated | § 483.5. |
| § 483.12(a)(2) | | Re-designated & revised | § 483.15(c)(1)(ii). |
| § 483.12(a)(2)(i)–(vi) | | Re-designated & revised | § 483.15(c)(1)(i)(A)–(F). |
| § 483.12(a)(3) | | Re-designated & revised | § 483.15(c)(2). |
| § 483.12(a)(3)(i) | | Re-designated & revised | § 483.15(c)(2)(ii)(A). |
| § 483.12(a)(3)(ii) | | Re-designated & revised | § 483.15(c)(2)(ii)(B). |
| § 483.12(a)(4)(i)–(iii) | | Re-designated & revised | § 483.15(c)(3)(i)–(iii). |
| § 483.12(a)(5)(i) | | Re-designated & revised | § 483.15(c)(4). |
| § 483.12(a)(5)(ii)(A)–(E). | | Re-designated & revised | § 483.15(c)(4)(ii)(A)–(E). |
| § 483.12(a)(6)(i)–(vii) | | Re-designated & revised | § 483.15(c)(5)(i)–(vii). |
| § 483.12(a)(7) | | Re-designated & revised | § 483.15(c)(7). |
| § 483.12(a)(8) | | Re-designated & revised | § 483.15(c)(8). |
| § 483.12(a)(9) | | Re-designated & revised | § 483.15(c)(9). |
| § 483.12(b)(1)(i)–(ii) | (b) *Notice of bed-hold policy and re-admission.* | Re-designated & revised | § 483.15(d)(1)(i)–(iii). |
| § 483.12(b)(2) | | Re-designated & revised | § 483.15(d)(2). |
| § 483.12(b)(3)(i)–(ii) | | Re-designated | § 483.15(e)(1)(i)(A)–(B). |
| § 483.12(b)(4) | | Re-designated & revised | § 483.15(e)(2). |
| § 483.12(c)(1) | (c) *Equal access to quality care* | Re-designated & revised | § 483.15(b)(1). |
| § 483.12(c)(2) | | Re-designated & revised | § 483.15(b)(2). |
| § 483.12(c)(3) | | Re-designated | § 483.15(b)(3). |
| § 483.12(d)(1) (i)–(ii) | (d) *Admissions policy* | Re-designated & revised | § 483.15(a)(2)(i)–(ii). |
| § 483.12(d)(2) | | Re-designated & revised | § 483.15(a)(3). |
| § 483.12(d)(3) (i)–(ii) | | Re-designated | § 483.15(a)(4)(i)–(ii). |
| § 483.12(d)(4) | | Re-designated | § 483.15(a)(5). |

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.13(a) | Resident behavior and facility practices. (a) *Restraints.* | Re-designated & revised | § 483.10(e), § 483.12, § 483.25(d)(1). |
| § 483.13(b) | (b) *Abuse* | Re-designated & revised | § 483.12. |
| § 483.13(c) | (c) *Staff treatment of residents* | Re-designated & revised | § 483.12(b). |
| § 483.13(c)(1) | | Re-designated | § 483.12(a). |
| § 483.13(c)(1)(i) | | Re-designated | § 483.12(a)(1). |
| § 483.13(c)(1)(ii) | | Re-designated & revised | § 483.12(a)(3). |
| § 483.13(c)(1)(ii)(A) | | Re-designated & revised | § 483.12(a)(3)(i). |
| § 483.13(c)(1)(ii)(B) | | Re-designated & revised | § 483.12(a)(3)(ii). |
| § 483.13(c)(1)(iii) | | Re-designated & revised | § 483.12(a)(4). |
| § 483.13(c)(2) | | Re-designated & revised | § 483.12(c)(1). |
| § 483.13(c)(3) | | Re-designated & revised | § 483.12(c)(2)–(3). |
| § 483.13(c)(4) | | Re-designated & revised | § 483.12(c)(4). |
| § 483.15 | Quality of life | Re-designated & revised | § 483.24. |
| § 483.15(a) | (a) *Dignity* | Re-designated & revised | § 483.24. |
| § 483.15(b) | (b) *Self-determination and participation.* | Re-designated & revised | § 483.10(f), § 483.10(f). |
| § 483.15(b)(1) | | Re-designated & revised | § 483.10(f)(1). |
| § 483.15(b)(2) | | Re-designated & revised | § 483.10(f)(3). |
| § 483.15(b)(3) | | Re-designated | § 483.10(f)(2). |
| § 483.15(c)(1) | (c) *Participation in resident and family groups* groups. | Re-designated & revised | § 483.10(f)(5). |
| § 483.15(c)(2) | | Re-designated & revised | § 483.10(f)(6)–(7). |
| § 483.15(c)(3) | | Re-designated | § 483.10(f)(5)(i)). |
| § 483.15(c)(4)–(6) | | Re-designated & revised | § 483.10(f)(5)(ii)–(iv). |
| § 483.15(d) | (d) *Participation in other activities* | Re-designated& revised | § 483.10(f)(8). |
| § 483.15(e) | (e) *Accommodation of needs* | Re-designated & revised | § 483.10(e). |
| § 483.15(e)(1) | | Re-designated & revised | § 483.10(e)(3). |
| § 483.15(e)(2) | | Re-designated & revised | § 483.10(e)(6). |
| § 483.15(f)(1) | (f) *Activities* | Re-designated & revised | § 483.24(c)(1). |
| § 483.15(f)(2) | | Re-designated & revised | § 483.24(c)(2). |
| § 483.15(f)(2)(i) | | Re-designated & revised | § 483.24(c)(2). |
| § 483.15(f)(2)(i)(A) | | Re-designated | § 483.24(c)(2)(i). |
| § 483.15(f)(2)(i)(B) | | Re-designated & revised | § 483.24(c)(2)(ii)(A). |
| § 483.15 (f)(2)(ii)–(iv) | | Re-designated & revised | § 483.24(c)(2)(ii)(B)–(D). |
| § 483.15(g)(1) | (g) *Social Services* | Re-designated & revised | § 483.40(d). |
| § 483.15(g)(2) | | Re-designated & revised | § 483.70(p). |
| § 483.15(g)(3)(i)–(ii) | (3) *Qualifications of social worker* | Re-designated & revised | § 483.70(p)(1)–(2). |
| § 483.15(h) | (h) *Environment* | Re-designated & revised | § 483.10(i). |
| § 483.15(h)(1) | | Re-designated & revised | § 483.10(i)(1). |
| § 483.15(h)(2) | | Re-designated | § 483.10(i)(2). |
| § 483.15(h)(3) | | Re-designated | § 483.10(i)(3). |
| § 483.15(h)(4) | | Re-designated & revised | § 483.10(i)(4). |
| § 483.15(h)(5) | | Re-designated | § 483.10(i)(5). |
| § 483.15(h)(6) | | Re-designated | § 483.10(i)(6). |
| § 483.15(h)(7) | | Re-designated | § 483.10(i)(7). |
| § 483.20 | Resident Assessment | No change | § 483.20. |
| § 483.20(a) | (a) *Admission orders* | No change | § 483.20(a). |
| § 483.20(b) | (b) *Comprehensive assessments*—(1) *Resident assessment instrument.* | Revised | § 483.20(b). |
| § 483.20(c)–(d) | (c) *Quarterly review assessment*<br>(d) *Use* | No change | § 483.20(c)–(d). |
| § 483.20(e) | (e) *Coordination* | Revised | § 483.20(e). |
| § 483.20(f)–(j) | (f) *Automated data processing requirement.*<br>(g) *Accuracy of assessments*<br>(h) *Coordination*<br>(i) *Certification*<br>(j) *Penalty for falsification* | No change | § 483.20(f)–(j). |
| § 483.20(k)(1) | (k) *Comprehensive care plans* | Re-designated & revised | § 483.21(b)(1). |
| § 483.20(k)(2) | | Re-designated | § 483.21(b)(2). |
| § 483.20(k)(2)(i) | | Re-designated | § 483.21(b)(2)(i). |
| § 483.20(k)(2)(ii) | | Re-designated & revised | § 483.21(b)(2)(ii)(A)–(F). |
| § 483.20(k)(2)(iii) | | Re-designated & revised | § 483.21(b)(2)(iii). |
| § 483.20(k)(3)(i)–(ii) | | Re-designated | § 483.21(b)(3)(i)–(ii). |
| § 483.20(l) | (l) *Discharge summary* | Re-designated & revised | § 483.21(c)(2). |
| § 483.20(l)(1) | | Re-designated & revised | § 483.21(c)(2)(i). |
| § 483.20(l)(2) | | Re-designated & revised | § 483.21(c)(2)(ii). |
| § 483.20(l)(3) | | Re-designated & revised | § 483.21(c)(2)(iv). |

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.20(m) | (m) *Preadmission screening for mentally ill individuals and individuals with mental retardation.* | Re-designated | § 483.20(k)(1). |
| § 483.20(m)(1)(i)–(ii) | | Re-designated | § 483.20(k)(1)(i)–(ii). |
| § 483.20(m)(2)(i)–(ii) | (2) *Definition.* For purposes of this section—. | Re-designated & revised | § 483.20(k)(3)(i)–(ii). |
| § 483.25 | Quality of care | Revised | § 483.25. |
| § 483.25(a) | (a) *Activities of daily living* | Re-designated & revised | § 483.24(a). |
| § 483.25(a)(1) | | Re-designated and revised | § 483.24(a),(b). |
| § 483.25(a)(1)(i) | | Re-designated and revised | § 483.24(b)(1). |
| § 483.25(a)(1)(ii) | | Re-designated and revised | § 483.24(b)(2). |
| § 483.25(a)(1)(iii) | | Re-designated and revised | § 483.24(b)(3). |
| § 483.25(a)(1)(iv) | | Re-designated and revised | § 483.24(b)(4). |
| § 483.25(a)(1)(v) | | Re-designated and revised | § 483.24(b)(5). |
| § 483.25(a)(2) | | Re-designated and revised | § 483.24(a)(1). |
| § 483.25(a)(3) | | Re-designated | § 483.24(a)(2). |
| § 483.25(b) | (b) *Vision and hearing* | Re-designated | § 483.25(a). |
| § 483.25(b)(1) | | Re-designated | § 483.25(a)(1). |
| § 483.25(b)(2) | | Re-designated | § 483.25(a)(2). |
| § 483.25(c) | (c) *Pressure sores* | Re-designated & revised | § 483.25(b)(1). |
| § 483.25(c)(1) | | Re-designated & revised | § 483.25(b)(1)(i). |
| § 483.25(c)(2) | | Re-designated & revised | § 483.25(b)(1)(ii). |
| § 483.25(d) | (d) *Urinary Incontinence* | Re-designated & revised | § 483.25(e)(2). |
| § 483.25(d)(1) | | Re-designated | § 483.25(e)(2)(i). |
| § 483.25(d)(2) | | Re-designated | § 483.25(e)(2)(ii). |
| § 483.25(e) | (e) *Range of motion* | Re-designated & revised | § 483.25(c). |
| § 483.25(e)(1) | | Re-designated | § 483.25(c)(1). |
| § 483.25(e)(2) | | Re-designated | § 483.25(c)(2). |
| § 483.25(f) | (f) *Mental and Psychosocial functioning.* | Re-designated & revised | § 483.40(b). |
| § 483.25(f)(1) | | Re-designated & revised | § 483.40(b)(1). |
| § 483.25(f)(2) | | Re-designated & revised | § 483.40(b)(2). |
| § 483.25(g) | (g) *Naso-gastric tubes* | Re-designated & revised | § 483.25(g)(4). |
| § 483.25(g)(1) | | Re-designated & revised | § 483.25(g)(4). |
| § 483.25(g)(2) | | Re-designated & revised | § 483.25(g)(5). |
| § 483.25(h) | (h) *Accidents* | Re-designated | § 483.25(d). |
| § 483.25(h)(1) | | Re-designated | § 483.25(d)(1). |
| § 483.25(h)(2) | | Re-designated | § 483.25(d)(2). |
| § 483.25(i) | (i) *Nutrition* | Re-designated & revised | § 483.25(g). |
| § 483.25(i)(1) | | Re-designated & revised | § 483.25(g)(1). |
| § 483.25(i)(2) | | Re-designated & revised | § 483.25(g)(3). |
| § 483.25(j) | (j) *Hydration* | Re-designated & revised | § 483.25(g)(2). |
| § 483.25(k) | (k) *Special needs* | Re-designated & revised | § 483.25(d). |
| § 483.25(k)(1) | (1) Injections; | Deleted | |
| § 483.25(k)(2) | (2) Parenteral and enteral fluids; | Re-designated & revised | § 483.25(h). |
| § 483.25(k)(3) | (3) Colostomy, ureterostomy, or ileostomy care;. | Re-designated | § 483.25(f). |
| § 483.25(k)(4) | (4) Tracheostomy care; | Re-designated & revised | § 483.25(i). |
| § 483.25(k)(5) | (5) Tracheal suctioning; | Re-designated & revised | § 483.25(i). |
| § 483.25(k)(6) | (6) Respiratory care; | Re-designated & revised | § 483.25(i). |
| § 483.25(k)(7) | (7) Foot care; and | Re-designated & revised | § 483.25(b)(2). |
| § 483.25(k)(8) | (8) Prostheses | Re-designated | § 483.25(j). |
| § 483.25(l) | (l) *Unnecessary drugs* | Re-designated | § 483.45(d). |
| § 483.25(l)(1)(i)–(vi) | | Re-designated | § 483.45(d)(1)–(6). |
| § 483.25(l)(2)(i)–(ii) | (2) *Antipsychotic Drugs* | Re-designated & revised | § 483.45(e)(1)–(2). |
| § 483.25(m)(1)–(2) | (m) *Medication Errors* | Re-designated & revised | § 483.45(f)(1)–(2). |
| § 483.25(n) | (n) *Influenza and pneumococcal immunizations.* | Re-designated | § 483.80(d)(1). |
| § 483.25(n)(1)(i)–(iv) | | Re-designated & revised | § 483.80(d)(1)(i)–(iv). |
| § 483.25(n)(2) | (2) *Pneumococcal disease* | Re-designated | § 483.80(d)(2). |
| § 483.25(n)(2)(i)–(iv) | | Re-designated & revised | § 483.80(d)(2)(i)–(iv). |
| § 483.25(n)(2)(v) | *Exception* | Deleted | |
| § 483.30 | Nursing services | Re-designated & revised | § 483.35. |
| § 483.30(a) | (a) *Sufficient staff* | Re-designated | § 483.35(a). |
| § 483.30(a)(1)(ii) | | Re-designated & revised | § 483.35(a)(1)(ii). |
| § 483.30(a)(2) | | Re-designated | § 483.35(a)(2). |
| § 483.30(b)(1) | (b) *Registered nurse* | Re-designated | § 483.35(b)(1). |
| § 483.30(b)(2) | | Re-designated | § 483.35(b)(2). |
| § 483.30(b)(3) | | Re-designated | § 483.35(b)(3). |
| § 483.30(c) | (c) *Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.* | Re-designated | § 483.35(e). |

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.30(c)(1)–(5) | | Re-designated | § 483.35(e)(1)–(5). |
| § 483.30(c)(6) | | Re-designated & revised | § 483.35(e)(6). |
| § 483.30(c)(7) | | Re-designated & revised | § 483.35(e)(7). |
| § 483.30(d)(1) | (d) *SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.* | Re-designated | § 483.35(f)(1). |
| § 483.30(d)(1)(i) | | Re-designated | § 483.35(f)(1)(i). |
| § 483.30(d)(1)(ii) | | Re-designated | § 483.35(f)(1)(ii). |
| § 483.30(d)(1)(iii) | | Re-designated | § 483.35(f)(1)(iii). |
| § 483.30(d)(1)(iii)(A) | | Re-designated | § 483.35(f)(1)(iii)(A). |
| § 483.30(d)(1)(iii)(B) | | Re-designated | § 483.35(f)(1)(iii)(B). |
| § 483.30(d)(1)(iv) | | Re-designated & revised | § 483.35(f)(1)(iv). |
| § 483.30(d)(1)(v) | | Re-designated & revised | § 483.35(f)(1)(v). |
| § 483.30(d)(2) | | Re-designated | § 483.35(f)(2). |
| § 483.30(e)(1)(i)–(iv) | (e) *Nurse staffing information* | Re-designated | § 483.35(g)(1)(i)–(iv). |
| § 483.30(e)(2)(i)–(ii) | | Re-designated | § 483.35(g)(2)(i)–(ii). |
| § 483.30(e)(3) | | Re-designated | § 483.35(g)(3). |
| § 483.30(e)(4) | | Re-designated | § 483.35(g)(4). |
| § 483.35 | Dietary services | Re-designated & revised | § 483.60. |
| § 483.35(a) | (a) *Staffing* | Re-designated & revised | § 483.60(a)(1). |
| § 483.35(a)(1) | | Re-designated & revised | § 483.60(a)(2). |
| § 483.35(a)(2) | | Re-designated & revised | § 483.60(a)(1)(i)–(iv). |
| § 483.35(b) | (b) *Sufficient staff* | Re-designated & revised | § 483.60(a)(3). |
| § 483.35(c) | (c) *Menus and nutritional adequacy* | Re-designated | § 483.60(c). |
| § 483.35(c)(1)–(3) | | Re-designated & revised | § 483.60(c)(1)–(3). |
| § 483.35(d) | (d) *Food* | Re-designated | § 483.60(d). |
| § 483.35(d)(1) | | Re-designated | § 483.60(d)(1). |
| § 483.35(d)(2) | | Re-designated & revised | § 483.60(d)(2). |
| § 483.35(d)(3) | | Re-designated | § 483.60(d)(3). |
| § 483.35(d)(4) | | Re-designated & revised | § 483.60(d)(5). |
| § 483.35(e) | (e) *Therapeutic diets* | Re-designated & revised | § 483.60(e). |
| § 483.35(f)(1) | (f) *Frequency of meals* | Re-designated & revised | § 483.60(f)(1). |
| § 483.35(f)(2) | | Deleted | |
| § 483.35(f)(3) | | Re-designated | § 483.60(f)(3). |
| § 483.35(f)(4) | | Deleted | |
| § 483.35(g) | (g) *Assistive devices* | Re-designated & revised | § 483.60(g). |
| § 483.35(h)(1) | (h) *Paid feeding assistants* | Re-designated | § 483.60(h)(1). |
| § 483.35(h)(1)(i)–(ii) | | Re-designated | § 483.60(h)(1)(i)–(ii). |
| § 483.35(h)(2)(i) | | Re-designated | § 483.60(h)(2)(i). |
| § 483.35 (h)(2)(ii) | | Re-designated & revised | § 483.60(h)(2)(ii). |
| § 483.35(h)(3)(i)–(ii) | | Re-designated & revised | § 483.60(h)(3)(i)–(ii). |
| § 483.35(h)(3)(iii) | | Re-designated & revised | § 483.60(h)(3)(iii). |
| § 483.35(i) | (i) *Sanitary conditions* | Re-designated & revised | § 483.60(i). |
| § 483.35(i)(1) | | Re-designated & revised | § 483.60(i)(1). |
| § 483.35(i)(2) | | Re-designated & revised | § 483.60(i)(2). |
| § 483.35(i)(3) | | Re-designated | § 483.60(i)(4). |
| § 483.40 | Physician services | Re-designated & revised | § 483.30. |
| § 483.40(a) | (a) *Physician supervision* | Re-designated | § 483.30(a). |
| § 483.40(a)(1)–(2) | | Re-designated | § 483.30(a)(1)–(2). |
| § 483.40(b) | (b) *Physician visits* | Re-designated | § 483.30(b). |
| § 483.40(b)(1) | | Re-designated | § 483.30(b)(1). |
| § 483.40(b)(2) | | Re-designated | § 483.30(b)(2). |
| § 483.40(b)(3) | | Re-designated & revised | § 483.30(b)(3). |
| § 483.40(c)(1)–(4) | (c) *Frequency of physician visits* | Re-designated | § 483.30(c)(1)–(4). |
| § 483.40(d) | (d) *Availability of physicians for emergency care.* | Re-designated | § 483.30(d). |
| § 483.40(e)(1) | (e) *Physician delegation of tasks in SNFs.* | Re-designated | § 483.30(f)(1). |
| § 483.40(e)(1)(i)–(iii) | | Re-designated | § 483.30(f)(1)(i)–(iii). |
| § 483.40(e)(2) | | Re-designated | § 483.30(f)(4). |
| § 483.40(f) | (f) *Performance of physician tasks in NFs.* | Re-designated | § 483.30(g). |
| § 483.45 | Specialized rehabilitative services | Re-designated & revised | § 483.65(a). |
| | (a) *Provision of services* | | |
| § 483.45(a)(1)–(2) | | Re-designated & revised | § 483.65(a)(1)–(2). |
| § 483.45(b) | (b) *Qualifications* | Re-designated | § 483.65(b). |
| § 483.55 | Dental services | No change | § 483.55. |
| § 483.55(a)(1) | (a) *Skilled nursing facilities* | Re-designated | § 483.55(a)(1). |
| § 483.55(a)(2) | | Re-designated | § 483.55(a)(2). |
| § 483.55(a)(3) | | Re-designated | § 483.55(a)(4). |
| § 483.55(a)(3)(i) | | Re-designated | § 483.55(a)(4)(i). |

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.55(a)(3)(ii) | | Re-designated & revised | § 483.55(a)(4)(ii). |
| § 483.55(a)(4) | | Re-designated & revised | § 483.55(a)(5). |
| § 483.55(b) | (b) *Nursing facilities* | Re-designated | § 483.55(b). |
| § 483.55(b)(1)(i)–(ii) | | Re-designated& revised | § 483.55(b)(1)(i)–(ii). |
| § 483.55(b)(2) | | Re-designated & revised | § 483.55(b). |
| § 483.55(b)(2)(i)–(ii) | | Re-designated & revised | § 483.55(b)(2)(i)–(ii). |
| § 483.55(b)(3) | | Re-designated & revised | § 483.55(b)(3). |
| § 483.60 | Pharmacy services | Re-designated & revised | § 483.45. |
| § 483.60(a) | (a) *Procedures* | Re-designated | § 483.45(a). |
| § 483.60(b) | (b) *Service consultation* | Re-designated | § 483.45(b). |
| § 483.60(b)(1)–(3) | | Re-designated | § 483.45(b)(1)–(3). |
| § 483.60(c)(1) | (c) *Drug regimen review* | Re-designated | § 483.45(c)(1). |
| § 483.60(c)(2) | | Re-designated & revised | § 483.45(c)(4). |
| § 483.60(d) | (d) *Labeling of drugs and biologicals* | Re-designated | § 483.45(g). |
| § 483.60(e)(1–(2) | (e) *Storage of drugs and biologicals* | Re-designated | § 483.45(h)(1)–(2). |
| § 483.65 | Infection control | Re-designated & revised | § 483.80. |
| § 483.65(a)(1)–(3) | (a) *Infection control program* | Re-designated & revised | § 483.80(a)(1)–(3). |
| § 483.65(b)(1) | (b) *Preventing spread of infection* | Re-designated & revised | § 483.80(a)(2)(iv). |
| § 483.65(b)(2) | | Re-designated & revised | § 483.80(a)(2)(v). |
| § 483.65(b)(3) | | Re-designated & revised | § 483.80(a)(2)(vi). |
| § 483.65(c) | (c) *Linens* | Re-designated | § 483.80(e). |
| § 483.70 | Physical environment | Re-designated | § 483.90. |
| § 483.70(a)(1)–(8) | (a) *Life safety from fire* | Re-designated | § 483.90(a)(1)–(8). |
| § 483.70(b)(1)–(2) | (b) *Emergency power* | Re-designated | § 483.90(b)(1)–(2). |
| § 483.70(c)(1)–(2) | (c) *Space and equipment* | Re-designated & revised | § 483.90(c)(1)–(2). |
| § 483.70(d) | (d) *Resident rooms* | Re-designated | § 483.90(d). |
| § 483.70(d)(1) | | Re-designated | § 483.90(d)(1). |
| § 483.70(d)(1)(i) | | Re-designated & revised | § 483.90(d)(1)(i). |
| § 483.70(d)(1)(ii)–(vii). | | Re-designated | § 483.90(d)(1)(ii)–(vii). |
| § 483.70(d)(2) | | Re-designated | § 483.90(d)(2). |
| § 483.70(d)(2)(i) | | Re-designated & revised | § 483.90(d)(2)(i). |
| § 483.70(d)(2)(ii)–(iv) | | Re-designated | § 483.90(d)(2)(ii)–(iv). |
| § 483.70(d)(3)(i)–(ii) | | Re-designated | § 483.90(d)(3)(i)–(ii). |
| § 483.70(e) | (e) *Toilet facilities* | Re-designated & revised | § 483.90(e). |
| § 483.70(f)(1) | (f) *Resident call system* | Re-designated & revised | § 483.90(f)(1). |
| § 483.70(f)(2) | (f) Resident call system | Re-designated | § 483.90(f)(2). |
| § 483.70(g)(1) | (g) *Dining and resident activities* | Re-designated | § 483.90(g)(1). |
| § 483.70(g)(2) | | Re-designated & revised | § 483.90(g)(2). |
| § 483.70(g)(3)–(4) | | Re-designated | § 483.90(g)(3)–(4). |
| § 483.70(h)(1)–(4) | (h) *Other environmental conditions* | Re-designated | § 483.90(h)(1)–(4). |
| § 483.75 | Administration | Re-designated | § 483.70. |
| § 483.75(a) | (a) *Licensure* | Re-designated | § 483.70(a). |
| § 483.75(b) | (b) *Compliance with Federal, State, and local laws and professional standards.* | Re-designated | § 483.70(b). |
| § 483.75(c) | (c) *Relationship to other HHS regulations.* | Re-designated & revised | § 483.70(c). |
| § 483.75(d)(1) | (d) *Governing body* | Re-designated | § 483.70(d)(1). |
| § 483.75(d)(2)(i)–(ii) | | Re-designated & revised | § 483.70(d)(2)(i)–(ii). |
| § 483.75(e) | (e) *Required training of nursing aides.* | Re-designated & revised | § 483.95(g). |
| § 483.75(e)(1) | (1) *Definitions. Licensed health professional.* | Re-designated & revised | § 483.5. |
| § 483.75(e)(1) | *Nurse aide* | Re-designated & revised | § 483.5. |
| § 483.75(e)(2)(i)–(ii) | (2) *General rule* | Re-designated & revised | § 483.35(d)(1)(i)–(ii). |
| § 483.75(e)(3) | (3) *Non-permanent employees* | Re-designated & revised | § 483.35(d)(2). |
| § 483.75(e)(4)(i)–(iii) | (4) *Competency* | Re-designated | § 483.35(d)(3)(i)–(iii). |
| § 483.75(e)(5)(i)–(ii) | (5) *Registry verification* | Re-designated | § 483.35(d)(4)(i)–(ii). |
| § 483.75(e)(6) | (6) *Multi-State registry verification* | Re-designated & revised | § 483.35(d)(5). |
| § 483.75(e)(7) | (7) *Required retraining* | Re-designated | § 483.35(d)(6). |
| § 483.75(e)(8)(i)–(iii) | (8) *Regular in-service education* | Re-designated & revised | § 483.35(d)(7), § 483.95(g). |
| § 483.75(f) | (f) *Proficiency of Nurse aides* | Re-designated | § 483.35(c). |
| § 483.75(g)(1) | (g) *Staff qualifications* | Re-designated | § 483.70(f)(1). |
| § 483.75(g)(2) | | Re-designated | § 483.70(f)(2). |
| § 483.75(h)(1) | (h) *Use of outside resources* | Re-designated | § 483.70(g)(1). |
| § 483.75(h)(2)(i)–(ii) | | Re-designated | § 483.70(g)(2)(i)–(ii). |
| § 483.75(i)(1) | (i) *Medical director* | Re-designated | § 483.70(h)(1). |
| § 483.75(i)(2)(i–ii) | | Re-designated | § 483.70(h)(2)(i)–(ii). |
| § 483.75(j)(1)(i)–(iv) | (j) *Laboratory services* | Re-designated | § 483.50(a)(1)(i)–(iv). |
| § 483.75(j)(2) | | Re-designated | § 483.50(a)(2). |

TABLE 1—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

| Existing CFR section | Title | Action | New CFR section |
|---|---|---|---|
| § 483.75(j)(2)(i)–(iv) | | Re-designated & Revised | § 483.50(a)(2)(i)–(iv). |
| § 483.75(k) | (k) *Radiology and other diagnostic services.* | Re-designated | § 483.50(b). |
| § 483.75(k)(1) | | Re-designated | § 483.50(b)(1). |
| § 483.75(k)(2) | | Re-designated & revised | § 483.50(b)(2). |
| § 483.75(l)(1) | (l) *Clinical records* | Re-designated & revised | § 483.70(i)(1). |
| § 483.75(l)(1)(i)–(iv) | | Re-designated & revised | § 483.70(i)(1)(i)–(iv). |
| § 483.75(l)(2) | | Re-designated & revised | § 483.70(i)(4). |
| § 483.75(l)(2)(i) | | Re-designated | § 483.70(i)(4)(i). |
| § 483.75(l)(2)(ii) | | Re-designated | § 483.70(i)(4)(ii). |
| § 483.75(l)(2)(iii) | | Re-designated | § 483.70(i)(4)(iii). |
| § 483.75(l)(3) | | Re-designated & revised | § 483.70(i)(3). |
| § 483.75(l)(4)(i)–(iv) | | Re-designated & revised | § 483.70(i)(2). |
| § 483.75(l)(5)(i)–(v) | | Re-designated & revised | § 483.70(i)(5)(i)–(v). |
| § 483.75(m)(1) | (m) *Disaster and emergency preparedness.* | *See Proposed Rule:* Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (78 FR 79081, December 27, 2013). | See 78 FR 79081. |
| § 483.75(m)(2) | | *See Proposed Rule:* Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (78 FR 79081, December 27, 2013). | See 78 FR 79081. |
| § 483.75(n)(1)(i)–(ii) | (n) *Transfer agreement* | Re-designated & revised | § 483.70(j)(1)(i)–(ii). |
| § 483.75(n)(2) | | Re-designated | § 483.70(j)(2). |
| § 483.75(o)(1)(i)–(iii) | (o) *Quality assessment and assurance.* | Re-designated & revised | § 483.75(g)(1)(i)–(iv). |
| § 483.75(o)(2)(i)–(ii) | | Re-designated & revised | § 483.75(g)(2)(i)–(iii). |
| § 483.75(o)(3) | | Re-designated & revised | § 483.75(h)(1). |
| § 483.75(o)(4) | | Re-designated | § 483.75(i). |
| § 483.75(p)(1) | (p) *Disclosure of ownership* | Re-designated | § 483.70(k)(1). |
| § 483.75(p)(2)(i)–(iv) | | Re-designated | § 483.70(k)(2)(i)–(iv). |
| § 483.75(p)(3) | | Re-designated | § 483.70(k)(3). |
| § 483.75(q) | (q) *Required training of feeding assistants.* | Re-designated & revised | § 483.95(h). |
| § 483.75(r)(1)–(3) | (r) *Facility closure-Administrator* | Re-designated | § 483.70(l)(1)–(3). |
| § 483.75(s) | (s) *Facility closure* | Re-designated & revised | § 483.70(m). |
| § 483.75(t) | (t) *Hospice services* | Re-designated | § 483.70(o). |

## V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information (COI) requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

### Omnibus Budget Reconciliation Act of 1987 Waiver

Ordinarily, we are required to estimate the public reporting burden for information collection requirements for these regulations in accordance with chapter 35 of title 44, United States Code. However, sections 4204(b) and 4214(d) of Omnibus Budget Reconciliation Act of 1987, Public Law 100–203 (OBRA '87) provide for a waiver of Paperwork Reduction Act (PRA) requirements for these regulations. We believe that this waiver still applies to those revisions and updates we made to existing requirements in part 483 subpart B. However, we provide burden estimates for the new information collection requirements finalized in this rule, specifically those requirements implemented as a result of the Affordable Care Act.

*Comment:* A few commenters raised concerns regarding the burden for information collection requirements for provisions covered under the waiver. Specifically, commenters indicated that the revised regulations will increase the amount of documentation that facilities must produce and maintain and these increases were not discussed in the COI

*Response:* We agree that under usual circumstances the paperwork burden related to documentation would be presented in the collection of information section; however in the proposed rule we indicated that sections 4204(b) and 4214(d) of OBRA '87 provide for a waiver of PRA requirements for these regulations. There have not been any amendments or other changes made by Congress to the PRA exemption regarding OBRA '87 provisions. Therefore, given that these regulations set forth requirements necessary to o implement sections 1819 and 1919 of the Act, we believe that the waiver still applies. We note that we specifically provided a discussion of the information collection actions for those requirements implemented through the Affordable Care Act because the Affordable Care Act did not provide PRA exemption for the added sections.

Sources of Data Used in Estimates of Burden Hours and Cost Estimates

We obtained the data used in this discussion on the number of the Medicare and Medicaid participating LTC facilities from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of May 1, 2016. We have not included data for nursing facilities that are not Medicare and/or Medicaid certified. Since the individual States periodically update the CASPER system, the number of SNFs and NFs may vary depending upon the date of the report. Thus, while number of facilities reflected in this final rule is accurate as of the date of the report, the actual number of facilities may be different as of the date of this final rule's publication.

Unless otherwise indicated, we obtained all salary information for the different positions identified in the following assessments from the US Bureau of Labor Statistics at *http://www.bls.gov/oes*. We calculated the estimated hourly rates based upon the national average salary for that particular position, including fringe benefits and overhead worth 100 percent of the base salary. Where we were able to identify positions linked to specific positions, we used that compensation information. However, in some instances, we used a general position description or we used information for comparable positions. For example, we were not able to locate specific information for LTC facility administrators and directors of nursing, so we used the average hourly wage for a medical and health services manager for these positions. Table 2 below summaries the various positions and salaries associated with the positions used in our analysis. We note that the same information has been used for our estimates in the impact analysis section.

TABLE 2—SOURCE INFORMATION USED FOR BURDEN ESTIMATES

[*Salaries include a 100 percent increase for fringe benefits and overhead]

| | |
|---|---|
| Number of LTC Facilities | 15,653 |
| Number of Operating Organizations | 7,314 |
| Salary of a RN | $61 |
| Salary of a Director of Nursing | $85 |
| Salary of an Administrator | $85 |
| Salary of a Nurse Aide | $25 |
| Salary of a Social Worker | $47 |
| Salary of an Office Assistant | $31 |
| Salary of an Attorney | $131 |
| Salary of a Physician | $185 |
| Salary of a Facilities Manager | $37 |

In addition, in estimating the burden associated with this final rule we also took into consideration the many free or low cost resources LTC facilities have available to them. The following is a non-exhaustive list of some of the available resources:

- *http://www.nhqualitycampaign.org*
- *http://www.ascp.com*
- *http://www.amda.com*
- *http://www.ahcancal.org*
- *http://www.leadingage.org*
- *http://www.americangeriatrics.org*
- *http://www.ntocc.org*

*A. ICRs Regarding Quality Assurance and Performance Improvement (§ 483.75)*

Each facility is currently required to maintain a QAA committee consisting of the director of nursing services, a physician designated by the facility and at least three other members of the facility's staff. The committee must meet at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary. The committee is required to develop and implement appropriate plans of action to correct identified quality deficiencies. Based on our experience with facilities' compliance with QAA requirements, we anticipate that they already have some of the resources needed to develop and implement a proactive QAPI program. In addition, some ICRs will be met through the technical assistance provided to facilities by CMS on the development of best practices, as required by the Affordable Care Act.

We proposed at § 483.75 that a facility have a QAPI program. The burden associated with these requirements will be the time and effort necessary to develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate the ongoing performance of the facility. The facility must establish a program to address the key components of the standards (program measures, program scope, and program activities). The existing regulations require that QAA committees identify and correct specific deficiencies. We believe facilities will use some of the resources they have to comply with the QAA requirements (such as collecting data), in the development of a QAPI-based, proactive approach to assessing services they provide (including those services furnished under contract or arrangement) and to improve the quality of care and quality of life provided to their residents.

Since the existing Interpretative Guidelines for facilities to comply with the Medicare regulations provide information on how to conduct quality improvement programs, we anticipate that some facilities are already utilizing the QAPI model. We also anticipate that facilities will use their existing resources to meet the requirements in this final rule. To the extent that facilities are utilizing a QAPI quality model and are proactively collecting data, evaluating their performance, and making and monitoring program improvements, they will be better prepared to comply with the QAPI requirements. However, for the purpose of this burden analysis, we assume that all facilities will need to develop a QAPI program.

Based on our experience with other Medicare providers that have developed QAPI programs, we estimate that, on average, it will take 56 hours for the facility to develop and document a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all services and programs of the facility, including services provided under contract or arrangement.

We estimate that the facility administrator will be largely responsible for developing the overall QAPI program and will spend approximately 30 hours on this activity; the director of nursing and a registered nurse will each spend approximately 10 hours each to review and provide input on clinical services activities; a physician will spend approximately 4 hours to review the program plan and provide medical direction and input; and one office assistant will spend approximately 2 hours to prepare and distribute draft and final program plans. We estimate that this will require a total of 876,568 (56 hours × 15,653 facilities) burden hours for all LTC facilities to develop a QAPI program.

We estimate that the cost for the administrator will be $2,550 ($85 × 30 hours). We estimate the cost for the director of nursing will be $850 ($85 × 10 hours). We estimate that the cost for an RN would be $610 ($61 per hour × 10 hours). We estimate that the cost for the physician will be $740 ($185 × 4 hours). We estimate that the cost for an office assistant will be $62 ($31 × 2 hours). The estimated one-time cost for each facility will total $4,812. The total one-time cost for all LTC facilities will be $75,322,236.

We anticipate that the ongoing, annual burden for each facility to collect and analyze data for QAPI activities will be 20 hours. We also anticipate that to document the improvement activities will require 20 hours. We estimate the total annual burden hours for all LTC facilities will be 626,120 (40 hours × 15,653 facilities). We anticipate that the staff time will be distributed as follows:

Administrator: collect and analyze data: 10 hours; implement and document improvement projects: 4 hours. (Total cost of $1,190 ($85 × 14 burden hours)).

Director of Nursing: collect and analyze data: 4 hours; implement and document improvement projects: 10 hours. (Total cost of $1,190 ($85 × 14 burden hours)).

RN: collect and analyze data: 4 hours; implement and document improvement projects: 6 hours. (Total cost of $610 ($61 × 10 burden hours).

Physician: analyze data: 1 hours. (Total cost of $185).

Office Assistant: collect and analyze data: 1 hours. (Total cost of $29).

Therefore, we estimate that the on-going annual cost for each facility will be a total of $3,204. We estimate that the total on-going annual cost for all LTC facilities will be $50,152,212.

*Comment:* A few commenters indicated that we underestimated the amount of time and work it will take for facilities to come into compliance with our proposed QAPI requirements. One commenter provided a QAPI implementation task list including costs associated with each task. The commenter noted that the QAPI task list was based on an independently owned nursing center that cares for a little over 100 residents and highlighted that this center has already begun implementation of QAPI. The commenter indicated that specific to this nursing center it would cost them around $30,000 to develop a QAPI plan and an on-going annual cost of around $82,000.

The commenter noted further that the burden estimates provided in the proposed rule for developing a QAPI plan are flawed because unlike other Medicare and Medicaid providers/suppliers, LTC facilities have to meet Requirements for Participation, not Conditions of Participation. The commenter indicated that due to this, LTC facilities will spend greater time developing a plan because they are at greater risk for decertification (than other Medicare and Medicaid providers/suppliers) if noncompliance is determined by CMS.

*Response:* We appreciate the commenter's feedback and examples. We recognize that implementing a QAPI program can involve many tasks. However, we note that the specific tasks will be based on the individual needs of each facility. We provided a broad estimate of what facilities will need to do in order to develop a QAPI plan. Some facilities may view our estimates as an underestimate, while for some other facilities our estimates may prove to be an overestimate. We believe that our estimate provides all LTC facilities with a general idea of the burden and time that may be involved with developing a QAPI plan.

We note that these requirements build on the knowledge gained during the CMS QAPI demonstration in LTC facilities. We believe facilities are familiar with the principles that we proposed and expect that some facilities have or are in the process of developing QAPI programs using the materials developed during the demonstration. These materials were provided to LTC facilities on June 7, 2013 (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13–37.pdf*) and remain available on the CMS Web site (see *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html*). Nonetheless, we recognize the level of work it will take for facilities to come into compliance with these requirements. To address this concern, that facilities may need additional time to comply with these provisions, in this final rule we provide a phased in implementation of these QAPI requirements over 3 years (see Section. II.B. Implementation Date). We believe that this additional time, along with the resources provided through the CMS QAPI demonstration, will allow facilities the time necessary to allocate their resources and efficiently develop their QAPI program.

Lastly, we disagree with the commenter's assertion that LTC facilities will spend more time developing their plans because they are at greater risk for being decertified since they have to meet requirements for participation rather than conditions of participation. We provide a detailed discussion regarding this concern in the general comments section and encourage commenters to review that section.

*B. ICRs Regarding Compliance and Ethics Program (§ 483.85)*

Section 483.85 requires the operating organization for each SNF and NF to have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under the Act and promoting quality of care. Each compliance and ethics program must contain at least the eight required elements in § 483.85(c). The operating organization for each facility must also review its compliance and ethics program annually, and revise its program, as needed. Furthermore, § 483.85(d) has additional requirements for operating organizations that operate five or more facilities.

For the purpose of determining a burden for this final rule, we have estimated a burden based on the number of SNF and NF operating organizations. We expect that the operating organization will develop the compliance and ethics program in collaboration with staff at their facilities and then share the implementation of the program with its operating facilities. Since it will be the individual facilities that will be surveyed and not the operating organization, operating organizations will need to ensure that the appropriate documentation is available at all of their individual facilities in order to demonstrate compliance with all of the relevant requirements in this final rule. Therefore, the burden we have assessed for the operating organization will encompass their working with staff at their individual facilities.

The current regulations for SNFs and NFs do not contain any requirements for a compliance and ethics program. However, SNFs and NFs, as well as all other health care facilities, must comply with all applicable statutes, regulations, and other mandatory guidance or face criminal, civil, or administrative sanctions. In addition, as discussed previously, the OIG had issued voluntary guidance about compliance and ethics programs for SNFs and NFs in 2000 and 2008. We also believe that it is standard practice for SNFs and NFs to have high-level personnel, such as the administrator, director of nursing, or the facilities director, be responsible for ensuring that the facility is in compliance with all of the applicable federal, state, and local laws. We believe that many, if not all, of the operating organizations for SNFs and NFs already have some type of compliance program in operation. Furthermore, since many of the proposed required components for the compliance and ethics programs are very similar to many of the listed elements for the programs in the OIG's voluntary guidance documents published in 2000 and 2008, we believe the compliance and ethics programs that are already being used by many facilities include many, if not all, of the components in this rule. However, since adherence to the OIG's guidance was voluntary and did not impose mandatory obligations, we also believe that some of these existing programs may not have all, or perhaps any, of the required components or may not be documented or included in the facility's standards, policies, or procedures. Therefore, we believe that all of the operating organizations for the SNFs

and NFs will need to review their current programs and possibly revise or, in some cases, develop new sections for their programs in order to comply with the requirements in this final rule.

Based on an analysis of the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) and CASPER data, there are 9,200 SNFs and NFs that are part of a multi-facility operating organization (an operating organization with 2 or more facilities). Furthermore, based on PECOS and CASPER data, for purposes of this regulation, we estimate that there are 7,314 total operating organizations (395 operating organizations with 5 or more facilities, 419 operating organizations with 2 to 4 facilities, and 6,500 operating organizations with single facilities). Based on our experience with SNFs and NFs, we expect that the administrator and the director of nursing will primarily be involved in developing the operating organization's compliance and ethics program. Thus, in determining the burden for all of the requirements in § 483.85, except for § 483.85(d), we will analyze the burden based on an administrator and the director of nursing performing the necessary tasks and activities. If the operating organization has a designated compliance officer, we expect that he or she will take the lead in developing the entire program with the assistance of the administrator and the director of nursing as needed or when required. Since we have estimated that the compliance officer and the director of nursing will receive about the same amount of compensation, $85 an hour, and that the necessary activities will require about the same numbers of hours, we believe our estimates will be about the same regardless of whether these tasks and activities were performed by the administrator and the director of nursing or by the compliance officer with the assistance of the administrator and the director of nursing.

As described previously, LTC facilities must already ''be in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility'' (§ 483.85(b)). Thus, we expect that LTC facilities are already performing many of the tasks and activities necessary to a compliance program and spending hours of their time on compliance issues, especially the LTC facilities in multi-facility operating organizations. However, we are not certain that most LTC facilities have formal programs that comply with the requirements in this proposed rule. Thus, we believe that LTC facilities will sustain a burden associated with the requirement to develop a program that complied with this final rule from the resources needed for each facility to review, revise, and, if needed, develop new sections for the operating organization's compliance and ethics program.

We estimate that complying with this requirement will require 10 burden hours from the administrator and 10 burden hours from the director of nursing for a total of 20 burden hours from these individuals at an estimated cost of $1,700 (20 hours × $85 hourly wage). In addition, since we are requiring compliance and ethics programs to be mandatory, we expect that facilities will have an attorney review their programs to ensure they are in compliance with the requirements in this rule. The cost of having an attorney review the operating organization's program will vary depending on whether the operating organization has in-house counsel or has to hire an attorney at a law firm. For the purposes of determining the burden, we will assume that each operating organization has in-house counsel. We expect that an attorney will need to review the facility's compliance and ethics program, make recommendations, and approve the final program. We estimate this will require 4 burden hours at an estimated cost of $524 ($131 hourly wage × 4 hours).

Based on this data, we estimate it will require a total of 24 burden hours (10 hours for an administrator + 10 hours for the director of nursing + 4 hours for an attorney) for each operating organization to develop a compliance and ethics program that complied with the requirements in this final rule at a cost of $2,224 ($1,700 for the administrator and director of nursing + $524 for an attorney). Therefore, we estimate it will require 175,536 annual burden hours (24 burden hours for each operating organization × 7,314 operating organizations) at a cost of $16,266,336 ($2,224 for each operating organization × 7,314 operating organizations) for all facilities to comply with this requirement.

Each operating organization will also need to develop the policies and procedures necessary to implement the operating organization's compliance and ethics program. The burden associated with this requirement will be the resources needed to review and revise any existing policies and procedures and, if needed, develop new policies and procedures. Based on our experience with SNFs and NFs, we expect that the administrator, director of nursing, or perhaps both of these individuals will develop these policies and procedures. We estimate that it will require 10 burden hours for each operating organization to comply with this requirement at a cost of $850 ($85 hourly wage for a health services manager × 10 hours). Therefore, we estimate that for all 7,314 operating organizations to comply with this requirement, it will require 73,140 burden hours (10 burden hours for each operating organization × 7,314 operating organizations) at a cost of $6,216,900 ($850 per operating organization × 7,314 operating organizations).

In addition to developing the compliance and ethics program, each operating organization will be required to develop training materials and/or other publications to disseminate information about the program to its entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. As stated previously, we believe that facilities are already performing many of the tasks necessary for a compliance program and spending many hours on compliance issues. Thus, we expect that many operating organizations already have some of the materials and/or other publications that will be needed to comply with this requirement. The burden associated with this requirement will be the resources needed to review and revise any existing materials and, if needed, develop new materials to comply with this requirement. Based on our experience with operating organizations, we expect that the compliance liaison (nursing staffs) will be involved in these activities.

We believe that the compliance liaison will need 8 hours to develop these materials. Thus, we estimate it will require 8 burden hours for each operating organization to comply with this requirement at a cost of $488 ($61 hourly wage × 8 hours). Therefore, based on the previous estimate, for all 7,314 operating organizations to comply with this requirement it will require 58,512 burden hours (8 hours × 7,314 operating organizations) at a cost of $3,569,232 ($488 per operating organization × 7,314 operating organizations).

We also proposed in § 483.85(e) that the operating organization for each facility must review its compliance and ethics program annually, and revise its program, as needed. Thus, after LTC facilities develop their compliance and ethics programs, these facilities will need to review and revise their programs, as needed, in the subsequent

years. Based on our experience with other healthcare facilities, we expect that most facilities are already periodically reviewing their programs, policies, and procedures. However, since an effective compliance and ethics program requires that a facility stay up-to-date with all SNF and NF requirements to reduce the prospect of criminal, civil, and administrative violations and promote quality of care, we believe that the facility would require more time to review this program as compared to its other programs, policies, and procedures that it must periodically review. In addition, since it is common for there to be changes in laws, regulations, and other requirements, we expect that most SNFs and NFs will need to make at least some revisions annually. Even if there are no changes in the applicable laws, regulations, or other requirements, SNFs and NFs may need to make changes in their training materials or other publications.

We expect that the administrator or the director of nursing, or perhaps both, will be responsible for reviewing this program annually to ensure it was up-to-date and in compliance with all of the relevant federal and state laws, regulations, and other guidance. We expect that to comply with this requirement will require 5 hours from the administrator and 5 hours from the director of nursing for 10 burden hours at a cost of $850 ($85 hourly wage for administrator and director of nursing × 10 hours). Therefore, based on the previous estimate, for all 7,314 facilities to comply with this requirement will require 73,140 burden hours (10 hours × 7,314 operating organizations) at a cost of $6,216,900 ($850 per facility × 7,314 operating organizations).

Based upon the previous estimates, for the first year that this requirement is in effect, it will require 42 burden hours (24 hours for developing the program + 10 hours for developing policies and procedures + 8 hours for developing training materials, publication or both) at a cost of $3,562 ($2,224 for developing the program + $850 for developing policies and procedures + $488 for developing training materials, publication or both) for each operating organization to comply with this requirement. Based on the estimates shown previously in this section, for all 7,314 operating organizations to comply with these requirements it would require 307,188 burden hours (42 hours per operating organization × 7,314 operating organizations) at an estimated cost of $26,052,468 ($3,562 per operating organization × 7,314 operating organizations). For all subsequent years, we estimate to comply with the information collection will annually require 10 burden hours at a cost of $850. For all 7,314 operating organizations, it will require 73,140 (10 hours × 7,314 facilities) burden hours at an estimated cost of $6,216,900 ($850 per operating organization × 7,314 operating organizations).

*Comment:* One commenter disagreed with our estimate of costs to develop and implement a compliance program and indicated that the estimate of $139 million for the first year and $120 million for the second year is unrealistically low. The commenter noted that some of the large operating organizations budget over a million dollars annually to implement a compliance and ethics program and that significant funding is required to draft new policies and procedures, implement internal or external monitoring/auditing. The commenter also notes that developing a compliance and ethics program may require hiring additional staff or consultants to provide process and oversight guidance. The commenter indicated that the cost to annually review the program is very costly and may cost anywhere between $5,000 and $75,000 per year, depending on facility size. In summary, the commenter noted that the number of facilities with existing compliance and ethics programs will vary and recommended that all providers have at least two years to implement the compliance and ethics requirements.

*Response:* We understand that the actual cost to develop and implement a compliance and ethics program, as well as all of the other LTC facility requirements, will vary based on the individual characteristics of each LTC facility. We note that in the impact analysis for the proposed rule we allocated an estimated cost of $19,319,040 for operating organizations with five or more facilities to establish a compliance officer to carry out the program. We also allocated an estimated cost of $95,052,256 for operating organizations with less than five facilities to establish a compliance liaison to carry out the program. This information has been updated for the final rule and we encourage readers to review the impact analysis section collectively with the collection of information section. To alleviate some of the burden placed on LTC facilities we have provided a phased in implementation period of the proposed requirements over 3 years. Specifically, the compliance and ethics requirements will have a implementation timeframe of 3 years following the effective date of this final rule. We believe that this will provide all LTC facilities, regardless of size, a considerate amount of time to budget these costs into their financial plans. A detailed discussion regarding the implementation plan for this final rule can be found in Section II.B. Implementation.

*C. ICRs Regarding Training Requirements (§ 483.95)*

Each facility is already required to complete a performance review of every NA at least once every 12 months, and must provide in-service education based on the outcome of these reviews. At § 483.95(g)(2) facilities are required to include dementia management and abuse prevention in their regular in-service education for all NAs.

Existing regulations at § 483.75(e)(8)(iii) (relocated to § 483.95 in this final rule) already required that NAs who provide services to individuals with cognitive impairments receive in-service training to address the care of the cognitively impaired. Based on the existing requirements, facilities already conduct training for some NAs on caring for residents who are cognitively impaired. Additionally, the existing requirements at § 483.75(e)(8)(ii) (relocated to § 483.95 in this final rule) stated that NAs must receive in-service training that addresses areas of weakness as determined in their performance reviews and may address the special needs of residents, as determined by the facility staff. Thus NAs receive annual training in dementia management and abuse prevention only if the training is indicated by their performance reviews.

Because this final rule specifically requires facilities to provide dementia management and abuse prevention training to all NAs, each facility will need to review their training procedures and materials to ensure that they are complying with the new requirements. For example, facilities may currently provide the in-service training (as identified from the performance review) utilizing an individual, targeted approach. In this final rule, all NAs are required to receive this training annually, and the facility will need to evaluate whether another format might be more appropriate.

Since we are not increasing the time needed to provide this training, we are not adding additional burden for the staff to train the NAs, since the existing requirements for facilities require them to provide in-service training to all NAs at least once every 12 months. We estimate that the burden associated with complying with this requirement will be a one-time burden due to the resources required to review and, if necessary,

modify the existing training materials to apply to all NAs, regardless of identified performance weaknesses. We expect that these activities will require the involvement of a RN or a LPN. Based on our experience with facilities, we anticipate that it will take each facility 4 hours to review and modify their existing training materials. Based on an hourly rate of $61 for an RN, we estimate that this will require 62,612 burden hours (4 hours × 15,653 facilities) at a cost of $244 for each facility. The total cost for all LTC facilities is estimated to be $3,819,332 ($244 × 15,653 facilities).

Table 3 below summarizes the estimated annual reporting and recordkeeping burdens for this final rule.

TABLE 3—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

| Regulation section(s) | OMB Control No. | Number of respondents | Number of responses | Burden per response (hours) | Total annual burden (hours) | Hourly labor cost of reporting ($) | Total labor cost of reporting ($) | Total cost ($) |
|---|---|---|---|---|---|---|---|---|
| § 483.75(a) | 0938—New | 15,653 | 15,653 | 56 | 876,568 | ** | 75,322,236 | 75,322,236 |
| § 483.75(b)(2) | 0938—New | 15,653 | 15,653 | 40 | 626,120 | ** | 50,152,212 | 50,152,212 |
| § 483.85(b) | 0938—New | 7,314 | 7,314 | 24 | 175,536 | ** | 16,266,336 | 16,266,336 |
| § 483.85(c) | 0938—New | 7,314 | 7,314 | 10 | 73,140 | ** | 6,216,900 | 6,216,900 |
| § 483.85(d)(1) | 0938—New | 7,314 | 7,314 | 8 | 58,512 | ** | 3,569,232 | 3,569,232 |
| § 483.85(e) | 0938—New | 7,314 | 7,314 | 10 | 73,140 | ** | 6,216,900 | 6,216,900 |
| § 483.95 | 0938—New | 15,653 | 15,653 | 4 | 62,612 | ** | 3,819,332 | 3,819,332 |
| Totals | | 22,967 | 76,215 | | 1,945,628 | | | 161,563,148 |

** The hourly labor wages are discussed in detail earlier in this section.
There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 3.

If you comment on these information collection and recordkeeping requirements, please submit your comments to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn.: William Parham, (CMS–3260–F), Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: CMS Desk Officer, CMS–3178–F, Fax (202) 395–6974.

## VI. Regulatory Impact Analysis (RIA)

### *A. Statement of Need*

CMS has not comprehensively reviewed the entire set of requirements for participation imposed on LTC facilities in many years. CMS staff conducted a review of the existing requirements as well as those issues identified by stakeholders as problematic over the years. Accordingly, the revisions to the requirements in this final rule will improve the quality of life, care, and services in facilities and optimize resident safety. In addition, the revisions in this final rule reflect current professional standards and improve the logical flow of the regulations.

### *B. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, taken together with COI section and other sections of the preamble, presents to the best of our ability the costs and benefits of the rulemaking.

### *C. Comments on the Initial Regulatory Impact Analysis*

As discussed previously, we received nearly 10,000 public comments in response to the proposed rule. While many of those comments discussed the overall burden that the proposed requirements will place on facilities, few addressed the specifics of our preliminary regulatory impact analysis. We discuss those specific comments below. When possible, as discussed in our responses, we adjust our final analysis to take into account these comments.

*Comment:* Several commenters highlighted the decrease in Medicaid funding provided to LTC facilities and additional changes in the delivery of care and reimbursement for LTC facilities as challenges for meeting the financial costs associated with this final rule. Specifically, commenters noted several additional initiatives currently taking place within the LTC industry such as value-based purchasing (VBP), the advancement of accountable care organizations (ACOs), dual demo projects, and bundled payments.

Commenters noted that LTC facilities are already struggling, have limited resources and limited staff, and will have difficulty meeting the financial costs of this final rule. Commenters indicated that the majority of the residents in LTC facilities are Medicaid recipients, while one commenter in particular highlighted the impact of those facilities located in Wisconsin. The commenter indicated that in 2013–2014 Wisconsin LTC facilitys lost on average $52.11 per day for each Medicaid resident they served. The commenter noted further that 65 percent of the residents in Wisconsin LTC facilities are Medicaid recipients. In addition, the commenter notes a recent reduction in expenditures for SNFs by $14 billion through 2020 and a decrease in SNF reimbursement payments. Several commenters suggested that to avoid closures, staff cuts, or compromised care, CMS should pay for the proposed changes instead of placing the financial impact of this regulation on LTC facilities. Likewise, several commenters recognized that Medicaid is funded by states and suggested the CMS should implement a phased in implementation of the requirements and withdraw some of the proposed requirements to better allow facilities to meet the financial costs of this regulation.

*Response:* We appreciate the comments from commenters. We understand that for some facilities Medicaid reimbursement accounts for a large portion of its funding, however the specifics regarding Medicaid funding is regulated by the State and outside the scope of this regulation. We also recognize that there are additional initiatives taking place within the industry that fall outside the requirements in the regulation and will have an impact on LTC facilities including SNF reimbursement. However, as noted previously SNF PPS payment rates have increased steadily over recent years, due to market basket updates. In addition, the cost associated with operating a business that is in compliance with the requirements for LTC facilities is the responsibility of the facility.

In an effort to acknowledge the concerns raised by commenters and potentially reduce the immediate financial impact that this final rule will impose on facilities, we are finalizing a phased-in implementation of the requirements over 3 years. Readers should refer to Section B. ''Implementation'' for our discussion of the phased-in implementation deadlines. In response to public comments and in consideration of the burden imposed on facilities, we have also removed or made several revisions in this final rule to increase flexibility and avoid creating unintentional consequences for facilities. Readers should refer to Section III. ''Provisions of the Final Regulations'' for a detailed discussion of the changes from the proposed rule to the final rule.

*Comment:* Some commenters indicated that this regulation will increase the workload for both state mental health agencies and long-term care ombudsman programs. Specifically, the commenter noted that this proposed rule will increase the reporting by SNFs of patients and PASARR findings to the State Mental Health Authority. Commenters noted that the amount of information to be reported and investigated by the state Ombudsman will increase dramatically. One commenter requested that CMS conduct a cost analysis regarding these increases in workload, as well as a cost analysis of the impact on Federal and State Medicaid budgets.

*Response:* We recognize that these LTC facility requirements may have an indirect impact on additional entities. However, due to data limitations, we are unable to quantify with any degree of certainty the impact that these revisions will impose on these outside entities.

*Comment:* One commenter requested that we revisit the estimated impact that this regulation will place on federal, state, county, city and tribal budgets. The commenter indicated that approximately 912 SNFs are owned and operated by a federal agency, state, county or city governments as well as tribal authorities. Specific to the 912 SNFs, the commenter suggested that the proposed changes represent an unfunded mandate of $42 million that was not accounted for in the proposed rule impact analysis.

*Response:* In the proposed rule we indicated that there were 15,691 LTC facilities that participated in the Medicare and Medicaid program. The 15,691 LTC facilities accounted for in the proposed rule include those SNFs that are owned or operated by a federal agency, as well as tribal authorities. Therefore, we disagree with the commenter and believe that the cost estimates in the proposed rule, and subsequently this final rule, account for those cost placed on the 912 SNFs identified by the commenter.

*Comment:* Some commenters noted that the proposed changes will increase the survey workload for each State Survey Agency and will ultimately increase both federal and state budgets. The commenter indicated that the proposed rule did not calculate the cost impact to the state survey agencies.

*Response:* We analyzed the additional time that may be required for surveyors to conduct their surveys based on the changes and accounted for the increase in the cost estimate for federal costs. We believe that the revisions in this final rule will have only an incremental impact on the workload of surveyors that is outside of their normal scope of practice. As a result of any regulation that we issue the survey process will be reviewed and surveyors are updated and trained on the new guidance. This standard process is no different for these regulations.

*Comment:* One commenter indicated that our calculations that used minutes rounded down the time. The commenter noted that our calculations for 5 minutes used .08 instead of .0833 and our calculations for 2 minutes used .03 instead of .0333.

*Response:* We understand that the use of varying rounding methods to convert minutes to decimals will have an impact on the total cost calculations and that different rounding methods could be used. Therefore, in this final regulation we have revised our calculations for those estimates that use minutes. Specifically, we have revised the inputs for our calculations by using unrounded numbers. For example, our calculations in the final rule for 5 minutes uses the input 5/60 rather than .08.

*Comment:* One commenter indicated that our use of 1,382,201 as the number of Medicare beneficiaries in our calculations did not take into consideration the admissions from a hospital as well as the turnover of long stay residents during a year.

*Response:* We made our best effort to locate an adequate estimate for the number of Medicare beneficiaries. We recognize that this estimate will vary depending on the data collection, however we believe that the use of information from a National study of LTC providers is an adequate data source for our calculations (see Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014'' *http://www.cdc.gov/nchs/fastats/nursing-home-care.htm*). We note that the commenter did not suggest an alternative source.

*Comment:* Commenters indicated that our estimate for providing notices to residents regarding their Medicaid eligibility is too low. The commenters indicated that the regulation emphasizes the importance of meaningful communication and that providing such

communication frequently requires additional time.

*Response:* Based on commenter concerns, in our final rule estimate we have increased the amount of time anticipated for a social worker to provide a resident with a notice of their Medicaid eligibility.

*Comment:* A number of commenters indicated that we underestimated the cost of informing residents of the facility's grievance process. Commenters indicated that establishing a grievance process and designating a grievance official will be costly.

*Response:* We have reviewed the new requirements for establishing a grievance policy against the existing requirements that facilities must met regarding a grievance process. After further review, we agree with commenters and have assessed a cost to the requirement for facilities to establish a grievance process that is coordinated by a grievance official in the final rule RIA.

*Comment:* Most commenters objected our proposal for a physician to evaluate a resident prior to hospital transfer unless a delay in transfer places the resident at risk. Commenters indicated that the requirement would impose a large financial impact on facilities.

*Response:* Based on the concerns raised by commenters, we have withdrawn this proposal. Please see our detailed discussion in Section II. L. of this preamble, ''Physician Services''.

*Comment:* We proposed to require facilities that receive approval of construction or reconstruction from State and local authorities or are newly certified after the effective date of the final rule, to have resident rooms must with bathrooms that are equipped with at least a commode, sink, and shower. One commenter indicated that many LTC facilities, many of which were built in the 1960's and 70s, are currently undergoing reconstruction projects. Another commenter indicated that including a shower in each bathroom will be cost prohibitive. In addition, commenters pointed out the need for additional square footage and the cost of the additional plumbing needed for a shower.

*Response:* In response to public comments, we have modified this requirement to require that bathrooms at least include only a sink and commode. In addition, we note that this requirement applies to those facilities that receive approval of construction or are newly certified after the effective date of this final rule. These requirement will not apply to those facilities that are currently being constructed or received approval for construction before the effective date of this final rule. A detailed discussion regarding the changes in the final rule can be found in Section II. Y., ''Physical Environment.''

*Comment:* A few commenters indicated that the requirement for an infection control officer requires a person to spend more than half of their time in this role, however the salary estimate in the proposed rule assumed only 15 percent of a FTE to this function.

*Response:* In this final rule, we have modified our proposal to require each facility to designate one individual as the infection preventionist (IP) for whom the infection prevention and control program (IPCP) is a major responsibility. We have revised the requirement to specify that each facility may designate more than one person as the IP and the IPCP no longer has to be a major responsibility of the individual(s).

*Comment:* Many commenters requested that we re-analyze the overall cost that this regulation will impose on LTC facilities. Commenters provided several comments indicating that, in general, the proposed financial impact is underestimated and inaccurate. The vast majority of these comments generalized the overall cost of the regulations and did not provide specifics regarding the calculations presented in the proposed rule. One commenter highlighted concerns regarding the clinical and financial feasibility of some of the proposals and provided an individualized analysis of the impact analysis presented in the proposed rule.

*Response:* In section D. below we provide the anticipated costs of the final rule. Given the concerns raised by commenters and the lack of specifics, we have broadly reviewed the impact analysis section for accuracy and made general improvements where possible. In addition, in several instances we have revised our initial estimates to reflect specific concerns raised by commenters. For example, we have revised the analysis associated with the requirement for facilities to designate a grievance official.

*Comment:* One commenter indicated that the proposed impact analysis did not meet the statutory requirements of OBRA 87 to take into consideration the costs of complying with requirements for participation when computing payments to SNFs.

*Response:* Generally payment policy related to SNFs falls outside the scope of regulations for the requirements of participation for LTC facilities because payment policy is implemented under separate regulation. However, 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.

*D. Anticipated Costs of the Final Rule*

As of this final rule, there are about 15,653 SNFs and NFs that are certified by Medicare and Medicaid. We use the number of SNFs and NFs to estimate the potential impacts of the final rule. We have used the same data source for the RIA that we used to develop the PRA burden estimates. As stated in the COI section, we obtained all salary information from the May 2015 National Occupational Employment and Wage Estimates, United States by the BLS at *http://www.bls.gov/oes/current/oes_nat.htm* and all salary estimates include benefits and overhead package worth 100 percent of the base salary. The analysis below overlaps with the COI section for some requirements, therefore readers may wish to consult both sections on some topics.

This final rule will require facilities to review their current practices and make changes to be in compliance with the health and safety standards as set forth in this final rule. However, it is important to note that many of the changes to the requirements are only re-designations of existing requirements that have been imposed on LTC facilities since the implementation of OBRA 87. In these instances, where existing requirements have been relocated to improve the clarity of the regulations, we do not anticipate that facilities will undertake new actions or bear any additional costs in response to the issuance of this regulation. In addition, based on our experience with

health care providers, we expect that many of the requirements in this final rule are standard medical or business practices and as a result will not impose an additional burden or new cost to facilities. We have made several assumptions in order to assess the time that it will take for a facility to comply with the requirements and the associated costs of compliance. There are uncertainties about the magnitude of the discussed effects of this regulation, however we have based our overall assumptions on our ongoing experiences with LTC facilities. Table 4 below summarizes the source information used for the RIA.

TABLE 4—SUMMARY OF SOURCE INFORMATION USED FOR RIA

| Number of LTC Facilities | * 15,653 |
|---|---|
| Number of LTC Facilities | *15,653 |
| Number of Operating Organizations with 5 or more facilities | 395 |
| Number of Operating Organizations with 5 or less facilities | 6,919 |
| Number of Medicare Beneficiaries | ** 1,369,700 |
| Hourly pay of a RN | $61 |
| Hourly pay of a Director of Nursing | $85 |
| Hourly pay of a LTC facility Administrator | $85 |
| Hourly pay of a Nurse Aide | $25 |
| Hourly pay of a Social Worker | $47 |
| Hourly pay of an Office Assistant | $31 |

**Note:** Hourly pay include a 100% increase for fringe benefits and overhead.
* Source: CASPER Data as of May 1, 2016.
** Source: Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014'' *http://www.cdc.gov/nchs/fastats/nursing-home-care.htm*.

We have summarized the anticipated impact that this final rule will have on LTC facilities by regulatory section.

1. Resident Rights § 483.10

Notification of Changes to Care Plan (§ 483.10(c)(2))

Existing requirements require that a resident, to the extent practicable, participate in the development of his or her care plan and be informed of the need to significantly alter treatment. We believe that the involvement and notification will include an opportunity to see the care plan. Periodic review after development of the care plan is also already required. However, we require a new right for the resident, the right to sign the care plan. The intent is to ensure that the resident, to the extent practicable and consistent with the resident's choices, demonstrates his or her participation in and review of his or her care planning and that participation is evident to care-givers, surveyors, and other interested parties. We estimate that it will take a registered nurse, no more than an additional 2 minutes per resident, to obtain a resident signature. We estimate that this may occur up to four times per year per resident. Based on an estimated 1,369,700 residents per year, the resulting burden will be $11,140,227 for all LTC facilitys. ($61 hourly wage for a nurse × (2/60) hour per occurrence × 1,369,700 residents × 4 occurrences per year).

Notification of a Need To Select a New Physician (§ 483.10(d)(4)

In this final rule, we require facilities to inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to comply with regulatory requirements, discuss alternatives, and honor the resident's preferences. Under existing requirements, the facility is already required to ensure that the resident is informed of the name, specialty, and way of contacting the physician responsible for his or her care. We have no basis to quantify how often this occurs or how often a facility will need to obtain an alternate provider. We believe that these conversations will be accomplished, and in most cases already occur, in the course of routine communication between a resident and caregivers. Thus, we do not believe this creates any new burden.

Notification of Charges § 483.10(f)(11)(iii)

We specify that if a resident requests an item or service for which the facility will charge, the facility must inform the resident both orally and in writing of the charge. Existing provisions require that facilities only ''inform'' the resident. We expect that ''informing'' has typically been accomplished orally; therefore the additional cost to facilities is associated with providing the written information at the time the oral information is given. We anticipate that this written information will most often be in the form of a list of standard charges for frequently requested items and the cost will be the cost of photocopying or printing the list. In infrequent cases, an individualized cost page may be needed. We estimate that a facility will spend no more than $50 per year on average to print the notices. We estimate the cost of a notice to be $0.10/page (based on the per page photocopying cost established at 45 CFR 5.43(c) for FOIA requests) with no more than 500 notices required per facility per year for a total estimated cost of $782,650 ($50 printing cost × 15,653 facilities) annually for all facilities.

Internet Access (§ 483.10(g)(9))

Section 483.10(g)(9) requires that a resident has the right to reasonable access and privacy for electronic communications such as email and video communications and internet research. This provision does not require that the facility provide internet access to any greater extent than the facility already has internet access (that is, a facility that has no internet access due to logistical deterrents is not required to overcome those obstacles based on this requirement) and the facility is allowed to transfer any additional expense to the resident if any additional expense is incurred. The facility is not obligated to provide each resident an individual means of access (that is, a personal computer or tablet). A community computer with associated rules for sharing, such as is commonly done in public libraries, may be an appropriate model. While we allow the facility to pass additional costs to the resident, we anticipate that some facilities may incur an initial hardware cost that is not attributable to an individual resident. In addition, we expect there will be minimal ongoing maintenance/replacement costs for the shared devices. We do not believe this requirement will add to the supervision burden for facility staff, as appropriate resident supervision is already required,

but it may require a director of nursing (DoN) or nursing home administrator (NHA) to establish rules for use. We estimate this will require quarter of an hour of DoN or NHA time to develop in those facilities that do not already have a policy established. Furthermore, we estimate that up to ten percent of facilities will need to develop an internet policy. Based on this information, we estimate that this requirement will impose a one-time cost of $33,263 on facilities (($85 hourly wage for a DoN or NHA × .25 hours) × (0.10 × 15,653 facilities)). We note that to determine the hourly wage for a DON or NHA, we used the salary information for a medical and health services manager within the SNF and NF industry from BLS data (as detailed previously).

Resident Groups in the Facility(§ 483.10(f)(5)(iii))

Facilities are currently required to provide a designated staff person to participate in resident and family groups. The revised requirement adds that the designated staff person must be approved by the resident or family group. We anticipate that the DoN will select a representative and obtain group agreement by providing a name or names to the group and the group will respond. We estimate that this will generally consume no more than an additional 15 minutes of the DoNs time in most cases. We believe some facilities already have such mutually agreed upon representatives. However, for we estimate that this additional requirement will cost facilities $332,626 ((.25 (15 minutes) × $85 (hourly wage for DoN)) × 15,653 LTC facilities).

Updating of Notices

We are finalizing provisions that will require facilities to review and update their existing notices of rights and services and inform residents of these updates. First, at § 483.10(f)(4)(vi)), we are finalizing our provision to require facilities to inform each resident of their visitation rights. Second, at § 483.10(g)(5) we have added additional state regulatory and information agencies that facilities must post the contact information for to be available to residents.

When assessing the burden of these requirements we make a few assumptions. First, we believe that notices regarding facility practices are periodically reviewed and updated as a standard business practice. In addition, we believe that a facility's visitation policy is already addressed in their notices of rights and services that must be provided to a resident regarding the rules and regulations that govern resident conduct and responsibilities during their stay in the facility.

Based on these assumptions, we expect that facilities will need to review and update their notices of rights and services on a one-time basis to specifically include the new visitation requirements, additional contact information, and grievance requirements. We believe that an office assistant may be tasked with updating the notices and distributing or posting, as appropriate, the updated information. We estimate that it will require an office assistant no more than 1 hour to make any necessary updates the notice at a total one-time cost to facilities of $485,243 (1 burden hours × $31 (hourly wage of office assistant) × 15,653 LTC facilities).

Medicaid Eligibility (§ 483.10(g)(17))

Current regulations facilities to provide notice to a resident of their Medicaid eligibility. We have revised the requirement so that those residents who are not eligible for Medicaid at admission will receive an additional notice when they do become eligible. This means some residents will require both a notice at admission and a second notice. As the notice of Medicaid eligibility is already required once, the new cost is associated with providing the notice an additional time. We anticipate that this will affect only a subset of residents (those eligible but not yet receiving Medicaid). Thus, based on a data analysis by AHCA, approximately 64 percent of LTC facility residents are already Medicaid recipients (that is, Medicaid is the payor of record), 14 percent are covered by Medicare, and 22 percent have another payor. Of those, only the 36 percent who are not receiving Medicaid may require the second notice of Medicaid eligibility. We assume that a portion of those will require ongoing care and become eligible for Medicaid. We also assume that some of those residents will apply for Medicaid at or shortly after admission or as a result of the first notice and not require the second notice. Based on these assumptions, we estimate that 20 percent of LTC facility residents (slightly more than half of those not already receiving Medicaid) will actually require a second notice of Medicaid eligibility. We anticipate that a social worker will track a resident's status of Medicaid eligibility and provide the notice. In the proposed rule, we estimated that it would take a social worker 3 minutes per resident to provide the notice. Based on public comments, for the final rule analysis we have added an additional 2 minutes to allow for proper communication, for a total of 5 minutes per resident. We estimate that it will cost $3.92 per resident who requires the additional notice or $1,072,932 to provide these notices to the applicable residents across all 15,653 facilities (($47 hourly wage for social worker × (5/60) of an hour) × (.20 estimate percent of all LTC facility residents who will require a second notice × 1,369,700 LTC facility residents)). We note that the actual per facility cost will vary significantly according to facility size and resident mix.

Grievances (§ 483.10(j))

We are finalizing our proposal to require facilities to establish a grievance policy and identify a grievance official who is responsible for overseeing the grievance process. Existing regulations provide residents with the right to voice grievances without discrimination or reprisal and require facilities to promptly resolve grievance. Based on these existing regulations, we expect that most facilities already have process for residents to file a grievance and a process in which they will investigate and respond. Therefore, the cost associated with establishing a grievance policy will be associated with designating an individual as the grievance official who is responsible for overseeing the grievance process. We do not specify who has to be the grievance official, but for purposes of estimating the cost we believe that an average facility will designate a social worker to be the grievance official and that individual will need to commit about 10 percent of a FTE to his or her responsibilities for overseeing the grievance process. We estimate that this will cost $153,023,728 for all LTC facilities to comply with requirement (10 percent of a social worker FTE × $47 hourly wage for a social worker × 2,080 hours (40 hours a week × 52 weeks = 2,080 hours) × 15,653 facilities).

2. Admission, Transfer, and Discharge Rights (§ 483.15)

Notice of Transfer (§ 483.15(c)(4))

Existing regulations require facilities to notify the resident and a representative of the resident before a facility transfers or discharges the resident. These final regulations add that a facility must also send notice to the Office of the State Long-Term Care Ombudsman. The notice is already created for the resident; this requirement poses an additional burden of printing a copy of the notice and sending it to the Office of the State Long-Term Care Ombudsman or, if a

secure means of electronic transmission is available, sending a notice electronically. We estimate the burden of this requirement to be $.10 per notice to make a copy, and $.58 for a single pre-stamped first class envelope (USPS retail) plus 5 minutes for an office assistant to address and mail the notice. This will apply primarily to residents who are involuntarily discharged from the facility and does not include residents who request the transfer or who are transferred on an emergency basis to an acute care facility. We estimate this notice may need to be sent to the Office of the State Long-Term Care Ombudsman for one third of all LTC facility residents, resulting in a cost of $1,340,936 (($.10 + $.58 + ($31 hourly wage for an office assistant × .(5/60) of an hour)) × (.3 percentage of LTC facility residents for whom a copy of a transfer notice needs sent to the Office of the State Long-Term Care Ombudsman × 1,369,700 LTC facility residents)) for all facilities. We note that the per-facility cost will vary significantly according to facility size and number of transfers out of each facility.

Update Transfer Notices (§ 483.15(c)(6))

We are finalizing our proposal to add a requirement for facilities to update a transfer notice if the information changes and provide the updated information to the recipients of the notice as soon as practicable once the updated information is available. We believe that updates regarding any changes are already occurring in facilities informally. Based on this assumption we estimate that updating the notice and providing it to the resident will require a social worker an additional 5 minutes per notice. In addition, we believe that this requirement will apply primarily to residents who are involuntarily discharged from the facility and does not include residents who request the transfer or who are transferred on an emergency basis to an acute care facility. We estimate this notice may need to be updated once for up to one third of LTC facility residents who are transferred. The resulting cost is $1,609,398 (($47 hourly wage for a social worker × (5/60) of an hour) × (.3 percent of nursing facility residents × 1,369,700 nursing facility residents)) for all facilities. We note that the per-facility cost will vary significantly according to facility size and number of transfers out of each facility.

3. Comprehensive Resident Centered Care Planning (§ 483.21)

Additional Members of the IDT (§ 483.21(b)(2)(ii))

We are finalizing our proposal to require that a nurse aide and member of nutrition services participate on the IDT. We note that based on concerns raised by commenters, we have removed our requirement for a social worker to participate on the IDT. We believe that this requirement will add to the current duties of each of these staff members and therefore would be a new economic cost to each facility. Communications about the status of a resident are a part of standard job duties. We envision that these staff members are already regularly discussing resident's needs and their plans of care. When assessing the amount of burden associated with this requirement, we believe that this requirement will produce an incremental increase in the staff time necessary to participate on the IDT. In addition, we do not specify the type of communication the IDT must use. IDT members may use electronic communication as well as informal discussions to participate in IDT meetings. We estimate that participation on the IDT will add an additional one hour of staff time to the duties of a NA and member of food services. While we do not require that a dietitian participate on the IDT, for purposes of estimating the cost we use the salary of a dietitian to represent the participation of a member of food services. We estimate that this requirement will cost $65,116,480 for all LTC facilities (($25 NA hourly wage + $55 dietitian hourly wage) × 52 hours (1hour per week × 52 weeks) × 15,653 facilities).

Discharge Planning (§ 483.21(c)(1)(vii))

We require that, for residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, facilities assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use. The facility also must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences. We believe that a social worker will be responsible for compiling the standardized data, reviewing the resident's preferences/goals, and pulling data that applies to these preferences/goals. We estimate that it will take a social worker approximately one hour of staff time to compile and review the data in order to align the data with each resident's preferences/goals. This staff time will only be required for those residents who are transferred to another SNF or discharged from the LTC facility. We are unable to determine the average number of residents who are transferred to another SNF or discharged from a LTC facility annually. We believe that a conservative estimate is that if there are an estimated 1,369,700 residents per year in LTC facilities, possibly a third of these residents are discharged or transferred to another SNF on an annual basis. Therefore, we estimate that this requirement will cost $21,244,047 ($47 social worker hourly wage × 1 hour staff time × 452,001 residents discharged or transferred to another SNF annually).

4. Nursing Services (§ 483.35)

We are finalizing our proposal to require facilities to ensure that licensed nurses have the specific competencies and skill sets necessary to care for residents' needs, as identified through resident assessments and care plans. This will require facilities to identify, document, and maintain any training, certification, and similar records in an existing personnel file or training record for direct care personnel. This specifically includes nursing services and food and nutrition services but may apply to any direct care provider. We anticipate that any initial competency requirements will be identified by the facility assessment with documentation of individual accomplishments managed by an administrative position, likely an office assistant, as an addition to existing documentation. We believe that this will impose an incremental burden of 8 hours per year per facility to identify and add the additional information to existing files (paper or electronic). We estimate that this requirement will cost $3,881,944 for all LTC facilities ($31 office assistant hourly wage × 8 hours per facility × 15,653 facilities).

5. Food and Nutrition (§ 483.60)

Requirements for Food Service Directors (§ 483.60(a)(2))

We are finalizing our provision to establish requirements for directors of food and nutrition services hired before or after the effective date of these requirements. We require that the director of food and nutrition services be certified as a certified dietary manager, certified food service manager or similar national certification for food service management and safety from a national certifying body; or has an

associate's or higher degree in food service management or hospitality from an accredited institution of higher learning, or meets established state requirements. Many states already establish additional staff qualifications for food service directors and we expect that most facilities already hire food service directors that meet these requirements. In addition, we note that if the facility choses to designate their current food service manager as their director of food and nutrition services, the final rule allows 5 years following the effective date of this final rule for these individuals to comply with these requirements. We do not anticipate that many hiring officials will spend additional time recruiting other appropriate candidates, however we can assume that a small percentage will pursue additional candidates and spend time verifying credentials. For purposes of calculating the anticipated cost, we estimate that 10 percent of facilities will need to hire a director of food and nutrition services after the effective date of this final rule and this will require an additional hour of the NHA's time beyond their current duties related to hiring staff. Based on this information, we estimate that it will cost $133,051 for facilities to comply with this requirement. (($85 NHA hourly wage × 1 hour) × (.1 percentage of affected facilities × 15,653 facilities)).

Menu Options (§ 483.60(c)(4))

We are finalizing our proposal to require facilities to have menus that reflect the cultural and ethnic needs of residents. We expect that facilities will have their menus updated by a qualified dietitian or other clinically qualified nutrition professional in the course of routine reviews and updates. Additional time will include the dietitian or other clinically qualified nutrition professional reviewing the facility assessment for pertinent factors and reviewing and updating the menus. We anticipate this will require 1 to 4 hours, on average 2 hours, depending on the size of the facility and complexity of resident needs. Based on this information, we estimate that it will cost $1,721,830 ($56 dietitian hourly wage × 2 hours × 15,653 facilities) for all LTC facilities to comply with this requirement.

6. QAPI (§ 483.75)

We are finalizing the requirement for facilities to develop a QAPI program. In addition to the QAPI requirement related ICR costs discussed in the COI section, we expect that facilities will incur additional costs that will be dependent upon the projects they selected for their quality improvement activities. In turn, the projects will be dependent upon resident needs, and the type, complexity, and quality of services already provided by the facility. Facilities have the flexibility to determine their quality performance improvement activities based on their assessment of needs of their residents and their prioritized performance improvement projects. For example, a facility that chose, as one of its projects, to improve residents' nutritional status and satisfaction with the facility's food services could incur costs for higher quality, more palatable food. A facility that chose, as one of its projects, to improve nurse aides' interactions with residents suffering from dementia could incur costs for nurse aide training and/or additional nurse aide staffing. A facility that chose, as one of its projects, to improve residents' psychosocial well-being could incur costs for conversion of double rooms to single rooms, and additional social worker, and/or increased social activities for residents. Because the number, degree, and costs of these activities are difficult, if not impossible, to quantify, we have calculated only the cost of the QAPI ICRs ($125,474,448 upfront) that will be associated with the QAPI requirements (discussed in the COI section of the preamble). We estimate that the ongoing annual cost for each facility to comply with the QAPI requirements will be $3,204 for each facility and for all facilities will be $50,152,212 ($3,204 × 15,653). (This discussion is detailed in the COI section.)

7. Infection Control (§ 483.80)

Facilities and their staffs are currently required to have an infection control program (§ 483.65). In this final rule, we have modified our proposal to require each facility to designate one individual as the infection preventionist (IP) for whom the infection prevention and control program (IPCP) is a major responsibility. We have revised the requirement to specify that each facility may designate more than one person as the IP and the IPCP no longer has to be a major responsibility of the individual(s). The IP is responsible for assessing the current program, making any changes to the IPCP necessary to comply with the program's requirements, and implementing and managing the IPCP. This individual will also be required to be a member of the facility's QAA committee. The percentage of a full time equivalent position (FTE) that will be required at each facility will vary greatly. We believe that each facility will have to determine the appropriate percentage based upon it facility assessment, especially its assessment of the acuity of its resident population. A facility with a generally healthy population of elderly individual will likely require many fewer hours than a facility with a large percentage of sub-acute residents or residents that are on ventilators. For the purposes of determining an estimate, we believe that the average facility will designate a RN to be the IP and that individual will need to commit about 15 percent of a FTE to his or her responsibilities under the IPCP. We estimate that this will require 15 percent of one RN FTE for each of the 15,653 facilities for a total cost of $297,907,896 (15% of an RN FTE × $61 average hourly wage for an RN × 2,080 hours (40 hours a week × 52 weeks = 2,080 hours) × 15,653 facilities).

8. Compliance and Ethics Program (§ 483.85)

Compliance Officer and Compliance Liaison Activities

We are finalizing our proposal to require facilities to develop a compliance and ethics program. As discussed in the COI section, we estimate the ICR burden associated with developing this program to be $26,052,468. We estimate that in carrying out this program the compliance officer (similar to an administrator) in each of the 395 organizations operating 5 or more facilities will commit 30 percent of a full time equivalent (FTE) in the compliance program operation, for a total cost of $20,950,800 (30% of FTE × 2080 × $85 × 395). We also estimate that in carrying out this program the compliance liaison (nursing staffs) in each of 6,919 facilities will commit 10 percent of an FTE, at a total cost of $87,788,272 (10% of FTE × 2080 × $61 × 6,919).

Annual Review of Program (483.85(e))

As detailed in the COI section, facilities are required to review their compliance and ethics program annually. Therefore, for subsequent years we estimate to comply with the ICR requirement to review and, if necessary, revise the operating organization's program annually will cost an estimated $6,216,900.

9. Physical Environment (§ 483.90)

Resident Rooms (§ 483.90(d)(1)(i))

For facilities that receive approval of construction or reconstruction plans by state and local authorities or are newly certified or undergoing reconstruction after the effective date of this final rule, we are finalizing our proposal to require

that resident rooms accommodate no more than two residents. A review of CASPER data on the number of new providers per fiscal year from 2008 to 2013 reveals an annually declining number of new facilities, down from 225 new providers in 2008 to 172 in 2012, with only 144 new providers as of August 2013. Of those, the majority were for-profit facilities of 99 beds or less. We further note the overall number of facilities has also declined slightly (by less than 2 percent) but steadily over the same period. A number of states already have similar requirements and represent an average of 7 percent of new providers for the years we reviewed. Therefore, we expect that these requirements will affect fewer than 140 facilities annually. We do not have statistics on the number of providers per year who undertake reconstruction. While we expect that semi-private rooms will increase constructions costs, we are unable to find data regarding the incremental increased cost to the facility of semi-private rooms versus configurations that accommodate up to four residents.

Toilet facilities (§ 483.90(e))

In this final rule, we have removed our proposal to require that for resident rooms newly constructed or undergoing reconstruction, each room must have its own bathroom equipped with at least a commode, sink and shower. We have revised the proposal to require that for newly constructed or newly certified facilities, each bathroom must be equipped with at least a commode and sink. A review of CASPER data on the number of new providers per fiscal year from 2008 to 2013 reveals an annually declining number of new facilities, down from 225 new providers in 2008 to 172 in 2012, with only 144 new providers as of August 2013. Of those, the majority were for-profit facilities of 99 beds or less. We further note the overall number of facilities has also declined slightly (by less than 2 percent) but steadily over the same period. In addition, several states require direct access and limit the number of rooms or residents who may be served by a toilet, lavatory (sink), and/or shower or bath. Given the decline in new facilities and the impact of state regulation, we estimate that this provision will impact fewer than 150 providers per year. While we are aware that ensuring each resident bedroom has an adjacent bathroom may increase construction costs, we were unable to find data regarding neither the number of facilities that do not currently have bathrooms adjacent to each resident room nor the incremental cost of adding bathrooms adjacent to each resident room in new construction.

10. Training Requirements (§ 483.95)

General Training Topics (§ 483.95a)

We are finalizing our proposal to require facilities to develop and/or update training materials to include topics on communication, resident rights, facility obligations, abuse, neglect, exploitation, infection control, and its QAPI program. We require that these training topics be provided for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles and that they be able to demonstrate competency in these topic areas. We also expect each facility to keep a record of these trainings. To reduce regulatory burden and create a reasonable requirement we have not specified the amount or types of training that a facility must provide. There are various free online training tools and resources that facilities can use to assist them in complying with this requirement. For example, the Agency for Healthcare Research and Quality (AHRQ) released a set of training modules to help educate LTC facility staff on key patient safety concepts to improve the safety of LTC facility residents (*http://www.ahrq.gov/professionals/systems/long-term-care/resources/facilities/ptsafety/*). In addition to the web based materials, instructor and student handbooks can be sent to facilities at no additional cost. Therefore, we believe that the cost associated with this requirement will be limited to the staff time required to review and update their current training materials.

Based on our experience with facilities, we expect that all facilities have some type of training program. However, we expect that each facility will need to compare their training programs to their facilities assessments as required at § 483.70(e) and ensure they cover the above training topics. We expect that complying with this requirement will require the involvement of a RN and the infection control and prevention officer (ICPO). We expect that a RN will spend more time reviewing, revising and/or developing new sections for the training program. The IP will need to weigh in on the infection control training related topics. We estimate that it will require 8 (6 for the RN ($61/hour) and 2 for the IP ($61/hour)) burden hours for each facility to develop a training program at a cost of $488. Thus, for all facilities to comply, it will cost an estimated $7,638,664 ($488 estimated cost for each facility × 15,653 facilities). We believe that the training will be considered part of regular ongoing training for the staff of each facility.

Compliance and Ethics Program Training (§ 483.95(f))

We require that SNF and NF operating organizations include as part of their compliance and ethics program an effective way to communicate their program's standards, policies, and procedures. We believe that all operating organizations would need to develop training materials and/or other publications to comply with the training requirement. This regulation requires higher standards for organizations operating 5 or more facilities, therefore for the purposes of the RIA our cost estimates differentiate by organization size. We estimate that training staff in organizations operating 1 to 4 facilities will mainly require the duties of a RN at a cost of $900,740 for all 7,765 facilities (6,621 single facilities operating organizations + 1,144 facilities in operating organizations with 2 to 4 facilities = 7,765 facilities) × 2 hours × $61 average hourly wage for a RN = $900,740). For the training in operating organizations with 1 to 4 facilities, we expect that operating organizations will be able to minimize these training costs by including the training on their compliance and ethics program with any current trainings or in-services that they already conduct for their staff. In addition, these facilities could also include this information in publication, print or electronic, that are available to their staff.

We estimate that training staff in organizations operating five or more facilities will require 2 hours of time of a compliance officer (similar to an administrator) conducting the training at the organizational level (387 organizations) at a cost of $61,920 (387 × 2 × $85 = $61,920) and 2 hours of time of a compliance liaison (similar to an RN) at the facility level (7,879 facilities × 2 × $61 = $913,964), for a total cost of $975,884 ($61,920 + $913,964 = $975,884).

Dementia Management and Abuse Prevention Training § 483.95(g)

This final rule will implement section 6121 of the Affordable Care Act which requires dementia management and abuse prevention training to be included in the current mandatory on-going training requirements for nurse aides. In addition, we have also extended this requirement to all direct care staff. Facilities will have the flexibility to determine the length of the training and the format of the training. Since we have

not increased the minimum hours for training, we anticipate that facilitates will maximize their on-going training efforts to improve outcomes through a more efficient training program by modifying their current training program to ensure that all NAs receive annual training in dementia management and abuse prevention. In addition, we believe that the majority of facilities will need to acquire training materials to either update or supplement what they are currently using to train staff. There are numerous online tools available to facilities at no cost. For the sole purpose of complying with section 6121 of the Affordable Care Act and ensuring that nurse aides receive regular training on caring for residents with dementia and on preventing abuse. CMS has published an online hand in hand tool kit that provides a detailed training series for LTC facilities on dementia education and abuse prevention (*http://www.cms-handinhandtoolkit.info/*). CMS, supported by a team of training developers and subject matter experts, created this training to address the need for nurse aides' annual in-service training on these important topics. The mission of the hand in hand training is to provide LTC facilities with a high-quality training program that emphasizes person-centered care in the care of persons with dementia and the prevention of abuse. Given the availability of these materials, we have not assessed a cost burden associated with acquiring training materials for this requirement, however, as discussed in the COI section, we estimate that it will cost facilities an estimated $3,819,332 to review and update their current in-service training material.

11. Administration § 483.70(e)

We are finalizing our requirement for 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. LTC facilities must already determine and plan for what staffing they will need, as well as the other resources that will be required to care for their residents and operate their facilities. Thus, we believe that conducting and documenting a facility assessment is a standard business practice and do not include a burden for this requirement in the impact analysis.

*E. Summary of Impacts*

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 cost per facility is estimated to be approximately $62,900 in the first year and $55,000 in 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*). Table 5 below presents a summary of the section by section estimated costs to comply with the requirements of this final rule.

TABLE 5—SECTION BY SECTION SUMMARY OF ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS FINAL RULE

| Regulatory section | Number of affected entities | Total 1st year cost to all LTC facilities ($ millions) | Total recurring annual cost to all LTC facilities ($ millions) | Estimated recurring annual cost per facility (rounded to the nearest $) |
|---|---|---|---|---|
| Resident Rights (§ 483.10) | 15,653 | $166.87 | $166.35 | $10,627 |
| Admission, Discharge, and Transfer Rights (§ 483.15) | 15,653 | 2.95 | 2.95 | 188 |
| Comprehensive Resident Centered Care Planning (§ 483.21) | 15,653 | 86.36 | 86.36 | 5,517 |
| Nursing Services (§ 483.35) | 15,653 | 3.88 | 3.88 | 248 |
| Food and Nutrition Services (§ 483.60) | 15,653 | 1.85 | 1.85 | 118 |
| QAPI (§ 483.75) | 15,653 | 125.47 | 50.15 | 3,204 |
| Infection Control (§ 483.80) | 15,653 | 297.91 | 297.91 | 19,032 |
| Compliance and Ethics Program | 7,314 (operating organizations). | 134.79 | 114.98 | 15,721 |
| Training (§ 483.95) | 15,653 | 11.46 | 11.46 | 732 |
| Total | | 831.35 | 735.90 | 55,388 |

*F. Cost to the Federal Government*

As a result of this final rule, CMS will update the interpretive guidance, update the survey process, and make IT systems changes. We anticipate the majority of the system costs will be incurred between FY17 and FY18. In order to implement these new standards, we anticipate initial federal start-up costs between $15 and $20 million. Once implemented, improved surveys to review the new requirements will require an estimated $15 to $20 million annually in federal costs.

*G. Benefits of Final Rule*

This final rule will implement comprehensive changes intended to update the current requirements for LTC facilities and create new efficiencies and flexibilities for facilities. In addition, these changes will support improved resident quality of life and quality of care. Quality of life in particular can be difficult to translate into dollars saved. However, there is a body of evidence suggesting the factors that improve quality of life may also increase the rate of improvement in quality and can have positive business benefits for facilities. Many of the quality of life improvements changes in this final rule are grounded in the concepts of person-centered care and culture change. These changes not only result in improved quality of life for the resident, they can result in improvements in the caregiver's quality of work life and in savings to the facility. Savings can be accrued through reduced turnover, decreased use of agency labor and decreased worker compensation costs. Although these savings are difficult to

quantify, we believe that they must be lower in magnitude than the costs borne by facilities; otherwise, facilities will change their policies even in the absence of this rulemaking.

In addition to finalizing changes that are likely to have long-term positive impacts on quality of life and quality of care, we have finalized several changes that may mitigate the costs associated with implementing some of our requirements. For example, including the use of electronic health records in these regulations may reduce the burden on facilities when providing a resident with a copy of his or her clinical record. We believe that the option to provide an electronic copy of the record may reduce the amount of time a staff person is taken away from other duties to copy the medical records. To increase access and reduce burden, this final rule allows physicians to delegate to a qualified dietitian or other clinically qualified nutrition professional the task of prescribing diet, including therapeutic diets, to the extent allowed by state law. We do not currently have data to estimate the savings that this will produce in SNFs and NFs, however we believe that it will allow for better use of both physician and dietitian time. Likewise, we also allow physicians to delegate to qualified therapists the task of prescribing physical, occupational, speech language, or respiratory therapies, but as with dietitians, we have no empirical evidence with which to quantify a cost savings. Again, however, we believe that this allows better use of both physician and therapist time.

With respect to dental services, we modified the language relating to dental services to remove references to a dentist's office and replace these references to 'dental services location.' This more explicitly accommodates options for dental care such as dental schools or provision of dental hygiene services on site at a facility. Based on the literature we reviewed, improved dental health as a result of improved access to dental care is highly likely to result in improved health and well-being of facility residents, including potentially fewer hospitalizations and less unanticipated weight loss. We have no definitive data on the direct reduction in hospitalizations and other complications stemming from or exacerbated by poor dental care and poor dental hygiene, but given the relationship of poor dental care and poor dental hygiene to other illnesses, savings are quite possible.

We have also made a number of changes in the area of food and nutrition services. These changes are expected to have multiple impacts, ranging from the improved nutritional status of residents to reduced food waste by the facility, to reductions in the incidence of food-borne illness. In FY 2012, there were over 9,000 deficiency citations associated with food and nutrition services. The most commonly cited deficiency in this grouping was, by far, associated with food sanitation. Out of 6,828 surveys, there were 5,490 citations for deficiencies in food procurement, storage, preparation, and service-sanitary, affecting 31.80 percent of providers. The improvements in food and nutrition services from this final rule have the potential to improve resident quality of life while also resulting in a reduced incidence of food-borne illness.[5]

We have also finalized revisions to strengthen requirements related to infection control. While a reduction in the incidence of healthcare associated infections will likely impact hospitalization of residents, as discussed below, it will also impact the care required for residents who remain in the facility. An effective infection prevention and control program can, among other benefits, identify infections early and prevent their spread. Several illness-causing organisms are of particular concern in LTC facilities. For example, Norovirus may cause illness following a very low infection dose. The illness is characterized by nausea, sudden onset of projectile vomiting (particularly in children), watery, non-bloody diarrhea, abdominal cramping, chills, body aches and fatigue. Dehydration is a common complication, especially in the elderly. The illness usually lasts 2 to 3 days. Outbreaks can impact residents and/or staff and cause significant inconvenience and cost. (Overview of the management of norovirus outbreaks in hospitals and nursing homes, compiled by the Wisconsin Division of Public Health, Bureau of Communicable Diseases, Communicable Disease Epidemiology Section, February 2004. Retrieved from *http://www.publichealthmdc.com/environmental/food/documents/ManagementofNorovirusInfectionOutbreaksinHospitalsandNursingHomes.pdf*). These illnesses can result in higher acuity of residents and increased care needs as well as increased use of either overtime or temporary staff to replace ill staff. Improved prevention, detection, and mitigation of illnesses can result in substantial savings to a facility. Unfortunately, specific rates of infection and the associated cost to treat residents or to replace absent staff have not been clearly quantified in available literature or data.

We note that the revisions in this final rule also target reducing avoidable or unnecessary hospitalizations. We are finalizing revisions regarding improved communication of critical information, competency-based care assignments, training, and systemic quality improvement. We believe that even a small reduction in the number of unnecessary hospitalizations could result in substantial savings.

Overall, we believe that this final rule will address a number of the shortcomings of the existing LTC requirements identified by stakeholders and experts. Unfortunately, without a predicted change in behavior or outcomes, we are unable to quantify the benefits of the final rule.

*H. Alternatives Considered*

As discussed previously, some of these provisions are mandated under the Affordable Care Act and the IMPACT Act, therefore, no major alternatives were considered. We could have finalized only those requirements that are required by statute, which would be a less burdensome approach on the LTC community. However despite the many changes in the delivery of health care services, the requirements for LTC care facilities have not been comprehensively updated in many years and our revisions address several issues, such as avoidable hospitalizations, staffing concerns, infection control, and behavioral health. In addition, we believe that it is necessary to modernize the regulations to reflect advances such as electronic communications and health information technology. Overall, we believe that finalizing a general reorganization and comprehensive revision will ensure that the requirements are consistent with current standards of practice and continue to meet statutory obligations, while also assisting individuals who are less familiar with these regulations to find information within the requirements. Therefore, we determined

[5] It is logical to assume that the requirement for nursing, food service and other competency either necessitates hiring more competent staff who command a higher wage—the cost of which would be included in the cost section—or the competency provision is essentially unnecessary because staff are already competent—in which case, there would be no benefits to facilities or their residents. As regards the menu options provision, the cost section mentions two hours of effort per facility. It might be plausible that a two-hour review would be sufficient to confirm that there is nothing in need of revision (in which case there are no benefits). However, if a review uncovers that there is potential for benefits due to menu revisions, then there will be further costs, such as training for food service workers or higher costs of raw ingredients.

it is most effective to make comprehensive changes at this time.

We considered alternatives to competency-based staffing requirement and looked closely at suggestions from commenters to establish and require minimum staffing levels and a RN 24 hours a day, 7 days a week in the nursing facility. We have begun voluntary payroll-based collection of staffing information from LTC facilities, and are preparing to begin mandatory collection of payroll-based staffing information from LTC facilities. The staff covered includes registered nurses, licensed practical or vocational nurses, certified nursing assistants, or other types of medical personnel as specified by CMS, along with census data, data on agency and contract staff, and information on turnover, tenure and hours of care provided by each category of staff per resident day. Ultimately, we believe this information, once a sufficient amount is collected and analyzed, could greatly assist us in re-evaluating this issue and have decided not to pursue staffing minimums at this time. We also considered modifying, rather than removing, our proposal to require an in-person evaluation by a physician before a resident is transferred to a hospital by indicating that a RN, in consultation with a physician, could perform the evaluation. However, based on the concerns raised by commenters regarding access to physicians and emergency situations, we determined it was best to withdraw the proposal.

For all provisions, we extensively reviewed the public comments and made revisions where possible to improve readability, provide clarity, increase flexibility, and reduce burden by avoiding any unnecessarily costly requirements.

*I. Accounting Statement*

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/omb/circulars_a004_a-4*), we have prepared an accounting statement.

TABLE 6—ACCOUNTING STATEMENT

| Category | Estimates | Units | | |
|---|---|---|---|---|
| | | Year dollar | Discount rate (%) | Period covered |
| Benefits: | | | | |
| Qualitative | Improve in quality of life and quality of care. | | | |
| Costs: | | | | |
| Annualized Monetized ($million/year) | 758 | 2015 | 7 | 2016–2020. |
| | 756 | 2015 | 3 | 2016–2020. |
| Qualitative | Unquantified possible cost associated with the bathroom requirement. | | | |

Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that most LTC facilities are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of nursing and residential care facilities are small entities; either by being nonprofit organizations or by meeting the Small Business Administration's (SBA) definition of a small business having revenues of less than $25.5 million in any 1 year (see the SBA's Web site at *http://www.sba.gov/content/small-business-size-standards*). As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule because the impact associated with the provision will be less than 1 percent of the revenue of the nursing facilities. According to a report by Kaiser Family Foundation published in 2015, the annual national spending on nursing facilities across all payers totaled $155.8 billion in 2013 (*http://kff.org/report-section/nursing-facilities-staffing-residents-and-facility-deficiencies-introduction/*). With the number of nursing facilities around 15,600, the average annual revenue of a nursing facility is about $10 million. The annual impact on a nursing facility would be around $63,000 in year 1 and $55,000 in year 2 and thereafter (see Table 5 of this section), so the average impact on the facility is less than 1 percent of revenue. Therefore, we have determined and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities. We note that the proposed rule, see 80 FR 42168 (July 16, 2015), incorrectly identified that the proposed rule would have a significant economic impact on a substantial number of small entities. The inclusion of this statement was an oversight.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This final rule pertains solely to SNFs and NFs. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This final rule contains mandates that will impose a one-time cost of about $831 million. Thus, we have assessed the various costs and benefits of this final rule. This final rule will not mandate any new requirements for state, local or tribal governments. For the private sector facilities, the regulatory impact section, together with the remainder of the preamble, constitutes the analysis required under UMRA.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have determined that this final rule does not contain policies that have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have Federalism implications as defined in the Executive Order 13132 and, consequently, a Federalism summary impact statement is not required.

Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

*K. Conclusion*

The requirements in this final rule will update the existing requirements for long-term care facilities to reflect current standards of practice. In addition, the revisions will provide added flexibility to providers, potentially improve efficiency and effectiveness, potentially enhance resident quality of care and quality of life, and potentially improve clinical outcomes. The analysis above, together with the remainder of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

**List of Subjects**

*42 CFR Part 405*

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

*42 CFR Part 431*

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

*42 CFR Part 447*

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

*42 CFR Part 482*

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 483*

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

*42 CFR Part 485*

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 488*

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

*42 CFR Part 489*

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

## PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

**Authority:** Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

### § 405.926 [Amended]

■ 2. In § 405.926, amend paragraph (f) by removing the reference ''§ 483.12'' and add in its place, the reference ''§§ 483.5(n) and 483.15''.

## PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 3. The authority citation for part 431 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

### § 431.206 [Amended]

■ 4. In § 431.206, amend paragraph (c)(3) by removing the reference ''§ 483.12'' and adding in its place the reference ''§ 483.15''.

### § 431.213 [Amended]

■ 5. In § 431.213, amend paragraph (h) by removing reference ''§ 483.12 (a)(5)(ii)'' and adding in its place the reference ''§ 483.15(b)(4)(ii) and (b)(8)'' and by removing the reference ''§ 483.12 (a)(5)(i)'' and adding in its place the reference ''§ 483.15(b)(4)(i) of this chapter''.

## PART 447—PAYMENTS FOR SERVICES

■ 6. The authority citation for part 447 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

### § 447.253 [Amended]

■ 7. In § 447.253, amend paragraph (b)(1)(iii)(B) by removing the reference ''§ 483.30(c)'' and adding in its place the reference ''§ 483.35(e)''.

## PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 8. The authority citation for part 482 continues to read as follows:

**Authority:** Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

■ 9. In § 482.58, paragraphs (b)(1) through (8) are revised to read as follows:

### § 482.58 Special requirements for hospital providers of long-term care services (''swing-beds'').

* * * * *

(b) * * *

(1) Resident rights (§ 483.10(a)(4)(iv), (b), (c), (d)(1), (d)(3), (e)(8), (g), (f)(4)(i), (f)(4)(iii), (f)(9), (h)(2), and (h)(3) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.15(c), § 483.15(c)(1), (c)(2), (c)(3)(i) through (iii), (c)(4), (c)(5)(i) through (vii), and (c)(7) of this chapter).

(3) Freedom from abuse, neglect and exploitation (§ 483.12 of this chapter).

(4) Patient activities (§ 483.24(c) of this chapter).

(5) Social services (§ 483.40(d) and § 483.70(p) of this chapter).

(6) Discharge planning (§ 483.21 of this chapter).

(7) Specialized rehabilitative services (§ 483.65 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

## PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 10. The authority citation for part 483 continues to read as follows:

**Authority:** Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 11. Section 483.1 is amended by revising paragraphs (a)(1) introductory text, (a)(3), and (b) and adding paragraphs (a)(4) and (a)(5) to read as follows:

**§ 483.1 Basis and scope.**

(a) * * *

(1) Sections 1819(a), (b), (c), (d), and (f) of the Act provide that—

* * * * *

(3) Sections 1919(a), (b), (c), (d), and (f) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(4) Sections 1128I(b) and (c) require that—

(i) Skilled nursing facilities or nursing facility have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations.

(ii) The Secretary establish and implement a quality assurance and performance improvement program for facilities, including multi-unit chains of facilities.

(5) Section 1150B establishes requirements for reporting to law enforcement crimes occurring in federally funded LTC facilities.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

■ 12. Section 483.5 is amended by—

■ a. Removing the paragraph designations for paragraphs (a), (b), (c), (d), (e), and (f) and placing the definitions in alphabetical order.

■ b. Adding introductory text.

■ c. Revising the definition of ''common area''.

■ d. Amending the definition of ''Composite distinct part'' by adding paragraph (2)(v).

■ e. Amending the definition of ''Facility'' by removing the italicized word ''*defined*''.

■ f. Adding the new definitions of ''Abuse'', ''Adverse event'', ''Exploitation'', ''Licensed health professional'', ''Misappropriation of resident property'', ''Mistreatment'', ''Neglect'', ''Nurse aide'', ''Person-centered care'', ''Resident representative'', ''Sexual abuse'', and ''Transfer and discharge'' in alphabetical order.

The revisions and additions read as follows:

**§ 483.5 Definitions.**

As used in this subpart, the following definitions apply:

*Abuse.* Abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. *Willful,* as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

*Adverse event.* An adverse event is an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof.

*Common area.* Common areas are areas in the facility where residents may gather together with other residents, visitors, and staff or engage in individual pursuits, apart from their residential rooms. This includes but is not limited to living rooms, dining rooms, activity rooms, outdoor areas, and meeting rooms where residents are located on a regular basis.

Composite distinct part. * * *

(2) * * *

(v) Use of composite distinct parts to segregate residents by payment source or on a basis other than care needs is prohibited.

* * * * *

*Exploitation.* Exploitation means taking advantage of a resident for personal gain through the use of manipulation, intimidation, threats, or coercion.

* * * * *

*Licensed health professional.* A licensed health professional is a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker; or registered respiratory therapist or certified respiratory therapy technician.

* * * * *

*Misappropriation of resident property* means the deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.

*Mistreatment* means inappropriate treatment or exploitation of a resident.

*Neglect* is the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.

*Nurse aide.* A nurse aide is any individual providing nursing or nursing-related services to residents in a facility. This term may also include an individual who provides these services through an agency or under a contract with the facility, but is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in § 488.301 of this chapter.

*Person-centered care.* For purposes of this subpart, person-centered care means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives.

*Resident representative.* For purposes of this subpart, the term resident representative means any of the following:

(1) An individual chosen by the resident to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;

(2) A person authorized by State or Federal law (including but not limited to agents under power of attorney, representative payees, and other fiduciaries) to act on behalf of the resident in order to support the resident in decision-making; access medical, social or other personal information of the resident; manage financial matters; or receive notifications;

(3) Legal representative, as used in section 712 of the Older Americans Act; or.

(4) The court-appointed guardian or conservator of a resident.

(5) Nothing in this rule is intended to expand the scope of authority of any resident representative beyond that authority specifically authorized by the resident, State or Federal law, or a court of competent jurisdiction.

*Sexual abuse* is non-consensual sexual contact of any type with a resident.

*Transfer and discharge* includes movement of a resident to a bed outside of the certified facility whether that bed

is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

■ 13. Section 483.10 is revised to read as follows:

**§ 483.10 Resident rights.**

(a) *Residents Rights.* The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility, including those specified in this section.

(1) A facility must treat each resident with respect and dignity and care for each resident in a manner and in an environment that promotes maintenance or enhancement of his or her quality of life, recognizing each resident's individuality. The facility must protect and promote the rights of the resident.

(2) The facility must provide equal access to quality care regardless of diagnosis, severity of condition, or payment source. A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all residents regardless of payment source.

(b) *Exercise of rights.* The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(1) The facility must ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights and to be supported by the facility in the exercise of his or her rights as required under this subpart.

(3) In the case of a resident who has not been adjudged incompetent by the state court, the resident has the right to designate a representative, in accordance with State law and any legal surrogate so designated may exercise the resident's rights to the extent provided by state law. The same-sex spouse of a resident must be afforded treatment equal to that afforded to an opposite-sex spouse if the marriage was valid in the jurisdiction in which it was celebrated.

(i) The resident representative has the right to exercise the resident's rights to the extent those rights are delegated to the resident representative.

(ii) The resident retains the right to exercise those rights not delegated to a resident representative, including the right to revoke a delegation of rights, except as limited by State law.

(4) The facility must treat the decisions of a resident representative as the decisions of the resident to the extent required by the court or delegated by the resident, in accordance with applicable law.

(5) The facility shall not extend the resident representative the right to make decisions on behalf of the resident beyond the extent required by the court or delegated by the resident, in accordance with applicable law.

(6) If the facility has reason to believe that a resident representative is making decisions or taking actions that are not in the best interests of a resident, the facility shall report such concerns in the manner required under State law.

(7) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf. The court-appointed resident representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law

(i) In the case of a resident representative whose decision-making authority is limited by State law or court appointment, the resident retains the right to make those decision outside the representative's authority.

(ii) The resident's wishes and preferences must be considered in the exercise of rights by the representative.

(iii) To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.

(c) *Planning and implementing care.* The resident has the right to be informed of, and participate in, his or her treatment, including:

(1) The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.

(2) The right to participate in the development and implementation of his or her person-centered plan of care, including but not limited to:

(i) The right to participate in the planning process, including the right to identify individuals or roles to be included in the planning process, the right to request meetings and the right to request revisions to the person-centered plan of care.

(ii) The right to participate in establishing the expected goals and outcomes of care, the type, amount, frequency, and duration of care, and any other factors related to the effectiveness of the plan of care.

(iii) The right to be informed, in advance, of changes to the plan of care.

(iv) The right to receive the services and/or items included in the plan of care.

(v) The right to see the care plan, including the right to sign after significant changes to the plan of care.

(3) The facility shall inform the resident of the right to participate in his or her treatment and shall support the resident in this right. The planning process must—

(i) Facilitate the inclusion of the resident and/or resident representative.

(ii) Include an assessment of the resident's strengths and needs.

(iii) Incorporate the resident's personal and cultural preferences in developing goals of care.

(4) The right to be informed, in advance, of the care to be furnished and the type of care giver or professional that will furnish care.

(5) The right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers.

(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.

(7) The right to self-administer medications if the interdisciplinary team, as defined by § 483.21(b)(2)(ii), has determined that this practice is clinically appropriate.

(8) Nothing in this paragraph should be construed as the right of the resident to receive the provision of medical treatment or medical services deemed medically unnecessary or inappropriate.

(d) *Choice of attending physician.* The resident has the right to choose his or her attending physician.

(1) The physician must be licensed to practice, and

(2) If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in paragraphs (d)(4) and (5) of this section to assure provision of appropriate and adequate care and treatment.

(3) The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.

(4) The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet

requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation with the resident and honor the resident's preferences, if any, among options.

(5) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

(e) *Respect and dignity.* The resident has a right to be treated with respect and dignity, including:

(1) The right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms, consistent with § 483.12(a)(2).

(2) The right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(3) The right to reside and receive services in the facility with reasonable accommodation of resident needs and preferences except when to do so would endanger the health or safety of the resident or other residents.

(4) The right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(5) The right to share a room with his or her roommate of choice when practicable, when both residents live in the same facility and both residents consent to the arrangement.

(6) The right to receive written notice, including the reason for the change, before the resident's room or roommate in the facility is changed.

(7) The right to refuse to transfer to another room in the facility, if the purpose of the transfer is:

(i) To relocate a resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) to relocate a resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.

(iii) solely for the convenience of staff.

(8) A resident's exercise of the right to refuse transfer does not affect the resident's eligibility or entitlement to Medicare or Medicaid benefits.

(f) *Self-determination.* The resident has the right to and the facility must promote and facilitate resident self-determination through support of resident choice, including but not limited to the rights specified in paragraphs (f)(1) through (11) of this section.

(1) The resident has a right to choose activities, schedules (including sleeping and waking times), health care and providers of health care services consistent with his or her interests, assessments, plan of care and other applicable provisions of this part.

(2) The resident has the right to make choices about aspects of his or her life in the facility that are significant to the resident.

(3) The resident has a right to interact with members of the community and participate in community activities both inside and outside the facility.

(4) The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident.

(i) The facility must provide immediate access to any resident by—

(A) Any representative of the Secretary,

(B) Any representative of the State,

(C) Any representative of the Office of the State long term care ombudsman, (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 *et seq.*),

(D) The resident's individual physician,

(E) Any representative of the protection and advocacy systems, as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*),

(F) Any representative of the agency responsible for the protection and advocacy system for individuals with a mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 *et seq.*), and

(G) The resident representative.

(ii) The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time;

(iii) The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time;

(iv) The facility must provide reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time; and

(v) The facility must have written policies and procedures regarding the visitation rights of residents, including those setting forth any clinically necessary or reasonable restriction or limitation or safety restriction or limitation, when such limitations may apply consistent with the requirements of this subpart, that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation.

(vi) A facility must meet the following requirements:

(A) Inform each resident (or resident representative, where appropriate) of his or her visitation rights and related facility policy and procedures, including any clinical or safety restriction or limitation on such rights, consistent with the requirements of this subpart, the reasons for the restriction or limitation, and to whom the restrictions apply, when he or she is informed of his or her other rights under this section.

(B) Inform each resident of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse (including a same-sex spouse), a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(C) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(D) Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences.

(5) The resident has a right to organize and participate in resident groups in the facility.

(i) The facility must provide a resident or family group, if one exists, with private space; and take reasonable steps, with the approval of the group, to make residents and family members aware of upcoming meetings in a timely manner.

(ii) Staff, visitors, or other guests may attend resident group or family group meetings only at the respective group's invitation.

(iii) The facility must provide a designated staff person who is approved by the resident or family group and the facility and who is responsible for providing assistance and responding to written requests that result from group meetings.

(iv) The facility must consider the views of a resident or family group and act promptly upon the grievances and

recommendations of such groups concerning issues of resident care and life in the facility.

(A) The facility must be able to demonstrate their response and rationale for such response.

(B) This should not be construed to mean that the facility must implement as recommended every request of the resident or family group.

(6) The resident has a right to participate in family groups.

(7) The resident has a right to have family member(s) or other resident representative(s) meet in the facility with the families or resident representative(s) of other residents in the facility.

(8) The resident has a right to participate in other activities, including social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(9) The resident has a right to choose to or refuse to perform services for the facility and the facility must not require a resident to perform services for the facility. The resident may perform services for the facility, if he or she chooses, when—

(i) The facility has documented the resident's need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(10) The resident has a right to manage his or her financial affairs. This includes the right to know, in advance, what charges a facility may impose against a resident's personal funds.

(i) The facility must not require residents to deposit their personal funds with the facility. If a resident chooses to deposit personal funds with the facility, upon written authorization of a resident, the facility must act as a fiduciary of the resident's funds and hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in this section.

(ii) *Deposit of funds.* (A) In general: Except as set out in paragraph (f)(10)(ii)(B) of this section, the facility must deposit any residents' personal funds in excess of $100 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) The facility must maintain a resident's personal funds that do not exceed $100 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(B) Residents whose care is funded by Medicaid: The facility must deposit the residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) The facility must maintain personal funds that do not exceed $50 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(iii) *Accounting and records.* (A) The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(B) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(C) The individual financial record must be available to the resident through quarterly statements and upon request.

(iv) *Notice of certain balances.* The facility must notify each resident that receives Medicaid benefits—

(A) When the amount in the resident's account reaches $200 less than the SSI resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(B) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(v) Conveyance upon discharge, eviction, or death. Upon the discharge, eviction, or death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the resident, or in the case of death, the individual or probate jurisdiction administering the resident's estate, in accordance with State law.

(vi) Assurance of financial security. The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(11) The facility must not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with § 489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See § 447.15 of this chapter, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) Services included in Medicare or Medicaid payment. During the course of a covered Medicare or Medicaid stay, facilities must not charge a resident for the following categories of items and services:

(A) Nursing services as required at § 483.35.

(B) Food and Nutrition services as required at § 483.60.

(C) An activities program as required at § 483.24(c).

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing assistance, and basic personal laundry.

(F) Medically-related social services as required at § 483.40(d).

(G) Hospice services elected by the resident and paid for under the Medicare Hospice Benefit or paid for by Medicaid under a state plan.

(ii) *Items and services that may be charged to residents' funds.* Paragraphs (f)(11)(ii)(A) through (L) of this section are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if they are not required to achieve the goals stated in the resident's care plan, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone, including a cellular phone.

(B) Television/radio, personal computer or other electronic device for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and confections.

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E) Personal clothing.

(F) Personal reading matter.

(G) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Cost to participate in social events and entertainment outside the scope of the activities program, provided under § 483.24(c).

(J) Non-covered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Except as provided in (e)(11)(ii)(L)(*1*) and (2) of this section, specially prepared or alternative food requested instead of the food and meals generally prepared by the facility, as required by § 483.60.

(*1*) The facility may not charge for special foods and meals, including medically prescribed dietary supplements, ordered by the resident's physician, physician assistant, nurse practitioner, or clinical nurse specialist, as these are included in accordance with § 483.60.

(*2*) In accordance with § 483.60(c) through (f), when preparing foods and meals, a facility must take into consideration residents' needs and preferences and the overall cultural and religious make-up of the facility's population.

(iii) *Requests for items and services.* (A) The facility can only charge a resident for any non-covered item or service if such item or service is specifically requested by the resident.

(B) The facility must not require a resident to request any item or service as a condition of admission or continued stay.

(C) The facility must inform, orally and in writing, the resident requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.

(g) *Information and communication.* (1) The resident has the right to be informed of his or her rights and of all rules and regulations governing resident conduct and responsibilities during his or her stay in the facility.

(2) The resident has the right to access personal and medical records pertaining to him or herself.

(i) The facility must provide the resident with access to personal and medical records pertaining to him or herself, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, within 24 hours (excluding weekends and holidays); and

(ii) The facility must allow the resident to obtain a copy of the records or any portions thereof (including in an electronic form or format when such records are maintained electronically) upon request and 2 working days advance notice to the facility. The facility may impose a reasonable, cost-based fee on the provision of copies, provided that the fee includes only the cost of:

(A) Labor for copying the records requested by the individual, whether in paper or electronic form;

(B) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media; and

(C) Postage, when the individual has requested the copy be mailed.

(3) With the exception of information described in paragraphs (g)(2) and (g)(11) of this section, the facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. Summaries that translate information described in paragraph (g)(2) of this section may be made available to the patient at their request and expense in accordance with applicable law.

(4) The resident has the right to receive notices orally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including;

(i) *Required notices as specified in this section.* The facility must furnish to each resident a written description of legal rights which includes—

(A) A description of the manner of protecting personal funds, under paragraph (f)(10) of this section;

(B) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment of resources under section 1924(c) of the Social Security Act.

(C) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State regulatory and informational agencies, resident advocacy groups such as the State Survey Agency, the State licensure office, the State Long-Term Care Ombudsman program, the protection and advocacy agency, adult protective services where state law provides for jurisdiction in long-term care facilities, the local contact agency for information about returning to the community and the Medicaid Fraud Control Unit; and

(D) A statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

(ii) Information and contact information for State and local advocacy organizations, including but not limited to the State Survey Agency, the State Long-Term Care Ombudsman program (established under section 712 of the Older Americans Act of 1965, as amended 2016 (42 U.S.C. 3001 *et seq.*) and the protection and advocacy system (as designated by the state, and as established under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15001 *et seq.*);

(iii) Information regarding Medicare and Medicaid eligibility and coverage;

(iv) Contact information for the Aging and Disability Resource Center (established under Section 202(a)(20)(B)(iii) of the Older Americans Act); or other No Wrong Door Program

(v) Contact information for the Medicaid Fraud Control Unit; and

(vi) Information and contact information for filing grievances or complaints concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements and requests for information regarding returning to the community.

(5) The facility must post, in a form and manner accessible and understandable to residents, and resident representatives:

(i) A list of names, addresses (mailing and email), and telephone numbers of all pertinent State agencies and advocacy groups, such as the State Survey Agency, the State licensure office, adult protective services where state law provides for jurisdiction in long-term care facilities, the Office of the State Long-Term Care Ombudsman program, the protection and advocacy

network, home and community based service programs, and the Medicaid Fraud Control Unit; and

(ii) A statement that the resident may file a complaint with the State Survey Agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with the advance directives requirements (42 CFR part 489 subpart I) and requests for information regarding returning to the community.

(6) The resident has the right to have reasonable access to the use of a telephone, including TTY and TDD services, and a place in the facility where calls can be made without being overheard. This includes the right to retain and use a cellular phone at the resident's own expense.

(7) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, including reasonable access to:

(i) A telephone, including TTY and TDD services;

(ii) The internet, to the extent available to the facility; and

(iii) Stationery, postage, writing implements and the ability to send mail.

(8) The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

(i) Privacy of such communications consistent with this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

(9) The resident has the right to have reasonable access to and privacy in their use of electronic communications such as email and video communications and for Internet research.

(i) If the access is available to the facility

(ii) At the resident's expense, if any additional expense is incurred by the facility to provide such access to the resident.

(iii) Such use must comply with state and federal law.

(10) The resident has the right to—

(i) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility; and

(ii) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

(11) The facility must—

(i) Post in a place readily accessible to residents, and family members and legal representatives of residents, the results of the most recent survey of the facility.

(ii) Have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years, and any plan of correction in effect with respect to the facility, available for any individual to review upon request; and

(iii) Post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

(iv) The facility shall not make available identifying information about complainants or residents.

(12) The facility must comply with the requirements specified in 42 CFR part 489, subpart I (Advance Directives).

(i) These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the resident's option, formulate an advance directive.

(ii) This includes a written description of the facility's policies to implement advance directives and applicable State law.

(iii) Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met.

(iv) If an adult individual is incapacitated at the time of admission and is unable to receive information or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's resident representative in accordance with State law.

(v) The facility is not relieved of its obligation to provide this information to the individual once he or she is able to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(13) The facility must display in the facility written information, and provide to residents and applicants for admission, oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(14) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and notify, consistent with his or her authority, the resident representative(s), when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (that is, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (that is, a need to discontinue or change an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.15(c)(1)(ii).

(ii) When making notification under paragraph (g)(14)(i) of this section, the facility must ensure that all pertinent information specified in § 483.15(c)(2) is available and provided upon request to the physician.

(iii) The facility must also promptly notify the resident and the resident representative, if any, when there is—

(A) A change in room or roommate assignment as specified in § 483.10(e)(6); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (e)(10) of this section.

(iv) The facility must record and periodically update the address (mailing and email) and phone number of the resident representative(s).

(15) *Admission to a composite distinct part.* A facility that is a composite distinct part (as defined in § 483.5 must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under § 483.15(c)(9).

(16) The facility must provide a notice of rights and services to the resident prior to or upon admission and during the resident's stay.

(i) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility.

(ii) The facility must also provide the resident with the State-developed notice of Medicaid rights and obligations, if any.

(iii) Receipt of such information, and any amendments to it, must be acknowledged in writing;

(17) The facility must—

(i) Inform each Medicaid-eligible resident, in writing, at the time of

admission to the nursing facility and when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in § 483.10(g)(17)(i)(A) and (B) of this section.

(18) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.

(i) Where changes in coverage are made to items and services covered by Medicare and/or by the Medicaid State plan, the facility must provide notice to residents of the change as soon as is reasonably possible.

(ii) Where changes are made to charges for other items and services that the facility offers, the facility must inform the resident in writing at least 60 days prior to implementation of the change.

(iii) If a resident dies or is hospitalized or is transferred and does not return to the facility, the facility must refund to the resident, resident representative, or estate, as applicable, any deposit or charges already paid, less the facility's per diem rate, for the days the resident actually resided or reserved or retained a bed in the facility, regardless of any minimum stay or discharge notice requirements.

(iv) The facility must refund to the resident or resident representative any and all refunds due the resident within 30 days from the resident's date of discharge from the facility.

(v) The terms of an admission contract by or on behalf of an individual seeking admission to the facility must not conflict with the requirements of these regulations.

(h) *Privacy and confidentiality.* The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

(2) The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.

(3) The resident has a right to secure and confidential personal and medical records.

(i) The resident has the right to refuse the release of personal and medical records except as provided at § 483.70(i)(2) or other applicable federal or state laws.

(ii) The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.

(i) *Safe environment.* The resident has a right to a safe, clean, comfortable and homelike environment, including but not limited to receiving treatment and supports for daily living safely. The facility must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible.

(i) This includes ensuring that the resident can receive care and services safely and that the physical layout of the facility maximizes resident independence and does not pose a safety risk.

(ii) The facility shall exercise reasonable care for the protection of the resident's property from loss or theft.

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 483.90(d)(2)(iv);

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71 to 81 °F; and

(7) For the maintenance of comfortable sound levels.

(j) *Grievances.* (1) The resident has the right to voice grievances to the facility or other agency or entity that hears grievances without discrimination or reprisal and without fear of discrimination or reprisal. Such grievances include those with respect to care and treatment which has been furnished as well as that which has not been furnished, the behavior of staff and of other residents; and other concerns regarding their LTC facility stay.

(2) The resident has the right to and the facility must make prompt efforts by the facility to resolve grievances the resident may have, in accordance with this paragraph.

(3) The facility must make information on how to file a grievance or complaint available to the resident.

(4) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in this paragraph. Upon request, the provider must give a copy of the grievance policy to the resident. The grievance policy must include:

(i) Notifying resident individually or through postings in prominent locations throughout the facility of the right to file grievances orally (meaning spoken) or in writing; the right to file grievances anonymously; the contact information of the grievance official with whom a grievance can be filed, that is, his or her name, business address (mailing and email) and business phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding his or her grievance; and the contact information of independent entities with whom grievances may be filed, that is, the pertinent State agency, Quality Improvement Organization, State Survey Agency and State Long-Term Care Ombudsman program or protection and advocacy system;

(ii) Identifying a Grievance Official who is responsible for overseeing the grievance process, receiving and tracking grievances through to their conclusion; leading any necessary investigations by the facility; maintaining the confidentiality of all information associated with grievances, for example, the identity of the resident for those grievances submitted anonymously; issuing written grievance decisions to the resident; and coordinating with state and federal agencies as necessary in light of specific allegations;

(iii) As necessary, taking immediate action to prevent further potential violations of any resident right while the alleged violation is being investigated;

(iv) Consistent with § 483.12(c)(1), immediately reporting all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, by anyone furnishing services

on behalf of the provider, to the administrator of the provider; and as required by State law;

(v) Ensuring that all written grievance decisions include the date the grievance was received, a summary statement of the resident's grievance, the steps taken to investigate the grievance, a summary of the pertinent findings or conclusions regarding the resident's concern(s), a statement as to whether the grievance was confirmed or not confirmed, any corrective action taken or to be taken by the facility as a result of the grievance, and the date the written decision was issued;

(vi) Taking appropriate corrective action in accordance with State law if the alleged violation of the residents' rights is confirmed by the facility or if an outside entity having jurisdiction, such as the State Survey Agency, Quality Improvement Organization, or local law enforcement agency confirms a violation of any of these residents' rights within its area of responsibility; and

(vii) Maintaining evidence demonstrating the results of all grievances for a period of no less than 3 years from the issuance of the grievance decision.

(k) *Contact with external entities.* A facility must not prohibit or in any way discourage a resident from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health department employees, including representatives of the Office of the State Long-Term Care Ombudsman, and any representative of the agency responsible for the protection and advocacy system for individuals with mental disorder (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10801 *et seq.*), regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

■ 14. Section 483.12 is revised to read as follows:

**§ 483.12 Freedom from abuse, neglect, and exploitation.**

The resident has the right to be free from abuse, neglect, misappropriation of resident property, and exploitation as defined in this subpart. This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.

(a) The facility must—

(1) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(2) Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints.

(3) Not employ or otherwise engage individuals who—

(i) Have been found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law;

(ii) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property; or

(iii) Have a disciplinary action in effect against his or her professional license by a state licensure body as a result of a finding of abuse, neglect, exploitation, mistreatment of residents or misappropriation of resident property.

(4) Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff.

(b) The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property,

(2) Establish policies and procedures to investigate any such allegations, and

(3) Include training as required at paragraph § 483.95.

(4) Establish coordination with the QAPI program required under § 483.75.

(5) Ensure reporting of crimes occurring in federally-funded long-term care facilities in accordance with section 1150B of the Act. The policies and procedures must include but are not limited to the following elements.

(i) Annually notifying covered individuals, as defined at section 1150B(a)(3) of the Act, of that individual's obligation to comply with the following reporting requirements.

(A) Each covered individual shall report to the State Agency and one or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime against any individual who is a resident of, or is receiving care from, the facility.

(B) Each covered individual shall report immediately, but not later than 2 hours after forming the suspicion, if the events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury.

(ii) Posting a conspicuous notice of employee rights, as defined at section 1150B(d)(3) of the Act.

(iii) Prohibiting and preventing retaliation, as defined at section 1150B(d)(1) and (2) of the Act.

(c) In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:

(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property, are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with State law through established procedures.

(2) Have evidence that all alleged violations are thoroughly investigated.

(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.

(4) Report the results of all investigations to the administrator or his or her designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

**§ 483.13 [Removed]**

■ 15. Remove § 483.13.

■ 16. Section 483.15 is revised to read as follows:

**§ 483.15 Admission, transfer, and discharge rights.**

(a) *Admissions policy.* (1) The facility must establish and implement an admissions policy.

(2) The facility must—

(i) Not request or require residents or potential residents to waive their rights as set forth in this subpart and in applicable state, federal or local licensing or certification laws, including but not limited to their rights to Medicare or Medicaid; and

(ii) Not request or require oral or written assurance that residents or potential residents are not eligible for,

or will not apply for, Medicare or Medicaid benefits.

(iii) Not request or require residents or potential residents to waive potential facility liability for losses of personal property

(3) The facility must not request or require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may request and require a resident representative who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(4) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term ''nursing facility services'' so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

(5) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

(6) A nursing facility must disclose and provide to a resident or potential resident prior to time of admission, notice of special characteristics or service limitations of the facility.

(7) A nursing facility that is a composite distinct part as defined in § 483.5 must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under paragraph (b)(10) of this section.

(b) *Equal access to quality care.* (1) A facility must establish, maintain and implement identical policies and practices regarding transfer and discharge, as defined in § 483.5 and the provision of services for all individuals regardless of source of payment, consistent with § 483.10(a)(2); (2) The facility may charge any amount for services furnished to non-Medicaid residents unless otherwise limited by state law and consistent with the notice requirement in § 483.10(g)(3) and (g)(4)(i) describing the charges; and

(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(c) *Transfer and discharge*—(1) *Facility requirements*—

(i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(C) The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident;

(D) The health of individuals in the facility would otherwise be endangered;

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(F) The facility ceases to operate.

(ii) The facility may not transfer or discharge the resident while the appeal is pending, pursuant to § 431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to § 431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose.

(2) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (c)(1)(i)(A) through (F) of this section, the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.

(i) Documentation in the resident's medical record must include:

(A) The basis for the transfer per paragraph (c)(1)(i) of this section.

(B) In the case of paragraph (c)(1)(i)(A) of this section, the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility to meet the need(s).

(ii) The documentation required by paragraph (c)(2)(i) of this section must be made by—

(A) The resident's physician when transfer or discharge is necessary under paragraph (c)(1)(A) or (B) of this section; and

(B) A physician when transfer or discharge is necessary under paragraph (b)(1)(i)(C) or (D) of this section.

(iii) Information provided to the receiving provider must include a minimum of the following:

(A) Contact information of the practitioner responsible for the care of the resident

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) All special instructions or precautions for ongoing care, as appropriate.

(E) Comprehensive care plan goals,

(F) All other necessary information, including a copy of the residents discharge summary, consistent with § 483.21(c)(2), as applicable, and any other documentation, as applicable, to ensure a safe and effective transition of care.

(3) *Notice before transfer.* Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and the resident's representative(s) of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a representative of the Office of the State Long-Term Care Ombudsman.

(ii) Record the reasons for the transfer or discharge in the resident's medical record in accordance with paragraph (c)(2) of this section; and

(iii) Include in the notice the items described in paragraph (b)(5) of this section.

(4) *Timing of the notice.* (i) Except as specified in paragraphs (b)(4)(ii) and (b)(8) of this section, the notice of transfer or discharge required under this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice must be made as soon as practicable before transfer or discharge when—

(A) The safety of individuals in the facility would be endangered under paragraph (b)(1)(ii)(C) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (b)(1)(ii)(D) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (b)(1)(ii)(B) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (b)(1)(ii)(A) of this section; or

(E) A resident has not resided in the facility for 30 days.

(5) *Contents of the notice.* The written notice specified in paragraph (b)(3) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request;

(v) The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman;

(vi) For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106–402, codified at 42 U.S.C. 15001 *et seq.*); and

(vii) For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.

(6) *Changes to the notice.* If the information in the notice changes prior to effecting the transfer or discharge, the facility must update the recipients of the notice as soon as practicable once the updated information becomes available.

(7) *Orientation for transfer or discharge.* A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility. This orientation must be provided in a form and manner that the resident can understand.

(8) *Notice in advance of facility closure.* In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at § 483.70(l).

(9) *Room changes in a composite distinct part.* Room changes in a facility that is a composite distinct part (as defined in § 483.5) are subject to the requirements of § 483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

(d) *Notice of bed-hold policy and return*—(1) *Notice before transfer.* Before a nursing facility transfers a resident to a hospital or the resident goes on therapeutic leave, the nursing facility must provide written information to the resident or resident representative that specifies—

(i) The duration of the state bed-hold policy, if any, during which the resident is permitted to return and resume residence in the nursing facility;

(ii) The reserve bed payment policy in the state plan, under § 447.40 of this chapter, if any;

(iii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (c)(3) of this section, permitting a resident to return; and

(iv) The information specified in paragraph (c)(3) of this section.

(2) *Bed-hold notice upon transfer.* At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the resident and the resident representative written notice which specifies the duration of the bed-hold policy described in paragraph (c)(1) of this section.

(e)(1) *Permitting residents to return to facility.* A facility must establish and follow a written policy on permitting residents to return to the facility after they are hospitalized or placed on therapeutic leave. The policy must provide for the following.

(i) A resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, returns to the facility to their previous room if available or immediately upon the first availability of a bed in a semi-private room if the resident

(A) Requires the services provided by the facility; and

(B) Is eligible for Medicare skilled nursing facility services or Medicaid nursing facility services.

(ii) If the facility that determines that a resident who was transferred with an expectation of returning to the facility cannot return to the facility, the facility must comply with the requirements of paragraph (c) as they apply to discharges.

(2) *Readmission to a composite distinct part.* When the facility to which a resident returns is a composite distinct part (as defined in § 483.5), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of return, the resident must be given the option to return to that location upon the first availability of a bed there.

**§ 483.20 [Amended]**

■ 17. In § 483.20—

■ a. Revise paragraph (b)(1) introductory text.

■ b. Revise paragraphs (b)(1)(xvi) and (xviii).

■ c. Revise paragraph (e).

■ d. Remove paragraphs (k) and (l).

■ e. Redesignate paragraph (m) as paragraph (k).

■ f. Revise newly designated paragraph (k).

The revisions read as follows:

**§ 483.20 Resident assessment.**

* * * * *

(b) * * *

(1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences, using the resident assessment instrument (RAI) specified by CMS. The assessment must include at least the following:

* * * * *

(xvi) Discharge planning.

* * * * *

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as

well as communication with licensed and nonlicensed direct care staff members on all shifts.

* * * * *

(e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid in subpart C of this part to the maximum extent practicable to avoid duplicative testing and effort. Coordination includes—

(1) Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care.

(2) Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.

* * * * *

(k) *Preadmission screening for individuals with a mental disorder and individuals with intellectual disability.* (1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental disorder as defined in paragraph (k)(3)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Intellectual disability, as defined in paragraph (k)(3)(ii) of this section, unless the State intellectual disability or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for intellectual disability.

(2) *Exceptions.* For purposes of this section—

(i) The preadmission screening program under paragraph (k)(1) of this section need not provide for determinations in the case of the readmission to a nursing facility of an individual who, after being admitted to the nursing facility, was transferred for care in a hospital.

(ii) The State may choose not to apply the preadmission screening program under paragraph (k)(1) of this section to the admission to a nursing facility of an individual—

(A) Who is admitted to the facility directly from a hospital after receiving acute inpatient care at the hospital,

(B) Who requires nursing facility services for the condition for which the individual received care in the hospital, and

(C) Whose attending physician has certified, before admission to the facility that the individual is likely to require less than 30 days of nursing facility services.

(3) *Definition.* For purposes of this section—

(i) An individual is considered to have a mental disorder if the individual has a serious mental disorder as defined in § 483.102(b)(1).

(ii) An individual is considered to have an intellectual disability if the individual has an intellectual disability as defined in § 483.102(b)(3) or is a person with a related condition as described in § 435.1010 of this chapter.

(4) A nursing facility must notify the state mental health authority or state intellectual disability authority, as applicable, promptly after a significant change in the mental or physical condition of a resident who has a mental disorder or intellectual disability for resident review.

■ 18. Section 483.21 is added to read as follows:

**§ 483.21 Comprehensive person-centered care planning.**

(a) *Baseline care plans.* (1) The facility must develop and implement a baseline care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident that meet professional standards of quality care. The baseline care plan must—

(i) Be developed within 48 hours of a resident's admission.

(ii) Include the minimum healthcare information necessary to properly care for a resident including, but not limited to:

(A) Initial goals based on admission orders.

(B) Physician orders.

(C) Dietary orders.

(D) Therapy services.

(E) Social services.

(F) PASARR recommendation, if applicable.

(2) The facility may develop a comprehensive care plan in place of the baseline care plan if the comprehensive care plan—

(i) Is developed within 48 hours of the resident's admission.

(ii) Meets the requirements set forth in paragraph (b) of this section (excepting paragraph (b)(2)(i) of this section).

(3) The facility must provide the resident and their representative with a summary of the baseline care plan that includes but is not limited to:

(i) The initial goals of the resident.

(ii) A summary of the resident's medications and dietary instructions.

(iii) Any services and treatments to be administered by the facility and personnel acting on behalf of the facility.

(iv) Any updated information based on the details of the comprehensive care plan, as necessary.

(b) *Comprehensive care plans.* (1) The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at § 483.10(c)(2) and § 483.10(c)(3, that includes measurable objectives and timeframes to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The comprehensive care plan must describe the following:

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under § 483.24, § 483.25, or § 483.40; and

(ii) Any services that would otherwise be required under § 483.24, § 483.25, or § 483.40 but are not provided due to the resident's exercise of rights under § 483.10, including the right to refuse treatment under § 483.10(c)(6).

(iii) Any specialized services or specialized rehabilitative 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.

(iv) In consultation with the resident and the resident's representative(s)—

(A) The resident's goals for admission and desired outcomes.

(B) The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.

(C) Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in paragraph (c) of this section.

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment.

(ii) Prepared by an interdisciplinary team, that includes but is not limited to—

(A) The attending physician.

(B) A registered nurse with responsibility for the resident.

(C) A nurse aide with responsibility for the resident.

(D) A member of food and nutrition services staff.

(E) To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.

(F) Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.

(iii) Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.

(3) The services provided or arranged by the facility, as outlined by the comprehensive care plan, must—

(i) Meet professional standards of quality.

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(iii) Be culturally-competent and trauma–informed.

(c) *Discharge planning*—(1) *Discharge planning process.* The facility must develop and implement an effective discharge planning process that focuses on the resident's discharge goals, the preparation of residents to be active partners and effectively transition them to post-discharge care, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must be consistent with the discharge rights set forth at § 483.15(b) as applicable and—

(i) Ensure that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident.

(ii) Include regular re-evaluation of residents to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(iii) Involve the interdisciplinary team, as defined by § 483.21(b)(2)(ii), in the ongoing process of developing the discharge plan.

(iv) Consider caregiver/support person availability and the resident's or caregiver's/support person(s) capacity and capability to perform required care, as part of the identification of discharge needs.

(v) Involve the resident and resident representative in the development of the discharge plan and inform the resident and resident representative of the final plan.

(vi) Address the resident's goals of care and treatment preferences.

(vii) Document that a resident has been asked about their interest in receiving information regarding returning to the community.

(A) If the resident indicates an interest in returning to the community, the facility must document any referrals to local contact agencies or other appropriate entities made for this purpose.

(B) Facilities must update a resident's comprehensive care plan and discharge plan, as appropriate, in response to information received from referrals to local contact agencies or other appropriate entities.

(C) If discharge to the community is determined to not be feasible, the facility must document who made the determination and why.

(viii) For residents who are transferred to another SNF or who are discharged to a HHA, IRF, or LTCH, assist residents and their resident representatives in selecting a post-acute care provider by using data that includes, but is not limited to SNF, HHA, IRF, or LTCH standardized patient assessment data, data on quality measures, and data on resource use to the extent the data is available. The facility must ensure that the post-acute care standardized patient assessment data, data on quality measures, and data on resource use is relevant and applicable to the resident's goals of care and treatment preferences.

(ix) Document, complete on a timely basis based on the resident's needs, and include in the clinical record, the evaluation of the resident's discharge needs and discharge plan. The results of the evaluation must be discussed with the resident or resident's representative. All relevant resident information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the resident's discharge or transfer.

(2) *Discharge summary.* When the facility anticipates discharge a resident must have a discharge summary that includes, but is not limited to, the following:

(i) A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.

(ii) A final summary of the resident's status to include items in paragraph (b)(1) of § 483.20, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or resident's representative.

(iii) Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).

(iv) A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.

■ 19. Section 483.24 is added to read as follows:

**§ 483.24 Quality of life.**

Quality of life is a fundamental principle that applies to all care and services provided to facility residents. Each resident must receive and the facility must 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.

(a) Based on the comprehensive assessment of a resident and consistent with the resident's needs and choices, the facility must provide the necessary care and services to ensure that a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable. This includes the facility ensuring that:

(1) A resident is given the appropriate treatment and services to maintain or improve his or her ability to carry out the activities of daily living, including those specified in paragraph (b) of this section,

(2) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene, and

(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to related physician orders and the resident's advance directives.

(b) *Activities of daily living.* The facility must provide care and services in accordance with paragraph (a) of this section for the following activities of daily living:

(1) Hygiene—bathing, dressing, grooming, and oral care,

(2) Mobility—transfer and ambulation, including walking,

(3) Elimination—toileting,

(4) Dining—eating, including meals and snacks,

(5) Communication, including

(i) Speech,

(ii) Language,

(iii) Other functional communication systems.

(c) *Activities.* (1) The facility must provide, based on the comprehensive assessment and care plan and the preferences of each resident, an ongoing program to support residents in their choice of activities, both facility-sponsored group and individual activities and independent activities, designed to meet the interests of and support the physical, mental, and psychosocial well-being of each resident, encouraging both independence and interaction in the community.

(2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who—

(i) Is licensed or registered, if applicable, by the State in which practicing; and

(ii) Is:

(A) Eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(B) Has 2 years of experience in a social or recreational program within the last 5 years, one of which was full-time in a therapeutic activities program; or

(C) Is a qualified occupational therapist or occupational therapy assistant; or

(D) Has completed a training course approved by the State.

■ 20. Section 483.25 is revised to read as follows:

**§ 483.25 Quality of care.**

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following:

(a) *Vision and hearing.* To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(b) *Skin integrity*—(1) *Pressure ulcers.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and

(ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

(2) *Foot care.* To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must—

(i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

(c) *Mobility.* (1) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.

(d) *Accidents.*The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(e) *Incontinence.* (1) The facility must ensure that a resident who is continent of bladder and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.

(2) For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—

(i) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary, and

(iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore continence to the extent possible.

(3) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

(f) *Colostomy, urostomy, or ileostomy care.* The facility must ensure that residents who require colostomy, urostomy, or ileostomy services, receive such care consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(g) *Assisted nutrition and hydration.* (Includes naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids). Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as usual body weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise;

(2) Is offered sufficient fluid intake to maintain proper hydration and health; and

(3) Is offered a therapeutic diet when there is a nutritional problem and the

health care provider orders a therapeutic diet.

(4) A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident; and

(5) A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.

(h) *Parenteral fluids.* Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

(i) *Respiratory care, including tracheostomy care and tracheal suctioning.* The facility must ensure that a resident who needs respiratory care, including tracheostomy care and tracheal suctioning, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, and § 483.65 of this subpart.

(j) *Prostheses.* The facility must ensure that a resident who has a prosthesis is provided care and assistance, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences, to wear and be able to use the prosthetic device.

(k) *Pain management.* The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(l) *Dialysis.* The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(m) *Trauma-informed care.* The facility must ensure that residents who are trauma survivors receive culturally-competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident.

(n) *Bed rails.* The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.

(1) Assess the resident for risk of entrapment from bed rails prior to installation.

(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.

(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.

(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

■ 21. In the table below, each section indicated in the first column is re-designated as the section indicated in the second column:

| Existing CFR section | New CFR section |
|---|---|
| § 483.30 | § 483.35 |
| § 483.35 | § 483.60 |
| § 483.40 | § 483.30 |
| § 483.45 | § 483.65 |
| § 483.60 | § 483.45 |
| § 483.65 | § 483.80 |
| § 483.70 | § 483.90 |
| § 483.75 | § 483.70 |

■ 22. In newly redesignated § 483.30—
■ a. Revise the introductory text.
■ b. Revise paragraph (b)(3).
■ c. Amend paragraph (e)(1) introductory text by removing the reference ''paragraph (e)(2)'' and adding in its place the reference ''paragraph (e)(4)''.
■ d. Resignate paragraph (e)(2) as paragraph (e)(4).
■ e. Add new paragraphs (e)(2) and (e)(3).

The revisions and additions read as follows:

**§ 483.30 Physician services.**

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician. A physician, physician assistant, nurse practitioner, or clinical nurse specialist must provide orders for the resident's immediate care and needs.

* * * * *

(b) * * *

(3) Sign and date all orders with the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

* * * * *

(e) * * *

(2) A resident's attending physician may delegate the task of writing dietary orders, consistent with § 483.60, to a qualified dietitian or other clinically qualified nutrition professional who—

(i) Is acting within the scope of practice as defined by State law; and

(ii) Is under the supervision of the physician.

(3) A resident's attending physician may delegate the task of writing therapy orders, consistent with § 483.65, to a qualified therapist who—

(i) Is acting within the scope of practice as defined by State law; and

(ii) Is under the supervision of the physician.

* * * * *

■ 23. In newly redesignated § 483.35—
■ a. Revise the introductory text.
■ b. Amend paragraph (a)(1)(i) by removing the reference ''paragraph (c)'' and adding in its place the reference ''paragraph (e)''.
■ c. Revise paragraph (a)(1)(ii).
■ d. Add paragraphs (a)(3) and (4).
■ e. Amend paragraphs (b)(1) and (b)(2) by removing the reference ''paragraph (c) or (d)'' and adding in its place the reference ''paragraph (e) or (f)''.
■ f. Redesignate paragraphs (c), (d) and (e) as paragraphs (e), (f), and (g), respectively.
■ g. Add new paragraphs (c) and (d).
■ h. Revise newly redesignated paragraphs (e)(6) and (7).
■ i. Revise newly redesignated paragraphs (f)(1)(iv) and (v).

The revisions and additions read as follows:

**§ 483.35 Nursing services.**

The facility must have sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e).

(a) * * *

(1) * * *

(ii) Other nursing personnel, including but not limited to nurse aides.

* * * * *

(3) The facility must ensure that licensed nurses have the specific

competencies and skill sets necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(4) Providing care includes but is not limited to assessing, evaluating, planning and implementing resident care plans and responding to resident's needs.

* * * * *

(c) *Proficiency of nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(d) *Requirements for facility hiring and use of nursing aides* —(1) *General rule.* A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless—

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of § 483.151 through § 483.154; or

(B) That individual has been deemed or determined competent as provided in § 483.150(a) and (b).

(2) *Non-permanent employees.* A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (d)(1) (i) and (ii) of this section.

(3) *Minimum competency.* A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in § 483.150(a) and (b).

(4) *Registry verification.* Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(5) *Multi-State registry verification.* Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act that the facility believes will include information on the individual.

(6) *Required retraining.* If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(7) *Regular in-service education.* The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. In-service training must comply with the requirements of § 483.95(g).

(e) * * *

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with a mental disorder who are eligible for such services as provided by the protection and advocacy agency; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility and their resident representatives of the waiver.

(f) * * *

(1) * * *

(iv) The Secretary provides notice of the waiver to the Office of the State Long-Term Care Ombudsman (established under section 712 of the Older Americans Act of 1965) and the protection and advocacy system in the State for individuals with developmental disabilities or mental disorders; and

(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives of the waiver.

* * * * *

■ 24. A new § 483.40 is added to read as follows:

**§ 483.40 Behavioral health services.**

Each resident must receive and the facility must provide the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.

(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with § 483.70(e). These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to § 483.70(e), and

(2) Implementing non-pharmacological interventions.

(b) Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays or is diagnosed with mental disorder or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being;

(2) A resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma and/or post-traumatic stress disorder does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable; and

(3) A resident who displays or is diagnosed with dementia, receives the

appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services, including specialized rehabilitation services as required in § 483.65; or

(2) Obtain the required services from an outside resource (in accordance with § 483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

(d) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident.

■ 25. In newly redesignated § 483.45—

■ a. Amend the introductory text by removing the reference ''§ 483.75(h) of this part'' and add in its place the reference ''§ 483.70(g)''.

■ b. Redesignate paragraph (c)(2) as paragraph (c)(4).

■ c. Add new paragraphs (c)(2) and (3).

■ d. Revise newly designated paragraph (c)(4).

■ e. Redesignate paragraphs (d) and (e) as paragraphs (g) and (h), respectively.

■ f. Add new paragraphs (d), (e), and (f).

The additions and revisions read as follows:

**§ 483.45 Pharmacy services.**

* * * * *

(c) * * *

(2) This review must include a review of the resident's medical chart.

(3) A psychotropic drug is 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.

(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been 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.

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

(d) *Unnecessary drugs—General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

(1) In excessive dose (including duplicate drug therapy); or

(2) For excessive duration; or

(3) Without adequate monitoring; or

(4) Without adequate indications for its use; or

(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

(e) *Psychotropic drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order.

(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

(f) *Medication errors.* The facility must ensure that its—

(1) Medication error rates are not 5 percent or greater; and

(2) Residents are free of any significant medication errors.

* * * * *

■ 26. Add § 483.50 to read as follows:

**§ 483.50 Laboratory, radiology, and other diagnostic services.**

(a) *Laboratory services.* (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

(2) The facility must:

(i) Provide or obtain laboratory services only when ordered by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of laboratory results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs asistance; and

(iv) File in the resident's clinical record laboratory reports that are dated

and contain the name and address of the testing laboratory.

(b) *Radiology and other diagnostic services.* (1) The facility must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in § 482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility must:

(i) Provide or obtain radiology and other diagnostic services only when ordered by a physician; physician assistant; nurse practitioner or clinical nurse specialist in accordance with State law, including scope of practice laws.

(ii) Promptly notify the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist of results that fall outside of clinical reference ranges in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's orders.

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

■ 27. Section 483.55 is amended by—

■ a. Amending paragraph (a)(1) by removing the reference ''§ 483.75(h) of this part'' and adding in its place the reference ''§ 483.70(g)''.

■ b. Redesignating paragraph (a)(3) and (4) as paragraphs (a)(4) and (5), respectively.

■ c. Adding a new paragraph (a)(3).

■ d. Revising newly redesignated paragraph (a)(4) introductory text and (a)(4)(ii).

■ e. Revising newly redesignated paragraph (a)(5).

■ f. Amending paragraph (b)(1) introductory text by removing the reference ''§ 483.75(h) of this part'' and adding in its place the reference ''§ 483.70(g)''.

■ g. Revising paragraph (b)(2) introductory text, (b)(2)(ii), and (b)(3).

■ h. Adding paragraphs (b)(4) and (5).

The revisions and additions read as follows:

**§ 483.55 Dental services.**

* * * * *

(a) * * *

(3) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility;

(4) Must if necessary or if requested, assist the resident—

* * * * *

(ii) By arranging for transportation to and from the dental services location; and

(5) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay.

(b) * * *

(2) Must, if necessary or if requested, assist the resident—

* * * * *

(ii) By arranging for transportation to and from the dental services locations;

(3) Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay;

(4) Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and

(5) Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.

■ 28. Newly redesignated § 483.60 is revised to read as follows:

**§ 483.60 Food and nutrition services.**

The facility must 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.

(a) *Staffing.* The facility must employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the food and nutrition service, taking into consideration resident assessments, individual plans of care and the number, acuity and diagnoses of the facility's resident population in accordance with the facility assessment required at § 483.70(e). This includes:

(1) A qualified dietitian or other clinically qualified nutrition professional either full-time, part-time, or on a consultant basis. A qualified dietitian or other clinically qualified nutrition professional is one who—

(i) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(ii) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(iii) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a)(1)(i) and (ii) of this section.

(iv) For dietitians hired or contracted with prior to November 28, 2016, meets these requirements no later than 5 years after November 28, 2016 or as required by state law.

(2) If a qualified dietitian or other clinically qualified nutrition professional is not employed full-time, the facility must designate a person to serve as the director of food and nutrition services who—

(i) For designations prior to November 28, 2016, meets the following requirements no later than 5 years after November 28, 2016, or no later than 1 year after November 28, 2016 for designations after November 28, 2016, is:

(A) A certified dietary manager; or

(B) A certified food service manager, or

(C) Has similar national certification for food service management and safety from a national certifying body; or

(D) Has an associate's or higher degree in food service management or in hospitality, if the course study includes food service or restaurant management, from an accredited institution of higher learning; and

(ii) In States that have established standards for food service managers or dietary managers, meets State requirements for food service managers or dietary managers, and

(iii) Receives frequently scheduled consultations from a qualified dietitian or other clinically qualified nutrition professional.

(3) *Support staff.* The facility must provide sufficient support personnel to safely and effectively carry out the functions of the food and nutrition service.

(b) A member of the Food and Nutrition Services staff must participate on the interdisciplinary team as required in § 483.21(b)(2)(ii).

(c) *Menus and nutritional adequacy.* Menus must—

(1) Meet the nutritional needs of residents in accordance with established national guidelines.;

(2) Be prepared in advance;

(3) Be followed;

(4) Reflect, based on a facility's reasonable efforts, the religious, cultural, and ethnic needs of the resident population, as well as input received from residents and resident groups;

(5) Be updated periodically;

(6) Be reviewed by the facility's dietitian or other clinically qualified nutrition professional for nutritional adequacy; and

(7) Nothing in this paragraph should be construed to limit the resident's right to make personal dietary choices.

(d) *Food and drink.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food and drink that is palatable, attractive, and at a safe and appetizing temperature;

(3) Food prepared in a form designed to meet individual needs;

(4) Food that accommodates resident allergies, intolerances, and preferences;

(5) Appealing options of similar nutritive value to residents who choose not to eat food that is initially served or who request a different meal choice; and

(6) Drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration.

(e) *Therapeutic diets.* (1) Therapeutic diets must be prescribed by the attending physician. (2) The attending physician may 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.

(f) *Frequency of meals.* (1) Each resident must receive and the facility must provide at least three meals daily, at regular times comparable to normal mealtimes in the community or in accordance with resident needs, preferences, requests, and plan of care.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except when a nourishing snack is served at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span.

(3) Suitable, nourishing alternative meals and snacks must be provided to residents who want to eat at non-traditional times or outside of scheduled meal service times, consistent with the resident plan of care.

(g) *Assistive devices.* The facility must provide special eating equipment and utensils for residents who need them and appropriate assistance to ensure that the resident can use the assistive devices when consuming meals and snacks.

(h) *Paid feeding assistants*—(1) *State-approved training course.* A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—

(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of § 483.160 before feeding residents; and

(ii) The use of feeding assistants is consistent with State law.

(2) *Supervision.* (i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

(ii) In an emergency, a feeding assistant must call a supervisory nurse for help.

(3) *Resident selection criteria.* (i) A facility must ensure that a feeding assistant provides dining assistance only for residents who have no complicated feeding problems.

(ii) Complicated feeding problems include, but are not limited to, difficulty swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(iii) The facility must base resident selection on the interdisciplinary team's assessment and the resident's latest assessment and plan of care. Appropriateness for this program should be reflected in the comprehensive care plan.

(i) *Food safety requirements.* The facility must—

(1) Procure food from sources approved or considered satisfactory by federal, state, or local authorities;

(i) This may include food items obtained directly from local producers, subject to applicable State and local laws or regulations.

(ii) This provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.

(iii) This provision does not preclude residents from consuming foods not procured by the facility.

(2) Store, prepare, distribute, and serve food in accordance with professional standards for food service safety.

(3) Have a policy regarding use and storage of foods brought to residents by family and other visitors to ensure safe and sanitary storage, handling, and consumption, and

(4) Dispose of garbage and refuse properly.

■ 29. In newly redesignated § 483.65, revise paragraphs (a) introductory text and (a)(2) to read as follows:

**§ 483.65 Specialized rehabilitative services.**

(a) *Provision of services.* If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, respiratory therapy, and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as set forth at § 483.120(c), are required in the resident's comprehensive plan of care, the facility must—

* * * * *

(2) In accordance with § 483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Act.

* * * * *

■ 30. In newly redesignated § 483.70—

■ a. Revise paragraph (c).

■ b. Revise paragraph (d)(2).

■ c. Add paragraph (d)(3).

■ d. Revise paragraph (e).

■ e. Remove paragraphs (f), (j), (k), (m), (o), and (q).

■ f. Redesignate paragraphs (g), (h), (i), (l), (n), (p), (r), (s), (t), and (u) as paragraphs (f), (g), (h), (i), (j), (k), (l), (m), (o), and (q), respectively.

■ g. Revise newly redesignated paragraphs (i)(1) introductory text, and (i)(2), (3), (4), and (5).

■ h. Revise newly redesignated paragraphs (j)(1)(i) and (ii).

■ i. Revise newly redesignated paragraph (m).

■ j. Add new paragraph (n).

■ k. Add new paragraph (p).

■ l. In the table below, for each newly redesignated paragraph indicated in the

first column, remove the reference indicated in the second column and add the reference indicated in the third column.

| Paragraphs | Remove | Add |
|---|---|---|
| (g)(1) ..... | (h)(2) ..... | (g)(2). |
| (k)(3) ..... | (p)(2) ..... | (k)(2). |
| (m) ..... | (r) ..... | (l). |
| (o)(2) introductory text. | (t)(1)(i) ..... | (o)(1)(i). |

The revisions and additions read as follows:

**§ 483.70 Administration.**

* * * * *

(c) *Relationship to other HHS regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR part 80); nondiscrimination on the basis of disability (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); nondiscrimination on the basis of race, color, national origin, sex, age, or disability (45 CFR part 92); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455) and protection of individually identifiable health information (45 CFR parts 160 and 164). Violations of such other provisions may result in a finding of non-compliance with this paragraph.

(d) * * *

(2) The governing body appoints the administrator who is—

(i) Licensed by the State, where licensing is required;

(ii) Responsible for management of the facility; and

(iii) Reports to and is accountable to the governing body.

(3) The governing body is responsible and accountable for the QAPI program, in accordance with § 483.75(f).

(e) *Facility assessment.* The facility must 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. The facility must also 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. The facility assessment must address or include:

(1) The facility's resident population, including, but not limited to,

(i) Both the number of residents and the facility's resident capacity;

(ii) The care required by the resident population considering the types of diseases, conditions, physical and cognitive disabilities, overall acuity, and other pertinent facts that are present within that population;

(iii) The staff competencies that are necessary to provide the level and types of care needed for the resident population;

(iv) The physical environment, equipment, services, and other physical plant considerations that are necessary to care for this population; and

(v) Any ethnic, cultural, or religious factors that may potentially affect the care provided by the facility, including, but not limited to, activities and food and nutrition services.

(2) The facility's resources, including but not limited to,

(i) All buildings and/or other physical structures and vehicles;

(ii) Equipment (medical and non-medical);

(iii) Services provided, such as physical therapy, pharmacy, and specific rehabilitation therapies;

(iv) All personnel, including managers, staff (both employees and those who provide services under contract), and volunteers, as well as their education and/or training and any competencies related to resident care;

(v) Contracts, memorandums of understanding, or other agreements with third parties to provide services or equipment to the facility during both normal operations and emergencies; and

(vi) Health information technology resources, such as systems for electronically managing patient records and electronically sharing information with other organizations.

(3) A facility-based and community-based risk assessment, utilizing an all-hazards approach.

* * * * *

(i) *Medical records.* (1) In accordance with accepted professional standards and practices, the facility must maintain medical records on each resident that are—

* * *

(2) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is—

(i) To the individual, or their resident representative where permitted by applicable law;

(ii) Required by law;

(iii) For treatment, payment, or health care operations, as permitted by and in compliance with 45 CFR 164.506;

(iv) For public health activities, reporting of abuse, neglect, or domestic violence, health oversight activities, judicial and administrative proceedings, law enforcement purposes, organ donation purposes, research purposes, or to coroners, medical examiners, funeral directors, and to avert a serious threat to health or safety as permitted by and in compliance with 45 CFR 164.512.

(3) The facility must safeguard medical record information against loss, destruction, or unauthorized use;

(4) Medical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or

(iii) For a minor, 3 years after a resident reaches legal age under State law.

(5) The medical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The comprehensive plan of care and services provided;

(iv) The results of any preadmission screening and resident review evaluations and determinations conducted by the State;

(v) Physician's, nurse's, and other licensed professional's progress notes; and

(vi) Laboratory, radiology and other diagnostic services reports as required under § 483.50.

(j) * * *

(1) * * *

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician or, in an emergency situation, by another practitioner in accordance with facility policy and consistent with state law; and

(ii) Medical and other information needed for care and treatment of residents and, when the transferring facility deems it appropriate, for determining whether such residents can receive appropriate services or receive services in a less restrictive setting than either the facility or the hospital, or reintegrated into the community, will be exchanged between the providers, including but not limited to the information required under § 483.15(c)(2)(iii).

* * * * *

(m) Facility closure. The facility must have in place policies and procedures to

ensure that the administrator's duties and responsibilities involve providing the appropriate notices in the event of a facility closure, as required at paragraph (l) of this section.

(n) *Binding arbitration agreements.* (1) A facility must not enter into a pre-dispute agreement for binding arbitration with any resident or resident's representative nor require that a resident sign an arbitration agreement as a condition of admission to the LTC facility.

(2) If, after a dispute between the facility and a resident arises, and a facility chooses to ask a resident or his or her representative to enter into an agreement for binding arbitration, the facility must comply with all of the requirements in this section.

(i) The facility must ensure that:

(A) The agreement is explained to the resident and their representative in a form and manner that he or she understands, including in a language the resident and their representative understands, and

(B) The resident acknowledges that he or she understands the agreement.

(ii) The agreement must:

(A) Be entered into by the resident voluntarily.

(B) Provide for the selection of a neutral arbitrator agreed upon by both parties.

(C) Provide for selection of a venue convenient to both parties.

(iii) A resident's continuing right to remain in the facility must not be contingent upon the resident or the resident's representative signing a binding arbitration agreement.

(iv) The agreement must not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with § 483.10(k).

(v) The agreement may be signed by another individual if:

(A) Allowed by state law;

(B) All of the requirements in this section are met; and

(C) That individual has no interest in the facility.

(vi) When the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee.

* * * * *

(p) *Social worker.* Any facility with more than 120 beds must employ a qualified social worker on a full-time basis. A qualified social worker is:

(1) An individual with a minimum of a bachelor's degree in social work or a bachelor's degree in a human services field including, but not limited to, sociology, gerontology, special education, rehabilitation counseling, and psychology; and

(2) One year of supervised social work experience in a health care setting working directly with individuals.

* * * * *

■ 31. A new § 483.75 is added to read as follows:

**§ 483.75 Quality assurance and performance improvement.**

(a) *Quality assurance and performance improvement (QAPI) program.* Each LTC facility, including a facility that is part of a multiunit chain, must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life. The facility must—

(1) Maintain documentation and demonstrate evidence of its ongoing QAPI program that meets the requirements of this section. This may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities;

(2) Present its QAPI plan to the State Survey Agency no later than 1 year after the promulgation of this regulation;

(3) Present its QAPI plan to a State Survey Agency or Federal surveyor at each annual recertification survey and upon request during any other survey and to CMS upon request; and

(4) Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request.

(b) *Program design and scope.* A facility must design its QAPI program to be ongoing, comprehensive, and to address the full range of care and services provided by the facility. It must:

(1) Address all systems of care and management practices;

(2) Include clinical care, quality of life, and resident choice;

(3) Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.

(4) Reflect the complexities, unique care, and services that the facility provides.

(c) *Program feedback, data systems and monitoring.* A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include, at a minimum, the following:

(1) Facility maintenance of effective systems to obtain and use of feedback and input from direct care staff, other staff, residents, and resident representatives, including how such information will be used to identify problems that are high risk, high volume, or problem-prone, and opportunities for improvement.

(2) Facility maintenance of effective systems to identify, collect, and use data and information from all departments, including but not limited to the facility assessment required at § 483.70(e) and including how such information will be used to develop and monitor performance indicators.

(3) Facility development, monitoring, and evaluation of performance indicators, including the methodology and frequency for such development, monitoring, and evaluation.

(4) Facility adverse event monitoring, including the methods by which the facility will systematically identify, report, track, investigate, analyze and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events.

(d) *Program systematic analysis and systemic action.* (1) The facility must take actions aimed at performance improvement and, after implementing those actions, measure its success, and track performance to ensure that improvements are realized and sustained.

(2) The facility will develop and implement policies addressing:

(i) How they will use a systematic approach to determine underlying causes of problems impacting larger systems;

(ii) How they will develop corrective actions that will be designed to effect change at the systems level to prevent quality of care, quality of life, or safety problems ; and

(iii) How the facility will monitor the effectiveness of its performance

improvement activities to ensure that improvements are sustained.

(e) *Program activities.* (1) The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care.

(2) Performance improvement activities must track medical errors and adverse resident events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the facility.

(3) As a part of their performance improvement activities, the facility must conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility must reflect the scope and complexity of the facility's services and available resources, as reflected in the facility assessment required at § 483.70(e). Improvement projects must include at least annually a project that focuses on high risk or problem-prone areas identified through the data collection and analysis described in paragraphs (c) and (d) of this section.

(f) *Governance and leadership.* The governing body and/or executive leadership (or organized group or individual who assumes full legal authority and responsibility for operation of the facility) is responsible and accountable for ensuring that—

(1) An ongoing QAPI program is defined, implemented, and maintained and addresses identified priorities.

(2) The QAPI program is sustained during transitions in leadership and staffing;

(3) The QAPI program is adequately resourced, including ensuring staff time, equipment, and technical training as needed;

(4) The QAPI program identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to resident based on performance indicator data, and resident and staff input, and other information.

(5) Corrective actions address gaps in systems, and are evaluated for effectiveness; and

(6) Clear expectations are set around safety, quality, rights, choice, and respect.

(g) *Quality assessment and assurance.* (1) A facility must maintain a quality assessment and assurance committee consisting at a minimum of:

(i) The director of nursing services;

(ii) The Medical Director or his or her designee;

(iii) At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and

(iv) The infection control and prevention officer.

(2) The quality assessment and assurance committee reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:

(i) Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including performance improvement projects required under the QAPI program, are necessary; and

(ii) Develop and implement appropriate plans of action to correct identified quality deficiencies; and

(iii) Regularly review and analyze data, including data collected under the QAPI program and data resulting from drug regimen reviews, and act on available data to make improvements.

(h) *Disclosure of information.* A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(i) *Sanctions.* Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

■ 32. Newly redesignated § 483.80 is revised to read as follows:

**§ 483.80 Infection control.**

The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

(a) *Infection prevention and control program.* The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(1) 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 a contractual arrangement based upon the facility assessment conducted according to § 483.70(e) and following accepted national standards;

(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;

(ii) When and to whom possible incidents of communicable disease or infections should be reported;

(iii) Standard and transmission-based precautions to be followed to prevent spread of infections;

(iv) When and how isolation should be used for a resident; including but not limited to:

(A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and

(B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances.

(v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and

(vi) The hand hygiene procedures to be followed by staff involved in direct resident contact.

(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

(b) *Infection preventionist.* The facility must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's IPCP. The IP must:

(1) Have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field;

(2) Be qualified by education, training, experience or certification;

(3) Work at least part-time at the facility; and

(4) Have completed specialized training in infection prevention and control.

(c) *IP participation on quality assessment and assurance committee.* The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.

(d) *Influenza and pneumococcal immunizations*—(1) *Influenza.* The

facility must develop policies and procedures to ensure that—

(i) Before offering the influenza immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

(iii) The resident or the resident's representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) *Pneumococcal disease.* The facility must develop policies and procedures to ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

(e) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

(f) *Annual review.* The facility will conduct an annual review of its IPCP and update their program, as necessary.

■ 33. Section 483.85 is added to read as follows:

**§ 483.85 Compliance and ethics program.**

(a) *Definitions.* For purposes of this section, the following definitions apply:

*Compliance and ethics program* means, with respect to a facility, a program of the operating organization that—

(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.

*High-level personnel* means individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization.

*Operating organization* means the individual(s) or entity that operates a facility.

(b) *General rule.* Beginning on November 28, 2017, the operating organization for each facility must have in operation a compliance and ethics program (as defined in paragraph (a) of this section) that meets the requirements of this section.

(c) *Required components for all facilities.* The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

(2) Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.

(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to

prevent and detect criminal, civil, and administrative violations under the Act.

(d) *Additional required components for operating organizations with five or more facilities.* In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:

(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in § 483.95(f).

(2) A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer.

(3) Designated compliance liaisons located at each of the operating organization's facilities.

(e) *Annual review.* The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care.

■ 34. In newly redesignated § 483.90—

■ a. Revise paragraph (c).

■ b. Revise paragraphs (e)(1)(i) and (e)(2)(i).

■ c. Revise paragraph (f).

■ d. Revise paragraph (g) introductory text and (g)(1).

■ e. Revise paragraph (h)(2).

■ f. Add paragraph (i)(5).

The revisions and additions read as follows:

**§ 483.90 Physical environment.**

* * * * *

(c) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, living, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's assessment and plan of care; and

(2) Maintain all mechanical, electrical, and patient care equipment in safe operating condition.

(3) Conduct regular inspection of all bed frames, mattresses, and bed rails, if any, as part of a regular maintenance program to identify areas of possible entrapment. When bed rails and mattresses are used and purchased separately from the bed frame, the facility must ensure that the bed rails, mattress, and bed frame are compatible.

(e) * * *

(1) * * *

(i) Accommodate no more than four residents. For facilities that receive approval of construction or reconstruction plans by State and local authorities or are newly certified after November 28, 2016, bedrooms must accommodate no more than two residents.

* * * * *

(2) * * *

(i) A separate bed of proper size and height for the safety and convenience of the resident;

* * * * *

(f) *Bathroom facilities.* Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction from State and local authorities or are newly certified after November 28, 2016, each resident room must have its own bathroom equipped with at least a commode and sink.

(g) *Resident call system.* The facility must be adequately equipped to allow residents to call for staff assistance through a communication system which relays the call directly to a staff member or to a centralized staff work area from—

(1) Each resident's bedside; and

* * * * *

(h) * * *

(2) Be well ventilated;

* * * * *

(i) * * *

(5) Establish policies, in accordance with applicable Federal, State, and local laws and regulations, regarding smoking, smoking areas, and smoking safety that also take into account non-smoking residents.

■ 35. Section 483.95 is added to subpart B to read as follows:

**§ 483.95 Training requirements.**

A facility must develop, implement, and maintain an effective training program for all new and existing staff; individuals providing services under a contractual arrangement; and volunteers, consistent with their expected roles. A facility must determine the amount and types of training necessary based on a facility assessment as specified at § 483.70(e). Training topics must include but are not limited to—

(a) *Communication.* A facility must include effective communications as mandatory training for direct care staff.

(b) *Resident's rights and facility responsibilities.* A facility must 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 at § 483.10, respectively.

(c) *Abuse, neglect, and exploitation.* In addition to the freedom from abuse, neglect, and exploitation requirements in § 483.12, facilities must also provide training to their staff that at a minimum educates staff on—

(1) Activities that constitute abuse, neglect, exploitation, and misappropriation of resident property as set forth at § 483.12.

(2) Procedures for reporting incidents of abuse, neglect, exploitation, or the misappropriation of resident property.

(3) Dementia management and resident abuse prevention.

(d) *Quality assurance and performance improvement.* A facility must include as part of its QAPI program mandatory training that outlines and informs staff of the elements and goals of the facility's QAPI program as set forth at § 483.75.

(e) *Infection control.* A facility must include as part of its infection prevention and control program mandatory training that includes the written standards, policies, and procedures for the program as described at § 483.80(a)(2).

(f) *Compliance and ethics.* The operating organization for each facility must include as part of its compliance and ethics program, as set forth at § 483.85—

(1) An effective way to communicate that program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.

(2) Annual training if the operating organization operates five or more facilities.

(g) *Required in-service training for nurse aides.* In-service training must—

(1) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year.

(2) Include dementia management training and resident abuse prevention training.

(3) Address areas of weakness as determined in nurse aides' performance reviews and facility assessment at § 483.70(e) and may address the special needs of residents as determined by the facility staff.

(4) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(h) *Required training of feeding assistants.* A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in § 483.160.

(i) *Behavioral health.* A facility must provide behavioral health training consistent with the requirements at § 483.40 and as determined by the facility assessment at § 483.70(e).

**§ 483.118 [Amended]**

■ 36. In § 483.118, amend paragraphs (b)(1) and (c)(2)(i) by removing the reference ''§ 483.12(a)'' and adding in its place the reference ''§ 483.15(b)''.

**§ 483.130 [Amended]**

■ 37. In § 483.130, amend paragraphs (m)(5) and (m)(6) by removing the reference ''§ 483.12(a)'' and adding in its place the reference § 483.15(b)''.

**§ 483.138 [Amended]**

■ 38. In § 483.138, amend paragraphs (a) introductory text and (b)(1) by removing the reference ''§ 483.12(a)'' and adding in its place the reference ''§ 483.15(b)''.

**§ 483.151 [Amended]**

■ 39. In § 483.151, amend paragraph (a)(3) by removing the reference ''§ 483.75(e)'' and adding in its place the reference ''§ 483.35(c) and (d) and § 483.95(g)''.

**§ 483.204 [Amended]**

■ 40. In § 483.204, amend paragraph (b) by removing the reference ''§ 483.12 of this part'' and adding in its place the reference ''§ 483.15(h)''.

**§ 483.206 [Amended]**

■ 41. In § 483.206, amend paragraph (a) by removing the reference ''(See § 483.5 and § 483.12(a)(1))'' and adding in its place the reference ''(See § 483.5)''.

## PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 42. The authority citation for part 485 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

**§ 485.635 [Amended]**

■ 43. In § 485.635, amend paragraph (a)(3)(vii) by removing the reference ''§ 483.25(i)'' and adding in its place the reference ''§ 483.25(d)(8)''.

■ 44. In § 485.645, paragraphs (d)(1) through (9) are revised and paragraph (d)(10) is added to read as follows:

**§ 485.645 Special requirements for CAH providers of long-term care services (''swing-beds'')**

* * * * *

(d) * * *

(1) Resident rights (§ 483.10(a)(4)(iv), (b), (c), (d)(1), (d)(3), (e)(8), (g), and (h)(3) of this chapter).

(2) Facility responsibilities (§ 483.11(d)(1)(i), (d)(1)(iii), (d)(4), (e)(11), (e)(12), (e)(14)(iii), and (f)(1)(i) of this chapter).

(3) Admission, transfer, and discharge rights (§ 483.5(n), § 483.15(b)(1), (b)(2), (b)(3)(i) through (iii), (b)(4), (b)(5)(i) through (vii), and (b)(7) of this chapter).

(4) Freedom from abuse, neglect and exploitation (§ 483.12 of this chapter).

(5) Patient activities (§ 483.25(c) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of § 485.25(c)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(6) Social services (§ 483.40(d) and § 483.75(p) of this chapter).

(7) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), and § 483.21(b) and (c) of this chapter), except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

(8) Specialized rehabilitative services (§ 483.65 of this chapter).

(9) Dental services (§ 483.55 of this chapter).

(10) Nutrition (§ 483.25(d)(8) of this chapter).

## PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 45. The authority citation for part 488 continues to read as follows:

**Authority:** Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a–7j, and 1395hh); Pub. L. 110–149, 121 Stat. 1819. Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

**§ 488.56 [Amended]**

■ 46. In § 488.56, paragraph (a) introductory text is amended by removing the reference ''§ 483.30'' and adding in its place the reference ''§ 483.35''.

■ 47. Section 488.301 is amended by revising the definitions of ''Abuse'', ''Neglect'', ''Nurse aide'', ''Paid feeding assistant'', and ''Substandard quality of care'' to read as follows:

**§ 488.301 Definitions.**

* * * * *

*Abuse* is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology. *Willful,* as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

* * * * *

*Neglect* is the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.

* * * * *

*Nurse aide* means an individual, as defined in § 483.5 of this chapter.

* * * * *

*Paid feeding assistant* means an individual who meets the requirements specified in § 483.60(h)(1) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

* * * * *

*Substandard quality of care* means one or more deficiencies related to participation requirements under § 483.10 ''Resident rights'', paragraphs (a)(1) through (a)(2), (b)(1) through (b)(2), (e) (except for (e)(2), (e)(7), and (e)(8)), (f)(1) through (f)(3), (f)(5) through (f)(8), and (i) of this chapter; § 483.12 of this chapter ''Freedom from abuse, neglect, and exploitation''; § 483.24 of this chapter ''Quality of life''; § 483.25 of this chapter ''Quality of care''; § 483.40 ''Behavioral health services'', paragraphs (b) and (d) of this chapter; § 483.45 ''Pharmacy services'', paragraphs (d), (e), and (f) of this chapter; § 483.70 ''Administration'', paragraph (p) of this chapter, and § 483.80 ''Infection control'', paragraph (d) of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or

widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

* * * * *

**§ 488.426 [Amended]**

■ 48. In § 488.426, paragraph (b) is amended by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)'' and paragraph (c) is amended by removing the reference ''§ 483.75(r)(1)(ii)'' and adding in its place the reference ''§ 483.70(l)''.

**§ 488.446 [Amended]**

■ 49. In § 488.446, the introductory text is amended by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)''.

## PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 50. The authority citation for part 489 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**§ 489.52 [Amended]**

■ 51. In § 489.52, amend paragraph (a)(2) by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)''.

**§ 489.55 [Amended]**

■ 52. In § 489.55, amend paragraph (b) by removing the reference ''§ 483.75(r)'' and adding in its place the reference ''§ 483.70(l)''.

Dated: September 1, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Dated: September 19, 2016.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

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