



FEDERAL REGISTER

Vol. 80

Thursday,

No. 136

July 16, 2015

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 431, 447, *et al.*

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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

[CMS-3260-P]

RIN 0938-AR61

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These proposed 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 proposals 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: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 14, 2015.

ADDRESSES: In commenting, please refer to file code CMS-3260-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3260-P, P.O. Box 8010, Baltimore, MD 21244.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3260-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850. If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Sheila Blackstock, (410) 786-6633, for issues related to Care transitions, QAPI.
Ronisha Blackstone, (410) 786-6633, for issues related to Comprehensive care planning, training.

Diane Corning, (410) 786-6633, for issues related to Behavioral health, infection control, facility assessment.

Lisa Parker, (410) 786-6633, for issues related to the Regulatory Impact Analysis.

Jeannie Miller, (410) 786-6633, for General information.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

Because of the many terms to which we refer by acronym in this proposed 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
ADRCS Aging and Disability Resource Center
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
CARIE Center for Advocacy Rights and Interests
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
IPCO Infection Prevention and Control Officer
IPCP Infection Prevention and Control Program
LSC Life Safety Code
LTC Long-Term Care
NATCEP Nurse Aide Training Competency Evaluation Program
NCEA National Center on Elder Abuse
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
 SMA State Medicaid Agency
 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 nursing homes 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 are reviewing 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 proposing to add new requirements where necessary, eliminate duplicative or unnecessary provisions, and reorganize 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 proposed revisions may eliminate or significantly reduce those instances where the requirements are duplicative, unnecessary, and/or burdensome.

2. Summary of the Major Provisions

Basis and Scope (§ 483.1)

- The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively known as the Affordable Care Act) provisions: We propose to add the statutory authority citations for sections 1128I(b) and (c) and section 1150B of the Act to include the compliance and ethics program, quality assurance and performance improvement (QAPI), and

reporting of suspicion of a crime requirements.

Definitions (§ 483.5)

- Expanded Definitions: We propose to add the definitions for “adverse event”, “documentation”, “posting/displaying”, “resident representative”, “abuse”, “sexual abuse”, “neglect”, “exploitation”, “misappropriation of resident property”, and “person-centered care”.

Resident Rights (§ 483.10)

- Comprehensive Restructuring: We propose to retain all existing residents’ rights but update the language and organization of the resident rights provisions to improve logical order and readability, clarify aspects of the regulation where necessary, and to update provisions to include advances such as electronic communications. This includes—
 - Eliminating language, such as “interested family member” and replacing the term “legal representative” with “resident representative.”
 - Addressing roommate choice.
 - Adding language regarding physician credentialing to specify that the physician chosen by the resident must be licensed to practice medicine in the state where the resident resides, and must meet professional credentialing requirements of the facility.

Facility Responsibilities (§ 483.11)

New Section

- New Section: We propose to add a new section to subpart B that focuses on the responsibilities of the facility (that is, protecting the rights of their residents, enhancing a resident’s quality of life) and brings together many of the facility responsibilities currently dispersed throughout existing regulations. This section parallels many residents’ rights provisions.

- Visitation: We propose to revise visitation requirements to establish open visitation, similar to the hospital conditions of participation (CoPs).

- Re-designation of Requirements: We propose to—

- Relocate provisions from existing Resident’s Rights (§ 483.10) section that pertain to the responsibilities of the facility into this section.

- Relocate the existing requirements in Quality of Life (§ 483.15) into this section.

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

- Revised Title: Formerly “Resident behavior and facility practices,” we propose to revise the title to “Freedom from abuse, neglect, and exploitation.”

- Prohibiting abuse, neglect, and exploitation: We propose to—
 - Specify 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.
 - Require facilities to develop and implement written policies and procedures that prohibit and prevent abuse, neglect, and mistreatment of residents or misappropriation of their property.

Transitions of Care (§ 483.15)

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

Resident Assessments (§ 483.20)

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

disability” throughout the section, as appropriate.

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

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

admission medications (both prescribed and over-the-counter).

- We propose to add to the post discharge plan of care a summary of what arrangements have been made for the resident’s follow up care and any post-discharge medical and non-medical services.

Quality of Care and Quality of Life (§ 483.25)

- Overarching Principles: We propose to clarify that quality of care and quality of life are overarching principles in the delivery of care to residents of nursing homes and should be applied to every service provided.
 - Activities of Daily Living (ADLs): We propose to clarify the requirements regarding a resident’s ability to perform ADLs.
 - Director of Activities Qualifications: We propose to solicit comments on whether the requirements for the director of the activities program remain appropriate and what should serve as minimum requirements for this position. We are not proposing specific changes at this time.
 - Updating Current Practices: We propose to modify existing requirements for nasogastric tubes to reflect current clinical practice, and to include enteral fluids in the requirements for assisted nutrition and hydration.
 - Special Need Issues: We propose to add a new requirement that facilities must ensure that residents receive necessary and appropriate pain management.
 - Re-designation of Requirements: We propose to relocate the provisions regarding unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations to § 483.45 Pharmacy services.

Physician Services (§ 483.30)

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

Nursing Services (§ 483.35)

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

Behavioral Health Services (§ 483.40)

New Section

• New Section: We propose to add 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.

• Staffing:

○ *Facility Assessment*: We propose to require facilities to determine their direct care staff needs, based on the facility's assessment.

○ *Competency Approach*: We propose to require that staff must have the appropriate competencies and skills to provide behavioral health care and services, which include caring for residents with mental and psychosocial illnesses and implementing non-pharmacological interventions.

○ *Social Worker*: We propose to add "gerontology" to the list of possible human services fields from which a bachelor degree could provide the minimum educational requirement for a social worker.

Pharmacy Services (§ 483.45)

• Drug Regimen Review:

○ We propose to add the requirement that a pharmacist review a resident's medical chart at least every 6 months and when the resident is new to the facility, a prior resident returns or is transferred from a hospital or other facility, and during each monthly drug regimen review when the resident has been prescribed or is taking a psychotropic drug, an antibiotic or any drug the QAA Committee has requested be included in the pharmacist's monthly drug review.

○ We propose to require the pharmacist to document in a written report any irregularities noted during the drug regimen review that lists at a minimum, the resident's name, the relevant drug, and the irregularity identified, to be sent to the attending physician and the facility's medical director and director of nursing.

○ We propose to require that the attending physician document in the resident's medical record that he or she has reviewed the identified irregularity and what, if any, action they have taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

• Irregularities: We propose to add a definition of "irregularities" that would include, but not be limited to, the definition of "unnecessary drugs."

• Psychotropic Drugs: We propose to revise existing requirements regarding

"antipsychotic" drugs to refer to "psychotropic" drugs.

○ We propose to require that facilities ensure residents who have not used psychotropic drugs not be given these drugs unless medically necessary.

○ We propose that residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue use of these psychotropic drugs.

○ We propose to define "psychotropic drug" as any drug that affects brain activities associated with mental processes and behavior.

○ We propose that PRN (Pro re nata or as needed) orders for psychotropic drugs be limited to 48 hours. Orders could not be continued beyond that time unless the primary care provider (for example, the resident's physician) reviewed the need for the medications prior to renewal of the order, and documented the rationale for the order in the resident's clinical record.

• Re-designation of Requirements: We propose to relocate provisions in § 483.25 "Quality of Care" regarding unnecessary drugs, antipsychotic drugs, medication errors, and influenza and pneumococcal immunizations into this section.

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

• Ordering Services: We propose to clarify that a physician assistant, nurse practitioner or clinical nurse specialist may order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope of practice laws.

• Laboratory Services: We propose to clarify that the ordering physician; physician assistant; nurse practitioner or clinical nurse specialist, be notified of abnormal laboratory results when they fall outside of clinical reference ranges, in accordance with facility policies and procedures for notification of a practitioner or per the ordering physician's, physician assistant's; nurse practitioner's or clinical nurse specialist's orders.

Dental Services (§ 483.55)

• For Skilled Nursing Facilities (SNFs): We propose to prohibit SNFs from charging a Medicare resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility.

• For Nursing Facilities (NFs): We propose to require NFs to assist residents who are eligible to apply for reimbursement of dental services as an

incurred medical expense under the Medicaid state plan.

• For both SNFs and NFs: We propose to clarify that with regard to a referral for lost or damaged dentures "promptly" means within 3 business days unless there is documentation of extenuating circumstances.

Food and Nutrition Services (§ 483.60)

• Staffing: We propose to require facilities to employ sufficient staff with the appropriate competencies and skills sets to carry out the functions of the dietary service while taking into consideration resident assessments, and individual plans of care, including diagnoses and acuity, as well as the facility's resident census..

• Dietitian Qualification: We propose to clarify that a "qualified dietitian" is one who is registered by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics or who meets state licensure or certification requirements. For dietitians hired or contracted with prior to the effective date of these regulations, we propose to allow up to 5 years to meet the new requirements.

• Director of Food Service: We propose to add to the requirement for the designation of a director of food and nutrition service that the person serving in this position be a certified dietary manager, certified food service manager, or have a certification for food service management and safety from a national certifying body or have an associate's or higher degree in food service management or hospitality from an accredited institution of higher learning. In states that have established standards for food service managers, this person must meet state requirements for food service managers.

• Menus and Nutritional Adequacy: We propose to add to the requirements that menus reflect the religious, cultural and ethnic needs and preferences of the residents, be updated periodically, and be reviewed by the facility's qualified dietitian or other clinically qualified nutrition professional for nutritional adequacy while not limiting the resident's right to make personal dietary choices.

• Providing Food and Drink: We propose to add to the requirements that facilities provide food and drink that take into consideration resident allergies, intolerances, and preferences and ensure adequate hydration.

• Ordering Therapeutic Diets: We propose to allow the attending physician to delegate to a registered or licensed dietitian the task of prescribing a resident's diet, including a therapeutic diet, to the extent allowed by state law.

- **Frequency of Meals:** We propose to require facilities to have available suitable and nourishing alternative meals and snacks for residents who want to eat at non-traditional times or outside of scheduled meal times in accordance with the resident's plan of care.

- **Use of Feeding Assistants:** We propose to require that facilities document the clinical need of a feeding assistant and the extent to which dining assistance is needed in the resident's comprehensive care plan.

- **Food Safety:** We propose to—
 - Clarify that facilities may procure food items obtained directly from local producers and are not prohibited from using produce grown in facility gardens, subject to compliance with applicable safe growing and food-handling practices.

- Clarify that residents are not prohibited from consuming foods that are not procured by the facility.

- Require facilities to have a policy regarding the use and storage of foods brought to residents by family and other visitors.

Specialized Rehabilitative Services (§ 483.65)

- **Provision of Services.** We propose to—

- Add respiratory services to those services identified as specialized rehabilitative services.

- Clarify what constitutes as rehabilitative services for mental illness and intellectual disability.

Outpatient Rehabilitative Services (§ 483.67)

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

Administration (§ 483.70)

- **Organization:** We propose to largely relocate various portions of this section into other sections of subpart B as deemed appropriate.

- **Facility Assessment:** We propose to require facilities to—

- Conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The facility must review and update that assessment, as necessary, and at least annually.

- Review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment.

- Address in the facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment.

- **Clinical Records:** We propose 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).

- **Binding Arbitration Agreements:** We propose specific requirements for the facility and the agreement itself to ensure that if a facility presents binding arbitration agreements to its residents that the agreements be explained to the residents and they acknowledge that they understand the agreement; the agreements be entered into voluntarily; and arbitration sessions be conducted by a neutral arbitrator in a location that is convenient to both parties. Admission to the facility could not be contingent upon the resident or the resident representative signing a binding arbitration agreement. Moreover, the agreement could not prohibit or discourage the resident or anyone else from communicating with federal, state, or local health care or health-related officials, including representatives of the Office of the State Long-Term Care Ombudsman.

Quality Assurance and Performance Improvement (QAPI) (§ 483.75) *New Section*

- **QAPI Program:** In accordance with the statute, we propose to require 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)

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

- **Infection Prevention and Control Officer (IPCO):** We propose to require facilities to designate an IPCO for whom the IPCP is their major responsibility and who would serve as a member of the facility's quality assessment and assurance (QAA) committee.

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

- **Compliance and Ethics Program:** We propose to require the operating organization for each facility to have in operation a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Act.

Physical Environment (§ 483.90)

- **Resident Rooms:** We propose to require facilities initially certified after the effective date of this regulation to accommodate no more than two residents in a bedroom.

- **Toilet Facilities:** We propose to require facilities initially certified after the effective date of this regulation to have a bathroom equipped with at least a toilet, sink and shower in each room.

- **Smoking:** We propose 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.

Training Requirements (§ 483.95) *New Section*

- We propose to add 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. We propose that training topics must include—

- **Communication:** We propose to require facilities to include effective communications as a mandatory training for direct care personnel.

- **Resident Rights and Facility Responsibilities:** We propose to require facilities to ensure that staff members are educated on the rights of the resident and the responsibilities of a facility to properly care for its residents as set forth in the regulations.

- **Abuse, Neglect, and Exploitation:** We propose to require facilities, at a minimum, to educate staff on activities that constitute abuse, neglect, exploitation, and misappropriation of resident property, and procedures for reporting these incidents.

- **QAPI & Infection Control:** We propose to require facilities to include mandatory training as a part of their QAPI and infection prevention and control programs that educate staff on the written standards, policies, and procedures for each program.

- Compliance and Ethics: In accordance with section 1128I of the Act, as added by the Affordable Care Act, we would require the operating organization for each facility to include training as a part of their compliance and ethics program. We propose to require annual training if the operating organization operates five or more facilities.
- In-Service Training for Nurse Aides: In accordance with sections

1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Act, as amended by the Affordable Care Act, we propose to require dementia management and resident abuse prevention training to be a part of 12 hours per year in-service training for nurse aides.

- Behavioral Health Training: We propose to require that facilities provide behavioral health training to its entire staff, based on the facility assessment at § 483.70(e).

3. Summary of Costs and Benefits
a. Overall Impact

We estimate the total projected cost of this rule would be \$729,495,614 in the first year. This results in an estimated first-year cost of approximately \$46,491 per facility and a subsequent-year cost of \$40,685 per facility on 15,691 LTC facilities.

b. Section-by-Section Economic Impact Estimates

ESTIMATED COST TO COMPLY WITH ALL THE REQUIREMENTS OF THE PROPOSED RULE

Regulatory area	Section	First year total cost	Total cost in year 2 and thereafter
Resident Rights	483.10	\$10,436,051	\$10,436,051
Facility Obligations	483.11	1,935,785	999,345
Transitions of Care	483.15	3,331,225	3,331,225
Comprehensive Resident Centered Care Planning	483.21	118,184,092	118,184,092
Physician Services	483.30	35,660,786	35,660,786
Nursing Services	483.35	3,640,312	3,640,312
Food and Nutrition Services	483.60	1,788,774	1,663,246
QAPI	483.75	118,419,977	47,402,511
Infection Control	483.80	283,944,336	283,944,336
Compliance and Ethics Program	483.85	139,356,716	120,327,296
Training	483.95
General Training Topics	483.95(a)	7,280,624	7,280,624
Compliance and Ethics Training	483.95(f)	1,876,624	1,876,624
Dementia Management and Abuse Training	483.95(g)	3,640,312	3,640,312
Total	729,495,614	638,386,760

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 Social Security 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 set forth in sections 1819 and 1919 of the Act and 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) 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 section 1819(f)(2)(A)(i)(I) and section 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.

C. Summary of Stakeholder Comments

In order to evaluate the need to update the requirements for long term care facilities, CMS provided LTC stakeholders and members of the general public with opportunities to provide suggestions and recommendations for our revision of the requirements. Specifically, we reached out to industry groups, advocates and other stakeholders by announcing our intention to conduct a comprehensive review of the requirements during CMS open door forums and other regularly scheduled stakeholder calls. We established an email box to receive

comments and feedback. In response to our outreach, we received more than 20 comments from a variety of stakeholder organizations and individuals. Comments ranged from those who were concerned that burden-reducing changes would weaken important protections for vulnerable seniors to those who believe the existing regulations are working well and no changes were necessary. We also received a number of comments that included very detailed and comprehensive recommendations for changes to our regulations. One consistent theme of the comments was the need to address staffing levels. Most comments suggested that we increase the required number of registered nurse (RN) hours of onsite duty per resident day. They also suggested that we strengthen our training requirements for staff and require trainings for specific skills and procedures. Another common theme in the comments was the need to revise the regulations so that they reflect a person-centered care approach and improve the quality of care and life for the residents. For example, commenters requested that residents be included in the care planning process and given complete control over their meal choices. Commenters also requested that we ensure the regulations are current and consistent with federal privacy legislation and the associated implementing regulations, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the HIPAA Privacy Rule (45 CFR part 160 and subparts A and E of part 164).

We have reviewed all of the stakeholder's comments and have taken them into consideration while drafting this proposed rule. We note that some commenters requested changes that conflicted directly with statute. Moreover, some of the comments we received were outside the scope of our review (that is, comments related to the LTC facility survey process or the interpretive guidance (IG)). However, we have shared all of the stakeholder's comments with appropriate CMS staff for their review and consideration. We appreciate all of the stakeholders input and responses to our outreach efforts thus far and believe that this proposed rule reflects our desire to promote person-centered care and improve the quality of care and services, while further protecting resident's safety, choice and well-being.

D. Why revise the LTC requirements?

Although there have been many discrete changes to specific provisions, the requirements for LTC facilities have not been comprehensively reviewed and

updated since 1991. The number of Medicare beneficiaries who accessed care in a SNF increased from 636,000 (or 19 per 1,000 enrollees) in 1989 to 1,839,000 (or 52 per 1,000 enrollees) in 2010, not including managed care enrollees (Data Compendium. 2002 edition. Centers for Medicare & Medicaid Services [on-line]. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/DataCompendium/index.html>).

In addition to the increase in the number of individuals accessing SNF care, the health concerns of individuals residing in LTC facilities have become more clinically complex. The LTC population includes a mix of elderly individuals, younger residents with intellectual or developmental disabilities who are chronically ill, and residents in need of post-acute rehabilitation services. Since the 1980's, the nursing home resident population has had some significant changes. Some of these changes have resulted in nursing homes having to care for many residents that generally have a higher acuity. One change has been a dramatic increase in the number of residents who are recuperating from an acute episode of an illness or injury and who would have usually been discharged from a hospital to their homes. In 1983, Medicare implemented the prospective payment system for hospitals (Decker, FH. Nursing homes, 1977–99: What has changed, what has not? Hyattsville, Maryland Center for Health Statistics. 2005, p. 3). In the subsequent years, there have been shorter hospital stays for Medicare beneficiaries and increased Medicare-funding for post-acute stays in nursing homes. Decker noted that while the discharge rate for individuals who had nursing home stays of 3 months or more had not changed significantly, the discharge rate for individuals who were discharged after a nursing home stay of 90 days or less accounted for virtually all of the increase. Thus, Decker used this as a benchmark for short versus long stays. The number of discharges per 100 nursing home beds in 1977 and 1985 were 86 and 77, respectively. However, by 1999, the discharge rate per 100 nursing home beds had increased by about 56 percent to 134 (Decker, p. 2). In addition, the percentage of these stays in which Medicare was the primary payer had more than tripled from 11 percent in 1985 to 39 percent in 1999. Medicare generally only covers the first 100 days of a stay in a skilled nursing facility (<https://www.medicare.gov/Pubs/pdf/10153.pdf>).

Another factor that has resulted in a higher acuity in the nursing home

resident population has been the increase in assisted-living facilities and other alternatives to nursing home care, such as home care (Decker, p. 5 and Harris-Kojetin, L., Sengupta, M., Park-Lee, E., and Valverde, R. Long-term care services in the United States: 2013 overview. National health care statistics reports; no 1. Hyattsville, MD: National Center for Health Statistics, 2013). This has resulted in nursing homes caring for residents that require more medical care and rehabilitation services. This is supported by the significant decrease in the percentage of residents that could perform their ADLs independently. In 1977, almost 67 percent of residents could eat independently (Decker, p. 5, Figure 6). However, by 1999, that percentage had decreased to almost 53 percent and by 2004 it was down to only about 41 percent (Decker and Jones, AL, Dwyer, LL, Bercovitz, AR, Strahan, GW. The National Nursing Home Survey: 2004 Overview. National Center for Health Statistics. Vital Health Stat 13(167). 2009, Figure 5.). In 1977, almost 30 percent of residents were independent in dressing; however, by 1999, that percent was down to almost 13 percent and by 2004 it was down to about 10 percent (Decker and Jones). By 2004, more than 50 percent of all nursing home residents either required extensive assistance with bathing, dressing, toileting, and transferring or were totally dependent for these ADLs (Jones, Figure 5 and Harris-Kojetin, Figure 24). Only 1.6 percent of all nursing home residents received no assistance for any ADL (Jones, Figure 4).

Nursing homes are also caring for a significant number of residents who require behavioral health services. In 2004, over 16 percent of nursing home residents received a primary diagnosis of a mental disorder upon admission (Jones, Figure 7). By the time residents were interviewed for the National Nursing Home Survey that percentage increased to almost 22 percent. The 1999 estimate was about 18 percent. In addition, nursing homes are caring for a significant number of patients with dementia and depression. By 2012, over 48 percent of nursing home residents had a diagnosis of Alzheimer's disease or another dementia and/or depression (Harris-Kojetin, p. 35, Figure 23). Similarly, in looking at the prevalence of four mental health conditions (depression, anxiety disorders, bipolar disorder, and schizophrenia) in nursing home residents 65 and older, the Institute of Medicine (IOM) found almost 50 percent had depression and almost 57 percent had one or more of those conditions (IOM (Institute of

Medicine) 2012. *The mental health and substance use workforce for older adults: In whose hands?* Washington, DC: The National Academies Press). In addition, substance abuse disorders are also increasing in the nursing home population. Substance abuse disorders are described in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)* (<http://www.dsm5.org/Documents/Substance%20Use%20Disorder%20Fact%20Sheet.pdf> Accessed on June 17, 2015). Thus, in this rule, when we discuss behavioral health or mental illness, we are also discussing substance abuse disorders.

To accommodate a more diverse population, the current care and service delivery practices of LTC facilities have changed to meet these changing service needs. These factors not only demonstrated a need to comprehensively review the regulations, but also informed our approach for revising the regulations. The following discussion highlights our approach to proposing revisions as well as some of the most significant revisions set forth in this proposed 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 considered prescriptive approaches, such as requiring specific numbers and types of staff based on facility size and acuity of residents, but were concerned that such an approach would conflict with requirements already established in many states, and would limit flexibility and innovation in designing new models of person-centered care delivery for residents. Thus, we are instead taking 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. Under this competency-based approach, we are proposing requirements that are compatible with existing state requirements and consistent with what we believe are already common practices by facilities. As discussed in further detail in this proposed rule in section II, "Provisions of the Proposed Rule," we propose to require facilities to assess their facility

capabilities and their resident population. Using the information from that assessment, facilities would be required to provide sufficient staff with the necessary competencies and skills to meet each resident's needs based on acuity, diagnosis, and the resident's person-centered comprehensive care plan. Based on our experience with LTC facilities, we believe most facilities already make these assessments, at least informally, in order to determine staffing needs; our revisions will ensure it is consistently performed and documented in all SNFs and NFs.

Application of facility assessments and competence-based staffing decisions would involve every service provided by a NF or SNF and apply to all members of the staff, including the interdisciplinary team. For example, a facility that provides dementia care would need to ensure it has sufficient numbers of staff and that the staff has the necessary training, education, and/or experience to care for individuals with dementia. These staff may be nursing service staff, behavioral health staff, or other appropriate care providers. Similarly, adding a competence-based requirement would ensure that a facility serving residents requiring post-acute rehabilitation care had sufficient staff with the required training, education and/or experience to care for individuals requiring those services. We propose that the focus be on the competencies and skill sets of the individuals delivering care and services rather than just on the overall number of care givers available. This competence-based approach is compatible with existing state requirements and business practices, and promotes both efficiency and effectiveness in care delivery. In addition to a competence-based approach, this proposed rule is intended to meet the spirit of current HHS quality initiatives that cut across various providers.

Current HHS Quality Initiatives

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. In drafting the proposed rule, we considered current initiatives underway to support these aims and improve care across providers as well as initiatives targeted specifically at nursing home residents.

As discussed below, we are proposing several revisions consistent with these efforts.

• Reducing Avoidable Hospitalization

Nearly two-thirds of nursing home residents are enrolled in Medicaid, and most are also enrolled in Medicare. These Medicare-Medicaid enrollees are among the most fragile and chronically ill individuals served by both programs. Although estimates vary, CMS research found that approximately 45 percent of hospitalizations among Medicare-Medicaid enrollees receiving either Medicare skilled nursing facility services or Medicaid nursing facility services could have been avoided (<http://innovation.cms.gov/initiatives/rahnfr/>). 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 has launched the "Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents" (<http://innovation.cms.gov/initiatives/rahnfr/>). CMS is supporting organizations that partner with nursing facilities to implement evidence-based interventions that both improve care and lower costs. The initiative is focused 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, in drafting this proposed rule, we looked at what, if any, minimum health and safety standards could be developed or strengthened that would contribute to a reduction in unnecessary hospital admissions of nursing home residents. First, we considered many factors that contribute to a decision to transfer a nursing home resident to a hospital. This is primarily a clinical decision, but it may be impacted by environmental or financial factors that are not amenable to change based on regulatory requirements. These concerns include family and resident preferences and demands, concern regarding the LTC facility's liability, and payment incentives. We believe, however, that there are some regulatory changes that would help reduce avoidable hospitalization of nursing home residents. We discuss those changes in section II, "Provisions of the Proposed Rule".

- **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. Therefore, to advance these initiatives, we have proposed revisions that we believe will provide more opportunities to achieve broad based improvement and contribute to reduced healthcare costs. We also believe this approach would be flexible enough to be adapted to any business model and would allow for targeted interventions specific to the facility.

- **Behavioral Health**

On March 29, 2012, CMS launched an initiative aimed at improving behavioral healthcare and safeguarding nursing home residents from the use of unnecessary antipsychotic medications. 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 nursing home residents, particularly those with dementia-related behaviors (<http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Spotlight/html>).

Similarly, with regard to minimum health and safety standards, we looked at possible regulatory changes that could lead to a reduction in the unnecessary use of antipsychotic medication and improvements in the quality of behavioral healthcare. After conducting a review of literature, stakeholder comments, and available Office of Inspector General (OIG) reports we found that many residents are not receiving the individualized quality of care mandated by the current requirements. We address this issue further in section II, “Provisions of the Proposed Rule”.

- **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. HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient’s care (HHS August 2013 Statement, “Principles and Strategies for Accelerating Health Information Exchange.”). 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. Ensuring that individuals and care providers can send, receive, find, and use a basic set of essential health information across the health care continuum will enhance care coordination and enable health system reform to improve care quality. This strategy is described in greater detail in “Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, available at <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf>. Developed with significant stakeholder input, this 10-year Roadmap describes barriers to interoperability across the current health IT landscape, the desired future state that the industry believes will be necessary to enable a learning health system, and a suggested path for moving from the current state to the desired future state. In addition, ONC has released the 2015 Interoperability Standards Advisory (available at <http://www.healthit.gov/standards-advisory>), which provides a list of the best available standards and implementation specifications to enable priority health information exchange functions. ONC expects to annually update the Advisory through a transparent and structured process that includes advice from the Health IT Standards Committee (ONC’s federal advisory committee) and the public at large.

HHS is committed to encouraging HIE among all health care providers, including those who are not eligible for the EHR Incentive Programs, to improve

care delivery and coordination across the entire care continuum. Our revisions to this rule are intended to recognize the advent of electronic health information technology and to accommodate and support adoption of ONC certified health IT and interoperable standards. We believe that 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). For more information, we direct stakeholders to the ONC guidance for EHR technology developers serving providers ineligible for the Medicare and Medicaid EHR Incentive Programs titled, “Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments,” which addresses use of the 2014 Edition of ONC certification criteria (available at http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf). ONC anticipates updating the 2014 Edition Certification Guidance once the ONC 2015 Edition Certification becomes final. Information on the development of standards applicable to the long-term care setting can be found at: <http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG> and <http://wiki.siframework.org/Longitudinal+Coordination+of+Care>.

- **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. For many trauma survivors, the transition to living in an institutional setting (and the associated loss of independence) can trigger profound re-traumatization. In addition, aspects of institutional settings can be significant triggers. While these triggers are highly individualized, some common triggers include: Experiencing

a lack of privacy or confinement in a crowded or small space; or being exposed to certain loud noises, or bright/flashing lights. It is also important to note that cognitive impairment, such as dementia, may worsen or further complicate a trauma survivor's response to triggers and may also introduce additional language barriers as individuals return to their first (non-English) languages. Culturally-competent, trauma-informed approaches that help to minimize triggers and re-traumatization, including those that address the unique care needs of Holocaust survivors and survivors of war, disasters, and other profound trauma are an important aspect of person-centered care for these individuals. 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.

- Requirements for Long Stay Residents

Ninety five percent of nursing homes in the United States are dually certified as SNF/NFs. That is, they provide both the Medicare SNF benefit, and the Medicaid NF benefit. Both benefits cover skilled nursing care and rehabilitation services, with a few minor differences, as noted in these proposed regulations. In addition, Medicaid NFs provide long term care for residents who require support for activities of daily living. Some residents covered by long term care insurance or paying privately may also be receiving long-term care in the nursing home indefinitely. For these residents, the facility is their home. For both residents and facilities, making the nursing facility a home is a different experience and undertaking than is a course of rehabilitation followed by discharge to the individual's residence in the community. The requirements have not reflected this distinction.

We received some comments that would apply primarily to serving long term residents. Some of the ideas and practices, known collectively as "Culture Change," are of benefit to all nursing home residents by making services and supports more person-centered, but are particularly crucial to the quality of life of long stay facility residents. Person-centered care is an aspect of culture change that focuses on the resident as the locus of control, supported in making their own choices

and having control over their daily lives. According to the authors of the "Long-Term Care Improvement Guide," "culture change" refers to the progression from institutional or traditional models of care to more individualized, consumer-directed practices that embrace choice and autonomy for care providers and recipients (Frampton, Susan, et al. "Making the Case for Change" Long-Term Care Improvement Guide 2010, retrieved from <http://www.residentcenteredcare.org/Pages/About%20the%20guide.html>). The authors go on to explain that this kind of care not only enhances quality for consumers and staff but also creates opportunities for the organization to improve operational benchmarks in areas such as quality of care, efficiency of operation, revenue generation and stabilized staffing. CMS has participated in the culture change movement and we are familiar with both the goals and challenges of this effort. We note that the many present efforts to serve individuals in the community rather than in an institution, for example, in compliance with the Supreme Court *Olmstead* decision (*Olmstead v. L.C ex rel. Zimring*, 527 U.S. 581, 119 S. Ct. 2176 (1999)), are primarily directed at long-stay nursing home residents rather than those receiving rehabilitation or skilled nursing care, and this characteristic may be relevant to facility requirements.

While CMS is engaged in the issues around long stay nursing home residents, we do not have enough verifiable information to propose specific changes to the regulations specifically applicable to long-stay situations at this time. We solicit comments on how the requirements could acknowledge the special needs of the long stay resident. In addition, because we also received comments regarding the need to specifically address the needs of short stay residents, we solicit comments on how the requirements could acknowledge the special needs of short stay residents. Nursing facility providers describe the challenges of serving these two rather different populations in a single model of care. We are particularly interested in any suggestions to improve existing requirements, within the authority of existing statute, where they make serving one or the other population difficult or less effective. The most useful comments will be those that offer suggestions to amend specific sections of the existing requirements or offer particular additions. For example, should new construction or capitalized

renovations be based on models of effective long term residence?

In addition to the requirements for participation, CMS is seeking comment on a number of issues related to the finalization and implementation of the proposed rule: Unintended consequences and unanticipated risks to SNF and NF residents, the involvement of stakeholders in developing sub-regulatory requirements and in implementing changes, and the timeline for proposed implementation following finalization of the rule.

The requirements for participation have not been substantially updated since the regulations implementing the Omnibus Budget Reconciliation Act of 1987 were finalized. As such, the intent of the proposed rule is modernization of the regulation, harmonization with other federal laws, and implementation of certain provisions of the Affordable Care Act. CMS is seeking comments on the scope and type of changes proposed here. Given the comprehensive nature of our proposed revisions, we are soliciting comments regarding potential unintended consequences or unanticipated risks to SNF and NF residents, either related to a specific proposal or in general, and what those concerns might be. In addition, we are interested in stakeholder comments related to an appropriate timeframe for nursing homes to implement these regulations. CMS generally implements changes to regulatory requirements for the survey and certification process within 12 months of a final rule.

Following finalization of this proposed rule, CMS anticipates that it may require a longer period of time to implement the changes outlined in the final rule. The additional time may be needed to develop revised interpretive guidance and survey processes, conduct surveyor training on the changes, and implement the software changes in the Quality Indicator Survey (QIS) system, which would include changing the underlying framework of the QIS system as many of the existing requirements have been re-organized. We also expect that it may take a longer period for nursing facilities to implement these changes and seek stakeholder suggestions regarding an appropriate implementation timeframes. Lastly, we seek comment on additional streamlining and reduction of outdated policies as a means of balancing the new policies being proposed.

Implementation of the Affordable Care Act Provisions

We are proposing to implement several provisions required by the Affordable Care Act. First, section 6102 of the Affordable Care Act, which added

new section 1128I to the Act requires the operating organizations for facilities (both SNFs and NFs as defined in sections 1819(a) and 1919(a) of the Act) to have in operation a compliance and ethics program. The compliance and ethics programs must be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care consistent with regulations that are promulgated under this new section.

Second, section 1128I of the Act requires the Secretary to establish and implement Quality Assurance and Performance Improvement (QAPI) program requirements for facilities, including multi-unit chains of facilities. Under this requirement, the Secretary must establish and implement standards relating to QAPI and provide technical assistance to facilities on the development of best practices in order to meet these standards. A facility must submit to the Secretary a plan for the facility to meet such standards and implement the best practices, including how to coordinate the implementation of a plan with quality assessment and assurance (QAA) activities already required under sections 1819(b)(1)(B) and 1919(b)(1)(B) of the Act as implemented at 42 CFR 483.75(o). This proposed rule would establish standards relating to QAPI for SNFs and NFs, as required by the Affordable Care Act.

Finally, section 6121 of the Affordable Care Act, amending sections 1819(f)(2)(A)(i)(I) and 1919(f)(2)(A)(i)(I) of the Act, requires dementia management and abuse prevention to be included as part of training requirements for nurse aides. We are proposing to amend the requirements that an institution must meet in order to participate as a SNF/NF in the Medicare and Medicaid programs, by requiring that the current mandatory on-going training requirements for nurse aides (NAs) include dementia management and resident abuse prevention training. This proposed rule would also clarify that the definition of NA includes an individual who provides NA services through an agency or under contract with a LTC facility, as provided in sections 6121(a)(2) and (b)(2) of the Affordable Care Act.

Executive Order 13563

In January 2011 the President issued Executive Order 13563 "Improving Regulation and Regulatory Review," which directs agencies to select the least burdensome approaches, to minimize cumulative costs, to simplify and harmonize overlapping regulations, and to identify and consider flexible approaches that maintain freedom of

choice for the American public. Executive Order 13563 also requires agencies to engage in a process of reviewing existing regulations to see if those rules make sense and continue to be justified. The provisions of this proposed rule are intended to meet the letter and spirit of Executive Order 13563, for reviewing existing regulations to see if those rules make sense and continue to be justified. The provisions of this proposed rule also meet the objectives of section 610 of the Regulatory Flexibility Act (RFA), which also requires agencies to review the impact of existing rules on small businesses or other small entities for possible reforms to reduce burden and costs. We conducted a general review of the regulations for outdated, confusing, and unnecessarily burdensome requirements and considered areas for improvement.

II. Provisions of the Proposed Regulation

Reorganization of Part 483 Subpart B

In our comprehensive review of part 483 subpart B, we felt that improvements could be made to the overall readability and logical order of the regulatory provisions. Therefore, we propose to revise the order of the regulatory provisions. As in the existing subpart B, required sections including basis and scope and definitions, would come first. Similar to the existing regulations, we propose to follow these sections with provisions assuring resident-centered care, including resident rights, facility responsibilities, freedom from abuse, neglect and exploitation, transitions of care, and individualized resident assessment and care planning. We propose to then include service-specific provisions, including quality of care, starting with physician services and concluding with administration. We propose to conclude subpart B with requirements for facility-wide programs such as infection control, compliance and ethics, training, and facility physical environment. We believe our proposed revised order significantly improves the readability and logical order of the regulations and would allow individuals less familiar with the regulations to find information they are seeking more easily. A crosswalk of the current provisions to the proposed provisions is included as Table A in section III of this proposed rule.

Cross Cutting Proposals

While some proposed changes require revisions that are contained in one specific section of the requirements,

other issues apply across multiple sections and thus would require changes in several sections of the regulations. These cross-cutting topics include proposals regarding unnecessary hospitalization, HAIs, antipsychotic medications, care planning, and QAPI. Below is a general discussion of our approach to revising the regulations to address these issues. Specific changes to the regulatory text are discussed in detail in the relevant requirements.

- **Unnecessary Hospitalization**

The transfer to an acute care hospital is a stressful event for a resident of a SNF or NF. As noted by The Office of the Assistant Secretary for Planning and Evaluation (ASPE) in its June 2011 report on Hospitalizations of Nursing Home Residents, such hospitalizations impose a high personal cost on nursing home residents, causing disruption, risk of complications and infections, and likelihood of reduced functioning on return to the nursing home (Ouslander, J.G., Lamb, G., Perloe, M., Givens, J.H., Kluge, L., Rutland, T., et al. (2010). *Potentially avoidable hospitalizations of nursing home residents: Frequency, causes, and costs*. Journal of the American Geriatrics Society, 58, 627–635.). Nursing home residents are especially vulnerable to the risks that accompany hospitalizations and transitions of care, including medication errors and hospital-acquired infections. Hospital episodes are even more difficult for residents with dementia, who become disoriented in new, unfamiliar settings. Preventing potentially avoidable hospitalizations of nursing home residents is an important quality-improvement initiative from the standpoint of the residents and their families, and also may yield cost reductions (Polniaszek, Susan, Walsh, Edith G. and Wiener, Joshua M. (2011) *Hospitalizations of Nursing Home Residents: Background and Options*. U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy).

In order to decrease unnecessary hospitalizations, the June 2011 report from ASPE gives options such as reporting potentially avoidable hospitalization rates on the CMS Nursing Home Compare Web site, increasing registered nurse (RN) staffing and the use of nurse practitioners (NPs), modifying the Medicare 3-day qualifying stay requirement, providing education and care tools, and changing Medicaid coverage policy to direct incentives to reduce avoidable

hospitalization of nursing home residents (“Hospitalizations of Nursing Home Residents: Background and Options” U.S. DHHS, Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy. June 2011). Of these options, we believe education is one of the areas that is most amenable to addressing through revising the requirements. Young *et al.* conclude, based on a cross-sectional survey of randomly selected nursing homes in New York State, that contributing factors to unnecessary hospitalizations amenable to change include communication effectiveness training, ensuring adequate access to prior medical history, laboratory results and ECGs, and encouraging physicians who practice at nursing homes to treat residents within the nursing home whenever possible (Journal of the American Geriatric Society, 58:901–907, May 2010). The availability of patient information, including resident medical history, assessment of current condition including recent laboratory and radiology results, availability of physicians or other practitioners to evaluate the patient if needed, and effective interdisciplinary team communication are areas we can impact through the requirements.

In this proposed rule, we propose to take a multifaceted approach to reducing unnecessary hospitalization which includes:

- Requiring that a facility notify the resident’s physician when there is a change in a resident’s status, including any pertinent information specified in § 483.15(b)(2)–(§ 483.11(e)(7)(ii))
- Addressing communication through a robust interdisciplinary team, comprehensive person-centered care planning process and through training requirements (§ 483.21).
- Proposing a requirement for practitioner assessment prior to transfer to a hospital, except in an emergency situation (§ 483.30(e)).
- Enhancing nursing care through a competency-based approach (§ 483.35).
- Strengthening the clinical record requirements to ensure adequate and appropriate information is available to evaluating practitioners (§ 483.70(i)).
- Ensuring ongoing evaluation of care process through implementation of a robust QAPI plan (§ 483.75)

This multifaceted approach would build on existing requirements and standard business practices through incremental change. We also believe that this approach would not only have a positive impact on reducing unnecessary readmissions, but may also improve other quality areas as well and

is intended to be flexible enough to encompass any care model and all facility populations.

• Reduction in Inappropriate Use of Antipsychotic Medications

Antipsychotic medications are frequently prescribed off-label, which means that the drug is being prescribed for a use that is not approved by the U.S. Food and Drug Administration (FDA), to residents with behavioral and psychological symptoms of dementia (BPSD). This has led to increased attention to the behavioral health management of nursing home residents with dementia and the potentially inappropriate use of antipsychotics in this population. Evidence suggests that antipsychotics have limited benefits in this population, and the potential to lead to adverse consequences such as the risk of movement disorders, falls, hip fractures, cerebrovascular accidents, and death. Additionally, the health profiles of this population are often medically complex and residents may take multiple medications that increase their risk of adverse effects and drug interactions. A previous OIG study found that when this population received these drugs, about half of the drugs were not given for medically accepted indications as required for Medicare coverage or recorded as being administered to the resident and one-fifth of the drugs were not given in accordance with federal safeguards to protect nursing facility residents from unnecessary antipsychotic drug use (OEI-07-08-00150). The potential overuse of antipsychotic agents is a symptom of a much larger problem—namely, that many nursing facilities may not have a systematic plan to provide comprehensive behavioral health care to residents with diagnoses such as dementia and BPSD.

In this proposed rule, we would take a multifaceted approach to reducing the unnecessary use of antipsychotic medications which would include:

- Requiring that each nursing home conduct a comprehensive assessment, including its physical characteristics (that is, size, location, and number of residents), its resident population (including both a psychosocial and mental health assessment), the competencies and knowledge of its staff, and the identification of any resources or support, including training and additional staff, that the facility would need to ensure the appropriate care and treatment for all residents (§ 483.70)
- Revising the current requirements that apply to antipsychotic drugs to also apply to any psychotropic drug; that is, any drug that affects brain activities

associated with mental processes and behavior (§ 483.45)

- Including a requirement that once the facility’s consultant pharmacist has identified an irregularity (such as, a drug given for an excessive duration of time or prescribed without adequate indications documented in the resident’s medical record), or has recommended a gradual dose reduction for one or more medication, the attending physician would be required to document in the resident’s medical record that he or she has reviewed the identified irregularity and what, if any, action they took 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 (§ 483.45)

Similar to our proposals for reducing unnecessary hospitalizations, this multifaceted approach would build on existing requirements and standard health care practices through incremental change. We believe that this approach would provide the best opportunity for a broad-based improvement in the areas of mental, behavioral, and psychosocial-related health care concerns, while also providing facilities with flexibility regarding how to address the type of staff and training or other resources and support they need to provide care and services in these areas.

• Healthcare Associated Infections (HAIs)

Although estimates vary widely, there are between 1.6 and 3.8 million HAIs in nursing homes every year. Annually, these infections result in an estimated 150,000 hospitalizations, 388,000 deaths, and between \$673 million and \$2 billion dollars in additional healthcare costs (Castle, et al. Nursing home deficiency citations for infection control, American Journal of Infection Control, May 2011; 39, 4). In some ways, the resident population in nursing homes presents unique regulatory challenges, particularly with respect to infection control. Residents in nursing homes not only receive skilled nursing care in these facilities, but for many individuals, these facilities are also their homes. In addition, nursing homes are required to provide social activities for residents which may include group activities or functions. These activities or functions, such as dining, social events, and religious services, may increase the risk of transmission and exposure to communicable diseases and infections. The diversity of the nursing home community presents each facility with unique challenges to meet the needs and choices of all of the

individuals they serve, creating a much harder task of regulating and managing infection control and prevention activities. Nursing home residents are often frail, elderly individuals and individuals with disabilities who have increased susceptibility to infections from malnutrition, dehydration, comorbidities, or functional impairments (for example, urinary and fecal incontinence), and medications that diminish immunity or immobility. In addition, as patients are discharged from hospitals to nursing homes sooner, the nursing home population increasingly has more residents with greater medical needs, which not only increases the acuity level but also likely results in higher invasive device use (for example, mechanical ventilators, central venous catheters, and enteral feeding tubes). Therefore, when developing our approach to promote prevention and control of HAIs, we took into consideration this diverse resident population, as well as the interaction residents will have with staff, visitors, and each other.

Similar to our approach to address unnecessary hospitalizations, we identified the following areas to consider addressing HAIs when revising the nursing home infection control requirements:

- Requirements for the facility to perform a facility-specific assessment of their resident population and facility (§ 483.70)
- Integration of the infection prevention and control program (IPCP) with the facility's QAPI processes (§ 483.75)
- Revising the description of the infection control program and adding a requirement to periodically review and update the program (§ 483.80)
- Requiring an antibiotic stewardship program that includes antibiotic use protocols and a system for monitoring antibiotic use (§ 483.80)
- Designation of specific infection prevention and control officers (IPCOs) (§ 483.80)
- Written policies and procedures for the IPCP (§ 483.80)
- Education or training related to the infection control program (§ 483.80)

Likewise, with the other cross-cutting provisions, we believe that taking a multifaceted approach when revising the infection control requirements would provide the best opportunity to achieve broad-based improvement while also being flexible enough to be adapted to any health care delivery model. These revisions may also result in positive impacts in the care and services to residents, reducing unnecessary

hospitalizations and overall lowered healthcare costs.

In the following sections we detail our proposed revisions to the requirements. The discussion follows our proposed reorganization of subpart B.

A. Basis and Scope (§ 483.1)

We propose 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 propose to spell out the term "skilled nursing facility".

B. Definitions (§ 483.5)

Current regulations at § 483.5 provide definitions for terms commonly used in the LTC requirements. We propose 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 would add value to the LTC requirements while promoting resident choice and safety.

We have retained the existing definitions for "facility" and "distinct part". We are aware of stakeholder concerns that defining "distinct part" and "composite distinct part" possibly allow facilities to segregate residents by payment source. On August 4, 2003, we published a final rule entitled, "Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities-Update" (68 FR 46036). Through this final rule, the definitions of "distinct part" and "composite distinct part" were added to this section and we believe the rationale for the addition at that time remains valid. While some SNFs function as separate, independent entities, we have recognized since the inception of the Medicare program that it is also possible for a SNF to operate as a component, or "distinct part" or "composite distinct part" of a larger organization. While we do not agree that "distinct part" and "composite distinct part" should be removed from the current regulations, based on concerns raised by some stakeholders, we have

modified the definition of "composite distinct part" to make it clear that a composite distinct part designation cannot be used as a means to segregate residents by payment status or on any basis other than care needs. Such segregation may violate a patient's privacy by implicitly revealing their payment source and lends itself to creating inequitable care situations. In addition, we have 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 propose to make minor revisions to the definition of "common area" to recognize that some facilities have living rooms or other areas where residents gather.

As discussed in detail below, based on our internal review and feedback from stakeholders, we propose 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 propose to relocate the definitions for "licensed health professional" and "nurse aide" to this section from the "Administration" section at § 483.75(e)(1). We believe that these definitions apply broadly to the regulations and would more appropriately be defined in this section of definitions. In addition, we propose 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 propose to amend the regulatory definition accordingly.

We propose to add the term "adverse event" to ensure clarity in our requirements relating to proposed requirements for QAPI. We discuss this definition further in section II.T. of the preamble and welcome comment on our

proposed definition. We also propose the addition of the term “resident representative” because the use of a representative is often common practice within the nursing home setting. We believe a resident can designate an individual to have certain rights and/or responsibilities, such as the ability to make decisions about a resident’s care, the ability to manage a resident’s finances, or the ability to participate in discussions about the residents care and the ability to access a resident’s medical information. For purposes of this regulation, we would 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. One individual may or may not fulfill both of these roles. We also note 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. Throughout this proposed regulation, where we use the term resident, it includes, as applicable, the resident representative. In addition, we propose to add a definition of “person-centered care”. For purposes of this subpart, we would define person-centered care 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.

The addition of the definitions of “abuse”, “sexual abuse”, “neglect”, “exploitation”, and “misappropriation of resident’s property” are being proposed to achieve clarity within the current regulations and eliminate confusion regarding what actions or circumstances rise to the level of these terms. For purposes of these regulations, “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. “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 propose 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 would 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.” Based on internal discussions and stakeholder input, we are aware of industry concerns regarding certain incidents that can take place within a nursing home that are not easily classified as abuse or neglect, but nonetheless are inappropriate and harmful. For example, there has been a substantial increase in the use of technology to exploit the elderly since these regulations were first implemented. When these regulations were originally implemented, social media and the wide use of cellular and personal electronic devices were not a major concern or topic of consideration in the protection of residents. These advances in technology have made it easier to invade someone’s privacy and therefore increase the risk of exploitation. We feel that there is a need to account for these technological changes to ensure that all nursing home residents are protected. We believe the addition of the terms “abuse”, “sexual abuse”, “neglect”, and “exploitation” would help to eliminate confusion as to what behaviors rise to the level of these terms and promote resident safety and would clarify that abuse includes abuse facilitated or enabled through the use of technology.

We also propose to add the term “misappropriation of resident property” to provide clarity. The term “misappropriation of resident property” is widely used throughout the regulations and in our interpretive guidance for surveyors of nursing homes; therefore, we felt that there was a need to ensure that the term was clearly defined 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 move the existing definition of “transfer and discharge” from § 483.12(a)(1) to § 483.5(p).

C. 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 propose 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 warrant it, and to update provisions to include technological advances such as electronic communications. In order to achieve these objectives, we propose 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 propose to add a new § 483.11, which would focus on the responsibilities of the facility, including relevant provisions currently included in § 483.10 and § 483.15. We propose multiple re-designations and revisions to improve logical order and readability, clarify aspects of the regulation that warrant it, and reflect technological advances such as electronic communications. Under our proposal, some existing provisions will have components in both § 483.10 and § 483.11. A detailed crosswalk of all of the proposed re-designations is provided in Table A in section III of this proposed rule. Re-designations without substantive changes are not discussed in detail below. We discuss below our proposed revisions to those provisions retained in or moved to § 483.10. Regulatory citations have been updated throughout to reflect the proposed new structure.

We propose to revise § 483.10 to focus specifically on resident rights. In proposed § 483.10(a)(2), we would clarify the resident’s right to be supported in his or her exercise of rights under this subpart. In proposed § 483.10(a)(3), we would clarify the resident’s right to designate a representative, the resident representative’s limitation to those rights delegated by the resident, and the resident’s retention of those rights not delegated, including the right to revoke a delegation. We have heard concerns that resident representatives may be accorded more decision making authority than their appointment or delegation permits. Our proposed clarification is intended to ensure that facilities do not afford more decision making authority to a resident representative than is intended by the

resident or permitted under applicable law. We note that resident representatives fall into three categories: court-ordered or otherwise designated under applicable law (e.g., state law), supported by documentation (that is, an advance directive), and informal/oral. The scope of resident representative authority may vary based on how they are designated.

In § 483.10(a)(4) we would address those residents who have been adjudged incompetent under the laws of a state. We would clarify the resident representative's limitation to exercising only the rights delegated, and the resident's retention of rights not delegated. Specifically, we would clarify that the resident who has been adjudged incompetent under the laws of a state retains 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. We believe that it is important for a resident who has been adjudicated incompetent to be treated with respect and dignity and to continue to make those decisions that are appropriate for him or her to make. Continuing to honor these residents' preferences and involving them in care planning will improve both quality of life and quality of care, resulting in better outcomes. Lastly, in our proposed rule "Medicare and Medicaid Programs; Revisions to Certain Patient's Rights Conditions of Participation and Conditions for Coverage" (CMS-3302-P) (79 FR 73873), published on December 12, 2014, at § 483.10(a)(4), we proposed to require that 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. In this regulation, we are proposing to redesignate 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). We believe that this revision is necessary to implement the Supreme Court decision in *United States v. Windsor*, 570 U.S.12, 133 S.Ct. 2675 (2013).

In proposed § 483.10(b), we have included resident rights related to planning and implementing care. It is important for each resident to understand his or her health conditions and the care and services he or she will receive and to be able to participate in

the care planning process. These rights are already included for the most part in the regulations, but we would update the language and co-locate related provisions. Thus, we propose to re-designate and revise in this provision 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 propose 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. These requirements support the standards set forth by the Secretary in the "Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs" on June 6, 2014 (see <http://www.acl.gov/Programs/CDAP/OIP/docs/2402-a-Guidance.pdf>). We further specify 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 propose 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 propose to specify the resident's right to participate in the development of his or her comprehensive care plan. We also propose 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 propose 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.

The ability of the resident to select his or her attending physician remains an important right. However, it is also important that the selected physician meet licensure requirements and be

willing and able to comply with the requirements of this subpart. Therefore, we propose 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 would add new § 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. If the physician chosen by the resident refuses or is unable to meet requirements specified in this part, we specify that the facility has the right, after informing and discussing with the resident, to seek alternate physician participation to assure the provision of appropriate and adequate care and treatment. If the resident chooses a new physician that meets the necessary requirements, the facility must respect that choice.

As indicated earlier, NFs not only provide medical care, but may also serve as a resident's home. This makes issues of respect and dignity particularly important. In § 483.10(d), we propose to re-designate a number of provisions relating to resident respect and dignity, based on existing § 483.13(a) and § 483.15. We further propose 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 note that married couples, whether opposite or same sex, are addressed by § 483.10(d)(5). Our proposed provision would provide 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. We recognize that in some instances, specific roommates requests cannot be accommodated by a facility for clinical, safety, or logistical reasons. However, we believe it is an important aspect of respect and dignity, as well as self-determination, for individuals to be able to choose who they live with, especially for long-term residents.

Self-determination is a critical element in the care and treatment of nursing home residents. In proposed § 483.10(e), we propose to revise a number of provisions relating to resident self-determination. We propose 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 discuss our rationale further in our discussion of proposed § 483.11(d)(2). We propose 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.

The ability to have access to information such as personal medical records and facility-specific information has changed significantly since the promulgation of the original requirements for long-term care facilities. We propose to co-locate provisions related to the resident's right to access facility specific information, medical records, information about advocacy and fraud control organizations, Medicare and Medicaid coverage, and notices that the facility is required to provide to the resident. These notices include, but are not limited to a written description of legal rights, a written description of the facility's policies to implement advance directives and applicable state law pertaining to advance directives, and information on how to apply for and use Medicare and Medicaid benefits. In addition, we will update the provisions as appropriate to take into account electronic medical records and other electronic communications. Specifically, in proposed § 483.10(f), we propose to re-designate and revise a number of provisions relating to resident access to information. First, we propose 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 note that effective communication for some residents requires the use of auxiliary aids and services and have revised this provision to reflect that. Next, we propose 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. The Aging and Disability Resource Center Program (ADRC), established under Section 202(20)(B)(iii) of the Older Americans Act; is a collaborative effort of the U.S. Administration on Community Living and the Centers for Medicare & Medicaid Services (CMS). ADRCs serve as single points of entry into the long-term supports and services system for older adults and people with disabilities. Sometimes referred to as a

“one-stop shops” or “no wrong door” systems, ADRCs address many of the frustrations consumers and their families experience when trying to find needed information, services, and supports. Through integration or coordination of existing aging and disability service systems, ADRC programs raise visibility about the full range of options that are available, provide objective information, advice, counseling and assistance, empower people to make informed decisions about their long term supports, and help people more easily access public and private long term supports and services programs. Additional information on ADRC programs is available at http://www.adrc-tae.acl.gov/tiki-index.php?page_ref_id=1325.

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 the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and subsequent promulgation of the HIPAA Privacy and Security Rules (see 45 CFR part 160 and subparts A, C, and E of part 164) as well as the subsequent enactment of the Health Information Technology for Economic and Clinical (HITECH) Act as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009 (ARRA) and the promulgation of the Omnibus HIPAA Final Rule (78 FR 5566). For simplicity, we will hereinafter collectively refer to these laws and their implementing regulations as “HIPAA.” We note that administration and enforcement of the privacy and security-related portions of the HIPAA regulatory scheme are delegated to the HHS Office for Civil Rights (OCR) and more detailed information related to these provisions can be accessed through the OCR Web site at <http://www.hhs.gov/ocr/privacy>.

We propose 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 recognize 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 this proposed regulation are not intended to conflict in any way with those 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, this proposed regulation would not diminish those rights. Therefore, we propose revisions that would clarify the relationship between the requirements of 45 CFR 164.524 and the revised version of § 483.10(f)(3)(i) and (ii). We propose 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 propose to specify in paragraph (f)(3)(ii) that the facility may impose a reasonable, cost-based fee for providing copies of the medical records, provided that the fee includes 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 requests that the electronic copy be provided on portable media; and postage, when the individual has requested the copy be mailed. This is consistent with 45 CFR 164.524(c)(4). This proposal does not address the creation or provision of summary reports, which may be provided in accordance with applicable law.

In § 483.10(g)(1) we propose to revise a number of provisions related to resident privacy and confidentiality to update the language to accommodate electronic communications. We propose 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 would retain the provisions of existing § 483.10(e)(2) and (3).

Today, individuals have a number of electronic options for communicating with others that are not addressed in the existing regulations for LTC facilities. Thus, we propose to update these regulations to take into consideration widespread advances in electronic communications technologies. In proposed § 483.10(h), we propose to re-designate and revise a number of provisions relating to resident communications. Specifically, we propose a new § 483.10(h)

Communications, with § 483.10(h)(1) revised to include TTY and 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. We also include internet access, which can serve as a communications medium as well as a means for residents to interact with entities and persons outside of the facility or to use various programs and tools for entertainment, shopping, conducting research and obtaining information.

In proposed § 483.10(i), we propose to revise the language to state that the resident has a right to a safe, clean, comfortable, homelike environment, and a right to receive treatment safely. In proposed § 483.10(j), we propose to revise language relating to resident grievances to add that a resident cannot be deterred from voicing a grievance for fear of reprisal or discrimination. This clarifies that even when no actual reprisal or discrimination occurs, intimidation and threats of reprisal or discrimination are not permissible.

D. Facility Responsibilities (§ 483.11)

We propose a new § 483.11 “Facility Responsibilities,” in which we combine many of the regulations addressing facility responsibilities which are currently dispersed throughout the existing provisions regarding resident rights and quality of life. This proposed revision is consistent with our overall objectives of updating the language and organization of the resident rights provisions to improve the logical order and readability, clarifying aspects of the regulation, and updating provisions to include advances such as electronic communications.

Consistent with § 483.10, the introductory language for proposed § 483.11 would establish, based on existing requirements, that the facility must 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 must protect and promote the resident’s rights as specified in § 483.10. Further, the facility must recognize each resident’s individuality and provide services in a person-centered manner. We propose 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 establish our expectation that the facility promote and protect the rights of the resident. These expectations are not new requirements, and are already set out in our regulations as resident’s rights. In order to ensure clarity, we have restated them clearly in this provision as the responsibility of the facility to recognize and effectuate those rights. Proposed § 483.11(a)(1) would provide that the facility ensure that the resident can exercise his or her rights without interference, coercion, discrimination, or reprisal from the facility. We propose 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 would specify 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 as delegated by the resident, with the condition that the facility could not extend greater authority to the resident representative than is permitted under applicable law. We reiterate this point in the proposed regulation as we respect the need to establish alternative decision makers under certain circumstances. However, we received and are concerned by external input suggesting that some facilities or staff members defer to resident representatives for decisions that exceed the scope of a court order, resident delegation, or other applicable law. Proposed § 483.11(a)(3) and (4) would clarify our expectations. In addition, we propose to add a new § 483.11(a)(5) that would 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, we would expect the facility to comply with any state reporting requirements that might apply. We understand that there is the potential for abuse and neglect in this relationship and want to ensure that facilities recognize their role in appropriately identifying and reporting concerns that rise to the level of abuse, neglect or exploitation. The United States Government Accountability Office (GAO) has published two reports

related to abuses that occur specifically in the context of guardianships. In September 2010, the GAO published “Guardianships: Cases of Financial Exploitation, Neglect and Abuse of Seniors” (GAO–10–1046). In July 2011, the GAO published “Incapacitated Adults: Oversight of Federal Fiduciaries and Court-Appointed Guardians Needs Improvement” (GAO–11–678). While these reports focus on the need for improved screening and monitoring of guardians, they also highlight the potential for abuse and neglect in this relationship. According to the National Center on Elder Abuse in the Administration on Aging, “the laws in most states require helping professions in the front lines—such as doctors and home health providers—to report suspected abuse or neglect. . . . Under the laws of eight states, ‘any person’ is required to report a suspicion of mistreatment” (http://www.ncea.aoa.gov/Stop_Abuse/Get_Help/Report/index.aspx). These reporting requirements may apply to abuse, neglect or exploitation by resident representatives.

In proposed § 483.11(b), facility responsibilities include ensuring that the resident is informed of, and participates in, his or her treatment to the extent practicable, consistent with § 483.10(b), and that the resident participates in care planning, making informed decisions, and self-administering drugs when appropriate. In addition to the self-administration of drugs, residents may also self-administer or take part in other health care practices, such as dialysis. We also expect that the facility, through the IDT and the care planning process, would determine if, and under what circumstances, this is appropriate. We also propose new requirements in § 483.11(b)(1) to require that the facility ensures that the care planning process facilitates the inclusion of the resident or resident representative, includes an assessment of the resident’s strengths and needs, and incorporates the resident’s personal and cultural preferences in developing goals of care. We note that person-centered planning involves providing those services and supports that assist individuals to live with dignity and to support their goals (including, but not limited to, goals to potentially return to a community setting). The Department of Health and Human Services has issued guidance 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. The principles in

that guidance regarding dignity and self-direction apply equally to individuals who reside in a nursing facility.

<http://www.acl.gov/Programs/CDAP/OIP/docs/2402-a-Guidance.pdf>. Our proposed requirements support those principles.

We propose 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 knows the name, specialty and means of contacting the professionals officially responsible for his or her care, whether that provider is a physician, nurse practitioner, physician assistant, or clinical nurse specialist. We further propose to add a new § 483.11(c)(2), consistent with our proposed § 483.10(c)(1), (2) and (3), to clarify that the facility has a responsibility to ensure that the resident's attending physician has appropriate professional credentials and meets 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 propose to add a new § 483.11(c)(3) to specify that if the resident subsequently finds a new physician who meets the necessary requirements, the facility would be required to honor that selection.

We propose a new § 483.11(d) to address the facility's responsibilities related to resident self-determination. We propose to re-designate § 483.10(j), regarding access to the resident, as § 483.11(d)(1), and revise 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. This would be an addition to the current requirement which provides a right of access to 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. This is consistent with our approach in other settings such as acute care hospitals, and in keeping with the person-centered focus of this proposed rule. In addition, we propose to add a new § 483.11(d)(2) to require that the facility have written policies and procedures regarding visitation rights of residents. This requirement would support resident self-determination, consistent with the person-centered focus of this proposed

rule, and would follow the requirements established for inpatient hospitals. As noted in the November 19, 2010 final rule (75 FR 70831 at 70832), regarding hospital visitation rights, physicians, nurses, and other staff caring for the resident might miss an opportunity to gain valuable information from those who may know the resident best with respect to the resident's medical history, conditions, medications, and allergies, particularly if the resident had difficulties recalling or articulating, or is totally unable to recall or articulate, this vital personal information. Many times, these individuals who may know the resident best can act as an intermediary for the resident, helping to communicate the resident's needs to facility staff. As stated in that November 19, 2010 final rule, we believe that restrictive visitation policies can effectively eliminate these advocates for many residents, potentially to the detriment of the resident's health and safety. Further, given that the facility is often the resident's home, we suggest that, as in hospitals, the hazards and challenges regarding open visitation are manageable. In fact, we believe an open visitation policy helps residents by providing a better support system and a more homelike environment. Moreover, this policy may create more trust and a better working relationship between facility staff, the resident, and the resident's support system. Thus, we believe it is vital to establish open visitation in SNFs and NFs.

We propose to re-designate § 483.15(c)(5) as § 483.11(d)(3)(ii) and revise 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. It is important that the facility representative be an individual who the group can work with and who does not have a chilling effect on the function of the group. We further clarify 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 propose a new § 483.11(d)(4), which would incorporate requirements currently specified in § 483.10(h) and would specify that the facility is responsible for ensuring that a resident is not required to perform services for the facility.

We propose a new § 483.11(d)(5), which would incorporate requirements from § 483.10(c) that focus on the facility's responsibility related to the protection of resident funds. Specifically, we propose 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 propose 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 received suggestions to reduce the time frame for these conveyances. We researched common time frames for the return of security deposits and found that most states (at least 33) allow 30-days, and sometimes longer for the return of security deposits. Therefore, we determined the current time frame is reasonable and we do not propose to make any changes to this section.

We propose 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/NF.

We propose in § 483.11(d)(6)(ii), re-designated from § 483.10(c)(8)(ii), to add to the limitations on charges to residents' funds. This provision currently provides general categories and examples of items and services that the facility may charge to residents' funds if the items are requested by a resident, and are not required to achieve the goals stated in the resident's care plan. In these instances, the resident is informed that there will be a charge and that the items are not paid for by Medicare or under a state plan. We propose 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. Refer to our discussion in

Section II. P. “Food and Nutrition Services for additional information. We propose 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 propose to establish a new § 483.11(e) to incorporate multiple provisions related to information and communication. With the exception of medical records, we propose 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. Medical records are addressed in proposed § 483.11(e)(2). As noted earlier, this proposal does not address the creation or provision of summary reports of medical records. Summary reports of medical records may be provided in accordance with applicable law. The language requirement is already a requirement for specific types of notices and information (see § 483.10(b)(1), § 483.10(b)(3), and § 483.12(a)(4)(i)). However, language is not the only barrier to effective communication and it is important for the resident to have the opportunity to understand all information that is provided. We also hope to provide facilities with some flexibility to implement this requirement. For example, in some cases, a resident representative may prefer to access information on the internet rather than receive a paper copy, or it may be more effective and efficient for a resident who is blind or visually impaired to listen to an audio file explaining resident rights. Some residents may require assistive technology or alternative formats. The key to this provision is ensuring that when there is a requirement to provide information, it is provided in a way to ensure both resident access and understanding.

We propose 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). Proposed (e)(2)(i) would require that facilities provide residents with access to his or her 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 provision would

include 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 believe in some circumstances an electronic copy may be a preferable and more efficient option for both the facility and the resident or resident’s representative, particularly where the record already exists in an electronic format. We propose at (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 propose 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 propose to add a new § 483.11(e)(3), incorporating and redesignating 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). 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 our proposed § 483.11(e)(1), it must be in a form and manner accessible to and understandable by the resident.

We propose 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 and certification 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 propose to require that the facility

post a statement that a resident may file a complaint with the state survey and certification agency. The facility is already required at existing § 483.10(b)(7), which would be redesignated at proposed § 483.11(e)(12), to provide this information in the written description of legal rights provided to the resident. However, we believe that posting this information will ensure that resident representatives as well as other support persons and residents continue to have access to updated and readily understandable information.

We propose 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. The required information would be the same information we propose to require under new § 483.15(b)(2) (information in transfer or discharge). This requirement, in concert with proposals to improve transitions of care, communications among and between practitioners, appropriate exchange of information, and quality assessment activities, will help ensure that the physician’s decisions relating to treatment or transfer of a resident to an acute care facility are made on the basis of the best information available. Widely available methodologies and tools may assist facilities in ensuring that effective information exchanges occur. For example, Situation, Background, Assessment, Recommendation (SBAR) is a common methodology for structured communication. Information and tools relating to SBAR are widely available, including but not limited to from sources such as the Agency for Healthcare Research and Quality (www.innovations.ahrq.gov), The Joint Commission (www.jointcommission.org), the Institute for Healthcare Improvement (www.ihl.org), the INTERACT (Interventions to Reduce Acute Care Transfers) project (<http://interact2.net>), and others.

We propose 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 propose 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 propose 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 propose to revise § 483.10(b)(5)(i) and (ii) and re-designate them as § 483.11(e)(10). The revised provision would specify 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 proposed paragraph (e)(11)(i) of this section.

We propose to revise and re-designate § 483.10(b)(6) as new § 483.11(e)(11). In addition, we propose 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. It is important that residents remain informed of these issues in order to ensure their ability to make informed decisions, both financial and health-care related.

To improve clarity, we propose 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 and certification 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 propose 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 and certification 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 propose a new § 483.11(e)(13) that would establish 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) would revise and replace § 483.10(k) and § 483.11(e)(13)(iii) would revise and replace § 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 propose a new § 483.11(f) to include provisions related to privacy and confidentiality. Proposed § 483.11(f)(1) would require that the facility respect the resident’s right to personal privacy. Proposed (f)(1)(ii) would incorporate the definition of personal privacy currently set out at § 483.10(e)(1). We propose 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 propose to redesignate 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 are proposing a new § 483.11(h) Grievances, which would incorporate

the facility responsibilities expressed in existing § 483.10(f) and would also require that facilities ensure that residents know how to file grievances. The proposed provision would also require that the facility establish a grievance policy to ensure the prompt resolution of grievances, and identify a Grievance Officer. Additionally, the facility would be 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.

The right to file a grievance is an important protection for residents and an important right of residents. The proposed revisions are intended to ensure that grievances are taken seriously and processed appropriately.

Finally, we propose a new § 483.11(i) which would require 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. Residents must have the ability to communicate freely with representatives of these entities when

they have concerns about quality or care and quality of life.

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

Currently, § 483.13 is titled “Resident Behavior and Facility Practices.” The focus of this section is to ensure that residents of SNFs and NFs are not subjected to abuse, neglect, misappropriation of resident property, and exploitation when they reside in a facility, to specify the facility responsibilities to prevent abuse, neglect and exploitation, and to establish requirements for the facility response to allegations that any of these has occurred. Thus, we propose to re-designate and revise this section as § 483.12, “Freedom from Abuse, Neglect and Exploitation,” to more accurately reflect the contents and intent. The term “exploitation” was not previously included in this regulatory provision. However, in reviewing available materials related to abuse such as The Joint Commission standards for accreditation of long term care facilities and language relating to “misappropriation of resident property,” currently defined at § 488.301, we believe it is appropriate and necessary to add this term here as well to address circumstances that may not rise to the level of abuse or neglect but nonetheless would be prohibited. Therefore, we propose in our discussion of the definitions section of this regulation to provide a definition of “exploitation”. Although there have been significant improvements in many areas of nursing home care, abuse remains a serious issue. According to CMS Certification and Survey Provider Enhanced Reports (CASPER) data, there were 474 noncompliance deficiency citations related to freedom from abuse in Fiscal Year (FY) 2011, and 475 citations in FY 2012, affecting 2.5 percent of nursing home providers. Our proposed updates and revisions to this section are intended to both recognize that abuse continues to occur, and to provide language that will build on progress to improve conditions in nursing homes begun by the nursing home reforms of the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203 (OBRA ’87).

Currently, paragraph § 483.13(a) addresses the use of restraints. We propose 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 would continue to prohibit the inappropriate use of restraints. Restraints can be used abusively. There may be very limited

circumstances where restraints would be appropriate in a nursing facility. We propose to further address restraints in proposed section § 483.25(d)(1) on Quality of Care and Quality of Life. The use of restraints has fallen significantly in the last decade and CMS continues to promote reduction in the use of physical restraints. (See CMS 2012 Nursing Home Action Plan; <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/2012-Nursing-Home-Action-Plan.pdf>). We note that many facilities have achieved a rate of zero percent restraint use (see <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/QAPINewsBrief.pdf>).

Existing paragraph § 483.13(b) would also be included in the new introductory paragraph to revised § 483.12. The revised introductory paragraph would set out the intent of this section. We propose 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. The proposed revision makes clear that the facility is responsible for protecting residents from abuse, neglect and exploitation by a person providing services, whether the individual has an employee relationship with the facility or is “otherwise engaged” by the facility—that is, providing services under a different arrangement, such as a volunteer or a contractor. 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 propose 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. Although a licensure disciplinary action would normally prevent a licensed professional from further practice in the state of licensure for some specified

period of time, we believe inclusion in the federal standards is necessary to ensure the safety of long term care facility residents. We believe that disciplinary action information is available through state licensing boards and that it is appropriate to explicitly hold licensed personnel to the same standard as nurse aides.

We propose 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 propose 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 propose to add a new § 483.12(b)(3) to require training, including training on resident’s rights, facility responsibilities, and recognition and reporting of abuse neglect and exploitation, which we would require in proposed § 483.95. Our proposals related to training are discussed in section X, “Training requirements” (§ 483.95) of this preamble. We believe both the requirements in proposed new § 483.12(b)(2) and (b)(3) are necessary to ensure effective and consistent investigative processes and to ensure that direct care/direct access workers are trained to recognize when treatment is abusive or constitutes neglect or exploitation. We are hopeful that training may reduce the frequency of these incidents. Finally, we propose 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 would 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 sec. 1150B(a)(3), includes notification of that individual’s obligation, as specified at 1150B(b)(1), 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 1150B(b)(2), the reporting required by 1150B(b)(1) must occur 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. A fuller discussion of these requirements was provided in a June 17, 2011 Survey and Certification Letter to State Survey Agency Directors and further addressed through a question and answers document in January, 2012. These documents are available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter11_30.pdf. We propose that enforcement of these requirements would be based on the terms of that guidance. We are specifically requesting comment on these proposed provisions and our proposed implementation of Section 1150B of the Act.

We propose 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 propose to add the term “exploitation” in proposed 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 propose 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.

F. Transitions of Care (§ 483.15)

We propose to re-designate current § 483.12 “Admission, transfer, and discharge rights” as new § 483.15, and revise 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. Extensive literature speaks to quality of care concerns related to the transitions.

In proposed new paragraph (a) we would begin with requirements for admissions policies, which would be moved to the beginning of the section to reflect chronological order. We propose a new paragraph (a)(1) to require that the facility establish an admissions policy.

Additionally, we would 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 propose 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 understand that residents are sometimes asked to waive facility responsibility for the loss of their personal property or are unable to use personal property because it is only permitted in the facility if safeguarded by the facility in a manner that makes the property usually inaccessible to the resident. These policies effectively take away the residents’ right to use personal possessions and relieve facilities from their responsibility to exercise due care with respect to residents’ personal property. We expect this requirement will encourage facilities to develop policies and procedures to safeguard residents’ personal possessions without effectively prohibiting a resident’s use of personal possessions. We further propose 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. For example, if a facility has a religious affiliation that guides its practices, any resulting special characteristics, requirements, or limitations would have to be communicated to potential residents at admission. Similarly, if a facility did not have the capability to care for residents requiring psychiatric care, potential residents would have to be advised of this prior to admission. The potential resident or resident representative could then make an informed initial decision about admission, should the need for specific types of care or services later become necessary, the need for an appropriate transfer will be more predictable and understandable to the resident. We believe this type of disclosure is current standard business practice, however, in keeping with proposed provisions related to specifying reasons for transfer or discharge as well as to ensure informed choices on the part of the resident at the time of admission, we would add this requirement explicitly.

We also propose 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 propose to re-designate § 483.12(a) as proposed § 483.15(b) and address transfers and discharges.

§ 483.15(b)(1)(ii)(C) would revise existing § 483.12(a)(2)(iii) and we would 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 proposed § 483.15(b)(1)(ii)(E), we would 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. This is consistent with existing guidance and would help to clarify the meaning of failure to pay. Finally, we propose 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). “Discharge/Eviction” was the most frequent nursing facility complaint category processed by the Long-Term Care Ombudsman Programs nationally in FY 2013 (8,478 complaints) and has been the first or second most frequent complaint category consistently since 2006. Involuntary discharges are often traumatic for residents. Transfer or discharge from a facility prior to an appeal determination can result in an unnecessary transfer out of and back to a facility.

In the proposed revision to paragraph § 483.15(b)(2), we would make a number of revisions based on the importance of effective communication between providers during transitions of care. First, we propose 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. While this type of documentation is presently required for hospitals with which the facility has a transfer agreement, such communication is important regardless of the setting to which the resident is being transferred or discharged. In addition, we propose 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 believe this proposal will discourage facilities from discharging residents inappropriately. We note that facilities are obligated under the Americans with Disabilities Act and the Rehabilitation Act not to discriminate against residents based on the severity of their disability. Discharging or transferring a resident without first implementing accommodations to better meet the resident's needs may be in conflict with these laws.

We propose 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 note that the exchange of information "needed for care and treatment of residents, and when the transferring facility deems it appropriate, for determining whether such residents can be safely and appropriately cared for in a less expensive setting than either the facility or the hospital" is already required under § 483.75(n) as a component of the transfer agreement a facility must have with one or more hospitals. However, that provision only applies to hospitals with which the facility has a transfer agreement and it does not require any minimum standards for the information to be exchanged. To provide safe, effective care to residents, we believe it is critical that timely and accurate clinical information follow the resident across care settings and providers. Transitions of care represent a period of increased risk for complications and adverse events for the individual. One way to reduce this risk is to ensure effective communication between care providers. In recognition of this, in August of 2011, the State of New Jersey mandated the use of a universal transfer form. Rhode Island and Massachusetts also require a universal transfer form and the American Medical Directors Association has developed and recommends the use of a universal transfer form. Additionally, other tools and information are available from CMS (see <http://www.medicare.gov/Pubs/pdf/11376.pdf>) and AHRQ (see <http://www.innovations.ahrq.gov/content.aspx?id=3285>) as well as through a number of professional organizations, including but not limited to the National Transitions of Care Coalition (www.ntocc.org). Examples of resources include TeamSTEPPS® Long Term Care Version (<http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/longtermcare/interact2.net/>), and the On-Time Quality Improvement Program (<http://www.ahrq.gov/professionals/systems/long-term-care/resources/ontime/qualityimprov/index.html>). We expect that new tools and information will be developed over time. Electronic health records could simplify the process of extracting necessary information when a resident is transferred from a nursing home and electronic summary of care documents provide a standardized way to exchange critical information between providers.

As noted earlier, 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. While current Medicare and Medicaid EHR Incentive programs have focused on providers other than SNFs and NFs, certified health IT possesses capabilities that can assist any health care provider to improve the quality, safety and efficiency of the care they deliver. For more information about how currently available certified health IT systems can enable the electronic exchange of a summary care record, providers should review "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments," which addresses use of the 2014 Edition of ONC certification criteria (available at http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf).

The 2015 Edition of certification criteria for health IT, published on March 30, 2015 at 80 FR 16902, proposes to define a common clinical data set. As discussed in the draft Interoperability Roadmap, HHS believes a core priority for improving health and health care quality through nationwide interoperability is the ability to electronically send, receive, find and use a common clinical data set. By aligning the data elements proposed below with this proposed common clinical data set, we believe facilities will be well-positioned to engage in electronic communication of information during the transfer process. In addition, new standards supporting the exchange of a summary care record include additional information directly applicable to SNF and NF settings. The HL7 Clinical Document Architecture (CDA) Release 2.0, now identified as the best available standard for exchange of a summary care record (www.healthit.gov/standards-advisory) and proposed for inclusion in the 2015 Edition of certification criteria for health IT (80 FR 16804) makes new standards available for pressure ulcers, functional and cognitive status, advanced directives, and other clinical health information that could be used for exchange in summary records, as well as a new dedicated Transfer Summary document that could be used for exchange in summary records. These standards were developed through a public-private collaboration including an ONC-sponsored Standards and Interoperability Longitudinal Coordination of Care Workgroup and HL7 (a private sector, American National Standards Institute (ANSI)-accredited standards development organization) and will support more robust interoperable health information exchange across the care continuum, including with and by nursing homes.

We note that we are not proposing to require a specific form, format, or methodology for this communication. Instead, we propose specific data elements or a set of information that must be communicated during the transfer process. We believe that existing state-mandated forms would meet our proposed requirements. We have reviewed literature related to transitions of care and re-hospitalization as well as the available universal transfer forms and work on the development of interoperability standards for EHRs and propose to require specific information consistent with our research. 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 have not established a time frame for this

we have not established a time frame for this

communication, as this may vary based on the circumstances surrounding the transfer; however, we would 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. We understand that limited information may initially be sent with a resident in an emergency situation; however, we would expect that if an initial communication does not include all of the required information, a subsequent communication to fill-out the missing information would occur in a timely manner. We are soliciting comment on both the information elements we are requiring and the time frame for transmission of the required information. While we are not proposing any specific form, format, or methodology for the communication of this information for all facilities, we strongly believe that those facilities that are electronically capturing this information should be doing so using certified health IT that will enable the real time electronic exchange with the receiving provider. By utilizing certified health IT, facilities can ensure that they are transmitting interoperable data that can be used by other settings, supporting more robust care coordination and higher quality care for patients.

In proposed paragraph (b)(3)(i), we would update the language currently in § 483.12(a)(4)(i) to reflect our “resident representative” language and propose 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. If a resident does not agree to have the notice sent to the State Long-Term Care Ombudsman, we would expect the refusal to be documented in the resident’s medical record. The requirement to send this notice the State Long-Term Care Ombudsman is another provision related to concerns about inappropriate discharges and was suggested by stakeholders to allow timely assistance to the resident in cases where the discharge is involuntary. In proposed paragraph (b)(3)(ii), we propose 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 paragraph § 483.15(b)(5)(iii), we propose 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 propose 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 propose 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 propose to re-designate § 483.12(a)(7) as § 483.15(b)(7) and revise 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. The facility must also document this orientation, including the resident’s understanding of the orientation (teach back or other methodology). To do otherwise would negate the intent of this provision. Finally, in § 483.15(b)(9), we propose to clarify that room changes in a composite distinct part are subject to the requirements of proposed § 483.10(d)(7).

Some states have requirements for facilities to reserve a resident’s bed when the resident is transferred to an acute care facility. These requirements and individual facility policies may vary widely and may impact the availability of the resident’s original bed or any bed when the resident is ready to return to the facility as well as have payment implications for the resident. In paragraph § 483.15(c) we propose 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 propose 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. We are soliciting comments on state and facility bed-hold policies and state reserve bed payment policies, including whether the proposed notices have adequately differentiated these. Further, we are interested in the impact, if any, of

reserve bed arrangements between some hospitals and some facilities. Finally, we propose to redesignate existing § 483.12(a)(3) as § 483.15(c)(3) and revise 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). As noted earlier, discharge/eviction is the most common category of complaint processed by the Long-Term Care Ombudsman Program. Residents often do not realize that there are requirements allowing them to return to a facility after a hospitalization or that they may have appeal rights. This provision is intended to ensure that residents have an opportunity to exercise an appeal right if they choose to do so.

G. Resident Assessments (§ 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 proposed restructuring of subpart B, current § 483.20(k) and § 483.20(l), which set forth requirements for care plans and discharge planning, would be removed and re-designated to proposed § 483.21(b) and § 483.21(c), respectively. Similarly § 483.20(m) would be re-designated as proposed § 483.20(k). The proposed 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. Consistent with our goal of encouraging person-centered care, we propose 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 revise the regulations to specify that CMS (not the State) prescribes the resident assessment instrument. At § 483.20(b)(1)(xvi) we propose 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. It is our understanding that many facilities are unclear as to what this provision requires. Our goal is to clarify for facilities what it means to coordinate resident assessments with PASARR. Therefore, we propose to add new § 483.20(e)(1) and § 483.20(e)(2). In new § 483.20(e)(1), we propose 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 propose to clarify that PASARR coordination also includes referring all level II residents and all residents with newly evident or possible serious mental illness, 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). Often facilities overlook the PASARR recommendations during a resident's assessment and the development of their care plan. The recommendations should be used as a tool by facilities to make a complete and accurate assessment of a resident with evident or possible mental illness. The addition of these two requirements would promote better coordination of a resident's assessment with the PASARR, allowing for a facility to better assess their residents with mental illness.

As mentioned earlier in this section, we are proposing to re-designate existing § 483.20(m) as § 483.20(k). In addition, we propose to make a few technical corrections at proposed § 483.20(k). First, we propose 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 mental illness and individuals with intellectual disability for admittance into a nursing facility. Newly proposed § 483.20(k)(2) would add to the regulation these statutory exceptions that were inadvertently omitted when this regulation was initially written. Second, we propose 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. Proposed § 483.20(k)(4) would add to the regulation this statutory requirement that was inadvertently omitted. Lastly, we propose to replace "mental retardation" with the term "intellectual disability" throughout § 483.20(k), as appropriate.

H. Comprehensive Person-Centered Care Planning (§ 483.21)

In accordance with the proposed reorganization of part 483, subpart B, we propose to add a new § 483.21 "Comprehensive Person-Centered Care Planning". This section would retain certain existing provisions of current § 483.20 as well as other additions and revisions discussed in detail below. Through the care planning process a facility should establish and document the services that the facility will provide to residents to assist them in attaining or maintaining their highest quality of life. Care planning drives the type of care that a resident receives and is essentially the framework for the quality of care that a facility will provide. The diversity of the nursing home population can create challenges for facilities in meeting care planning requirements, and improper care planning or the lack of care planning by a facility can negatively impact the quality of care that a resident receives while in a nursing home.

OIG reports reveal some gaps in care planning within LTC facilities. According to a July 2012 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 OIG found that nearly all records (99 percent) reviewed in their study failed to meet one or more Medicare requirements for beneficiary assessments and/or care plans. Furthermore, 9 percent of records contained care plans that were not developed or updated within the required 7 days from the completion of the Minimum Data Set (MDS), while 6 percent of records did not include care plans at all. The report also found that less than 5 percent of the records actually contained care plans that were developed by the required interdisciplinary team. Moreover, 91 percent of the records did not contain evidence that the resident, resident's family, or the resident's legal representative participated in the care planning process. Nearly two-thirds of these records lacked documentation as to why participation was not practicable.

Similarly, a February 2013 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>), studied the extent to which LTC facilities meet requirements for care planning. The OIG report found that for 37 percent of the stays, facilities did not meet Medicare requirements for care planning. The February 2013 OIG report also found that for 31 percent of nursing home stays, facilities did not meet requirements specific to discharge planning. However, the report noted that despite these deficiencies, Medicare paid approximately \$4.5 billion for the stays that did not meet quality of care requirements and approximately \$1.9 billion for those that did not meet the discharge planning requirements.

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. To emphasize the level of importance for care planning and to increase the visibility of the requirements, we propose 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 proposed § 483.21, entitled "Comprehensive Person-Centered Care Planning." This new section would contain all of the existing requirements for care planning. We believe that relocating the requirements to a new section dedicated solely to care planning would emphasize the importance of care planning as well as provide clarity to the regulations. In addition to relocating existing provisions, we are also adding new requirements as discussed in detail below.

Proposed § 483.21(a)

Currently, § 483.20(k)(2)(i) requires that a comprehensive care plan be developed for each resident within 7 days after completion of the comprehensive resident assessment. Section 1819(b)(3)(C)(i) of the Act requires that the comprehensive resident assessment be completed within 14 days after a resident is admitted. These timeframes allow a facility up to 21 days to develop a comprehensive care plan for a new resident. While we believe that most facilities are indeed developing their care plans much sooner than required, the February 2013 OIG report reveals that some facilities are not. During our dialogue with stakeholders, concerns

were expressed about the ability of a facility to delay development of a care plan for 21 days without consequence to residents. We recognize that during these 21 days facilities could use admission orders to determine a resident's care; however, we believe that there are common health concerns found in the residents of LTC facilities that need to be identified and addressed in a care plan to prevent resident decline or injury. Some of these problems include behavioral intervention in dementia care, dietary issues, fall risks, supervision, and the ability to perform activities of daily living (ADLs). These areas need to be assessed and issues identified quickly in order to prevent adverse events such as injuries, unintended weight loss and dehydration, and instances of wandering off. Without a proper interim care plan within the initial period of residency, residents could receive poor quality care simply due to the fact that staff does not receive the relevant information they need to be effective and provide high quality care and services to the resident. This could also place residents at a much higher risk of hospital readmission. Therefore, we are proposing 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. This baseline interim care plan would include the necessary instructions for the proper professional care and services to meet the immediate needs of a new resident. This proposal would increase resident safety and safeguard against adverse events that are most likely to occur right after admission.

We believe that residents are receiving initial services and care based on physician's orders within the first 24 to 48 hours of admission and therefore propose to require that the proposed baseline care plan be completed within 48 hours of a resident's admission. It is our expectation that facilities would continuously revise and update this baseline care plan as needed until the comprehensive assessment and care plan could be developed. We believe that most facilities are assessing residents as soon as possible and establishing plans of care earlier than the regulatory deadline; however this requirement would eliminate the possibility that residents could reside in a facility for 21 days without any care planning. Also, requiring facilities to complete this baseline interim care plan within 48 hours would promote continuity of care across shift changes

by improving communication among nursing home staff during a period when residents are especially vulnerable to adverse health events.

At § 483.21(a)(1)(ii), we propose 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. 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.

Finally, at § 483.21(a)(2), we propose 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 then have to 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 propose to re-designate this section as a new § 483.21(b). In addition, we are also proposing revisions to this section that we believe would provide clarity, promote resident safety, and encourage person-centered care. First, we propose to add a new § 483.21(b)(1)(iii), that would require any specialized services or specialized rehabilitation services that a nursing facility provided pursuant to a PASARR recommendation to be included in the resident's care plan. This inclusion would improve coordination between the nursing facilities and a resident's PASARR. In addition, we propose to require that if a facility disagrees with the findings of the PASARR, it must indicate this disagreement and the reasons for it in the resident's medical record.

We also propose to add a new § 483.21(b)(1)(iv) that would require discharge assessment and planning to be a part of developing the comprehensive care plan. We are proposing 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. This

proposal seeks to improve resident satisfaction and encourage facilities to operate in a person-centered fashion that addresses resident choice and preferences. Upon a resident's request, this discharge assessment may include referral to a community transition planning agency to explore community living options, resources, and available supports and services. We propose 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. Furthermore, we also acknowledge that residents' preferences and goals of care may change throughout the length of their stay in a facility, so we also want to emphasize that there needs to be an ongoing discussion with the resident or their representatives of the goals of care.

Also in the spirit of person-centered care, we are proposing to specify additional mandatory members of the interdisciplinary team (IDT). 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 are proposing 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. For example, a qualified mental health professional should be involved when residents are diagnosed with mental health conditions or prescribed psychotropic drugs. Similarly, based on a resident's needs, a chaplain or other spiritual care provider could be deemed appropriate for inclusion in the development of a residents care plan. However, we believe there would be other appropriate staff in specific disciplines that all residents need to also be a part of the IDT. Therefore, we propose 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. Including these critical team members in the IDT and the care planning process would ensure that the individual needs of a particular resident are being assessed and appropriately addressed.

NAs spend much of their time interacting directly with the residents providing them day-to-day care. Their

knowledge of a resident care plan and medical needs directly relates to how well they can care for a resident. Dietary concerns and unplanned weight loss are major concerns for the LTC population, especially for the elderly population. Since nutrition is a fundamental part of a resident's overall health and well-being, it is important that a member of the food and nutrition services staff be knowledgeable of the resident's needs and preferences to achieve their maximum practicable well-being. Social workers serve as a critical link with families in many ways, including arranging post-discharge services and addressing mental and behavioral health care needs. The involvement of social services and food and nutrition services would also promote and enhance a resident's choice regarding their day-to-day activities and meals as well as encourage facilities to take a more comprehensive approach to providing individualized quality of care and quality of life specific to each resident.

Additionally, we propose 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. We want to ensure that residents have the ability to choose who they want to be a part of making decisions about their care. This participation can incorporate many forms of communication such as conference calls or using electronic tools for video conferencing. Further, at § 483.21(b)(2)(ii)(F) we propose 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. Residents should be involved in making decisions about their care and facilities should be held accountable for their attempts to involve the resident when it is appropriate and provide an explanation when they determine that it is not feasible or appropriate. We believe the addition of these requirements would increase resident choice, but also seek to improve the communication between the facilities and the residents regarding the aspects of a resident's care, choice, and the services to be provided by facility to maintain or improve a resident's care.

Lastly, we have added 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. As discussed previously, culturally-competent (including language, culture

preferences and other cultural concerns), trauma-informed approaches that help to minimize triggers and re-traumatization, and that address the unique care needs of Holocaust survivors and other trauma survivors, are an important aspect of person-centered care for these individuals.

We note that certified health IT can support efforts by LTC facilities to develop robust comprehensive care plans that can be shared with other providers across the continuum of care. We strongly believe that facilities that use certified health IT applications should seek to generate comprehensive care plans using technology solutions, in order to further improve access and communication among staff. ONC has identified the HL7 Clinical Document Architecture (CDA) Release 2.0: Consolidated CDA Templates for clinical notes as the best available standard for care plans (see the Interoperability Standards Advisory at <http://www.healthit.gov/standards-advisory>). The dedicated care plan document contained within this standard is designed to help providers reconcile and resolve conflicts between different plans of care and to help the care team prioritize goals and interventions. As part of the 2015 Edition of certification criteria for health IT, ONC proposed to certify health IT systems to their ability to generate a Care Plan document according to this standard (see 80 FR 16842).

Proposed § 483.21(c)

Current regulations at § 483.20(l) set forth the requirements for discharge planning. As mentioned above, we propose to re-designate this section as a new § 483.21(c). Transitions between settings of care are often complex for residents as well as for LTC facilities given that each facility differs greatly in its organization, practices and cultures. As mentioned earlier, the population receiving care and service in LTC facilities is diverse and includes those who have complex health and continuing care needs and rely on various services to help meet these needs. Furthermore, these individuals may have increased susceptibility to infections, malnutrition, dehydration, comorbidities, or functional impairments. All of these factors contribute to a person's increased vulnerability to receiving suboptimal care during a period of transition from one care setting to another. Older adults often receive healthcare in multiple settings thus requiring multiple transitions of care. For example, an older adult with an acute or chronic illness may receive healthcare at an

inpatient hospital setting, followed by treatment at a LTC facility, possibly followed by discharge to their home to receive services from a visiting nurse or a primary care physician in an outpatient setting. The February 2013 OIG report found that for the current discharge planning requirements (summary of a resident's stay and a post-discharge plan of care), many SNF stays that did not meet the discharge planning requirements did not have a post-discharge plan of care. Results of the study also indicated that, in some instances, staff provided only verbal instructions to the beneficiary and in one example a resident did not receive specific instructions about medications. Another study found that one in five Medicare beneficiaries are re-hospitalized within 30 days, largely a result of medication errors, resident confusion about and subsequent failure to follow up on care instructions and the management of multiple chronic conditions (Parry, C., & Coleman, E. A. (2010). *Active Roles for Older Adults in Navigating Care Transitions: Lessons Learned from the Care Transitions Intervention*. Open Longevity Science, 43–50).

Relevant literature indicates that different priorities and organizational structures result in little coordination and lack of understanding about what occurs across settings. (McCloskey R. A. *Qualitative Study on the Transfer of Residents between a Nursing Home and an Emergency Department*. *Journal of the American Geriatrics Society* [serial online]. April 2011; 59(4):717–724. Available from: Academic Search Complete, Ipswich, MA. Accessed November 14, 2012.) For example, staff in a LTC facility setting may decide that a resident's condition requires acute care services and transfer the resident to the hospital for an assessment. The physicians in the hospital setting may not believe the resident's condition warrants acute care and thus may send the resident back to the nursing home, or may admit the resident when a hospital level of care is not indicated. Proper discharge planning across all provider settings helps improve the communication regarding a resident's needs and promotes safer care transitions.

Given the heightened need to ensure safe transitions of care across all providers, we are proposing to strengthen the current LTC requirements for discharge planning. These proposals would also support CMS' initiative to safely reduce hospital readmissions and unnecessary hospitalizations by improving communication and ensuring that

residents are being empowered and educated about their care. Our proposals also emphasize that discharge planning should focus on the necessary steps to achieve discharge consistent with a resident's goals and preferences. 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.

At § 483.21(c)(1) we propose to improve the discharge planning for LTC facilities by adding a requirement that facilities must develop and implement an effective discharge planning process. 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. In addition, we propose 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. The discharge plan must also be updated, as needed, to reflect these changes. We also propose 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 propose 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. In order to incorporate residents and their families in the discharge planning process, we also propose to require that the discharge plan address the resident's

goals of care and treatment preferences. Facilities would 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 indicated 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 would document who made the determination and why.

As required under section 1899B(i)(1) of the Act, to help inform the discharge planning process, we propose 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 propose 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, under the proposed regulation, the facility would have to 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. In order to emphasize resident preferences, we would expect that the facility would compile the relevant data and present it to the resident and their resident representative in an accessible and understandable format and with useful content. For example, the facility could provide the aforementioned quality data on other post-acute care providers that are within the resident's desired geographic area. Facilities would then need to assist residents and their resident representative as they seek to understand the data and use it to help them choose a high quality post-acute care provider, or other setting for discharge, as appropriate.

Finally, at § 483.21(c)(1)(viii), we propose 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 propose 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 propose 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 propose to revise the current requirements for the post-discharge plan of care to specify that a recapitulation of a resident's stay would include, but not be limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results. We also propose 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 should include community care options, resources, and available supports and services presented and arranged by the community care provider as needed. Some local community transition agencies include Area Agencies on Aging (AAAs), Aging and Disability Resource Centers (ADRCs), or Centers for Independent Living (CILs), which can provide information and assist the resident in arranging for available community supports and services prior to discharge. Adding this requirement would hold facilities accountable for their role in preparing residents for care transitions from one setting to another and assist in decreasing a resident's risk for complications and hospitalization.

In addition, the discharge planning process should ensure that residents receive adequate information that is understandable and prepares them to be active partners and advocates for their healthcare upon discharge. Yet residents and/or their representatives frequently are unable to understand their diagnoses, list their medications and describe their purpose and side effects, or explain their follow-up plan of care instructions, all key factors of a resident's healthcare needs. Therefore, at § 483.21(c)(2)(iii) we propose to add

a new requirement that would require facilities to reconcile all pre-discharge medications both prescribed and non-prescription, with the resident's post discharge medications. This medication reconciliation would be included as part of the discharge summary. The addition of this requirement would ensure that residents avoid unnecessary medications and prevent drug interactions. This proposal would also improve transitions across varying care settings by avoiding unnecessary situations, such as placing a resident on duplicate prescriptions leading to an adverse event and unnecessary hospitalization.

Lastly, in keeping with the theme of resident centered care, we also propose 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. Furthermore, upon a resident's request, facilities should also include the community transition planning agency to assist the resident and facility with housing, personal care assistance, assistive technology, and other resources.

We encourage facilities to explore how the use of certified health IT can support their efforts to electronically develop and share standardized discharge summaries. Information about how currently available certified health IT systems can enable the electronic exchange of a summary care record is available in "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments," which addresses the use of the 2014 Edition of ONC certification criteria (available at http://www.healthit.gov/sites/default/files/generalcertexchange_guidance_final_9-9-13.pdf). Facilities may also wish to review the Discharge Summary document that is included in the HL7 Clinical Document Architecture (CDA) Release 2.0, now identified as the best available standard for the summary care record (see the Interoperability Standards Advisory at <http://www.healthit.gov/standards-advisory>).

I. 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 nursing home 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 nursing homes. These principles apply

to every service provided by a SNF or NF. Sections 1819(b)(1)(A) and 1919(b)(1)(A) of the Act require that a SNF or NF care for its residents in a manner and in an environment that will promote maintenance or enhancement of the quality of life of each resident. Services and care must be provided in accordance with established standards of practice, in a manner intended to support achievement of a resident's individualized goals for attaining or maintaining his or her highest practicable physical, mental, and psychosocial well-being, as set out in the plan of care. In addition, services and care must be provided in a manner intended to support each resident's overall well-being, as perceived by the resident, including emotional, social and physical aspects of his or her life. We propose to comprehensively revise and re-organize the current § 483.25 to ensure person-centered, quality care and quality of life for this vulnerable population. In this proposed revised section, we would focus on a limited set of concerns that do not clearly fit in other general sections of the regulation but which are of significant importance for each resident's health and safety and which contribute substantially to their quality of care, quality of life and person-centered issues such as dignity, respect, self-esteem and self-determination. These concerns have both medical and psychosocial aspects and include activities of daily living which are those self-care activities that an individual performs daily, including everyday routines involving functional mobility and personal care, such as bathing, dressing, toileting, and meal preparation and consumption. Diminished ability or inability to perform these activities renders an individual vulnerable and dependent on others for assistance.

First, we propose to retitle this section "Quality of Care and Quality of Life", reflecting the overarching application of these principles. In our proposed revised introductory paragraph, we 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. We focus throughout this section, as we have in other areas, on establishing person-centered requirements that acknowledge both the resident's needs and the resident's right to make choices.

Second, in § 483.25(a), we propose to address the residents' ability to perform 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, as 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. This means that a resident is offered the appropriate treatment and services to improve or maintain his or her ability to carry out ADLs and, if a resident is unable to do so, he or she receives the necessary care and services from qualified staff to maintain good nutrition, functional mobility, grooming, and personal and oral hygiene. We propose to divide the requirements of existing § 483.25(a)(1) into proposed § 483.25(a) and (b). Existing (a)(2) and (a)(3) would be redesignated as § 483.25(a)(1) and (a)(2), respectively. We propose a new § 483.25(a)(3) to clarify that, in keeping with the requirement to provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, 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. It has come to our attention that there are nursing facilities that have implemented a facility-wide policy of not initiating basic life support. They will, instead, call 911 and wait for the arrival of emergency personnel, unless the resident does not want CPR at all. We believe that the determination to provide or not provide basic life support such as CPR should be made on an individual resident basis rather than as a facility-wide policy. The determination should be based on a resident's advance directives, the presence or absence of do-not-resuscitate orders, and accepted professional standards. Further, we believe that the provision of CPR in applicable emergency situations and subject to an individual's advance directives is a generally accepted expectation in healthcare facilities.

In proposed § 483.25(b), we would establish those activities that we include as ADLs. These activities are currently listed in § 483.25(a)(1)(i) through (v). We propose to update the language of that list, although the underlying activities

remain unchanged. We would 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. We note that communications are not considered an ADL in standard instruments such as the Barthel Index of Activities of Daily Living or the Index of Independence in Activities of Daily Living (Katz, 1963). However, we believe that the ability to communicate is a vital aspect of an individual's daily life and a resident's ability to do so should continue to be included in our provisions relating to ADLs. We also highlight the inclusion of oral hygiene in this section. In the elderly population, periodontal disease has been linked to a wide variety of systemic diseases, including diabetes, cardiovascular disease, arthritis, neurodegenerative diseases, respiratory diseases, and nutritional deficits. One study suggests that maintaining optimal oral health may do more to reduce healthcare expenditures in an elder's remaining lifespan than any other public health measure. According to a 2000 report by HHS, 23 percent of 65- to 74-year olds have severe periodontal disease. Nursing home residents in particular are recognized as receiving inadequate oral care. Even if a resident enters a nursing facility with good oral health, that oral health is likely to decline within 6 months. Thus, we emphasize here that if a resident is unable to brush and floss his or her teeth or otherwise maintain good oral hygiene, the facility must ensure that he or she receives the necessary care and services from qualified staff to maintain good oral hygiene.

In proposed § 483.25(c), we propose to relocate the current requirements related to an activities program as required in existing § 483.15(f). An ongoing individualized activities program that incorporates an individual's interests and hobbies can and should be integral to maintaining and improving a resident's physical, mental, and psychosocial well-being and his or her independence. Thus, we propose 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. This reflects our focus on person-centered care as well as our recognition of the development of support programs

and community resources in some areas that may allow for resident involvement or reintegration into the community setting for some nursing home residents. We received stakeholder input on the requirements for the director of a facility activities program and considered, but did not modify the requirements for the director of the activities program. However, we are soliciting comments on the current requirements to determine if they remain appropriate and, if not, what the evidence is for changing the current requirements for this position and what stakeholders would recommend as minimum requirements for this position.

We propose a new § 483.25(d), "Special Care Issues," which we revise, re-locate, and add 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. Each of these special concerns is related to an ADL but has a significant medical component or is an issue that could significantly impact a resident's ability to perform or engage in ADLs. For example, there are specific medical professional standards of practice that affect when and how tube-feedings are initiated and performed. At the same time, the resident's need for tube-feeding reflects the resident's significantly diminished ability to perform or participate in ADLs related to eating. Similarly, pain management is a medical issue, but can significantly alter a resident's ability to engage in an activities program of choice, perform transfers or ambulate, impairs quality of life and can contribute to depression. As many of the concerns in this section were previously included in § 483.25, we discuss here only the provisions we propose to add or modify.

Specifically, we propose to re-designate and revise § 483.13(a), "Restraints," as § 483.25(d)(1). While we would 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 would 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 would 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. As noted in our discussion above regarding the proposed requirement "Freedom from Abuse, Neglect, and Exploitation" (§ 483.12), there are very limited circumstances where restraints may be appropriate in a nursing facility. However, many facilities have achieved a rate of zero percent restraint use, and CMS continues to promote reduction in the use of physical restraints. We considered proposing requirements for the use of restraints and seclusion that parallel the more extensive requirements for restraint and seclusion currently set forth in the Conditions of Participation for Hospitals at § 483.13(e). However, given the progress towards zero restraint use under existing guidance and taking into consideration the different types of care provided in the two settings, we have chosen to pursue a less burdensome approach and codify existing guidance. In addition, we are proposing requirements for the use of psychotropic medications, including the use of PRN orders, at § 483.45(e), discussed below, to ensure that these medications are only used to treat specific conditions that are diagnosed and documented in the resident's clinical record. We welcome comments on our approach as well as suggestions for more extensive requirements.

We propose a new § 483.25(d)(2) to establish specific requirements when a facility uses bed rails on a resident's bed. Specifically, we propose 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. Bed rails can pose a significant safety risk to residents. Between January 1, 1985 and January 1, 2013, FDA received 901 incidents of patients caught, trapped, entangled, or strangled in hospital beds. The reports included 531 deaths, 151 nonfatal injuries, and 220 cases where staff needed to intervene to prevent injuries. Most patients were frail, elderly or confused. Additional information and resources regarding the use of bed rails

is available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default.htm>. We propose 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.” Here, we propose 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 propose to address mobility both range of motion and other limitations of mobility. We propose 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 propose 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. Fecal or bowel incontinence affects a substantial number of nursing home residents. Urinary and fecal incontinence affect 50 percent or more of nursing home residents and frequently occur together because immobility and dementia are primary risk factors for both conditions (John F Schnelle, Felix W Leung, Urinary and fecal incontinence in nursing homes, *Gastroenterology*, Volume 126, Supplement 1, January 2004, Pages S41–S47, ISSN 0016–5085, 10.1053/j.gastro.2003.10.017. (<http://www.sciencedirect.com/science/article/pii/S0016508503015658>)). In an older study, 20 percent of nursing home study participants developed fecal incontinence over a 10 month period (Chassagne P, Landrin I, Neveu C, et al. Fecal incontinence in the institutionalized elderly: incidence, risk factors, and prognosis. *Am J Med* 1999;106:185–90.), and a 1998 survey of 18,000 Wisconsin nursing home residents found a prevalence of up to 50 percent (Nelson RL, Furner S, Jesudason

V. Fecal incontinence in Wisconsin nursing homes. *Dis Colon Rectum* 1998;41:1226–9). Fecal incontinence may be related to impaired skin integrity, including pressure ulcers, as well as depression and anxiety. We retain, unchanged, colostomy, ureterostomy, and ileostomy care in § 483.25(d)(7).

In § 483.25(d)(8), we propose 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 propose to include gastrostomy tubes with nasogastric tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy. We also propose 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 propose 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 propose 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. The American Geriatric Society (AGS), in their May 2013 position statement on feeding tubes in advanced dementia, states that institutions such as hospitals, nursing homes and other care settings should promote choice, endorse shared and informed decision-making, and honor patient preferences regarding tube feeding. The statement further notes that enteral feeding is not associated with better outcomes in older adults with advanced dementia, but is associated with agitation, increased use of restraints, and worsening pressure ulcers and is not recommended for older

adults with advanced dementia and recommends careful hand-feeding. (<http://www.americangeriatrics.org/files/documents/feeding.tubes.advanced.dementia.pdf>). Our proposed requirements are consistent with the AGS position statement.

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

We propose to add a new § 483.25(d)(13) to ensure that residents receive necessary and appropriate pain management. Pain that impairs function affects 45 percent to 80 percent of nursing home residents, with half of those experiencing daily pain (Davis, M., & Srivastava, M. (2003). Demographics, assessment and management of pain in the elderly. *Drugs & Aging*, 20(1), 23–57). Also, Thomas Cavalieri noted that pain in the elderly is often unrecognized and undertreated. He further recognized that ineffective pain management can have a significant impact on the quality of life of older adults, including contributing to depression, isolation, and loss of function. (*J Am Osteopath Assoc* September 1, 2002 vol. 102 no. 9 481–485). Further, Cheryl Phillips, MD, speaking to the United State Senate Special Committee on Aging on behalf of the American Geriatrics Society, reported that pain is common among nursing home residents and is undertreated in an estimated 45 percent to 80 percent of residents with substantial pain. According to Dr. Phillips untreated pain is associated with multiple consequences, including poor oral intake and weight loss, inability to sleep, depression, loss of mobility and increased risk of falls, increased risk of pressure ulcers, depression, anxiety, decreased socialization, sleep disturbance, increased emergency room transfers and increased re-hospitalization rates (Testimony of Cheryl Phillips, MD before the Special Committee on Aging, United States Senate, March 24, 2010. http://www.americangeriatrics.org/files/documents/Adv_Resources/AGS.Testimony.Senate.Aging.Pain.Management.in.Nursing.Homes.pdf).

More recently, in 2011, the Institute of Medicine issued a comprehensive report on pain entitled “Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research” (<http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming->

Prevention-Care-Education-Research.aspx). This report identifies pain as a national challenge, affecting more Americans than heart disease, diabetes, and cancer combined, and as a factor that significantly increases the cost of health care across all settings, including nursing facilities.

Clearly, adequate pain management is critical to the health, safety, and quality of life for nursing home residents. Therefore, we propose to explicitly include oversight of pain management as a special concern. We propose 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 propose 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 propose 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 propose 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 propose 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 below in our section on pharmacy services.

J. Physician Services (§ 483.30)

Under the reorganization discussed above, requirements regarding physician services currently located at § 483.40 would be moved to proposed § 483.30. We would retain the current requirements but propose a few additions as discussed below. In our review of the requirements for LTC facilities, we have considered what, if any, minimum health and safety standards are appropriate and necessary to ensure that residents of SNFs and NFs are not unnecessarily hospitalized. CMS has focused recently on reducing the number of avoidable hospitalizations of nursing home

residents. We believe that many of our proposals will support this objective.

We propose to revise the introductory text of new § 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. This is consistent with the current requirement at § 483.20(a) that the facility must have physician's orders for the resident's immediate care and ensure that each resident receives care for his or her specific needs until a comprehensive assessment and care planning can be completed.

We also propose 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. This requirement, in concert with proposals to improve transitions of care, communications among and between practitioners, appropriate exchange of information, and quality assessment activities, will help ensure that the decision to transfer a resident to an acute care facility is made on the basis of a clinical assessment and the best evidence available. Physicians are already required under § 483.12(a)(3) to document in the medical record when a resident is discharged or transferred as a result of the facility's inability to meet the needs of the resident. However, an evaluation of a resident by a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist prior to a resident's transfer may identify options that could allow for the resident to be treated in place and avoid an unnecessary hospitalization. Additionally, in the event the resident needs to be transferred, the evaluation would provide valuable assessment information for the receiving facility.

At § 483.30(f)(2), we propose 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. We believe this flexibility is

beneficial to both the physician and the resident and is consistent with the training and experience of qualified dietitians and other clinically qualified nutrition professionals, as discussed below in section II. P. of this preamble, "Food and Nutrition Services."

Similarly, at § 483.30(f)(3), we propose 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. We believe this flexibility is beneficial to both the physician and the resident, allowing the physician to determine how to best use his or her time and allowing the resident to have more frequent adjustments to therapy as his or her condition or abilities change. Furthermore, we believe this is consistent with the training and experience of qualified therapists acting in accordance with their state scope of practice acts. Moreover, we believe therapists already write therapy orders that are routinely endorsed by a physician without change.

K. Nursing Services (§ 483.35)

Under the proposed reorganization, requirements for nursing services currently located at § 483.30 would be located at proposed § 483.35. The current regulations at § 483.30 address certain aspects of nursing home 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. Since the promulgation of the original regulations, state requirements and industry standards, as well as research, literature and related policy in other healthcare settings regarding nursing home staffing have all evolved. Issues such as nursing home administrator standards, minimum nurse staffing standards, requirements related to specialized personnel such as dietitians, pharmacists, therapists and practitioners with behavioral health and/or geriatric training/experience as well as utilization of nurse practitioners, clinical nurse specialists, and physician assistants have all been raised as concerns or options to address care and services provided in the LTC setting.

We are aware of long-standing interest in increasing the required hours of nurse staffing per day. We have heard suggestions that we impose a minimum number of hours per resident day or require a RN to be on site 24 hours a day 7 days a week. Existing regulations at § 483.30 mirror the statutory language at sections 1819(b)(4)(C)(i) and 1919(b)(4)(C)(i) of the Act requiring

(with certain exceptions) an RN providing services in a facility 8 consecutive hours a day, 7 days a week, licensed nurses 24 hours a day and “sufficient staff” to meet residents’ needs. We may also waive the nurse staffing requirements in specific circumstances.

There is abundant research that associates increased RN staffing with improved quality of care. Rather than specify how many nurses must be on duty, most focus on the number of hours of nursing care a resident must receive to achieve certain quality objectives. A 2001 DHHS Report to Congress provides substantial information about potential minimum requirements, although it stops short of making a recommendation. A 2011 study by Zhao and Haley demonstrated that higher RN staffing hours per resident day was associated with significantly lower malpractice paid-losses and higher NA hours per resident day was found to be related to higher malpractice paid-losses. At least one study notes that the relationship is not necessarily linear—that is, it takes more resources to achieve a certain level of improvement, but beyond that the improvement slows. (Zhang, Unruh, Liu, and Wan, 2006. “Minimum Nurse Staffing Ratios for Nursing Homes.”)

CMS’s own study reported that facilities with staffing levels below 4.1 hours per resident day (HRPD) for long stay residents may provide care that results in harm and jeopardy to residents (Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, Phase II Final Report, 2001, Abt Associates). A study by Schnelle and colleagues (2004) also supports a threshold level of 4.1 total nursing hours per resident day to ensure that the processes of nursing care are adequate (Nursing Facilities, Staffing, Residents, and Facility Deficiencies, 2005–2010. Charlene Harrington, Ph.D.; Helen Carrillo, M.S.; Megan Dowdell, M.A.; Paul P. Tang, B.S.; Brandee Woleslagle Blank, M.A.). A staffing level of 4.1 hours per resident day is the most common number put forward as a minimum standard. However, the conclusions in the 2001 Abt Associates study previously cited were rejected by the then Secretary of HHS due to “serious reservations about the reliability of staffing data at the nursing home level.” Based on existing data, according to the Centers for Disease Control’s National Center for Health Statistics National Study of Long-Term Care Providers (2013), the average hours of nursing care per resident per day for nursing homes is 3.83 (.52 RN, .85 LPN or LVN, and 2.46 Aide) plus an

additional .08 hours of Social Worker time. This does not include therapist time, although virtually all nursing homes (99.3%) offer therapeutic services and therapeutic services are critical to helping residents ‘attain or maintain the highest practicable physical, mental, and psychosocial well-being’—in order for a facility to achieve its statutory mandate that a nursing facility provide services and activities to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.” (see sections 1819(b)(2) and 1919(b)(2) of the Act). However, as a result of section 1128I of the Act, as added by the ACA, CMS is currently developing systems to collect staffing information that is auditable back to payroll data. Once implemented, this new system is expected to increase accuracy and timeliness of data. When this improved staffing data is collected at the nursing home level, more accurate and reliable estimates of the care hours provided by staff categories will be available, potentially leading to updated research and reconsideration of HPRD requirements and recommendations.

An alternative approach to mandating a specific number of hours per resident day is to mandate the presence of a registered nurse in a nursing home for more hours per day than is currently required, potentially 24 hours a day 7 days a week, subject to the statutory waiver. We note that a number of states already require this. Increased presence of RNs in nursing facilities would address several issues. First, greater RN presence has been associated in research literature with higher quality of care and fewer deficiencies. Second, it has been reported in the literature that LPNs or LVNs may find themselves practicing outside of their scope of practice because, at least in part, there are not enough RNs providing direct patient care. Increasing the number of hours a day that an LTC facility must have RNs in the nursing home would alleviate this issue. While imposing a mandate for more RNs raises concerns about the adequacy of the supply of registered nurses, a December 2014 HRSA report on the future of the nursing workforce suggests that growth in RN supply will actually outpace demand in the period between 2012 and 2025 (U.S. Department of Health and Human Services. “The Future of the Nursing Workforce: National- and State-Level Projections, 2012–2025.” Health Resources and Services Administration, Bureau of Health Workforce, National Center for Health Workforce Analysis. (December 2014)). The study notes that

the national projections mask a distributional imbalance of RNs at the state level and that there is considerable variation in the geographic distribution of the growth in RN supply. Sixteen states are projected to have a shortage by 2025, particularly Arizona, Colorado, and North Carolina (<http://bhpr.hrsa.gov/healthworkforce/supplydemand/nursing/workforceprojections/nursingprojections.pdf>). In looking at the employment of registered nurses in nursing homes, the BLS reported in its May 2012 Occupational Employment Statistics (<http://www.bls.gov/oes/2012/may/oes291141.htm>) that 139,440 registered nurses were employed in nursing care facilities (skilled nursing facilities); in the May 2014 Occupational Employment Statistics (<http://www.bls.gov/oes/current/oes291141.htm>) that number has risen to 148,970. At the same time, the number of nursing homes has decreased somewhat from 15,844 based on FY 2012 to 15,691 in 2015, based on CASPER data.

Perhaps somewhat contrary to much of the discussion and literature, a 2011 review of the literature on nurse staffing and quality of care raises questions about the direct cause and effect relationship between the nursing workforce and quality of care. Specifically, the authors conclude that “A focus on numbers of nurses fails to address the influence of other staffing factors (for example, turnover and agency staff use), training and experience of staff, and care organization and management.” They note that the studies they reviewed presented 42 measures of quality and 52 ways of measuring staffing. They also note that it is “difficult to offer conclusions and recommendations about nurse staffing based on the existing research evidence.” (Spillsbury, Hewitt, Stirk and Bowman “The relationship between nurse staffing and quality of care in nursing homes: a systematic review” *The International Journal of Nursing Studies* 48(2011)732–750.) An October 2011 research article by John R. Bowlblis concludes that minimum direct care staffing requirements for nursing homes “change staffing levels and skill mix, improve certain aspects of quality, but can lead to use of care practices associated with lower quality” (HSR: Health Services Research 46:5 (2011) 1945). In short, there is concern that a facility can have sufficient numbers of staff, but if those staff do not have the skills and competencies to do the

necessary work, quality will not improve.

While we believe that existing requirements for sufficient staff need further clarification, we do not believe that we have sufficient information at this time to require a specific number of staff or hours of nursing care per resident. Furthermore, we do not necessarily agree that imposing such a requirement is the best way to clarify what is “sufficient” to the exclusion of other factors that are important in improving the quality of care for each resident. The American Nurses Association (ANA), in its 2012 Principles for Nurse Staffing, describe appropriate nurse staffing as “a match of registered nurse expertise with the needs of the recipient of nursing care services in the context of the practice setting and situation.” The ANA further notes that “staffing needs must be determined based on an analysis of healthcare consumer status (for example, degree of stability, intensity, and acuity), and the environment in which the care is provided. Other considerations to be included are: professional characteristics, skill set, and mix of the staff and previous staffing patterns that have been shown to improve outcomes. The International Council of Nurses (ICN) included similar considerations in its 2012 statement of principles of safe staffing levels (http://www.icn.ch/images/stories/documents/pillars/sew/ICHRN/Policy_Statements/Policy_statement_Safe_staffing_levels.pdf). The ICN policy statement includes as one of its key principles that “safe staffing levels must reflect the skills, experience and knowledge required to meet patient care needs, taking acuity levels into account.” A second key principle states that safe staffing “involves a range of factors including (but not limited to) a sufficient number of staff available, an appropriate level and mix of skills, a manageable workload of both teams and individuals; . . .”. We agree. We believe that the focus should be on the skill sets and specific competencies of assigned staff to provide the nursing care a resident needs rather than a static number of staff or hours of nursing care that does not consider resident characteristics such as stability, intensity and acuity and staffing abilities including professional characteristics, skill sets and staff mix. We are concerned that establishing a specific number of staff or hours of nursing care could result in staffing to that number rather than to the needs of the resident population. A competency-based staffing approach would require

the facility to evaluate its population and its resources in accordance with proposed § 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. This would include, but not be limited to, allocating the appropriate number of competent staff to a care situation. Based on evolving demographic shifts and staffing patterns, we believe a competency based approach will help to maintain flexibility in facility staffing and capability. 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. We maintain that such an approach is essential to person-centered care. We considered combining this approach with a minimum staffing requirement. Options included establishing minimum nurse hours per resident day, establishing minimum nurse to resident ratios, requiring that an RN be present in every facility either 24 hours a day or 16 hours a day, and requiring that an RN be on-call whenever an RN was not present in the facility. We also considered multiple combinations of these options and note that states have implemented a variety of these options. We welcome comment on all of these options. In particular, we are aware that the IOM has recommended in several reports that we require the presence of at least one RN within every facility at all times. We specifically invite comments on the costs of mandating a 24 hour RN presence. We also invite comment on the benefits of a mandatory 24 hour RN presence, including cost savings and improved resident outcomes, as well as any unintended consequences of implementing this requirement. We further welcome evidence of appropriate thresholds for minimum staffing requirements (for both nurses and direct care workers) and evidence of the actual cost of implementing recommended thresholds, including taking into account current staffing levels as well as projected savings from reduced hospitalizations and other adverse events.

As noted earlier, current regulations at § 483.30 mirror the statutory language at sections 1819(b)(4)(C)(i) and 1919(b)(4)(C)(i) of the Act, requiring (with certain exceptions) an RN providing services in a facility 8 consecutive hours a day, 7 days a week, licensed nurses 24 hours a day current regulations and requiring the facility to

have “sufficient” nursing staff. This standard has been praised by some in that it provides facilities with flexibility to determine the level of staffing needed in order to meet the needs of each resident, based upon individual assessments and plans of care. However, the current standard has been criticized by others who have found it lacking sufficient clarity to indicate to facilities what level of staffing is sufficient to provide residents with even minimal standards of care and quality of life. In this proposed rule, we have proposed an approach of a facility assessment process, requiring facilities to determine adequate staffing based on this assessment, which includes but is not limited to the number of residents, resident acuity, range of diagnoses, and the content of care plans. (proposed §§ 483.35 and 483.70). We solicit comments on whether this proposed approach can reasonably be expected to enable facilities to determine and provide adequate levels of staffing to meet the needs of each resident.

We recognize that many States have developed minimum staffing levels of CNAs in their nursing facility licensure requirements. States have implemented a variety of methods to address staffing levels to best meet resident care and quality of life needs. Some States have implemented a CNA hours-per-resident-day model (some include part or all of the hours of licensed nurses into this calculation). For example, Washington, DC requires a minimum daily average of 4.1 hours of direct nursing care per resident per day (with opportunity to adjust the requirements above or below this level, as determined by the Director of Department of Health), an RN on site 24/7, plus additional nursing and medical staffing requirements. http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Nursing_Facility_Regulations_Health_Care_Facilities_Improvement_2012.pdf.

Some States have implemented a ratio of numbers of full-time equivalent CNAs per resident. For example, Maine requires no fewer than one direct care provider for every five residents during the day shift, one per ten in the evening, and one per fifteen in the night. Arkansas requires no less than one direct care provider for every six residents during the day shift, one per nine in the evening, and one per fourteen in the night, plus requirements for minimum numbers of licensed nurses per residents per shift. We solicit comments on whether CMS should consider adopting one of these or other approaches in determining adequate direct care staffing. We invite information regarding research on these

approaches which indicate an association of a particular approach or approaches and the quality of care and/or quality of life outcomes experienced by resident, as well as any efficiencies that might be realized through such approaches.

States have found that requirements for increased staffing levels resulted in improved resident care outcomes and decreased deficiencies. For example, after increasing its nurse staffing levels, Florida found “evidence that quality of care has substantially improved in Florida nursing homes since the introduction of increased nurse staffing levels and other quality standards since 2001. Average deficiencies per facility have decreased. Importantly, the citations for the more serious deficiencies have decreased dramatically and remain lower than the national average. Measures of resident care outcomes have improved in 2007 after the new staffing standards of 2.9 hours per resident day were instituted.” Hyer, K. et al, (2009) University of South Florida, Analyses on Outcomes of Increased Nurse Staffing Policies in Florida Nursing Homes: Staffing Levels, Quality and Costs (2002–2007); i. At this time, we have deferred deciding on any potential specific requirement pending evaluation of additional data that will be collected on payroll based staffing data.

We are proposing to revise the section to incorporate language to require that nursing service personnel have the competencies and skill sets necessary to provide nursing and related services to assure the safety of residents and help them to attain or maintain the highest practicable physical, mental, and psychosocial well-being. The facility would have to take into account its assessment of all residents as well as the skill-sets of individual staff when making staffing decisions. We also propose revisions to improve the logical order and readability of these regulatory provisions.

We propose to include in the introductory language of proposed § 483.35 “Nursing Services” the requirement that, in addition to having sufficient staff to provide nursing care to each resident in accordance with his or her care plan and individual needs, the facility ensure that staff have appropriate competencies and skill sets to assure resident safety. We would also require that the determination of what is sufficient staff as well as the determination of the necessary competencies and skill sets take into account the number, acuity and diagnoses of the facility’s resident population.

We propose to clarify at § 483.35(a)(1)(ii) that nurse aides are included in the term “other nursing personnel.” Currently, a number of provisions regarding nurse aides are included in the regulatory provisions under § 483.75 Administration. Nurse aides provide much, if not most, of the direct care provided in nursing facilities and as a practical matter are managed within most organizations by the nursing services department in medical models of care delivery. We include nurse aides in proposed § 483.35 in recognition of this fact and to ensure clarity of our intent.

We propose 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 propose 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. This continues our focus on ensuring that not only are there a sufficient number of staff in a facility, but also that staff have the necessary abilities, knowledge and competencies to be effective and efficient in carrying out the work necessary to meet the needs of each resident receiving care in the facility.

Consistent with our clarification that nurse aides are included in the term “other nursing personnel,” we propose to move most of the provisions relating to nurse aides previously located in § 483.75 to proposed § 483.35. Specifically, we propose to re-designate § 483.75(f) “Proficiency of Nurse Aides” as § 483.35(c). We propose 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. A proposed revision to the definition of a nurse aide is included in our proposed revisions to § 483.5 and is included in our earlier discussion of that section. The regulations at proposed § 483.35(d)(2) are re-designated from § 483.75(e) and address non-permanent employees Non-permanent caregivers are expected to meet competency, knowledge and skill requirements to the same extent as permanent personnel. These caregivers may have less familiarity than permanent staff with a facility’s residents and processes. Therefore, this must be considered when using, orienting, and assigning non-permanent staff. We also propose to add the term “minimum” to § 483.35(c)(3) to clarify

that this paragraph identifies the minimum requirements for hiring a nurse aide. Meeting this minimum standard does not automatically meet the competency requirement specified in § 483.35 that would be specific to the needs of each individual resident.

L. 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 propose to add a new section § 483.40 to address this requirement as it relates to behavioral health services.

Serious mental illness and cognitive and/or functional impairment are strong predictors of admission into a nursing home. Although estimates vary, the industry literature indicates that a large number of nursing home residents have a significant mental health disorder. In 2004, over 16 percent of nursing home residents received a primary diagnosis of a mental disorder upon admission (Jones, Figure 7). By the time residents were interviewed for the National Nursing Home Survey that percentage increased to almost 22 percent. The 1999 estimate was about 18 percent. In addition, nursing homes are caring for a significant number of patients with dementia and depression. By 2012, over 48 percent of nursing home residents had a diagnosis of Alzheimer’s disease or another dementia and/or depression (Harris-Kojetin, p. 35, Figure 23).

In a 2003 report, the OIG concluded that not all residents of LTC facilities receive the behavioral health services they need. Additionally, there is evidence that there is not full compliance with the requirement to provide medically-related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident (“Psychosocial Services in Skilled Nursing Facilities,” Department of Health and Human Services, Office of the Inspector General, OEI–02–01–00610, March 2003).

Given the prevalence of mental health disorders and other cognitive impairments and in order to achieve the LTC requirements’ goal of the highest practicable mental and psychosocial well-being for each resident, it is critical that LTC facilities ensure that behavioral health issues are addressed. Therefore, we propose to add a new section § 483.40 to include requirements for both behavioral health services and for social workers. These provisions

work in conjunction with other provisions we propose, including those related to reducing the inappropriate use of psychotropic medications.

Currently, sections 1819(b)(7) and 1919(b)(7) of the Act require that a facility with more than 120 beds employ at least one social worker on a full-time basis or assure the provision of social services. However, all facilities are required to 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. Meeting one requirement does not negate the need to meet other requirements. In keeping with our competency focus, we propose to include in new § 483.40 requirements to ensure that there are sufficient direct care staff with the appropriate competencies and skills to provide the necessary care to residents with mental illness and cognitive impairment. The needed competencies and skill sets include knowledge and training, including non-pharmacologic interventions, necessary to provide the care for residents with mental illnesses and psychosocial disorders. Thus, LTC facilities would be required to have the staff, including social workers, necessary to provide the social services needed by their residents.

We propose, in § 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). Necessary competencies and skills include knowledge of and appropriate training and supervision for caring for residents with the mental illness and psychosocial or adjustment problems as well as residents with a history of trauma and/or post-traumatic stress disorder that have been identified in the facility assessment. Furthermore, staff must be trained in implementing non-pharmacological interventions. We propose to specify in new paragraph (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 propose to specify that a resident whose assessment does not reveal or who does not have a diagnosis of a mental illness or psychosocial adjustment difficulty will not display a pattern of decreased social interaction and/or increased withdrawal, 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 mental illness 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 § 483.45; or obtain the required services from an outside provider of specialized rehabilitative services in accordance with proposed § 483.75(g).

We encourage facilities to take advantage of the many tools and resources available to them for free or at low cost. Facilities may also contact CMS staff at dnh_behavioralhealth@cms.hhs.gov, to be put in touch with state coalition leads and state-level resources.

M. Pharmacy Services (§ 483.45)

Currently, the LTC requirements require that each resident's drug regimen be reviewed by a pharmacist at least once a month (§ 483.60(c)). Based on our experience with LTC facilities, some pharmacists review the medical chart for each resident when they perform the drug regimen review, and others simply review the medication administration record (MAR).

We believe that there are specific circumstances under which the pharmacist must at least periodically review the resident's medical record concurrently with the drug regimen review. Those circumstances include transitions in care, specifically when the resident is new to the facility or is returning or being transferred from another facility. We also believe it is critical when a resident is on a psychotropic or antimicrobial medication. In addition, we propose specific requirements related to the use of psychotropic drugs, § 483.45(e), and antibiotics, § 483.80(a)(2). We believe having the pharmacist review residents' medical charts when these medications are prescribed would not only assist the pharmacist in detecting irregularities related to these drugs but also enhance or contribute to the goal of ensuring that these medications are used only when medically appropriate for the resident.

We also believe that the pharmacist's review could contribute to our proposed requirements for infection control and antibiotic stewardship. By reviewing the resident's medical chart, the pharmacist could review whether an infection or communicable disease has been documented in the chart, whether the antibiotic is usually prescribed for that condition, and whether it has been prescribed for the recommended length of time. To maximize the effectiveness of this review, we would recommend that the pharmacist be familiar with the facility's antibiotic use protocols and its system for monitoring antibiotic use. Thus, we propose that a pharmacist be required to review the resident's medical record coincident with the drug regimen review 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. We are proposing the last criteria to give each facility's QAA Committee the ability to request that certain drugs receive more scrutiny during the monthly drug regimen review. For example, anticoagulants and antidiabetic medications have been identified as being related to adverse events related to medications in SNFs (Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries. Office of Evaluations and Inspections, Report OEI-06-11-00370. Office of Inspector General, Department of Health & Human Services. (2014)). Our proposal would give the facility's QAA Committee the ability to add specific drugs or drug categories that need additional scrutiny so that those residents on those drugs would have their medical record reviewed by a pharmacist as part of the monthly drug review. In addition, we encourage the QAA Committee to collaborate with the pharmacist to enhance the committee's understanding and oversight of the facility's pharmaceutical practices, especially concerning the use of psychotropic drugs and its antibiotic stewardship, as well as their QAPI activities.

The current LTC requirements at § 483.25(l)(2) also specifically identify antipsychotic drugs and provide specific safeguards for their use. Section 483.25(l)(2)(i) requires that residents who have not previously been prescribed antipsychotics not be given them unless the medication is necessary

to treat a specific condition as diagnosed and documented in the clinical record. Also, § 483.25(l)(2)(ii) requires that residents taking antipsychotics should receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue use of these drugs. In this proposed rule, we are moving this requirement to § 483.45(e).

Antipsychotics are a particular concern for residents. These drugs have serious side effects and can be especially dangerous for the elderly. Since the LTC requirements became effective in 1992, there has been a reduction in the number of antipsychotics prescribed to residents. However, we are concerned that as the use of antipsychotic drugs has decreased, the use of other psychotropic medications has increased. Therefore, we propose to expand the drugs to which proposed § 483.45(e) applies to include all psychotropic medications. In conducting our research into a definition for psychotropic medications, we discovered different definitions. We are proposing to use the definition used in the November 2001 OIG report, "Psychotropic Drug Use in Nursing Homes" (OEI-02-00-00490), which is that they are drugs that affect brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (1) Antipsychotic, (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. We are proposing the last category, "(6) any other drug that results in effects similar to the drugs listed above," to address other medications. We are also specifically soliciting comments on this definition and the types of drugs that should be included.

In addition, we are concerned about the PRN use of psychotropic medications. A PRN order is often used to titrate or adjust the dosage of a psychotropic medication until an appropriate therapeutic dose is determined for the resident. However, we have received reports that some residents remain on PRN orders for psychotropic medications for extended periods of time. Therefore, we are proposing that LTC facilities ensure that 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. In addition, every PRN order for a psychotropic drug is limited to 48 hours and cannot be continued beyond that

time unless the resident's primary care provider, for example, his or her physician, documents the justification for this continuation in the resident's clinical record. We would also appreciate comments on the use of PRN orders for these medications and our proposal to limit PRN prescriptions for these drugs to 48 hours unless the resident's primary care provider provides a rationale for the continuation of the PRN order in the resident's clinical record.

The current LTC requirements also require the pharmacist conducting the monthly drug regimen review must report any irregularities to the attending physician and the director of nursing. The term "irregularities" is not defined in the regulation and no examples are given. We propose to define "irregularities" to include, but not be limited to, the use of any drug that meets the criteria set forth in proposed paragraph (d) for an unnecessary drug. In addition, we propose to require that the pharmacist performing the monthly drug regimen review must report any "irregularities" to the attending physician and the facility's medical director and the director of nursing, and that these reports must be acted upon (re-designated in proposed § 483.45(c)(4)). However, it does not indicate how the pharmacist is to notify these individuals or how to ascertain if the report was acted upon. Based on our experience with facilities, this reporting of irregularities has been communicated in different ways, including by simply making a note in the resident's medical chart that the drug will be continued as ordered. We are concerned that the pharmacist's report of irregularities may not be given the appropriate review and consideration that is merited. Therefore, we propose that the medical director be added to the individuals who should be notified of irregularities in residents' drug regimens. We also propose 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 noted. We are not proposing the manner in which this report is developed or transmitted because we want nursing homes to have the flexibility to comply with this proposed requirement in the most efficient manner considering their circumstances. For example, for many nursing homes, the facility may develop an electronic form that the pharmacist can fill out on-line as he or she is performing the reviews and pre-populating the emails to which the form is to be sent to include, at a minimum, the attending physician, medical

director, and director of nursing. Other nursing homes may need to develop a paper form and ensure that copies are transmitted to the appropriate individuals. To ensure that the reported irregularities are acted upon, we are also proposing that 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.

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. Furthermore, the requirements for the facility to maintain a medication error rate of no greater than 5 percent and to keep residents free of any significant medication errors is set forth in current § 483.25(m). After reviewing the existing provisions, we believe that these requirements should be relocated from § 483.25 "Quality of Care" to proposed § 483.45 "Pharmacy services." All of these requirements are concerned with medications and medication errors. Although medication errors and unnecessary drugs are clearly part of the quality of care that residents receive, we believe it is more appropriate and logical to relocate these requirements under the general section at proposed § 483.45, "Pharmacy Services." This relocation should make it easier for individuals to locate the requirements concerning medications since they will all be set forth in the pharmacy services section.

We 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 for a specific condition that requires these medications. Our proposed requirements are intended to protect nursing home residents from drugs that are not being prescribed for their benefit. Our proposed requirements for gradual drug reductions, if not clinically contraindicated, and for behavioral interventions are intended to reduce or, if possible, eliminate the need for these medications. Likewise, our proposed requirement for a 48 hour limitation on PRN orders for psychotropic medications is intended to safeguard the resident's health. We are concerned about reports that PRN orders for these

drugs may remain in effect for an extended time without being reviewed by the resident's physician or primary care provider. These proposed requirements are completely in alignment with the concepts and requirements of person-center care and the requirement that residents receive 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 (Proposed §§ 483.21 and 483.40). Therefore, we do not believe these proposed requirements should discourage the use of psychotropic medications when these drugs are required for the resident's benefit.

N. 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. In an effort to improve the readability of our regulations and follow our proposed reorganization of subpart B, we propose to relocate and re-designate both § 483.75(j) and § 483.75(k) to a new proposed § 483.50 entitled, "Laboratory, Radiology, and Other Diagnostic Services." This proposed new section would include all of the content from current § 483.75(j) and § 483.75(k) relocated to § 483.50(a) and § 483.50(b), respectively. We propose to retain the existing requirements with some revisions as discussed in detail below.

Current § 483.75(j)(a)(2)(i) and § 483.75(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 propose 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 would be located at proposed § 483.50(a)(2)(i) and (b)(2)(i), respectively. Furthermore, we would allow for these orders only if the practitioners are acting in accordance with state law, including scope of practice laws and facility policy. We believe that this proposal reflects current practice models and recognizes the importance of non-physician

practitioners in LTC facilities. These revisions would also increase access to care by avoiding possible delays in treatment of residents as well as eliminate burden to attending physicians by clarifying the services that non-physician practitioners can provide.

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 are sympathetic to stakeholder concerns regarding the potential for disruption that notification of attending physicians for nonemergency results or findings could cause. Therefore, we are proposing 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 propose 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 propose in § 483.50(a)(2)(ii) to clarify that the laboratory must promptly notify the ordering professional if results fall outside of clinical reference or expected "normal" ranges, unless the orders for the test or the facility's policies and procedures require otherwise. While we want to ensure that the lab notifies the appropriate professional, we also want to reduce unnecessary notification of staff. We believe this revision would improve the notification process, therefore saving time and reducing burden, while still ensuring resident safety.

We received a comment from stakeholders requesting that we revise the regulations to explicitly state that laboratory and diagnostic services be provided or obtained from "a certified or accredited company." Current § 483.75(j)(1)(i) (now re-designated in proposed § 483.50(a)(1)(i)), provides that laboratory services provided in a facility are subject to the requirements set forth in 42 CFR part 493 under the Clinical Laboratory Improvement Amendment (CLIA). Part 493 sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens. In addition, current § 483.75(k)(1)(i) specifies that if a facility provides its own diagnostic services, the services must meet the requirements set forth in § 482.26. Section 482.26 sets forth the conditions of participation that a hospital must meet to provide diagnostic radiologic services including staff qualifications.

Similarly, current § 483.75(k)(ii) specifies that if the facility does not provide its own diagnostic services, it must have an agreement to obtain the services from a provider or supplier that is approved to provide the services under Medicare. We believe that the current requirements for laboratory and diagnostic services to be furnished by qualified laboratories and facilities are sufficient, and are proposing to retain it without change.

O. Dental Services (§ 483.55)

Under the proposed reorganization, requirements regarding dental services would remain at § 483.55. Section 1862(a)(12) of the Act states, in part, that Medicare will not cover dental services such as the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. State plans 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. We recognize that dental care supports the overall well-being of all facility residents. 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 propose limited changes to update and clarify this section. First, we propose 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. We considered, but are not specifying in this proposed rule, the circumstances under which a facility is responsible, believing that facilities already make this determination, but we do specify that the determination must be made pursuant to facility policy. We welcome comment on this issue. Second, we propose 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 propose 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. We note that facilities could comply with these provisions by referring and transporting residents to a dental clinic or dental school rather than a dentist's office. We also understand that in some facilities, dental services are provided in the facility. In these instances, the facility

would be in compliance with these provisions by assisting resident access to the dental office within the facility. Finally, we propose 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 believe that it is imperative that the loss or damage is addressed and corrected quickly to avoid adverse consequences such as weight loss. We propose 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.

P. Food and Nutrition Services
(§ 483.60)

Dietary standards for residents of LTC facilities are critical to both quality of care and quality of life. An August 2011 report by the Pioneer Network Food and Dining Clinical Standards Task Force notes research by Simmons and others (Simmons SF, Lim B & Schnelle JF. (2002). Accuracy of Minimum Data Set in identifying residents at risk for undernutrition: Oral intake and food complaints. *Journal of the American Medical Directors' Association*, 3(May/June):140-145) that 50 to 70 percent of residents leave 25 percent or more of their food uneaten at most meals and that documentation by facility staff on food consumption is inaccurate. A 2005 position paper by the American Dietetic Association suggests that malnutrition is one of the most serious problems in LTC and is associated with poor outcomes ([http://www.journals.elsevierhealth.com/periodicals/yjada/article/S0002-8223\(05\)01742-6/fulltext](http://www.journals.elsevierhealth.com/periodicals/yjada/article/S0002-8223(05)01742-6/fulltext)). Malnutrition, protein-energy under nutrition (PEU), and dehydration can have a deleterious cascade effect on residents, resulting in a downward spiral of declining physical, mental and psychosocial well-being. An earlier (2000) report sponsored by the Commonwealth Fund stated that between 35 percent and 85 percent of nursing home residents are malnourished and between 3 percent and 50 percent are substandard in bodyweight (<http://www.commonwealthfund.org/-/media/Files/Publications/Fund%20Report/2000/Jul/Malnutrition%20and%20Dehydration%20in%20Nursing%20Homes%20%20Key%20Issues%20in%20Prevention%20and%20>

Treatment/burger_mal_386%20pdf.pdf). Thus, in considering requirements for food and nutrition services in facilities, we seek to establish minimum health and safety standards that support the nutritional well-being of all nursing home residents while respecting each resident's right to make informed choices about his or her care, including decisions about diet. Given the diversity of nursing home residents, it may be challenging for facilities to meet every resident's individual preferences every time; however, we believe by incorporating a facility assessment, along with individual assessments, more can be done to ensure residents are offered meaningful choices in diets that are nutritionally adequate and satisfying to the individual. At the same time, we do not intend to require a facility to provide on an ongoing basis a diet that would be impractical or financially unreasonable. Therefore, we propose revisions described below consistent with our goals to provide flexibility for the facility while enhancing resident choice. We believe that this will lead to overall improvement in the nutritional status of nursing home residents.

It is not enough; however, to ensure that residents have choices in what they eat. Many nursing home residents have other barriers to eating, including dental issues, medical issues, medication-related issues, physical limitations and the need for proper positioning and assistance at mealtimes. With so many issues facing nursing home residents, adequate nutrition requires both an understanding of the facility's population as a whole and an interdisciplinary approach for each resident. This includes ensuring that sufficient staff are available and have the appropriate skill sets, competencies, and training to assess and plan an overall facility dietary program as well as assess and assist individual residents at meals and with snacks. Some individual residents may require assistance to get to a dining area or to sit up in a comfortable position conducive to eating. Other residents may require the correct application and set up of assistive devices or may need an individual to sit with them and actively assist them throughout the meal. Thus, our proposed revisions include person-centered requirements that are outcome focused and intended to ensure each resident is provided, in a dignified manner, the nutritional and dietary care and services needed to meet the statutory goal of attaining or maintaining his or her highest practicable mental, physical and

psychosocial well-being. We propose to revise this section as follows:

We propose to re-designate existing § 483.35 "Dietary Services" as new proposed § 483.60 "Food and Nutrition Services" and revise the introductory language to include taking resident preferences into consideration. We propose 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 proposed § 483.60(a)(1) we would 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. The role of the dietitian is critical in the delivery of food and nutrition services. Dietitians are part of the interdisciplinary team and play a significant role, working with other clinicians, to treat wounds, weight-gain or -loss, protein malnutrition, dehydration, and nutrition-related chronic diseases such as diabetes, congestive heart failure and chronic obstructive pulmonary disease. The dietitian is the subject-matter expert for making person-centered recommendations to ensure the nutritional well-being of each resident. In addition to individual evaluations, the dietitian plays a vital role in developing the nursing home's overall menus. This means the dietitian must understand the general and individual needs of the population of the nursing home, encompassing not just minimum nutritional needs, but also diversity and cultural variety of the residents and work with the director of food service to craft menus to serve the facility population. Finally, the dietitian plays a role in managing and monitoring the dietary staff and food quality, including nutritional standards, food service standards, and infection control standards. In order to ensure the highest level of expertise to meet these requirements, we are proposing to require minimum qualifications for dietitians working in SNFs or NFs. We propose 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. Currently, five states (AZ, CA, CO, NJ, and VA) do not license or certify

dietitians. We note that the California State Personnel Board requires valid certificate of registration with the Commission on Dietetic Registration of the American Dietetic Association to qualify for state employment in various dietetic positions. We would allow for the retention of dietitians hired or contracted prior to the effective dates of the revised regulations, for a period of no longer than 5 years after the effective date of a finalized requirement. We propose to change the requirement for employment of a dietitian on a full-time, part-time or consultant basis to allow for employment of other clinically qualified nutrition professionals who are recognized (licensed or certified) by the state in which the SNF or NF operates. Retaining the option to employ a dietitian or other clinically qualified nutrition professional less than full-time would allow flexibility for small facilities and alternative care delivery models. We note that regardless of how the facility chooses to obtain the services of a dietitian or other clinically qualified nutrition professional, the facility must ensure it achieves the required outcomes for food and nutrition services, both in terms of providing a nourishing, palatable, balanced diet and in terms of ensuring that each resident is provided the necessary services, both assessment and care delivery, to achieve his or her highest practicable physical, mental, and psychosocial well-being.

In re-designated § 483.60(a)(2), we propose to continue to require that, 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 receives frequently scheduled consultation from a qualified dietitian. We do not currently establish any standards for a director of food and nutrition services. However, we believe that this position is responsible for critical aspects of food and nutrition services and we believe this individual should have specialized training to manage menus, food purchasing, and food preparation; to be able to apply nutrition principles, document nutrition information, ensure food safety and sanitary procedures, and to manage staff and work teams. We propose to require that the director of food and nutrition services, if hired or designated after the effective date of these regulations, must 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, the director of food and nutrition services may 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, the director of food and nutrition services would meet our proposed requirement if he or she meets applicable state requirements to be a food service manager or dietary manager. We do not suggest that a the director of food and nutrition services replaces the specialized expertise of qualified dietitians or other clinically qualified nutrition professionals; however, with their expertise in managing dietary operations in a facility, they may provide needed expertise and assistance in combination with a qualified dietitian or other clinically qualified nutrition professional to achieve the necessary quality of food and nutrition services for residents.

In new § 483.60(a)(4), we propose 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. The current regulations require that the facility employ sufficient support personnel to carry out the functions of the dietary service. Our proposed revisions would clarify that those support personnel must have the requisite skill sets that take into account an assessment of the facility and considering the individual needs of residents. We believe that most facilities already meet this requirement; however, because nutrition and dining safety are critical to the well-being of residents, we think it is important to be more explicit in our expectations. In particular, we think it is imperative that facilities consider not just the number of residents when making staffing decisions, but the acuity and diagnoses

of residents in order to provide effective and appropriate food and nutrition services. SNF and NF residents have become sicker and more complex over time and this must be factored into staffing decisions, both in terms of how many staff are present and the skill sets and competencies the staff need to have.

We propose a new § 483.60(b) to specify that a member of food and nutrition services also participate in the IDT. The registered dietitian or other clinically qualified nutrition professional is a critical member of the IDT; however, in some cases another member of food and nutrition services with the appropriate skill sets and competencies may be an acceptable alternative. Nutrition is an integral aspect of a resident's well-being, thus it is critical an individual knowledgeable about the facility capabilities as well as the resident's needs and preferences participate in the interdisciplinary team in order to ensure that resident can achieve or maintain his or her maximum practicable well-being.

In proposed § 483.60(c)(1), we would change "Recommended Dietary Allowances" to "established national guidelines or industry standards." For example, United States Department of Agriculture provides an online, interactive tool for healthcare professions to calculate daily nutrient recommendations for dietary planning based on the Dietary Reference Intakes (DRIs) at <http://fnic.nal.usda.gov/fnic/interactiveDRI/>. The DRIs are the Food and Nutrition Board of the Institute of Medicine's update to the Recommended Dietary Allowances, developed in partnership with Health Canada. Since 1998, the Institute of Medicine has issued a series of DRIs that offer quantitative estimates of nutrient intakes to be used for planning and assessing diets applicable to healthy individuals in the United States and Canada. Additional information on the DRIs, including access to 14 nutrient specific reports and several summary charts, are available in the USDA Food and Nutrition Information Center at <http://fnic.nal.usda.gov/>. We also propose 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. While we do not require that every resident be afforded every possible choice at any time, we are cognizant of the importance of appropriate choice availability. Utilizing information from a facility assessment and from residents and resident groups should assist in ensuring that appropriate options are

available to residents under most circumstances.

In proposed § 483.60(d), we propose minor revisions to incorporate the addition of drinks, to clarify that “proper” means 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. We believe it is critical to specifically include dietary fluids in our regulations pertaining to food and nutrition services. Hydration is a critical aspect of nutrition and elderly people who do not receive adequate fluids are more susceptible to urinary tract infections, pneumonia, decubitus ulcers, and confusion and disorientation. Chidester, J.C., and Spangler, A.A., “Fluid Intake in the Institutionalized Elderly,” *Journal of the American Dietetic Association* 97 (1997):23–30. Orthostasis, confusion and disorientation, function decline, recurrent falls, pressure sores, urinary tract infections, pneumonia, and skin infections are all common conditions associated with inadequate fluid intake in frail, elderly long-term care residents. Feinsod, F., Levenson, S., Rapp, K., Rapp, M., Beechinor, E., & Liebmann, L. (2004). “Dehydration in frail, older residents in long-term care facilities.” *Journal of The American Medical Directors Association*, 5(2 Suppl), S35–S41. Available from: MEDLINE with Full Text, Ipswich, MA. A 1999 study by Gaspar revealed that only 8 of 99 nursing home residents observed met their standard water requirement based on two 24 hour observation periods. (Gasper, P.M. “Water Intake of Nursing Home Residents.” *Journal of Gerontologic Nursing*. 1999;25(4):22–29.)

In new § 483.60(e) “Therapeutic diets,” we propose to retain the requirement in current § 483.35(e) that therapeutic diets be prescribed by the attending physician. However, we propose 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. While the statute requires physician supervision of each resident’s nursing home care, we believe that the physician can delegate authority to a dietitian or other clinically qualified nutrition professional to write dietary orders, so long as the authority is consistent with dietitian or other clinically qualified nutrition

professional practice allowed under state law. In this instance, the physician is responsible for making the decision of whether or not to delegate this task and remains responsible for the resident’s care even if the task is delegated. Further, if necessary, the physician would be able to modify a diet order with a subsequent physician order. We believe this is consistent with other tasks that the physician may delegate and may allow for more efficient use of physician time and effort and more frequent assessment and updating of diet orders by an on-site dietitian or other clinically qualified nutrition professional. We believe qualified dietitians and other clinically qualified nutrition professionals are well qualified to assess a resident’s nutritional status and design and implement a nutritional treatment plan in consultation with the resident’s interdisciplinary team. In order for residents to receive timely nutritional care, the qualified dietitian or other clinically qualified nutrition professional must be viewed as an integral member of the IDT who, as the team’s clinical nutrition expert, is responsible for a resident’s nutritional evaluation and treatment in light of the resident’s medical diagnosis. Without allowing for the delegation for writing diet orders to qualified dietitians or other clinically qualified nutrition professionals, nursing homes will not be able to effectively realize the improved resident outcomes and overall cost savings that we believe would be possible with these changes. However, we note that because a few states elect not to use the regulatory term “registered” and choose instead to use the term “licensed” (or use no modifying term at all), we are proposing to use the term “qualified dietitian.” Our intention is to include all qualified dietitians, regardless of the modifying term (or lack thereof), as long as each qualified dietitian meets the requirements of his or her respective state laws. We also recognize that there are other nutrition professionals who are equally qualified to provide required services and we are expressly including these or other clinically qualified nutrition professionals to the extent they are authorized under state law.

We propose to modify § 483.35(f) in re-designated § 483.60(f) regarding frequency of meals. Specifically, we propose to modify the requirement that facilities provide and residents receive 3 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 propose

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, and focus instead on when residents prefer to eat and on ensuring that meal service is provided to meet residents’ clinical and nutritional needs. Rather, we propose to require instead 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 plan of care. By suitable, nourishing alternative meals, we mean that when a resident misses a meal or snack, an alternative of comparable nutritive value to the missed meal or snack should be provided. We do not intend to require a 24-hour-a-day full service food operation or an on-site chef. Suitable alternatives may be meals prepared in advance that can be appropriately served by appropriately trained facility staff at non-traditional times. For example, staff may be trained to safely re-heat soup and serve a sandwich as a reasonable alternative for a resident who prefers to eat a late supper, so long as it meets the resident’s nutritional needs, takes into consideration the resident’s preferences, and is prepared using safe food handling techniques.

We propose 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 propose 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). We believe the use of paid feeding assistants provides a valuable flexibility to nursing facilities and can serve to ensure that residents requiring dining assistance are able to receive it. In § 483.60(h)(2)(ii), we propose to eliminate the reference to the resident call system. 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.” Paid feeding assistants should be able to call for assistance in whatever manner is most efficient rather than be limited to a specific call system. We focus on the outcome of getting assistance rather than on the mechanism used to request it. We also propose to have the IDT

make the determination if a resident is appropriate for assistance by a paid feeding assistant which would be separate from a charge nurse's ability and responsibility to make work assignments on a more immediate basis reflecting the current situation.

In proposed § 483.60(i), we clarify in new § 483.60(i)(1)(i) that facilities may procure food directly from local producers—farmers or growers, in accordance with state and local laws or regulations. We further propose to clarify in new § 483.60(i)(1)(ii) that this provision does not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and handling practices, such as using pesticides in accordance with manufacturers' instructions. We note that facilities are required under proposed § 483.70(b) and (c) to be in compliance with applicable federal, state and local laws, regulations and codes and professional standards as well as other HHS regulations. We believe this includes food service requirements applicable to facilities and note that most states and territories have adopted some version of the FDA model food code (<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms/ucm108156.htm>). We expect that facilities comply with these requirements as required by state law. Consistent with § 483.70(b), we propose 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 considered requiring a Hazard Analysis and Critical Control Points (HACCP) program in facilities; however, we are concerned about the application of this requirement in innovative and small health care delivery models. We understand this may be a requirement under some state or local laws and solicit comment on whether or not a HACCP program should be required in all SNFs and NFs. We propose 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. A resident has the right to make choices, including the right to decide whether or not to accept food from family, friends, or other visitors and guests. However, the facility has a responsibility to help family, visitors, and residents understand safe food handling practices. If facility staff is assisting with reheating or other preparation activities for food brought by visitors, the facility staff

must use safe food handling practices and encourage visitors and residents who are contributing to food preparation to also use these safe practices. We believe having a policy in place to address use and storage of foods brought to residents will help ensure consistent application of safe and sanitary food handling practices by staff when these foods are present in the facility.

Q. 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 mental illness. Following our proposed reorganization of part 483 subpart B, we propose to relocate these existing provisions to proposed § 483.65 with minor revisions. Consistent with specialized rehabilitative services, the need for respiratory therapy and respiratory illnesses are very common among older adults; however, the current regulations do not discuss respiratory therapy. According to data collected by the Centers for Disease Control and Prevention (CDC), 6.7 percent of nursing home residents have some form of disease of the respiratory system at the time of their admission into a nursing home (The National Nursing Home Survey, 2004 overview: National Center for health Statistics [on-line]. <http://www.cdc.gov/nchs/about/major/nnhsd/nnhsd.htm>. Accessed January 10, 2013). In addition to the occurrence of respiratory illnesses at admission, outbreaks of respiratory tract infections are also common in LTC facilities among older adults. In LTC facilities, rates of pneumonia as high as 42 percent and case-fatality rates exceeding 70 percent have been reported in outbreaks due to the influenza virus (Loeb M, McGeer A, McArthur, Peeling R, Petric M, Simor A. Surveillance for outbreaks of respiratory tract infections in nursing homes (cover story). *CMAJ: Canadian Medical Association Journal* [serial online]. April 18, 2000;162(8):1133–1137. Available from: Health Policy Reference Center, Ipswich, MA. Accessed January 23, 2013).

Given these statistics and our prior knowledge about the need for respiratory related treatment and therapy in facilities, we propose at re-designated § 483.65(a) to specifically add respiratory therapy to the list of specialized rehabilitative services.

Adding this service to the regulations would reflect the more current needs of facility residents. The addition of this service would also explicitly require facilities to provide or obtain these services when necessary and meet the needs of residents facing respiratory issues. However, this would not change coverage policy regarding respiratory therapy. At § 483.65(a)(2), we propose to clarify that when it is necessary for facilities to obtain these services from an outside source, the provider should be a certified Medicare and/or Medicaid provider.

Secondly, we propose to clarify the meaning of specialized rehabilitative services in relation to PASARR. Current requirements do not clarify what specialized rehabilitative services for mental illness are and this has led to confusion among providers, states, and others. Therefore, to eliminate confusion and provide clarification, we propose to add in § 483.65 a cross reference to the PASARR regulations at § 483.120(c) which define the mental health or intellectual disability services a nursing facility must provide to all residents who need these services. In addition, we would correct a typographical error deleting the redundant “mental health” before “rehabilitative services for mental illness and intellectual disability”.

R. Outpatient Rehabilitative Services (§ 483.67)

We propose 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 note 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 understand that some, and possible many, facilities provide rehabilitative services on an outpatient basis and that these services may be paid for under Medicare Part B (see section 1861(p) of the Act, implementing regulations at 42 CFR 410.60(b), and the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 15, § 220.1.4.) Therefore, we believe it is necessary to ensure that services meet health and safety standards. We propose to require facilities that provide outpatient rehabilitative therapy services to meet requirements similar to those already established for hospitals. Specifically, we propose 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. The requirements include at proposed § 483.67(a) that the organization of the service must be appropriate to the scope of the services offered. In proposed § 483.67(b), we are proposing 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 propose to require that the facility must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered. In addition, we propose 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. In proposed § 483.68(c) we would 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 propose to require that the provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice. We believe the addition of these provisions is necessary to ensure that outpatient rehabilitative services provided by facilities meet health and safety standards.

S. Administration (§ 483.70)

We propose to re-designate current § 483.75 "Administration" as § 483.70. In paragraph (c), we propose 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 would 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). In proposed § 483.70(d)(2)(i) we would 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 propose to add a new § 483.70(d)(2)(iii) to specify that the nursing home administrator would report to and be accountable to the governing body. We are concerned that the governing body can appoint the nursing home administrator but is not, on an ongoing basis, required to remain cognizant of the operations and management of the facility. Given that the governing body is responsible for implementing the management and operations of the facility, we believe it is important to ensure that it remains informed and knowledgeable regarding those issues. We also propose 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). We propose to re-designate and revise existing § 483.75(e) and (f), provisions regarding nurse aides, to our proposed section on Nursing Services at § 483.35 or our proposed new section on Training at § 483.95. We refer readers to see the separate discussions under those sections.

We propose 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. Please see our separate discussions of the new section.

We are proposing a new § 483.70(e) which would establish a new requirement for an annual facility assessment. This new requirement would be a central feature of our revisions to subpart B and is intended to be used by the facility for multiple purposes, including but not limited to activities such as determining staffing requirements, establishing a QAPI program, and conducting emergency preparedness planning. This is similar to existing common business practices for strategic planning and capital budget planning and we believe that facilities will find this assessment useful beyond what is required to meet our requirements. This 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. This assessment would

have to be facility and community-based, utilizing an all-hazards approach. The facility would have to review and update the assessment as necessary, but at least annually and whenever there was, or the facility planned for, any change that would require a substantial modification to any part of the assessment. We propose 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, 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.

In conducting the facility assessment, we did not propose that the facility include any input from either the resident or any other individuals who have a personal interest in the resident. We 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. However, we encourage facilities to determine when it would be appropriate to seek input from the resident, the resident's representative or any of the resident's family or friends and consider that

information in formulating their assessment.

We propose 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 propose to re-designate existing § 483.75(l) as proposed § 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 propose minor revisions in it to clarify that the clinical record must contain the resident's comprehensive plan of care and physician's and other licensed professional's progress notes. It is important that the clinical record reflect the services provided across disciplines to ensure information is readily available when needed and to facilitate communication among the interdisciplinary team. Existing paragraph (m) would 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).

In proposed § 483.70(j), "Transfer Agreement," we propose 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 and consistent with state law and facility policy. We believe this is both appropriate and necessary to promote prompt treatment and protect resident safety. We further propose to specify here that the information exchange required by existing paragraph § 483.75(n)(ii) be modified to require that the exchanged information include, at a minimum, the information we propose to require under new paragraph § 483.15(b)(2)(iii)(B). As discussed earlier, the effective exchange of information can reduce the risk inherent to transitions of care and promote improved resident outcomes.

We propose to incorporate existing § 483.75(o), assessment and quality assurance, into proposed § 483.75(c). New § 483.75 will also include requirements established under section 6102 of the Affordable Care Act for a QAPI program. We refer readers to the separate discussion on QAPI, in Section II.S. of this proposed rule.

Provisions on Disclosure of Ownership, Facility Closure-Administrator, Facility Closure, and Hospice services are re-designated as paragraphs § 483.75(k), (l), (m), and (o) respectively, and the cross-reference in proposed (m) updated, but otherwise unchanged. We propose to address

training of paid feeding assistants in our proposed new § 483.95—Training requirements.

We propose 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. Alternative dispute resolution (ADR), including binding arbitration, has become increasingly popular in recent years. However, unlike other forms of ADR, binding arbitration requires that both parties waive the right to any type of judicial review or relief. While this can be a valid agreement when entered into by individuals with equal bargaining power, we are concerned that the facilities' superior bargaining power could result in a resident feeling coerced into signing the agreement. Also, if the agreement is not explained to the resident, he or she may be waiving an important right, the right to judicial relief, without fully understanding what he or she is waiving. Also, the increasing prevalence of these agreements could be detrimental to residents' health and safety and may create barriers for surveyors and other responsible parties to obtain information related to serious quality of care issues. This results not only from the residents' waiver of judicial review, but also from the possible inclusion of confidentiality clauses that prohibit the resident and others from discussing any incidents with individuals outside the facility, such as surveyors and representatives of the Office of the State Long-Term Care Ombudsman.

We propose 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 must not contain any language that prohibits or discourages 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). The explanation must state, at a minimum, that the resident is waiving his or her right to judicial relief for any potential cause of action covered by the agreement. The agreement must be entered into by the resident voluntarily and provide for the selection of a neutral arbitrator and a venue

convenient to both parties, the resident and the facility. An agreement will not be considered to have been entered into voluntarily by the resident if the facility makes it a condition of admission, readmission, or the continuation of his or her residence at the facility. Thus, we believe that any agreement for binding arbitration should not be contained within any other agreement or paperwork addressing any other issues. It should be a separate agreement in which the resident must make an affirmative choice to either accept or reject binding arbitration for disputes between the resident and the facility. Finally, in order to address concerns about conflict of interest when the resident has a guardian that is affiliated with the facility, we propose to specify that the guardians or representatives cannot consent to an agreement for binding arbitration on the resident's behalf unless that individual is allowed to do so under state law, all of the other requirements in this section is met, and the individual has no interest in the facility. We are also aware that there are concerns that these agreements should be prohibited in the case of nursing home residents. Therefore, we are also soliciting comments on whether binding arbitration agreements should be prohibited.

We propose to relocate the requirement for and qualifications of a social worker from the current § 483.15(g)(3) to proposed § 483.70(p). In addition, there is a list of human services fields from which a bachelors degree could provide the minimum educational requirement for a social worker. We propose to add "gerontology" to that list of human services fields. We would also welcome comments related to qualifications for the social worker, especially whether state licensure should remain the threshold requirement or if additional requirements are appropriate.

Finally, in our proposed rule "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. In this proposed regulation, we are proposing to redesignate § 483.75(u) (as set out in the April 20, 2015 proposed rule at 80 FR 22044) to § 483.70(q).

T. 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 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 regulations are promulgated, 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. This proposed rule would establish these programmatic 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. While our proposal retains the existing QAA requirements at § 483.75(o), these requirements alone do not conform to the current health care industry standards that proactively design quality improvement into each program at the outset, monitor data (indicators, measures and reports of staff/residents/families), determine root causes of problems, design and use performance improvement projects (PIPs) to promote continuous improvement, develop and implement plans that effect system improvement, and monitor the success of this

systematic approach to improving quality. The focus of a QAPI approach is to optimize quality improvement activities and programs comprehensively and proactively, even in areas where no specific deficiencies are noted. The QAPI program should include standards for quality assurance, active feedback systems to monitor performance, and continuous efforts to optimize program design through quality improvement activities and proactive strategies. The QAPI requirements we propose would not replace the QAA committee requirements but would enhance and be coordinated with these requirements.

The QAPI program utilizes objective data to study and continually make improvements to all aspects of an organization's operations and services. It enables facilities to take a systematic approach to reviewing its operating systems and processes of care and identifying and implementing opportunities for improvement. QAPI has significant potential to be an efficient and effective method for improving the quality of care and performance of health care providers.

In 2001, the Institute of Medicine released a pivotal report, "Crossing the Quality Chasm" in which it stated that "the American healthcare delivery system is in need of fundamental change" and recognized that "quality problems are everywhere affecting many patients (<http://www.iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx>). In a 2004 educational publication co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association (AHLA), "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, (<https://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>), the authors discuss the IOM report and state that the oversight of quality and patient safety is becoming clearly recognized as a core fiduciary responsibility of health care organizations. They further note that promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization and suggest that "contemporary health care quality, patient safety and cost efficiency initiatives provide an opportunity for health care organizations to make a positive difference to society while promoting their missions and enhancing

their financial success." Therefore, pursuant to the requirements of the Affordable Care Act and as discussed in detail below, we are proposing to add a new § 483.75 entitled, "Quality Assurance and Performance Improvement."

At proposed § 483.75(a), we would 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 propose that the facility's governing body, or designated persons functioning as a governing body, ensure that the QAPI program is defined, implemented, and maintained and addresses identified priorities. As discussed above, facilities are required to submit the QAPI plan to the Secretary. Therefore, we propose in new § 483.75(a)(1) that the facility would maintain documentation and demonstrate evidence of its QAPI program. This includes but is not limited to the QAPI plan. We propose in new § 483.75(a)(2) that the facility must submit the QAPI plan to the State Agency or federal surveyor, as the agent of the Secretary, at the first annual recertification survey that occurs at least 1 year after the effective date of these regulations. In addition, we propose in new § 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. In addition, we propose in new § 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, will consider such plan in making its certification recommendation and providing evidence to the CMS Regional Office for a compliance determination. We propose this recurring requirement to ensure that the QAPI program is ongoing and that the facility meets the standards established in this section.

At § 483.75(b), we establish requirements for the design and scope of the QAPI program. We propose 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 would always include clinical care, quality of life, and resident choice. It would have 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 propose in new § 483.75(c) to establish requirements for QAPI program feedback, data systems and monitoring. We propose at new § 483.75(c)(1) that, as part of its QAPI process, the facility would have to 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. In new § 483.75(c)(2), we propose 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. In new § 483.75(c)(3), we would require that the policies and procedures include a description of the methodology and frequency for developing, monitoring, and evaluating performance indicators. Finally, in new § 483.75(c)(4), we propose 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. This would include methods by which the facility would obtain information on adverse events and potential adverse events from residents, family and direct care/direct access staff, and how the facility would address and investigate the adverse event or potential adverse event and provide feedback to those same individuals. Adverse events remain a serious problem in LTC facilities. A recent OIG report estimated that 22 percent of Medicare beneficiaries experienced adverse events during a skilled nursing facility stay. Many of those adverse events were preventable. (Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries. Office of

Evaluations and Inspections, Report OEI-06-11-00370. Office of Inspector General, Department of Health & Human Services. (2014)). According to the World Health Organization (WHO), an adverse event is an injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. A near miss is a serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted; it is also called a potential adverse event. (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems. 2005 http://www.who.int/patientsafety/events/05/Reporting_Guidelines.pdf). Examples of situations that would qualify as an adverse event for a facility include, but are not limited to, medication errors, resident injury due to falls, resident injury due to abuse or neglect by caregivers or other residents, failure to identify acute change in condition, pressure ulcers due to inappropriate care and the spread of disease due to errors in infection prevention and control. Near misses in any of these situations would be considered potential adverse events. As discussed in section II.B. of this preamble, we propose to define an adverse event as an untoward, undesirable, and usually unanticipated event that cause death or serious injury, or the risk thereof, consistent with the definition currently established at 42 CFR 482.70 and already in use for transplant centers. However, we are aware that there are other definitions and welcome comments on this definition.

We propose to establish a new § 483.75(d) to address QAPI program systematic analysis and action. We propose 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 propose 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 and effects analysis, for example) to determine underlying causes of problems impacting larger systems. These policies would address the development of corrective actions that would be designed to affect change

at the systems level, and how the facility would monitor the effectiveness of its performance improvement activities to ensure that improvements were sustained.

In § 483.75(e), we propose to establish requirements for program activities. Specifically, we would require at new § 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 propose 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, QAPI program activities would be required to include Performance Improvement Projects (PIPs). Under our proposal, the facility would be required to conduct distinct performance improvement projects. The number and frequency of improvement projects conducted by the facility would have to reflect the scope and complexity of the facility's services and available resources. We propose that each facility would 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. We considered not establishing a minimum requirement or establishing a requirement based on facility size and welcome comment on whether or not there should be a specific number of PIPS and what that number should be. We also considered establishing mandatory PIPs and requiring facilities to implement at least one PIP selected from the mandatory PIPs. We solicit comment on establishing mandatory PIPs, specifically regarding the feasibility for and impact on facilities.

Finally, in new § 483.75(f), we propose to require that the facility ensure, through the governing body or executive leadership, that an ongoing QAPI program is 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, 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.

These proposed requirements for the QAPI program are an outgrowth of the QAPI demonstration project conducted by CMS working with stakeholders, providers and experts. Our proposed requirements directly reflect five elements that were identified through this process as critical to the success of a QAPI program. We discuss this project below under “Technical Assistance for facilities.”

We propose to re-designate § 483.75(o) as § 483.75(g). In § 483.75(g)(1) we propose to revise the language to clarify that the QAA committee membership requirements are a minimum requirement. Facilities may, at their discretion, include additional individuals on their QAA committee. For example, some facilities may wish to include a pharmacist on the QAA committee to coordinate QAPI activities related to reducing the inappropriate use of psychotropic medications. The QAA committee may also benefit from including individuals such as a resident council president, the director of social services or the activities director. We also propose to add the requirement that the Infection Control and Prevention Officer (ICPO) participate in the quality assessment and assurance committee. We consider the ICPO’s coordination with the quality assurance committee and with QAPI activities important to the success of the infection control and prevention program and discuss the need for this further in our section on infection control.

In § 483.75(g)(2), we propose to specify that the quality assessment and assurance committee 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 propose to specify that the committee coordinate and evaluate activities under the QAPI program, including performance improvement projects, and that the committee 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). Section 6102(c)(1) of the Affordable Care Act specifically requires that the implementation of the QAPI plan be coordinated with the quality assessment and assurance activities conducted

under sections 1819(b)(1)(B) and 1919(b)(1)(B) of the Act. As there is significant overlap in the expectations for the QAPI program and the quality assessment and assurance committee, we believe that the existing committee is the appropriate resource to coordinate the QAPI program.

We propose to add a new § 483.75(h) to address disclosure of information. We propose 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 would 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 propose to re-designate § 483.75(o)(4) as § 483.75(i).

In sum, we believe these proposed requirements would ensure that facilities establish and implement QAPI plans that result in continuous quality improvement throughout the facility and enhanced quality of care, quality of life and resident and staff satisfaction, while providing facilities with the flexibility to design, monitor, and maintain QAPI approaches best suited to the type and complexity of services they provide and the needs of their residents.

Technical Assistance for Facilities

In addition to establishing the standards for a QAPI program in this proposed rule, we would provide technical assistance to nursing homes on the development of best practices relating to QAPI. Since 2011, we have worked with stakeholders, providers and experts to develop tools, resources and technical assistance to implement a QAPI program. A demonstration project tested implementation strategies and effectiveness of QAPI tools, resources and technical assistance. Through this process, five critical elements, which are reflected in our proposed requirements, have been identified for a successful QAPI program. The five elements are as follows:

- Design and Scope.
- Governance and Leadership.

- Feedback, Data Systems and Monitoring.
- Performance Improvement Projects.
- Systematic Analysis and Systemic Action.

QAPI materials developed through this process are available at no cost to all facilities at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/QAPI.html>. In addition, facilities may choose from a wide variety of existing professionally recognized quality assurance and performance improvement resources. We discuss a non-exhaustive list of some of these resources below.

Under the direction of CMS, the Medicare Quality Improvement Organization (QIO) Program (www.cms.hhs.gov/QualityImprovementOrgs) consists of a national network of 53 QIOs—one in each state, plus the District of Columbia, Puerto Rico, and the Virgin Islands. QIOs work with beneficiaries, healthcare providers, consumers and stakeholder to achieve national priorities focused on three broad aims of—(1) better care; (2) improved health; and (3) lower costs. QIOs work with nursing homes (among other providers) to focus on a number of quality improvement measures, such as decreasing healthcare associated conditions, providing direct technical assistance and engaging with nursing homes and other long term care providers participating in the National Nursing Home Quality Care Collaborative.

Advancing Excellence in America’s Nursing Homes (<http://www.nhqualitycampaign.org>) is a national campaign to encourage, assist and empower nursing homes to improve the quality of care and life for residents. It is composed of LTC providers, medical professionals, consumers, employees, and is an ongoing, coalition-based campaign focused on improvements in care and services for the elderly, chronically ill and disabled, as well as those recuperating in a nursing home environment. The mission of the Advancing Excellence in America’s Nursing Homes Campaign is to help nursing homes achieve excellence in the quality of care and quality of life for the more than 1.5 million residents in America’s nursing homes by improving clinical and organizational outcomes, among other goals. The Campaign works to achieve its mission by providing free practical and evidence-based resources to support quality improvement efforts in America’s nursing homes.

The State Medicaid Agencies (SMAs) and HHS's Administration for Community Living (ACL) provide online information resources for community care and transition programs, options, supports and services, community care transition planning entities, and contacts and links: www.medicaid.gov; www.mfp-tac.com; and www.acl.gov. Finally, CMS provides links to resources in its existing Interpretive Guidelines that provide information on how to develop and enhance quality improvement programs.

U. Infection Control (§ 483.80)

Healthcare-associated infections (HAIs) often result in considerable suffering for residents in LTC facilities as well as increased costs for the healthcare system. Although estimates vary widely, there are between 1.6 and 3.8 million HAIs in nursing homes every year. Annually, these infections result in an estimated 150,000 hospitalizations, 388,000 deaths, and between \$673 million to \$2 billion dollars in additional healthcare costs (Castle, et al. Nursing home deficiency citations for infection control, American Journal of Infection Control, May 2011; 39, 4). Individuals receiving care in a nursing home may have increased susceptibility to infections as a result of malnutrition, dehydration, comorbidities, or functional impairments, such as urinary and fecal incontinence, or medications that diminish immunity, or immobility. In addition, residents may have a higher risk of exposure to infectious agents in the facility due to socialization among residents, staff, and visitors. The National Action Plan to Prevent Health Care Associated Infections includes a chapter focused on long term care settings that pertains to nursing facilities: <http://www.hhs.gov/ash/initiatives/hai/actionplan/hai-action-plan-ltcf.pdf>. According to the Plan, the most common HAIs in nursing facilities are urinary tract infections, lower respiratory tract infections, skin and soft tissue infections, and gastroenteritis.

Since 1992, our requirements for LTC facilities currently set out at § 483.65 have required these facilities to establish and maintain infection control programs designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection. The program must investigate, control, and prevent infections in the facility; issue and maintain protocols to guide decisions about what procedures, such as isolation, should be applied to an individual resident, and maintain a

record of incidents and corrective actions related to infections. Under § 483.65(b)(1), when the infection control protocol recommends that a resident be isolated to prevent the spread of infection, the facility must isolate the resident. Under § 483.65(b)(2) of our regulations, 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. Under § 483.65(b)(3), the facility must require staff to wash their hands after each direct resident contact. Section 483.65(c) requires LTC facilities to handle, store, process, and transport linens so as to prevent the spread of infection.

Each of these requirements remains important; however, as a result of advances in the study and practice of infection prevention and control and given the impact of HAIs, we find that the current requirements for infection control in our requirements warrant updating and strengthening. In developing our proposals, we reviewed the existing requirements for SNFs and NFs, as well as the current requirements for other Medicare providers and suppliers related to infection control. We also reviewed available research and literature related to infection prevention and control in nursing homes and published infection control guidelines for long term care facilities from the Society for Healthcare Epidemiology of America (SHEA) and the Association for Professionals in Infection Control (APIC) (Smith, P.W., et al., SHEA/APIC Guideline: Infection Prevention and Control in the Long-Term Care Facility, Infection Control and Hospital Epidemiology, Vol. 29, No. 9 (September 2008), pp. 785–814).

We especially want to emphasize the importance of infection prevention and surveillance. As discussed below, we propose that each facility's infection prevention and control program (IPCP) include an antibiotic stewardship program, which includes antibiotic use protocols and antibiotic monitoring. Antibiotic resistance has emerged as a national healthcare concern and even the appropriate use of antibiotics can contribute to antibiotic resistance. Nursing homes are the next frontier where new antibiotic resistant organisms may emerge and flourish. Organisms such as *Clostridium difficile* (C-diff) and methicillin-resistant *Staphylococcus aureus* (MRSA) are known concerns. Nursing homes need to have the tools to participate in surveillance, learn and use infection control and containment practices, and

adopt a proactive approach to preventing spread while being good stewards of antibiotics to preserve effectiveness of the agents we have today. While avoiding the inappropriate use of antibiotics is critical, one of the best mechanisms to combat the rise in antibiotic resistance is to prevent infections and, when they do occur, prevent the spread of the infection to others (Spellberg, Brad, et al., The Future of Antibiotics and Resistance, The New England Journal of Medicine, 368:4 (January 24, 2013), pp. 299–302). In addition, the Centers for Disease Control and Prevention (CDC) has identified four core actions to prevent antibiotic resistance (Frieden, Tom, et al., Antibiotic Resistance Threats in the United States, 2013, Centers for Disease Control and Prevention (2013)). Those four core actions are preventing infections and the spread of those infections, tracking or monitoring, improving antibiotic prescribing and stewardship, and developing new medications and tests. The first three actions are within the control of the nursing home. Thus, we propose to require that the IPCP incorporate preventing and controlling infections and communicable diseases, and an antibiotic stewardship program, which includes both antibiotic use protocols and a system to monitor antibiotic use. We believe these requirements will improve antibiotic use by ensuring that the residents who require antibiotics are prescribed the appropriate antibiotics for the medically necessary time. This should reduce unnecessary antibiotic use and the risk to residents from being prescribed an unnecessary antibiotic or an inappropriate antibiotic for an inappropriate time. The surveillance and prevention aspects of the LTC facilities' IPCP are crucial to the health of the residents, as well as for individuals who work or visit the facility.

Based on our research, we propose to revise the regulatory description of the infection control program to: include infection prevention, identification, surveillance, and antibiotic stewardship; require each facility to periodically review and update its program; require performance of an analysis of their resident population and facility; designate an infection prevention and control officer(s) (IPCO); integrate the IPCO with the facility's quality assurance and performance improvement (QAPI) program; establish written policies and procedures for the IPCP; and provide the IPCO and facility staff with education or training related to the IPCP.

Specifically, as part of our overall reorganization of these regulations to improve clarity, we propose to redesignate the provisions under existing § 483.65 as § 483.80. We propose 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 propose to revise paragraph (a) to read "Infection prevention and control program" and add new § 483.80(a)(1), (2) and (3) to specify the elements of the IPCP. We propose to require that the program must follow accepted national standards, be based upon the facility assessment conducted according to proposed § 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 would 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. The facility would be required to train staff related to the IPCP as specified below in proposed § 483.95.

We are not proposing specific requirements for the standard and transmission-based precautions to be followed to prevent the spread of infections and isolation. Medical science and our knowledge of infectious agents are constantly improving. In addition, we can expect that new infectious agents will be identified in the future. Facilities need the flexibility to determine the appropriate care for their residents who have infectious agents, including whether isolation is appropriate and the circumstances of that isolation.

Antibiotics are one of the most frequently prescribed medications in

nursing homes. Antibiotics may account for approximately 40 percent of the drugs given in nursing homes (NAP, p. 216). It has been estimated that between 25 and 75 percent of antibiotic prescriptions in nursing homes may be inappropriate. This extensive use of antibiotics results in the risk of not only adverse drug reactions, but also the development of antibiotic-resistant or even multidrug resistant organisms (MDROs). Thus, the inappropriate use of antibiotics poses a significant risk to the resident population (Smith, 2008). In order to effectively address the problem of healthcare-associated infections, a LTC facility must have an effective IPCP that includes antibiotic stewardship. Therefore, we are proposing 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 propose to add a new paragraph (b) to require that the facility designate an IPCO who is responsible for the IPCP and who has received specialized training in infection prevention and control. While all staff members 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. We understand that infection control is often assigned to a nurse who may have other administrative or patient care responsibilities. We want to allow sufficient flexibility for facilities to determine the qualifications of and the time needed for an IPCO to devote to the IPCP based on the facility assessment but also ensure that an IPCO has the time and other resources necessary to properly develop, implement, monitor and maintain the IPCP for the facility. Thus we require that the IPCP be a major responsibility for the individual assigned as the facility's IPCO. In addition, while nurses and other healthcare professionals may be likely candidates for the IPCO role, many of these professionals may have only received training in basic infection control practices in their core professional preparation for licensure. The responsibility and necessary knowledge for an IPCP likely goes well beyond basic infection control training. Therefore, we propose to require that the IPCO be a healthcare professional with specialized training in infection prevention and control beyond their

initial professional degree. Considering the diverse nature of the resident population and of the healthcare delivery model, the qualifications, training, and time needed by an IPCO at each facility would vary widely, thus we are not at this time proposing more specific requirements. We do, however, solicit comment on the issue of IPCO qualifications as well as the requirements for an effective IPCP.

In new § 483.80(c), we propose to require that the IPCO be a member of the facility's Quality Assessment and Assurance (QAA) committee. While the literature suggests and we agree that an infection control committee is a good idea, we are also mindful that many nursing homes have limited staff and that requiring an infection control committee could be overly burdensome, especially for small facilities. We believe that requiring that the IPCO work with the facility's QAA committee, which is responsible for implementing the facility's QAPI plan, as well as coordinating and evaluating activities under the QAPI plan, as discussed in section II.S. of this preamble, would achieve many of the same benefits. Thus we do not propose to require that a facility have an infection control committee, only that the IPCO be a member of the facility's QAA committee to ensure that the IPCO is an active participant in the facility's QAPI plan. If a facility does have an infection control committee, we would still expect the IPCO to be a member of the QAA committee.

We are also proposing 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 are proposing to remove this exception because it is no longer the standard of care.

We also propose to add a new § 483.80(f) to require that the facility review its IPCP annually and update the program as necessary. Due to changes in the issues and practice of infection prevention and control and changes in the facility itself, an annual update is important to ensuring the effectiveness of the IPCP.

We are proposing 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

propose using the term “resident representative” instead of “legal representative.” We believe this is a broader term and encompasses individuals whom the resident has personally identified as their representative. A more detailed discussion of this change is set forth in Section II. “Provisions of the Proposed Rule”, B. Definitions.

Finally, we propose moving the requirement concerning linens from the current § 483.65(c) to the proposed § 483.80(e). Otherwise, the language is identical.

V. 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) 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. The current regulations governing SNFs and NFs at § 483.75(b) require these facilities to 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.” In addition, according to § 483.75(c), SNFs and NFs must be in compliance with “the applicable provisions of other HHS regulations, including but not limited to those pertaining to . . . fraud and abuse (42 CFR part 455).” However, the current regulations do not require that SNFs and NFs have in place compliance and ethics programs as required by the Affordable Care Act.

In this proposed rule, we seek to address how nursing facilities can best establish internal controls, prevent fraudulent activities, and promote quality of care through these elements as implementing written procedures and standards of conduct, designating a compliance officer, and other specific requirements. This proposed rule would require SNFs, NFs, and dually-participating SNF/NFs to have in place an effective compliance and ethics program that would require facilities to use internal controls to more efficiently monitor adherence to applicable statutes, regulations, and program requirements to deter, reduce, and detect violations and promote quality of care for nursing home residents. SNFs and NFs must meet the requirements in part 483 to participate in the Medicare

and Medicaid programs and therefore, we are proposing that the requirements for effective compliance and ethics programs as set forth in section 1128I of the Act be incorporated into the SNF and NF Requirements in Part 483. Specifically, we are proposing to add a new § 483.85 entitled, “Compliance and ethics program”.

Prior OIG Guidance

The DHHS Office of the Inspector General (OIG) has issued several industry-specific guidance documents on compliance. In the March 16, 2000, **Federal Register** (65 FR 14289), the OIG published its “Final Compliance Program Guidance for Nursing Facilities” (herein after referred to as the 2000 OIG Guidance). In this guidance, the OIG uses the term “nursing facility” to include SNFs and NFs that meet the requirements of sections 1819 and 1919 of the Act, respectively. The OIG guidance was intended to assist SNFs and NFs in the development of comprehensive compliance programs that would promote facilities’ adherence to applicable statutes and regulations in the federal health care programs, as well as meet private insurance program requirements. It indicated that the guidance was voluntary for nursing homes and did not establish any mandatory requirements. The OIG also noted that compliance programs promote a nursing home’s goals of providing quality care to its residents and enhancing operation functions, as well as strengthen the government’s efforts in preventing and reducing fraud and abuse. The 2000 OIG Guidance listed the following seven basic elements that, at a minimum, should be included in any effective comprehensive compliance program:

- The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that promote the nursing facility’s commitment to compliance (for example, including adherence to the compliance program as an element in evaluating managers and employees) and address specific areas of potential fraud and abuse, such as claims development and submission processes, quality of care issues, and financial arrangements with physicians and outside contractors.
- The designation of a compliance officer and other appropriate bodies (for example, a corporate compliance committee) charged with the responsibility for developing, operating and monitoring the compliance program. The officers and committees, report directly to the owner(s),

governing body, and or chief executive officers.

- The development and implementation of regular, effective education and training programs for all affected employees.
 - The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process, such as a hotline or other reporting system, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and protect whistleblowers from retaliation.
 - The use of audits and other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems.
 - The development of policies and procedures addressing the non-employment or retention of excluded individuals or entities and the enforcement of appropriate disciplinary action against employees or contractors who have violated corporate or compliance policies and procedures, applicable statutes, regulations, or federal, state, or private payer health care program requirements.
 - The development of policies and procedures with respect to the investigation of identified systemic problems, which include direction regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action, repayments, and preventive measures (see 65 FR 14291).
- In the September 30, 2008 **Federal Register** (73 FR 56832), the OIG published additional guidance entitled, “OIG Supplemental Compliance Program Guidance for Nursing Facilities” (hereinafter referred to as the “2008 OIG Guidance”). In this supplemental guidance, the OIG again indicated that the guidance was only a recommendation and provided voluntary guidelines to assist SNFs and NFs. It noted that facilities should regularly conduct periodic reviews of the implementation and execution of their compliance programs, such as on an annual basis (73 FR 56848). It also reiterated that the basic elements of a compliance program include all of the following:
- Designation of a compliance officer and compliance committee.
 - Development of compliance policies and procedures, including standards of conduct.
 - Development of open lines of communication.
 - Appropriate training and teaching.
 - Internal monitoring and auditing.
 - Response to detected deficiencies.

- Enforcement of disciplinary standards.

Although the basic elements of an effective compliance program listed in the 2008 OIG guidance are more concise, they appear to be essentially the same as those provided in the original 2000 OIG guidance to which the supplemental guidance directs facilities to review for further details on the elements.

Comments Solicited in the September 23, 2010 Proposed Rule

Section 6401(a)(3) of the Affordable Care Act, as amended by subsection 1304(1) of HCERA, established a new paragraph 1866(j)(8) of the Act. This paragraph requires that all providers of medical or other items or services or suppliers shall, as a condition of enrollment in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP), establish a compliance program that contains core elements to be established by "the Secretary in consultation with the Inspector General [of DHHS]." SNFs and NFs are subject to the compliance program requirements under both section 6102 and section 6401(a) of the Affordable Care Act since section 6401(a) of the Affordable Care Act applies to all providers and suppliers enrolling into the Medicare and Medicaid programs, and CHIP.

In order to consider the view of the industry stakeholders, on September 23, 2010, we published a 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). In section II.E. of that proposed rule, we solicited public comments on compliance program requirements that are required by both sections 6102 and 6401(a) of the Affordable Care Act. We listed the seven basic elements of an effective compliance and ethics program that were taken from Chapter 8 of the U.S. Federal Sentencing Guidelines Manual (75 FR 58228) and specifically sought comments on those elements. Some of the commenters were supportive of using those elements as a basis for the core elements of any required compliance program for Medicare, Medicaid, and CHIP. In addition, a few commenters from the healthcare industry indicated that they had already incorporated at least some of those elements into their existing compliance programs. Only one of those commenters appeared to be from the nursing home industry. Some

commenters expressed concerns about, among other things, the use of those elements, how compliance would be evaluated, and how long they would be given to get their compliance and ethics programs in compliance with our requirements.

The 2010 proposed rule was published as a final rule with comment period in the February 2, 2011 **Federal Register** (76 FR 5862). In that final rule with a comment period, we stated that we did not intend to finalize any of the compliance and ethics plan requirements of sections 6102 and 7401(a) of the Affordable Care Act in that final rule at that time. Rather, we intended to propose both compliance plan requirements in future rulemaking (76 FR 5942). This proposed rule only implements section 6102 of the Affordable Care Act, which applies only to SNFs and NFs. The requirements under section 6401(a) of the Affordable Care Act, which apply to all providers and suppliers including SNFs and NFs, will be addressed in separate rulemaking at a later time. We will consider this proposed and subsequent final rule as we are developing the rule for section 6401(a) of the Affordable Care Act to ensure consistency.

We would like to express our appreciation to all of the individuals and groups that submitted comments in response to our solicitation, which greatly assisted us in developing this proposed rule regarding the requirements of section 6102 of the Affordable Care Act. In addition to reviewing the public comments received, we have met with and will continue to work with the OIG to discuss the statutory provisions for sections 6102 and 6401(a) of the Affordable Care Act and the lessons the OIG has learned about establishing effective and comprehensive compliance programs in general.

Proposed § 483.85(a) and § 483.85(b)

At proposed § 483.85(a), we would define the terms "compliance and ethics program," "high-level personnel", and "operating organization." We are proposing 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 proposed § 483.85(c). We are proposing 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. 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 do not propose using the term "managing employee" that is contained in the current nursing home requirements. Section 1126(b) of the Act defines a managing employee as, "with respect to an entity, an individual, including a general manager, business manager, administrator, and director who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity." In describing the required components for the compliance and ethics program in section 1128I(b)(4) of the Act, the Congress specifically used the term "high-level personnel." The term "high-level personnel" was also used in the September 23, 2010 proposed rule that solicited comments on, among other things, the compliance and ethics program requirements that are required by section 6102 of the Affordable Care Act. While the definition of "managing employee" refers to an individual with either operational or managerial control over the entity or who directly or indirectly conducts the day-to-day operations of the entity, the proposed definition of "high-level personnel" includes the term "substantial" and adds someone who has "a substantial role in the making of policy within the operating organization." We believe the differences in these two terms clearly convey our intention that only individuals who exercise the greatest control over the operating organization are to have the overall responsibility and oversee its compliance and ethics program. Therefore, we propose to retain the terminology used in the Affordable Care Act and the former proposed rule.

We are also proposing 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 nursing homes are part of corporate chains, there are still some nursing homes that are owned by an individual or a small group of individuals. Therefore, we added

“individual(s)” to the definition to make it clear that all nursing homes, regardless of their legal structure, are required to comply with these requirements.

In § 483.85(b), we propose that the operating organization for each facility must have in operation a compliance and ethics program (as defined in proposed § 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 propose 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, which we discuss below.

The operating organization would have to 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 (proposed § 483.85(c)(1)).

We expect that each operating organization would establish its own written compliance and ethics standards, policies, and procedures. We also expect that each operating organization’s standards, policies, and procedures would include, among other things, financial disclosure obligations, conflicts of interest standards, and requirements for promptly reporting any abuse or neglect of a resident. Additionally, within their program, each operating organizations should designate 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 establish disciplinary standards so that the operating organization’s entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers’ expected roles, are

clearly aware of the consequences of program violations. We also expect that these disciplinary standards would promote consistent enforcement of the operating organization’s program through disciplinary mechanisms, as required in proposed § 483.85(c)(7). We acknowledge that there may be instances when an individual who chooses to report a suspected violation anonymously may subsequently be subject to discipline for not reporting the suspected violation. Each operating organization should be aware of this possibility and address how it would be handled in their program.

The operating organization would 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)).

The program would 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 (proposed § 483.85(c)(3)). The resources devoted should include both human and financial resources.

The operating organization would be 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. (Proposed § 483.85(c)(4)). “Due care” generally means the care that a reasonable person would use under the same or similar circumstances (*see, e.g.,* <http://thelawdictionary.org/due-care/> (accessed on April 17, 2015)). While the degree of due care would vary depending upon the circumstances, we would expect that the operating organization would apply the degree of scrutiny commensurate with the level of discretion being delegated to the individual. For example, the level of scrutiny applied to the compliance officer should be much higher than the level given to an employee who has minimal discretionary authority over the residents’ activities.

The operating organization would 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 would include, but not be 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 (proposed § 483.85(c)(5)).

The compliance program would need to 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 Social Security 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 (proposed § 483.85(c)(6)).

The operating organization would 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. An operating organization would be required to consistently enforce its standards and procedures through appropriate disciplinary mechanisms (proposed § 483.85(c)(7)).

After an operating organization detected a violation, it would have to 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 (proposed § 483.85(c)(8)).

The “reasonable steps” that should be taken when a violation is detected should be clearly identified in the operating organization’s program. We expect that the steps would differ depending upon the size of the operating organization, the position of the individual reporting the violation,

and possibly the type of violation. For example, an operating organization's program may state that a staff member should immediately notify their immediate superior when he or she detects a violation. However, if it is the immediate superior or the operating organization's management whom the staff member believes is committing the violation, the staff member should have an alternative process to report the violation, such as, the Office of the State Long-Term Care Ombudsman or other appropriate agency or law enforcement authority. In addition, the operating organization's program should include those steps that are necessary to comply with any mandatory reporting requirements, such as those concerning suspected resident neglect or abuse. Under those circumstances, reporting to an immediate supervisor or manager may not be sufficient and the program should clearly indicate how any suspected neglect or abuse is to be reported. We also expect that ethics compliance would be a strong component of each operating organization's program.

In sections 11281(b)(3)(F) and (G) of the Act, which correspond to proposed § 483.85(c)(7) and (8), the term "offense," is used instead of "violation." We believe that the terms are used interchangeably. We have used "violations" throughout the proposed regulatory text. The eight previously described components would be mandatory for all of the SNF and NF operating organizations' compliance and ethics programs.

Proposed § 483.85(d)

In proposed § 483.85(d), we would 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 should report directly to the governing body for the operating organization. We believe this is necessary to ensure that the compliance officer is not unduly influenced by other managers or executive officers, such as the general counsel, chief financial officer or chief operating officer. Thus, we are proposing the compliance officer should not be subordinate to the general counsel, chief financial officer or the chief operating officer. We considered requiring all operating organizations to designate a compliance officer. However, some smaller operating organizations may not have the staff to

have one individual to whom the compliance and ethics program could be a major responsibility. However, it is very important that there be an individual that staff, as well as others, may contact for questions or concerns and to whom they could report suspected violations. Therefore, we are proposing that all operating organizations designate a compliance and ethics program contact. We welcome comments on this issue.

In § 483.85(d), in addition to all of the other requirements in proposed § 483.85(a), (b), and (c), we propose 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 (§ 483.85(d)(3)).

The compliance officer should be among those individuals designated as high-level personnel of the operating organization with the overall responsibility to oversee the operating organization's compliance and ethics program as required by proposed § 483.85(c)(2). We also believe that the compliance officer must have the authority to raise compliance and ethics issues directly with the Board of Directors, President, CEO, and General Counsel or their equivalents in the operating organization. We have not defined "major responsibility" in this rule because we believe that operating organizations must have flexibility in designating their compliance officers. The category of "five or more operating organizations" encompasses small chains of facilities with as few as five nursing homes up to very large nursing home chains with hundreds of nursing homes. For some operating organizations to have an effective compliance and ethics program, they will need a compliance officer who can devote all of her or his time to the program. However, some operating organizations will have the resources to have a dedicated individual whose sole responsibility is the compliance and ethics program and others will not. For operating organizations that have insufficient resources to appoint a compliance officer whose sole responsibility is the operating organization's program, we would expect that the operating organization

would ensure that the assigned compliance officer has sufficient time and other resources to fulfill all of his or her responsibilities under the operating organization's compliance and ethics program.

In selecting their designated compliance officers, we also expect that operating organizations would consider potential conflicts of interest. For example, if the compliance officer was also the director of accounting, he or she might have a conflict of interest if there were an allegation of deliberate billing errors. In addition, if the compliance officer was also related to other high-level personnel in the operating organization, staff members might be hesitant to report certain violations that might involve the compliance officer's family members. Therefore, we expect that operating organizations would take appropriate action concerning any actual or potential conflicts of interest when selecting their compliance officers. In addition, we believe that the compliance officer should report directly to the governing body.

The facility would be required to designate compliance liaisons at each of the operating organization's facilities (proposed § 483.85(d)(3)). We have not provided a specific definition for a "designated compliance liaison" in this rule. We believe that operating organizations need to have flexibility in defining these positions and their responsibilities. We 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. At 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.

In addition to the additional elements for operating organizations that operate five or more facilities, as set out previously in proposed paragraph (d), we also anticipate that their programs would be more formal. However, the formality of these programs will be addressed in other guidance, including the interpretative guidelines, which will be developed to provide more instruction on how this rule should be implemented after it is finalized.

We welcome comments on the proposed additional requirements for operating organizations with five or more facilities and how to address the formalizing of these programs. In addition to the auditing and monitoring systems described in proposed § 483.85(c), we also considered

requiring periodic external audits specifically focusing on financial records and quality of care issues. We would welcome comments on a requirement for these types of audits or any other additional requirements for operating organizations that operate five or more facilities.

Proposed § 483.85(e)

Lastly, at § 483.85(e), we propose 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.

Laws, regulations, and administrative requirements are subject to change. Without an annual review, an operating organization's compliance and ethics program could easily become out of date. As an operating organization becomes aware of changes in these requirements, it should modify its program to ensure it is current with these requirements. Importantly, the operating organization's performance in prior years should also be used to improve its program. In addition, as an operating organization revises its program, it should ensure that those changes are communicated to all of the individuals identified in proposed § 483.85(c)(5).

In proposed § 483.85(a), we use the term "reasonable" or "reasonably" in the definition of a compliance and ethics program and in three of the proposed required components of the program in proposed § 483.85(c)(1), (6) and (8). These terms are used in the Affordable Care Act legislation. We 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.

W. Physical Environment (§ 483.90)

The physical environment of a nursing facility is integral to the resident's health and safety. Therefore, 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 have recently published a proposed rule which would adopt many provisions of the 2012 LSC "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities," 79 FR 21552, April 16, 2014. Those requirements have been or are being addressed in separate rule-making and we are not proposing any substantial changes or revisions. As part of our comprehensive review and restructuring, we propose to 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" would be 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 new § 483.90(c) "Space and equipment", we propose 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. While this assessment is considered in developing the resident's plan of care, we believe including it separately for consideration will help avoid any gaps in the facility's ability to provide required services based on space and equipment needs and help ensure person-centeredness. We propose to eliminate the word "essential" from new § 483.90(c)(2) (re-designated from § 483.70(c)(2)), as we believe that all equipment the resident may be exposed to, whether it is deemed essential or not, must be maintained in safe operating condition in order to ensure resident safety. In addition, we propose 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. As noted earlier, bed rails can pose a significant entrapment hazard, so ensuring that they are used safely warrants explicit reference here.

Currently, in existing § 483.70(d), the regulations allow for bedrooms that accommodate up to four residents. We believe that this number of residents per room is inconsistent with current common practice, is not person-centered nor supportive of achieving the

resident's highest practicable mental, physical and psychosocial well-being and is not an environment that promotes maintenance or enhancement of each resident's quality of life. Therefore, we propose to require in new § 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. 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 believe that semi-private rooms are far more supportive of privacy and dignity. While a facility is not a permanent home for all of its residents, this provision is particularly critical for those residents whose only home is the nursing facility. We considered, but did not propose to require private rooms. We note that many states have physical environment requirements that exceed our requirements. These requirements vary widely, but many 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. Proposed § 483.90(d) also would require that the bed size and height be not only convenient for the resident's needs, but also safe. The Food and Drug Administration (FDA) reports that between Jan 1, 1985 and January 1, 2013, it received 901 incidents of patients caught, trapped, entangled, or strangled in hospital beds. Most patients were frail, elderly or confused. (see <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/hospitalbeds/default.htm>). Therefore, we believe that bed safety should be an explicit consideration for facilities. Guidance for facilities as well as other information related to bed safety is available from FDA, which issued, on March 10, 2006, its "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment." (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm>). Section 483.70(e) currently requires that each bedroom be equipped with or located near toilet and bathing facilities. We propose in new § 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 propose 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. 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 understand that this is common in new construction, and we believe it is important to ensure that residents can achieve their highest practicable mental, physical and psychosocial well-being and maintain self-respect and dignity. Further, we expect that this will ease care delivery. Ensuring facilities in each room may minimize staff time and effort to assist residents to and from the bathroom, reduce the likelihood of avoidable incontinence episodes, and enhance the facility's ability to effectively implement toileting protocols for residents who are good candidates for these interventions.

Proposed § 483.90(f), re-designated from § 483.70(f), requires a resident call system. The intent of this provision is to ensure that a resident can easily call for assistance in his or her room or bathroom. This is a critical safety issue. The existing language refers to a "nurse's station." This language may, in many cases, be outdated. Therefore, we propose to 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. This provides flexibility that will be supportive of innovation in care delivery and still provide the elements necessary for resident needs and safety.

Proposed § 483.90(g), re-designated from § 483.70(g) addresses dining and activity rooms and includes a requirement to designate non-smoking areas. We propose to eliminate the language "with non-smoking areas identified", as it is inconsistent with current practice. Many, if not all, states have specific requirements related to the permissibility of smoking in healthcare facilities and related issues. In current practice, facilities are likely to be non-smoking facilities or may have designated smoking areas. Therefore, we propose to add a new paragraph (h)(5)

to new § 483.90(h) that would 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. The inclusion of a tobacco cessation policy is consistent with the recommendations of the U.S. Preventive Services Task Force (<http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryDraft/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1?ds=1&s=Smoking>) as well as the National Strategy for Quality Improvement in Health Care (<http://www.ahrq.gov/workingforquality/about.htm>). Smoking cessation, even among older, frail adults, produces significant health and quality of life benefits (Cataldo, JK. J Gerontol Nurs, 2007 Aug; 33(8):32–41). While we would expect that, when appropriate, tobacco cessation would be a matter to be discussed between a resident and his or her primary care provider and to be addressed in a resident's care plan, based on the individual's preferences and goals of care, we believe that including the overarching policy within the facility policy related to smoking would be beneficial.

X. Training Requirements (§ 483.95)

We are proposing to add a new § 483.95 to subpart B that would set forth training requirements. We propose 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 propose 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 encourage facilities to take advantage of the many free or low cost resources available to them. Various resources and training materials are available at <http://www.nhqualitycampaign.org>.

Communication Training

We propose at § 483.95(a) to include effective communications as a required training topic for direct care personnel. Effective communication has been identified as important in reducing unnecessary hospitalizations as well as for improving a nursing home resident's overall quality of life and quality of care. Breakdowns in communications are a known contributor to adverse events of all types. CMS noted in its 2012 Nursing Home Action Plan that

critical information often is not communicated from one set of providers to another during a care transition. According to the Agency for Health Research and Quality, detecting and promptly reporting changes in a nursing home resident's condition are critical for ensuring the resident's well-being and safety. These changes may represent a patient safety problem, and they can be a signal that the resident is at increased risk for falling, medication errors, and other complications. Training all nursing home staff, particularly direct care staff, to be on the lookout for changes in a resident's condition and to effectively communicate those changes is one tool LTC facilities can employ to improve patient safety, create a more person-centered environment, and reduce the number of adverse events or other resident complications. AHRQ offers training materials to train front line personnel in nursing homes in effective communications (Improving Patient Safety in Long-Term Care Facilities: Training Modules. AHRQ Publication No. 12–0001. July 2012. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/qual/ptsafetyltc/index.html>). AHRQ's TeamSTEPS® Long Term Care Version is a training program to enhance communication for front line staff in nursing homes. (<http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/longtermcare>). AHRQ's On-Time Pressure Ulcer Prevention program provides training for nursing homes with an EHR to use the EHR to improve communications of changes in residents' pressure ulcer risk factors to help staff intervene earlier. (www.ahrq.gov/professionals/systems/long-term-care/resources/on-time/qualityimprov/index.html). An evaluation of nursing homes in New York State showed a reduction of 59% in the incidence of pressure ulcers that integrated 3 EHR pressure ulcer risk reports into day-to-day workflow. (Olsho, L., Spector, W., Williams, C. et al. Evaluation of AHRQ's On-Time Pressure Ulcer Prevention Program: A Facilitator-assisted Clinical Decision Support Intervention for Nursing Homes. Medical Care 2014 Mar;52(3):258–66.) In an analysis of interviews of direct care workers, communication and teamwork were also identified as important in delirium prevention and appropriate management (Peacock, R., Hopton, A., Featherstone, I., & Edwards, J. (2012). Care home staff can detect the difference between delirium, dementia and depression. Nursing Older People, 24(1),

26–30.) Finally, enhanced communication skills can have a positive impact on job satisfaction and turnover, factors that can also impact resident care (Rubin, G., Balaji, R. V., & Barcikowski, R. (2009). Barriers to nurse/nursing aide communication: the search for collegiality in a southeast Ohio nursing home. *Journal of Nursing Management*, 17(7), 822–832. doi:10.1111/j.1365–2834.2008.00913.x)

We are not proposing to require a specific amount of time, specific communications topics, or specific training mechanisms to meet this requirement. While we believe communications training is vital, we also believe that each facility should 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. We also recognize that training needs are likely to change over time. The specific communications training may even vary within the facility, based on its aspects of care and service. We also note that states may have their own requirements, at the facility or professional levels that already require training. We have, therefore, only proposed this as a training topic that must be incorporated into a facility's ongoing training expectations for all employees. We welcome comments on whether or not more specific requirements are necessary.

Resident's Rights Training

We propose 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. We believe that it is necessary to ensure that direct care workers are trained to recognize when treatment is abusive or constitutes neglect or exploitation. We also believe that training in these areas is likely to reduce incidents. In addition, the effective training of staff on the requirements for participation is likely to have a positive effect on the operation of a facility.

Abuse, Neglect, and Exploitation Training

At § 483.95(c) we propose to require that a facility provide training to its staff on the freedom from abuse, neglect, and exploitation requirements found in § 483.12. We propose 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. We believe that in order for staff to be proactive and prevent these types of incidents, they must first be educated on what they are and how to report them. We believe that requiring this training would not only educate a facilities staff, but would also improve operations and increase the level of accountability for staff members.

Quality Assurance and Performance Improvement Training

At § 485.95(d), we propose to require that a facility must provide mandatory QAPI training to its staff. This training would outline the elements and goals of the facility's QAPI program. All facility staff should be aware of what a QAPI program entails and how the facility intends to implement and monitor their program. Given that a facility's QAPI program is meant to encompass input from facility staff, it is imperative that staff members are adequately trained on the elements of the facility's QAPI program.

Infection Control Training

As discussed earlier, HAIs result in considerable suffering to nursing home residents and considerable costs to the healthcare system. Therefore, at § 483.95(e) we propose 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.

Compliance and Ethics Training

At § 483.95(f)(1), we propose 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 do not specify how a facility should develop this training; however the training must explain in a practical manner the requirements under the compliance and ethics program. In addition, at § 483.95(f)(2) we propose to require that if the operating organization operates five or more facilities, it must include mandatory training annually.

Required In-Service Training for Nurse Aides

The Need for Nurse Aide Training in Dementia Management

Dementia among nursing home residents is prevalent and increasing. According to the Certification and

Survey Provider Enhanced Reports (CASPER) data, in June 2009, 47 percent of all nursing home residents had a diagnosis of Alzheimer's or other dementia in their nursing home record. The Alzheimer's Association noted in a report entitled, "2010-Alzheimer's Disease Facts and Figures," at http://www.alz.org/documents_custom/report_alzfactsfigures2010.pdf that the number of Americans surviving into their 80s and 90s and beyond is expected to grow dramatically due to advances in medicine and medical technology, as well as social and environmental conditions. Since the incidence and prevalence of Alzheimer's disease and other dementias increase with age, the number of people with these conditions will also grow rapidly. The Alzheimer's Association also noted in the report that two-thirds of those dying with dementia die in nursing homes, compared with 20 percent of cancer patients and 28 percent of residents dying from all other conditions in nursing homes.

According to the OIG in a 2002 report entitled, "Nurse Aide Training," (OEI-05-01-00030), 63 percent of the nursing home supervisors interviewed said that training has not kept pace with the care demands imposed by current resident diagnoses. Many of these supervisors pointed out that they are seeing more combative and violent residents. Many supervisors and nurse aides stated that nurse aides need more training in caring for residents with behavioral and cognitive disorders, such as Alzheimer's disease. Also, six state Nurse Aide Training Competency Evaluation Program (NATCEP) directors specifically emphasized the need for more training in caring for residents with cognitive disorders.

According to a September, 2008 report prepared for CMS entitled, "Improving Nurse Aide Training," by Abt Associates, Inc. (Contract #500-95-0062/TO#3), studies have shown that educational programs are more likely to be successful when the education is ongoing. Students are also more receptive to new information that is relevant to their current work environment, rather than information that is presented during the initial training. This report suggests that ongoing training in dementia management and abuse prevention, in addition to the already-required initial training, would be valuable.

Based on the information included in these reports, we believe that ongoing training in dementia management and abuse prevention for NAs is necessary and could enhance the overall quality of care that residents receive in LTC facilities.

The Need for Nurse Aide Training in Abuse Prevention

Based on CASPER data for 2007–2009, nursing homes received 3,124 citations for abuse and mistreatment of residents. In 2003, State Long-Term Care Ombudsman programs nationally investigated 20,673 complaints of abuse, gross neglect, and exploitation on behalf of nursing home and board and care residents. Among the types of abuse categories, physical abuse was the most common type reported.

A GAO report entitled, “More Can Be Done to Protect Residents from Abuse,” ((GAO–02–312) March 1, 2002 <http://www.gao.gov/newitems/do2312.pdf>) revealed that experts who have conducted studies on the issue of physical and sexual abuse of nursing home residents have reported that abuse is a serious problem with potentially devastating consequences. Nursing home residents have suffered serious injuries or, in some cases, have died as a result of abuse.

A report by the National Association of State Units on Aging, published in 2005, entitled, “Nursing Home Abuse Risk Prevention Profile and Checklist” concluded that understaffing and inadequate training of NAs are major causes of abuse, especially for individuals with dementia.

The Center for Advocacy Rights and Interests (CARIE) reports on their Web site (<http://www.carie.org/programs-services/for-provider-professionals/abuse-prevention/>) the results of a research study conducted by Beth Hudson Keller, Director of Education and Training at the Philadelphia CARIE, and Dr. Karl Pillemer, Associate Professor at Cornell University, on nursing home abuse. The research showed that nursing assistants in 10 Philadelphia-area nursing homes self-reported abusive behaviors over a one-month period. During this period,

- 51 percent reported yelling at a resident in anger;
- 23 percent insulted or swore at a resident;
- 8 percent threatened to hit or throw something at a resident;
- 17 percent excessively restrained a resident;
- 2 percent had slapped a resident; and
- 1 percent had kicked or hit a resident with a fist

CARIE believes that training helps to increase staff awareness of abuse and neglect and potentially abusive situations. In addition, training equips workers with appropriate conflict intervention strategies and reduces incidents of abuse and neglect in LTC

settings, thus improving the quality of life for residents.

According to the National Center on Elder Abuse (NCEA), training can, among other things, enable NAs to build confidence and develop skills in defusing volatile situations, alert them to the penalties for abuse, and help NAs cope with the stresses that are associated with care giving. Also, as stated above, the 2008 Abt Report suggested that ongoing NA training in abuse prevention should result in fewer instances of resident abuse.

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 ongoing training in both dementia management and patient abuse prevention training, “if the Secretary determines appropriate.” While all NAs currently receive initial training by the states in dementia management and abuse prevention, the regulation does not require that training be provided by LTC facilities to all NAs during their annual 12 hours of in-service training. However, since NAs are the primary caregivers in LTC facilities, we believe ongoing training of NAs is critical to prevent abuse of patients and to ensure NAs can provide appropriate care for residents particularly those individuals suffering from dementia. As discussed previously, various studies and reports have indicated that these areas need improvement.

We are proposing to amend the LTC requirements by requiring the current mandatory on-going training requirements for NAs include dementia management and resident abuse training. LTC facilities are required at existing § 483.75(e)(8) to complete a performance review of every NA at least once every 12 months, and facilities must provide regular in-service education based on the outcome of these reviews. The in-service training must be sufficient to ensure the continuing competence of NAs, and must be no less than 12 hours per year. The training must address areas of weakness, as determined in the NA’s performance reviews and may address the special needs of residents as determined by the facility staff. The existing requirement at § 483.75(e)(8)(iii) requires NAs that provide services to individuals with cognitive impairments to receive in-service training to address the care of the cognitively impaired.

We propose to relocate these training requirements for CNAs at § 483.75(e)(8) to proposed § 483.95(g). Specifically, we propose 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 propose 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 newly redesignated § 483.95(g)(3), we propose 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). We note that states have the option of requiring additional hours of in-service training, as they deem appropriate. According to the 2008 Abt report, “Improving Nurse Aide Training”, with regard to ongoing training, only four states required more than 12 annual in-service hours. Florida required 18 hours and Alaska, California, and Oklahoma required 24 hours.

Since we are proposing that these four additional topics be addressed within the current in-service training requirement, we would like to solicit comments on whether it would be beneficial to require additional ongoing hours to accommodate this training. As discussed in the 2008 report by the Abt Associates, “Improving Nurse Aide Training,” based on analyses of surveys of NAs, NATCEP directors, and nursing home administrators, the report concluded, that there was no evidence that additional hours resulted in better quality care or outcomes for residents. The report also concluded that simply adding more training hours without evaluating the efficacy of the training would yield very little return on investment. Therefore, we are requesting public comment, including the results of any additional studies that would support an increase in the required hours for in-service training above the currently required 12 hours.

Training for Feeding Assistants

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 propose to relocate this provision without change to proposed § 483.95(h).

Behavioral Health Training

We propose 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), the facility would be responsible for using their facility assessment to determine the behavioral health related needs of their residents. Then the facility would ensure that their staff is provided with

behavioral health training that correlates with the needs of their residents.

III. 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 would change due to the reorganization of subpart B in this proposed rule.

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B

Existing CFR Section	Title	Action	New CFR section
§ 483.1	Basis and Scope	Revised	§ 483.1.
§ 483.5(a)–(c)	(a) <i>Facility defined</i> (b) <i>Distinct part.</i> (c) <i>Composite distinct part.</i>	Re-designated	§ 483.5 in alphabetical order.
§ 483.5 (d)	(d) <i>Common area</i>	Re-designated & revised	§ 483.5 in alphabetical order.
§ 483.5(e)	(e) <i>Fully sprinklered</i> (f) <i>Major modification.</i>	Re-designated	§ 483.5 in alphabetical order.
§ 483.10	Resident rights	Revised	§ 483.10.
§ 483.10(a)(1)	(a) <i>Exercise of rights</i>	No change	§ 483.10(a)(2).
§ 483.10(a)(2)	(a) <i>Exercise of rights</i>	Revised	§ 483.10(a)(2).
§ 483.10 (a)(3)		Re-designated and revised	§ 483.10(a)(4).
§ 483.10 (a)(4)		Re-designated and revised	§ 483.10(a)(3).
§ 483.10 (b)(1)	(b) <i>Notice of rights and services</i>	Re-designated & revised	§ 483.11(e)(9).
§ 483.10(b)(2)		Re-designated & revised	§ 483.10(f)(3).
§ 483.10(b)(3)		Re-designated	§ 483.10(b)(1).
§ 483.10 (b)(4)		Revised	§ 483.10(b)(4).
§ 483.10(b)(5)		Re-designated & revised	§ 483.11(e)(10).
§ 483.10 (b)(6)		Re-designated & revised	483.11(e)(11).
§ 483.10(b)(7)		Re-designated & revised	483.11(e)(12).
§ 483.10(b)(8)		Re-designated & revised	§ 483.11(e)(5)(i)–(v).
§ 483.10(b)(9)		Re-designated & revised	§ 483.11(c)(1).
§ 483.10(b)(10)		Re-designated & revised	§ 483.11(e)(6).
§ 483.10(b)(11)		Re-designated & revised	§ 483.11(e)(7).
§ 483.10(b)(12)		Re-designated	§ 483.11(e)(8).
§ 483.10(c)(1)	(c) <i>Protection of resident funds</i>	Re-designated & revised	§ 483.10(e)(9), § 483.11(d)(5).
§ 483.10(c)(2)		Re-designated	§ 483.11(d)(5)(i).
§ 483.10(c)(3)		Re-designated & revised	§ 483.11(d)(5)(ii).
§ 483.10(c)(4)		Re-designated	§ 483.11(d)(5)(iii).
§ 483.10(c)(5)		Re-designated	§ 483.11(d)(5)(iv).
§ 483.10(c)(6)		Re-designated & revised	§ 483.11(d)(5)(v).
§ 483.10(c)(7)		Re-designated	§ 483.11(d)(5)(vi).
§ 483.10(c)(8)		Re-designated & revised	§ 483.11(d)(6).
§ 483.10(d)	(d) <i>Free choice</i>	Re-designated & revised	§ 483.10(c).
§ 483.10(d)(1)		Re-designated & revised	§ 483.10(c).
§ 483.10(d)(2)		Re-designated & revised	§ 483.10(b).
§ 483.10(d)(3)		Re-designated & revised	§ 483.10(a)(4)(iv), § 483.10(b)(5).
§ 483.10(e)	(e) <i>Privacy and confidentiality</i>	Re-designated & revised	§ 483.10(g).
§ 483.10(e)(1)		Re-designated	§ 483.10(g)(2).
§ 483.10(e)(2)		Re-designated & revised	§ 483.10(g)(4).
§ 483.10(e)(3)		Re-designated & revised	§ 483.10(g)(4).
§ 483.10(e)(3)(i)		Re-designated & revised	§ 483.10(g)(4).
§ 483.10(e)(3)(ii)		Re-designated & revised	§ 483.10(g)(4).
§ 483.10(f)	(f) <i>Grievances</i>	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) <i>Examination of survey results</i>	Re-designated	§ 483.10(f)(4).
§ 483.10(g)(1)		Re-designated & revised	§ 483.10(f)(4)(i), § 483.11(e)(3).
§ 483.10(g)(2)		Re-designated	§ 483.10(f)(4)(ii).
§ 483.10(h)	(h) <i>Work</i>	Re-designated & revised	§ 483.10(e)(8).
§ 483.10(h)(1)		Re-designated & revised	§ 483.10(e)(8).
§ 483.10(h)(2)		Re-designated & revised	§ 483.10(e)(8), § 483.11(d)(4).
§ 483.10(h)(2)(i)–(iv)		Re-designated	§ 483.11(d)(4)(i)–(iv).
§ 483.10(i)	(i) <i>Mail</i>	Re-designated & revised	§ 483.10(g)(1) & (h)(3).
§ 483.10(i)(1)		Re-designated & revised	§ 483.10(g)(1), § 483.11(f)(1)(i).
§ 483.10(i)(2)		Re-designated & revised	§ 483.10(h)(3)(ii), § 483.11(e)(14)(iii).
§ 483.10(j)(1)	(j) <i>Access and visitation rights</i>	Re-designated & revised	§ 483.10(e)(3), § 483.11(d)(1).
§ 483.10(j)(1)(i)–(vi)		Re-designated & revised	§ 483.11(d)(1)(i)(A)–(F).
§ 483.10(j)(1)(vii)		Re-designated & revised	§ 483.11(d)(1)(ii).
§ 483.10(j)(1)(viii)		Re-designated & revised	§ 483.11(d)(1)(iii).
§ 483.10(j)(2)		Re-designated	§ 483.11(d)(1)(iv).
§ 483.10(j)(3)		Re-designated & revised	§ 483.11(f)(3).
§ 483.10(k)	(k) <i>Telephone</i>	Re-designated & revised	§ 483.10(h)(1).
§ 483.10(l)	(l) <i>Personal property</i>	Re-designated & revised	§ 483.10(d)(2).

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR Section	Title	Action	New CFR section
§ 483.10(m)	(m) <i>Married couples</i>	Re-designated	§ 483.10(d)(4).
§ 483.10(n)	(n) <i>Self-Administration of Drugs</i>	Re-designated & revised	§ 483.10(b)(6).
§ 483.10(o)(1)–(2)	(o) <i>Refusal of certain transfers</i>	Re-designated & revised	§ 483.10(d)(7)(i)–(ii), 483.11(d)(8).
§ 483.12(a)	Admission, transfer and discharge rights (a) <i>Transfer and discharge.</i>	Re-designated & revised	§ 483.15(b).
§ 483.12(a)(1)	(1) <i>Definition:</i>	Re-designated	§ 483.5.
§ 483.12(a)(2)		Re-designated & revised	§ 483.15(b)(1)(ii).
§ 483.12(a)(2)(i)–(vi)		Re-designated & revised	§ 483.15(b)(1)(ii)(A)–(F).
§ 483.12(a)(3)		Re-designated & revised	§ 483.15(b)(2).
§ 483.12(a)(3)(i)		Re-designated & revised	§ 483.15(b)(2)(ii)(A).
§ 483.12(a)(3)(ii)		Re-designated & revised	§ 483.15(b)(2)(ii)(B).
§ 483.12(a)(4)(i)–(iii)		Re-designated & revised	§ 483.15(b)(3)(i)–(iii).
§ 483.12(a)(5)(i)		Re-designated & revised	§ 483.15(b)(4).
§ 483.12(a)(5)(ii)(A)–(E)		Re-designated & revised	§ 483.15(b)(4)(ii)(A)–(E).
§ 483.12(a)(6)(i)–(vii)		Re-designated & revised	§ 483.15(b)(5)(i)–(vii).
§ 483.12(a)(7)		Re-designated & revised	§ 483.15(b)(7).
§ 483.12(a)(8)		Re-designated & revised	§ 483.15(b)(8).
§ 483.12(a)(9)		Re-designated & revised	§ 483.15(b)(9).
§ 483.12(b)(1)(i)–(ii)	(b) <i>Notice of bed-hold policy and readmission.</i>	Re-designated & revised	§ 483.15(c)(1)(i)–(iii).
§ 483.12(b)(2)		Re-designated & revised	§ 483.15(c)(2).
§ 483.12(b)(3)(i)–(ii)		Re-designated	§ 483.15(c)(3)(i)–(ii).
§ 483.12(b)(4)		Re-designated & revised	§ 483.15(c)(4).
§ 483.12(c)(1)	(c) <i>Equal access to quality care</i>	Re-designated & revised	§ 483.15(b)(1)(i)(A).
§ 483.12(c)(2)		Re-designated & revised	§ 483.15(b)(1)(i)(B).
§ 483.12(c)(3)		Re-designated	§ 483.15(b)(1)(i)(C).
§ 483.12(d)(1) (i)–(ii)	(d) <i>Admissions policy</i>	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).
§ 483.13(a)	Resident behavior and facility practices. (a) <i>Restraints.</i>	Re-designated & revised	§ 483.10(d)(1), § 483.25(d)(1).
§ 483.13(b)	(b) <i>Abuse</i>	Re-designated & revised	§ 483.12.
§ 483.13(c)	(c) <i>Staff treatment of residents</i>	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)(2).
§ 483.13(c)(1)(ii)(A)		Re-designated & revised	§ 483.12(a)(2)(i).
§ 483.13(c)(1)(ii)(B)		Re-designated & revised	§ 483.12(a)(2)(ii).
§ 483.13(c)(1)(iii)		Re-designated & revised	§ 483.12(a)(3).
§ 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	§ 483.11.
§ 483.15(a)	(a) <i>Dignity</i>	Re-designated & revised	§ 483.11.
§ 483.15(b)	(b) <i>Self-determination and participation.</i>	Re-designated & revised	§ 483.10(e), § 483.11(d).
§ 483.15(b)(1)		Re-designated & revised	§ 483.10(e)(1).
§ 483.15(b)(2)		Re-designated & revised	§ 483.10(e)(2).
§ 483.15(b)(3)		Re-designated	§ 483.10(e)(10).
§ 483.15(c)(1)	(c) <i>Participation in resident and family groups groups.</i>	Re-designated & revised	§ 483.10(e)(4).
§ 483.15(c)(2)		Re-designated & revised	§ 483.10(e)(5)–(6).
§ 483.15(c)(3)		Re-designated	§ 483.11(d)(3).
§ 483.15(c)(4)–(6)		Re-designated & revised	§ 483.11(d)(3)(i)–(iii).
§ 483.15(d)	(d) <i>Participation in other activities</i>	Re-designated & revised	§ 483.10(e)(7).
§ 483.15(e)	(e) <i>Accommodation of needs</i>	Re-designated & revised	§ 483.10(d).
§ 483.15(e)(1)		Re-designated & revised	§ 483.10(d)(3).
§ 483.15(e)(2)		Re-designated & revised	§ 483.10(d)(6).
§ 483.15(f)(1)	(f) <i>Activities</i>	Re-designated & revised	§ 483.25(c)(1).
§ 483.15(f)(2)		Re-designated & revised	§ 483.25(c)(2).
§ 483.15(f)(2)(i)		Re-designated & revised	§ 483.25(c)(2).
§ 483.15(f)(2)(i)(A)		Re-designated	§ 483.25(c)(2)(i).
§ 483.15(f)(2)(i)(B)		Re-designated & revised	§ 483.25(c)(2)(ii)(A).
§ 483.15(f)(2)(ii)–(iv)		Re-designated & revised	§ 483.25(c)(2)(ii)(B)–(D).
§ 483.15(g)(1)	(g) <i>Social Services</i>	Re-designated & revised	§ 483.40(d).
§ 483.15(g)(2)		Re-designated & revised	§ 483.70(p).
§ 483.15(g)(3)(i)–(ii)	(3) <i>Qualifications of social worker</i>	Re-designated & revised	§ 483.70(p)(1)–(2).
§ 483.15(h)	(h) <i>Environment</i>	Re-designated & revised	§ 483.11(g).
§ 483.15(h)(1)		Re-designated & revised	§ 483.11(g)(1).
§ 483.15(h)(2)		Re-designated	§ 483.11(g)(2).

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR Section	Title	Action	New CFR section
§ 483.15(h)(3)	Re-designated	§ 483.11(g)(3).
§ 483.15(h)(4)	Re-designated & revised	§ 483.11(g)(4).
§ 483.15(h)(5)	Re-designated	§ 483.11(g)(5).
§ 483.15(h)(6)	Re-designated	§ 483.11(g)(6).
§ 483.15(h)(7)	Re-designated	§ 483.11(g)(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 .. (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. (g) Accuracy of assessments. (h) Coordination. (i) Certification.		
	(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)–(G).
§ 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).
§ 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	§ 483.25(a).
§ 483.25(a)(1)	Re-designated and revised	§ 483.25(a), (b).
§ 483.25(a)(1)(i)	Re-designated and revised	§ 483.25(b)(1).
§ 483.25(a)(1)(ii)	Re-designated and revised	§ 483.25(b)(2).
§ 483.25(a)(1)(iii)	Re-designated and revised	§ 483.25(b)(3).
§ 483.25(a)(1)(iv)	Re-designated and revised	§ 483.25(b)(4).
§ 483.25(a)(1)(v)	Re-designated and revised	§ 483.25(b)(5).
§ 483.25(a)(2)	Re-designated and revised	§ 483.25(a)(1).
§ 483.25(a)(3)	Re-designated	§ 483.25(a)(2).
§ 483.25(b)	(b) Vision and hearing	Re-designated	§ 483.25(d)(3).
§ 483.25(b)(1)	Re-designated	§ 483.25(d)(3)(i).
§ 483.25(b)(2)	Re-designated	§ 483.25(d)(3)(ii).
§ 483.25(c)	(c) Pressure sores	Re-designated & revised	§ 483.25(d)(4)(i).
§ 483.25(c)(1)	Re-designated & revised	§ 483.25(d)(4)(i)(A).
§ 483.25(c)(2)	Re-designated & revised	§ 483.25(d)(4)(i)(B).
§ 483.25(d)	(d) Urinary Incontinence	Re-designated & revised	§ 483.25(d)(6)(ii).
§ 483.25(d)(1)	Re-designated	§ 483.25(d)(6)(ii)(A).
§ 483.25(d)(2)	Re-designated	§ 483.25(d)(6)(i)(C).
§ 483.25(e)	(e) Range of motion	Re-designated & revised	§ 483.25(d)(5).
§ 483.25(e)(1)	Re-designated	§ 483.25(d)(5)(i).
§ 483.25(e)(2)	Re-designated	§ 483.25(d)(5)(ii).
§ 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(d)(8)(iv).
§ 483.25(g)(1)	Re-designated & revised	§ 483.25(d)(8)(iv).
§ 483.25(g)(2)	Re-designated & revised	§ 483.25(d)(8)(v).
§ 483.25(h)	(h) Accidents	Re-designated	§ 483.25(d)(10).
§ 483.25(h)(1)	Re-designated	§ 483.25(d)(10)(i).
§ 483.25(h)(2)	Re-designated	§ 483.25(d)(10)(ii).
§ 483.25(i)	(i) Nutrition	Re-designated & revised	§ 483.25(d)(8).
§ 483.25(i)(1)	Re-designated & revised	§ 483.25(d)(8)(i).
§ 483.25(i)(2)	Re-designated & revised	§ 483.25(d)(8)(iii).
§ 483.25(j)	(j) Hydration	Re-designated & revised	§ 483.25(d)(8)(ii).
§ 483.25(k)	(k) Special needs	Re-designated & revised	§ 483.25(d).

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR Section	Title	Action	New CFR section
§ 483.25(k)(1)	(1) Injections;	Deleted.	
§ 483.25(k)(2)	(2) Parenteral and enteral fluids; ..	Re-designated & revised	§ 483.25(d)(9).
§ 483.25(k)(3)	(3) Colostomy, ureterostomy, or ileostomy care;	Re-designated	§ 483.25(d)(7).
§ 483.25(k)(4)	(4) Tracheostomy care;	Re-designated & revised	§ 483.25(d)(11).
§ 483.25(k)(5)	(5) Tracheal suctioning;	Re-designated & revised	§ 483.25(d)(11).
§ 483.25(k)(6)	(6) Respiratory care;	Re-designated & revised	§ 483.25(d)(11).
§ 483.25(k)(7)	(7) Foot care; and	Re-designated & revised	§ 483.25(d)(4)(ii).
§ 483.25(k)(8)	(8) Prostheses.	Re-designated	§ 483.25(d)(12).
§ 483.25(l)	(l) <i>Unnecessary drugs</i>	Re-designated	§ 483.45(d).
§ 483.25(l)(1)(i)–(vi)	(1) <i>Antipsychotic Drugs</i>	Re-designated	§ 483.45(d)(1)–(6).
§ 483.25(l)(2)(i)–(ii)	(2) <i>Antipsychotic Drugs</i>	Re-designated & revised	§ 483.45(e)(1)–(2).
§ 483.25(m)(1)–(2)	(m) <i>Medication Errors</i>	Re-designated & revised	§ 483.45(f)(1)–(2).
§ 483.25(n)	(n) <i>Influenza and pneumococcal immunizations.</i>	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) <i>Pneumococcal disease</i>	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)	<i>Exception</i>	Deleted.	
§ 483.30	Nursing services	Re-designated & revised	§ 483.35.
§ 483.30(a)	(a) <i>Sufficient staff</i>	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) <i>Registered nurse</i>	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) <i>Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.</i>	Re-designated	§ 483.35(e).
§ 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) <i>SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.</i>	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) <i>Nurse staffing information</i>	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) <i>Staffing</i>	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)–(iii).
§ 483.35(b)	(b) <i>Sufficient staff</i>	Re-designated & revised	§ 483.60(a)(3).
§ 483.35(c)	(c) <i>Menus and nutritional adequacy.</i>	Re-designated	§ 483.60(c).
§ 483.35(c)(1)–(3)	Re-designated & revised	§ 483.60(c)(1)–(3).
§ 483.35(d)	(d) <i>Food</i>	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) <i>Therapeutic diets</i>	Re-designated & revised	§ 483.60(e).
§ 483.35(f)(1)	(f) <i>Frequency of meals</i>	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) <i>Assistive devices</i>	Re-designated & revised	§ 483.60(g).
§ 483.35(h)(1)	(h) <i>Paid feeding assistants</i>	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).

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR Section	Title	Action	New CFR section
§ 483.35(h)(3)(iii)		Re-designated & revised	§ 483.60(h)(3)(iii).
§ 483.35(i)	(i) <i>Sanitary conditions</i>	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) <i>Physician supervision</i>	Re-designated	§ 483.30(a).
§ 483.40(a)(1)–(2)		Re-designated	§ 483.30(a)(1)–(2).
§ 483.40(b)	(b) <i>Physician visits</i>	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) <i>Frequency of physician visits</i>	Re-designated	§ 483.30(c)(1)–(4).
§ 483.40(d)	(d) <i>Availability of physicians for emergency care.</i>	Re-designated	§ 483.30(d).
§ 483.40(e)(1)	(e) <i>Physician delegation of tasks in SNFs.</i>	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) <i>Performance of physician tasks in NFs.</i>	Re-designated	§ 483.30(g).
§ 483.45	Specialized rehabilitative services	Re-designated & revised	§ 483.65(a).
§ 483.45(a)(1)–(2)	(a) <i>Provision of services</i>	Re-designated & revised	§ 483.65(a)(1)–(2).
§ 483.45(b)	(b) <i>Qualifications</i>	Re-designated	§ 483.65(b).
§ 483.55	Dental services	No change	§ 483.55.
§ 483.55(a)(1)	(a) <i>Skilled nursing facilities</i>	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).
§ 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) <i>Nursing facilities</i>	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) <i>Procedures</i>	Re-designated	§ 483.45(a).
§ 483.60(b)	(b) <i>Service consultation</i>	Re-designated	§ 483.45(b).
§ 483.60(b)(1)–(3)		Re-designated	§ 483.45(b)(1)–(3).
§ 483.60(c)(1)	(c) <i>Drug regimen review</i>	Re-designated	§ 483.45(c)(1).
§ 483.60(c)(2)		Re-designated & revised	§ 483.45(c)(4).
§ 483.60(d)	(d) <i>Labeling of drugs and biologicals.</i>	Re-designated	§ 483.45(g).
§ 483.60(e)(1)–(2)	(e) <i>Storage of drugs and biologicals.</i>	Re-designated	§ 483.45(h)(1)–(2).
§ 483.65	Infection control	Re-designated & revised	§ 483.80.
§ 483.65(a)(1)–(3)	(a) <i>Infection control program</i>	Re-designated & revised	§ 483.80(a)(1)–(3).
§ 483.65(b)(1)	(b) <i>Preventing spread of infection</i>	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) <i>Linens</i>	Re-designated	§ 483.80(e).
§ 483.70	Physical environment	Re-designated	§ 483.90.
§ 483.70(a)(1)–(8)	(a) <i>Life safety from fire</i>	Re-designated	§ 483.90(a)(1)–(8).
§ 483.70(b)(1)–(2)	(b) <i>Emergency power</i>	Re-designated	§ 483.90(b)(1)–(2).
§ 483.70(c)(1)–(2)	(c) <i>Space and equipment</i>	Re-designated & revised	§ 483.90(c)(1)–(2).
§ 483.70(d)	(d) <i>Resident rooms</i>	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) <i>Toilet facilities</i>	Re-designated & revised	§ 483.90(e).
§ 483.70(f)(1)	(f) <i>Resident call system</i>	Re-designated & revised	§ 483.90(f)(1).
§ 483.70(f)(2)	(f) <i>Resident call system.</i>	Re-designated	§ 483.90(f)(2).
§ 483.70(g)(1)	(g) <i>Dining and resident activities</i>	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).

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR Section	Title	Action	New CFR section
§ 483.70(h)(1)–(4)	(h) <i>Other environmental conditions.</i>	Re-designated	§ 483.90(h)(1)–(4).
§ 483.75	Administration	Re-designated	§ 483.70.
§ 483.75(a)	(a) <i>Licensure</i>	Re-designated	§ 483.70(a).
§ 483.75(b)	(b) <i>Compliance with Federal, State, and local laws and professional standards.</i>	Re-designated	§ 483.70(b).
§ 483.75(c)	(c) <i>Relationship to other HHS regulations.</i>	Re-designated & revised	§ 483.70(c).
§ 483.75(d)(1)	(d) <i>Governing body</i>	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) <i>Required training of nursing aides.</i>	Re-designated & revised	483.95(g).
§ 483.75(e)(1)	(1) <i>Definitions. Licensed health professional.</i>	Re-designated & revised	483.5.
§ 483.75(e)(1)	<i>Nurse aide</i>	Re-designated & revised	483.5.
§ 483.75(e)(2)(i)–(ii)	(2) <i>General rule</i>	Re-designated & revised	§ 483.35(d)(1)(i)–(ii).
§ 483.75(e)(3)	(3) <i>Non-permanent employees</i>	Re-designated & revised	§ 483.35(d)(2).
§ 483.75(e)(4)(i)–(iii)	(4) <i>Competency</i>	Re-designated	§ 483.35(d)(3)(i)–(iii).
§ 483.75(e)(5)(i)–(ii)	(5) <i>Registry verification</i>	Re-designated	§ 483.35(d)(4)(i)–(ii).
§ 483.75(e)(6)	(6) <i>Multi-State registry verification</i>	Re-designated & revised	§ 483.35(d)(5).
§ 483.75(e)(7)	(7) <i>Required retraining</i>	Re-designated	§ 483.35(d)(6).
§ 483.75(e)(8)(i)–(iii)	(8) <i>Regular in-service education</i>	Re-designated & revised	§ 483.35(d)(7), § 483.95(g).
§ 483.75(f)	(f) <i>Proficiency of Nurse aides</i>	Re-designated	§ 483.35(c).
§ 483.75(g)(1)	(g) <i>Staff qualifications</i>	Re-designated	§ 483.70(f)(1).
§ 483.75(g)(2)		Re-designated	§ 483.70(f)(2).
§ 483.75(h)(1)	(h) <i>Use of outside resources</i>	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) <i>Medical director</i>	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) <i>Laboratory services</i>	Re-designated	§ 483.50(a)(1)(i)–(iv).
§ 483.75(j)(2)		Re-designated	§ 483.50(a)(2).
§ 483.75(j)(2)(i)–(iv)		Re-designated & Revised	§ 483.50(a)(2)(i)–(iv).
§ 483.75(k)	(k) <i>Radiology and other diagnostic services.</i>	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) <i>Clinical records</i>	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) <i>Disaster and emergency preparedness.</i>	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) <i>Transfer agreement</i>	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) <i>Quality assessment and assurance.</i>	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) <i>Disclosure of ownership</i>	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) <i>Required training of feeding assistants.</i>	Re-designated & revised	§ 483.95(h).
§ 483.75(r)(1)–(3)	(r) <i>Facility closure-Administrator</i>	Re-designated	§ 483.70(l)(1)–(3).
§ 483.75(s)	(s) <i>Facility closure</i>	Re-designated & revised	§ 483.70(m).

TABLE A—TITLE 42 CROSS-REFERENCES TO PART 483 SUBPART B—Continued

Existing CFR Section	Title	Action	New CFR section
§ 483.75(t)	(t) <i>Hospice services</i>	Re-designated	§ 483.70(o)

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-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 would be 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 proposed in this rule, specifically those requirements implemented as a result of the Affordable Care Act.

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 various Medicare and Medicaid nursing

facilities from Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of April 1, 2015. We have not included data for nursing facilities that are not Medicare and/or Medicaid certified. According to our CASPER database, there are 15,691 SNFs and NFs participating in the Medicare and Medicaid programs. 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 this number is accurate as of the date of the report, the actual number of facilities may be different as of the date of this proposed 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 used the data from this Web site because it identifies many different healthcare industry occupations and specialties and updates that data monthly. We calculated the estimated hourly rates based upon the national median salary for that particular position, including fringe benefits and overhead worth 48 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 nursing home administrators and directors of nursing, so we used the average hourly wage for a medical and health services manager for these positions. We welcome any comments on the accuracy of our compensation estimates.

In estimating the burden associated with this proposed rule, we also took into consideration the many free or low cost resources nursing facilities have available to them. 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>

We will discuss the burden for each provision included in this proposed rule

in the order in which they appear in the CFR.

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 propose at § 483.75 that a facility have a QAPI program. The burden associated with these proposed requirements would 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 would have to establish a program to address the key components of the proposed standards (program measures, program scope, and program activities). The existing regulations require that QAA committees identify and correct specific deficiencies. We believe facilities would 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 would use their existing

resources to meet the requirements in this proposed 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 would be better prepared to comply with the QAPI requirements. However, for the purpose of this burden analysis, we assume that all facilities would 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 would 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/coordinator would be largely responsible for developing the overall QAPI program and would spend approximately 30 hours on this activity; the director of nursing and a registered nurse would each spend approximately 10 hours each to review and provide input on clinical services activities; a physician would spend approximately 4 hours to review the program plan and provide medical direction and input; and one office assistant would spend approximately 2 hours to prepare and distribute draft and final program plans. We estimate that this would require a total of 878,696 burden hours for all 15,691 facilities (56 hours \times 15,691 facilities) to develop a QAPI program.

We estimate that the cost for the administrator/coordinator would be \$2,400 (\$80 \times 30 hours). We estimate the cost for the director of nursing would be \$800 (\$80 \times 10 hours). We estimate that the cost for an RN would be \$580 (\$58 per hour \times 10 hours). We estimate that the cost for the physician would be \$688 (\$172 \times 4 hours). We estimate that the cost for an office assistant would be \$58 (\$29 \times 2 hours). The estimated one-time cost for each facility would total \$4,526. The total one-time cost for all 15,691 facilities would be \$71,017,466.

We anticipate that the ongoing, annual burden for each facility to collect and analyze data for QAPI activities would be 20 hours. We anticipate that to document the improvement activities would require 20 hours. We estimate the total annual burden hours for all facilities would be 627,640 (40 hours \times 15,691 facilities). We anticipate that the staff time would be distributed as follows:

Administrator/Coordinator to collect and analyze data: 10 hours \times \$80 an

hour = \$800; to implement and document improvement projects: 4 hours \times \$80 = \$320. (Total cost of \$1,120)

Director of Nursing: 4 hours to collect and analyze data \times \$80 an hour = \$320; to implement and document improvement projects: 10 hours \times \$80 an hour = \$800. (Total cost of \$1,120)

RN: 4 hours to collect and analyze data and 6 hours to implement and document improvement projects; 10 hours \times \$58 an hour = \$580.

Physician: 1 hour to analyze data \times \$172 an hour = \$172

Office Assistant: 1 hour collect and analyze data \times \$29 an hour = \$29

We estimate that the annual cost for each facility would be \$3,021. The total annual cost for all facilities would be \$47,402,511 (\$3,021 \times 15,691).

B. ICRs Regarding Compliance and Ethics Program (§ 483.85)

Proposed § 483.85 would require the operating organization for each SNF and NF to have in operation a compliance and ethics program that would be effective in preventing and detecting criminal, civil, and administrative violations under the Act and promoting quality of care no later than 1 year after the effective date of the final rule. Each compliance and ethics program must contain at least the eight required elements in proposed § 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, proposed § 483.85(d) has additional requirements for operating organizations that operate five or more facilities.

For the purpose of determining a burden for this proposed rule, we have estimated a burden based on the number of SNF and NF operating organizations. Once this rule is finalized and becomes effective, it would be enforced through the survey process. We expect that the operating organization would 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 would be the individual facilities that would be surveyed and not the operating organization, operating organizations would 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 proposed rule. Therefore, the burden we have assessed for the operating organization would 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 nursing homes include many, if not all, of the components proposed 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 would 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 proposed rule.

According to the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) as of March 2015, there are 9,023 SNFs and NFs that are part of a multi-facility operating organization (an operating organization with 2 or more facilities). Furthermore based on PECOS data, for purposes of this regulation, we estimate that there are 7,445 total operating organizations (387 operating organizations with 5 or more facilities, 437 operating organizations with 2 to 4 facilities, and 6,621 operating organizations with single facilities). Based on our experience with SNFs and NFs, we expect that the administrator and the director of nursing would primarily be involved in

developing the operating organization's compliance and ethics program. Thus, in determining the burden for all of the requirements in proposed § 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 would 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 would receive about the same amount of compensation, \$80 an hour, and that the necessary activities would require about the same numbers of hours, we believe our estimates would 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, nursing homes 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" (proposed § 483.85(b)). Thus, we expect that nursing homes 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 nursing homes in multi-facility operating organizations. However, we are not certain that most nursing homes have formal programs that comply with the requirements in this proposed rule. Thus, we believe that nursing homes would sustain a burden associated with the requirement to develop a program that complied with this proposed 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 would 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 \$1,600 (20 hours × \$80 hourly wage). In addition, since we are proposing that compliance and ethics programs should now be mandatory, we expect that facilities would 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 would need to review the facility's compliance and ethics program, make recommendations, and approve the final program. We estimate this would require 4 burden hours at an estimated cost of \$492 (\$123 hourly wage × 4 hours).

Based on this data, we estimate it would 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 proposed rule at a cost of \$2,092 (\$1,600 for the administrator and director of nursing + \$492 for an attorney). Therefore, we estimate it would require 178,680 annual burden hours (24 burden hours for each operating organization × 7,445 operating organizations) at a cost of \$15,574,940 (\$2,092 for each operating organization × 7,445 operating organizations) for all facilities to comply with this requirement.

Each operating organization would 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 would 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 would develop these policies and procedures. We estimate that it would require 10 burden hours for each operating organization to comply with this requirement at a cost of \$800 (\$80 hourly wage for a health services manager × 10 hours). Therefore, we estimate that for all 7,445 operating organizations to comply with this requirement, it would require 74,450 burden hours (10 burden hours for each operating organization × 7,445 operating organizations) at a cost of \$5,956,000 (\$800 per operating organization × 7,445 operating organizations).

In addition to developing the compliance and ethics program, each operating organization would 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 nursing homes 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 would be needed to comply with this requirement. The burden associated with this requirement would 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) would be involved in these activities.

We believe that the compliance liaison would need 8 hours to develop these materials. Thus, we estimate it would require 8 burden hours for each operating organization to comply with this requirement at a cost of \$464 (\$58 hourly wage × 8 hours). Therefore, based on the previous estimate, for all 7,445 operating organizations to comply with this requirement it would require 59,560 burden hours (8 hours × 7,445 operating organizations) at a cost of \$3,454,480 (\$464 per operating organization × 7,445 operating organizations).

We also propose 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 nursing homes develop their compliance and ethics programs, these facilities would 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 would 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, would 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 would require 5 hours from the administrator and 5 hours from the director of nursing for 10 burden hours at a cost of \$800 (\$80 hourly wage for administrator and director of nursing × 10 hours). Therefore, based on the previous estimate, for all 7,445 facilities to comply with this requirement would require 74,450 burden hours (10 hours × 7,445 operating organizations) at a cost of \$5,956,000 (\$800 per facility × 7,445 operating organizations).

Based upon the previous estimates, for the first year that this requirement is in effect, it would 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 \$3,356 (\$2,092 for developing the program + \$800 for developing policies and procedures + \$464 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 7,445 operating organizations to comply with these requirements it would require 312,690 burden hours (42 hours per operating organization × 7,445 operating organizations) at an estimated cost of \$24,985,420 (\$3,356 per operating organization × 7,445 operating organizations). For all subsequent years,

we estimate to comply with the information collection would annually require 10 burden hours at a cost of \$800. For all 7,445 operating organizations, it would require 74,450 (10 hours × 7,445 facilities) burden hours at an estimated cost of \$5,956,000 (\$800 per operating organization × 7,445 operating organizations).

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. The proposed requirement at § 483.95(f)(1) would require a facility to include dementia management and abuse prevention in their regular in-service education for all NAs.

Section § 483.75(e)(8)(iii) of the current regulations already requires 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 current requirement at § 483.75(e)(8)(ii) states 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 proposed rule would specifically require facilities to provide dementia management and abuse

prevention training to all NAs, each facility would 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 proposed rule, all NAs would be required to receive this training annually, and the facility would need to evaluate whether another format might be more appropriate.

Since we are not proposing to increase 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 would 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 would require the involvement of a RN or a LPN. Based on our experience with facilities, we anticipate that it would take each facility 4 hours to review and modify their existing training materials. Based on an hourly rate of \$58 for an RN that includes fringe benefits, we estimate that this would require 62,764 burden hours (4 hours × 15,691 facilities) at a cost of \$3,640,312 (\$232 per facility × 15,691 facilities).

Table 1 below summarizes the estimated annual reporting and recordkeeping burdens for this proposed rule.

TABLE 1—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 capital/maintenance costs (\$)	Total cost (\$)
§ 483.75(a)	0938—New	15,691	15,691	56	878,696	**	71,017,466	0	71,017,466
§ 483.75(b)(2)	0938—New	15,691	15,691	40	627,640	**	47,402,511	0	47,402,511
§ 483.85(b)	0938—New	7,445	7,445	24	178,680	**	15,574,940	0	15,574,940
§ 483.85(c)	0938—New	7,445	7,445	10	74,450	**	5,956,000	0	5,956,000
§ 483.85(d)(1)	0938—New	7,445	7,445	8	59,560	**	3,454,480	0	3,454,480
§ 483.85(e)	0938—New	7,445	7,445	10	74,450	**	5,956,000	0	5,956,000
§ 483.95	0938—New	15,691	15,691	4	62,764	**	3,640,312	0	3,640,312
Totals	23,136	76,853	1,956,240	106,001,709

** 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 1.

If you comment on these information collection and recordkeeping requirements, please submit your comments electronically as specified in

the ADDRESSES section of this proposed rule.

Comments must be received on or by September 14, 2015.

V. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not

able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis (RIA)

A. Introduction

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. We estimate

the total projected cost of this rule would be \$729,495,614 million in the first year. This results in an estimated first-year cost of approximately \$ 46,491 per facility and a subsequent-year cost of \$40,685 per facility on 15,691 LTC facilities. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

B. Statement of Need

CMS has not comprehensively reviewed the entire set of requirements for participation it imposes on LTC facilities in many years. CMS staff as well as stakeholders identified problematic requirements over the years. Accordingly, we decided to conduct a review of the requirements in an effort to improve the quality of life, care, and services in facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations. Based on our analysis, we decided to pursue those regulatory revisions that would reflect the advances that have been made in healthcare delivery and that would improve resident safety.

C. Anticipated Impacts on SNFs and NFs

There are about 15,691 SNFs and NFs that are certified by Medicare and Medicaid. We use these figures to estimate the potential impacts of the proposed rule. In addition, 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 2014 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 48 percent of the base salary. The analysis below overlaps with the COI section for some requirements and much of the economic impact of the rule would be due to the cost for facilities to comply with the information collection requirements. The COI section contains more technical and legal detail, therefore readers may wish to consult both sections on some topics.

This proposed rule would 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 proposed rule. Many of the proposals in this rule are current and standard medical or business practices and as a result do not pose an additional burden or new cost to facilities. We have made several assumptions and estimates in order to

assess the time that it would take for a facility to comply with the proposed provisions and the associated costs of compliance.

Resident Rights § 483.10

Notification of Changes to Care Plan (§ 483.10(b)(5)(F))

As noted above, current requirements already 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 would include an opportunity to see the care plan. Periodic review after development of the care plan is also already required. However, we propose 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 caregivers, surveyors, and other interested parties. We estimate that it should take a caregiver, probably a 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 1,382,201 residents per year, the resulting burden would be \$9,620,119 for all nursing homes. (\$58 hourly wage for a nurse × .03 hour per occurrence × 1,382,201 residents × 4 occurrences per year = \$9,620,119).

Notification of a Need To Select a New Physician (§ 483.10(c)(3) and § 483.11(c)(2))

The facility would have 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 current requirements, the facility must already 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 upon which we can quantify how often this occurs or how often a facility would 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.

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. This requirement is modified to specify orally and in writing; the previous requirement was just 'to inform.' We expect that "informing" has typically been accomplished orally; therefore the burden would be in providing the written information at the time the oral information is given. We anticipate that this written information would most often be in the form of a list of standard charges for frequently requested items and the cost would be the cost of photocopying or printing the list. In infrequent cases, an individualized cost page may be needed. We estimate that a facility would 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 \$784,550 (\$50 printing cost \times 15,691 facilities) annually for all facilities.

Internet Access (§ 483.10(h)(2))

Proposed 483.10(h)(2) proposes to require that a resident has the right to reasonable access and privacy for electronic communications such as email and video communications and internet research. This requirement is proposed in a way that the facility is not required to 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. Finally, we do not believe this 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 would require quarter of an hour of DON or NHA time to develop in those facilities that do not already have a

policy established. We believe that up to ten percent of facilities will need to develop an internet policy in the first year, at a total cost of \$31,382 ($(\$80 \text{ hourly wage for a DON or NHA} \times .25 \text{ hours}) \times (0.10 \times 15,691 \text{ facilities}) = \$31,382$).

Facility Obligations (§ 483.11)

Mutually Agreeable Facility Representative (§ 483.11(d)(3)(iii))

Facilities are currently required to provide a facility representative to participate in resident and family groups. Any added burden is in establishing an individual who is mutually agreed to. We believe it is most likely 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 should generally consume no more than an additional 15 minutes of the DONs time in most cases. We believe some, and perhaps many, facilities already have such mutually agreed upon representatives; however, for estimation purposes, we estimate an additional 15 minutes of DON time at a cost of \$80 per hour for 15,691 facilities, resulting in a total cost of \$313,820.

Visitation Related Notices (§ 483.11(d)(2))

We believe that—(1) these notices are periodically reviewed and updated as a standard business practice, (2) the DON and Nursing Home Administrator will develop the associated policy, and (3) visitation is already addressed in the notice of rights and services. While we believe that the notice of rights and services is or should be periodically reviewed by each nursing facility as a standard practice, we expect that the notice will need to be updated on a one-time basis specifically to include the new visitation policy. We estimate that an office clerk will require no more than 30 minutes to update the notice and that will cost each facility approximately \$14.50 ($\$29 \text{ hourly wage for an office clerk} \times .5 \text{ hour} = \14.50) or a total of \$227,520 for all facilities ($\$10.50 \times 15,691 = \$227,520$).

Posting of Contact Information (§ 483.11(e)(5))

The facility must post a list of names and contact information. This information must already be gathered for the notice of legal rights, so the new burden is limited to the posting. This means printing out and placing the notice in an appropriate location and/or on an accessible Web site and perhaps updating the information annually. Based on other current requirements,

the location for this information should already be identified and an office clerk should be able to update, print and post a listing in 10 minutes. We estimate this will cost each facility approximately \$4.93 or a total of \$77,357 for all facilities. ($\$29 \text{ hourly wage for an office clerk} \times .17 \text{ of an hour} \times 15,691 \text{ facilities} = \$77,357$).

Medicaid Eligibility (§ 483.11(e)(11)(i))

The facility must provide notice to each Medicaid-eligible resident, in writing, at the time of admission and when the resident becomes eligible for Medicaid. This means some residents will require a second notice. As the notice is already required once, the burden is in providing the notice an additional time. We anticipate that this will affect only a subset of residents (those eligible but not yet receiving Medicaid) and that the notice will be unchanged from the admission notice. Thus the burden is in identifying eligible residents and delivering the second notice. We anticipate that this will require a social worker no more than 3 minutes per eligible resident. Based on a data analysis by AHCA, approximately 64 percent of nursing home 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. For burden calculation purposes, we estimate that 20 percent of nursing home residents (slightly more than half of those not already receiving Medicaid) will require a second notice of Medicaid eligibility. The per facility cost will vary significantly according to facility size and resident mix and will be about \$2.20 per resident who requires notification, or \$608,168 for all such residents across all 15,691 facilities. ($(\$44 \text{ hourly wage for social worker} \times .05 \text{ of an hour}) \times (.20 \text{ estimate percent of all nursing home residents who will require a second notice} \times 1,382,201 \text{ nursing home residents}) = \$608,168$).

Update the Description of Legal Rights (§ 483.11(e)(13))

Our proposed changes will require that facilities review and possibly update their description of legal rights to include additional names and contact information as well as some additional

language to meet the requirements of the revised regulatory language. Collecting and verifying some of this information may require some additional research. We anticipate that a social worker would need 45 minutes to review information and conduct the necessary research and an office clerk would need an additional 15 minutes to update the notice. The cost per facility is estimated at \$30 per facility or a total of \$631,563 for all facilities. $((\$44 \text{ hourly wage for a social worker} \times .75 \text{ of an hour}) + (\$29 \text{ hourly wage for an office clerk} \times .25 \text{ of an hour}) \times 15,691 \text{ facilities} = \$631,563)$.

Grievances (§ 483.11(h)(1))

A facility must make information regarding the grievance process and how to file a grievance available to residents. We believe this information is already included in the notice of legal rights, but it may need reviewed and updated. It would take an office clerk approximately 10 minutes to review and update the notice. This would cost each facility \$4.93 or a total of \$77,357 for all facilities. $(\$29 \text{ hourly wage for an office clerk} \times .17 \text{ of an hour} \times 15,691 \text{ facilities} = \$77,357)$.

Transitions of Care (§ 483.15)

Notice of Transfer (§ 483.15(b)(4))

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 clerk 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 nursing home residents, resulting in a cost of \$1,243,981 for all facilities. The per-facility cost will vary significantly according to facility size and number of transfers out of each facility. $((\$.10 + \$.58 + (\$29 \text{ hourly wage for an office clerk} \times .08 \text{ of an hour})) \times (.3 \text{ percentage of nursing home residents for whom a copy of a transfer notice needs sent to the Office of the State Long-Term Care Ombudsman} \times 1,382,201 \text{ nursing home residents}) = \$1,243,981)$.

Update Transfer Notices (§ 483.15(b)(7))

The proposed requirement requires the facility to update transfer notices if information in the notice changes and to provide the updated information to the resident. We believe that the updates already occur informally and estimate that updating the notice and providing it to the resident will require a social worker an additional 5 minutes per notice. As discussed above, this requirement will apply primarily to residents who are involuntarily discharged from the facility and does not include resident 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 nursing home residents who are transferred. The resulting cost is \$1,459,604 for all facilities. $((\$44 \text{ hourly wage for a social worker} \times .08 \text{ of an hour}) \times (.3 \text{ percent of nursing facility residents} \times 1,382,201 \text{ nursing facility residents}) = \$1,459,604)$. The per-facility cost will vary significantly according to facility size and number of transfers out of each facility.

We believe the DON or administrator would perform a comprehensive review of all required notices after all the cumulative changes noted above are made and that this cumulative review would require approximately 30 minutes at a cost of \$40 per facility or \$627,640 for all facilities $(\$80 \text{ hourly wage for a NHA or DON} \times .5 \text{ of an hour} \times 15,691 \text{ facilities} = \$627,640)$.

Comprehensive Resident Centered Care Planning (§ 483.21)

Additional Members of the IDT (§ 483.21(b)(2)(ii))

We would require that a NA, member of nutrition services, and social worker participate on the IDT. We believe that this requirement would 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 would only 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 would add an additional one hour of staff time to the duties of a NA, member of food services, and social worker. 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 would cost \$97,911,840 $(\$120 \text{ hourly wage} (\$23 \text{ NA hourly wage} + \$53 \text{ dietitian hourly wage} + \$44 \text{ social worker hourly wage} = \$120) \times 52 \text{ hours} (1 \text{ hour per week} \times 52 \text{ weeks}) \times 15,691 \text{ facilities})$.

Discharge Planning (§ 483.21(c)(1)(vii))

We would 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 would 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 would 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 would only be required for those residents who are transferred to another SNF or discharged from the nursing home. We are unable to determine the average number of residents who are transferred to another SNF or discharged from a nursing home annually. We believe that a conservative estimate would be that if there are an estimated 1,382,201 residents per year in nursing homes, possibly a third of these residents are discharged or transferred to another SNF on an annual basis. Therefore, we estimate that this requirement would cost \$20,272,252 $(\$44 \text{ social worker hourly wage} \times 1 \text{ hour staff time} \times 460,733 \text{ residents discharged or transferred to another SNF annually})$.

Physician Services (§ 483.30)

Practitioner Evaluation of a Resident (§ 483.30(e))

We believe that a physician, NP, CNS or PA often evaluate in person a

resident prior to hospital transfer unless a delay in transfer places the resident at risk. However, we also believe that there are instances when an evaluation does not occur and could prevent an avoidable hospital transfer. We estimate that it will require a physician, NP, CNS, or PA 30 minutes to evaluate a resident prior to transfer. For purposes of estimating this cost we will use the hourly wage of a physician. Research shows that more than 15 percent of long-term nursing home residents are hospitalized in any given 6 month period and approximately 40 percent of nursing home to hospital transfers are considered inappropriate (David C. Grabowski, A. James O'Malley and Nancy R. Barhydt, *The Costs And Potential Savings Associated With Nursing Home Hospitalizations*, Health Affairs, 26, no.6 (2007):1753–1761). If we use 30 percent to estimate the number of in-person evaluations required per year (15 percent per 6 months), the resulting calculation provides a lower bound estimate of \$35,660,786 ($(\$172 \text{ hourly wage for a physician} \times .5 \text{ of an hour}) \times (30 \text{ percent of facility residents who require an in-person evaluation prior to transfer} \times 1,382,201 \text{ facility residents}) = \$35,660,786$).¹

Nursing Services (§ 483.35)

Competency Requirements (§ 483.35, § 483.60)

Our focus on competency requirements requires identification of and documentation of 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. Initial competency requirements would be identified via facility assessment with documentation of individual accomplishments managed by an administrative position, likely an office clerk, as an addition to existing documentation. We estimate the incremental burden of adding the additional information to existing files (paper or electronic) at 8 hours per year per facility, or \$232. The cost for all facilities is estimated at \$3,640,312. ($\$29 \text{ office clerk hourly wage} \times 8 \text{ hours per facility} \times 15,691 \text{ facilities} = \$3,640,312$)

¹ We refer to this estimate as a lower bound because the input that is available—residents who are hospitalized—may be lower (due to repeat admissions) than the input that would be most appropriate for this calculation—the number of hospitalizations.

Food and Nutrition (§ 483.60)

Requirements for Food Service Directors (§ 483.60(a)(2))

The proposed provision establishes requirements for directors of food and nutrition services hired after the effective date of these requirements or, for current directors of food and nutrition services, within 5 years of the effective date of these requirements. We would 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 the proposed requirements. We anticipate that some hiring officials may spend some additional time recruiting appropriate candidates for the food service manager position and verifying credentials, although we believe this is a small percentage of facilities. When necessary, we estimate this will require an extra hour of the NHA's time. The burden is imposed only on those facilities needing to hire a food service manager after the effective date of the regulation. We anticipate that this will affect less than 10 percent of all facilities during the five-year time horizon we are analyzing in this regulatory impact analysis. The cost per affected facility is approximately \$80 and the total cost for all affected facilities is estimated to be \$125,528. ($(\$80 \text{ NHA hourly wage} \times 1 \text{ hour}) \times (.1 \text{ percentage of affected facilities} \times 15,691 \text{ facilities}) = \$125,528$).

Menu Options (§ 483.60(c))

We expect that our proposed requirement for menus to reflect the cultural and ethnic needs of residents would require that menus be updated by a qualified dietitian or other clinically qualified nutrition professional in the course of routine reviews and updates. Additional time would 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 would require 1 to 4 hours, on average 2 hours, depending on the size of the facility and complexity of resident needs. While we believe that some facilities already meet this requirement, for estimation purposes,

we multiply the \$53 hourly wage of a qualified dietitian or other clinically qualified nutrition professional for 2 hours for 15,691 facilities, for a total cost of \$1,663,246.

Facility Assessment (§ 483.70(e))

The proposed provision establishes requirements for each LTC facility 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 will not include a burden for this requirement in the impact analysis.

QAPI (§ 483.75)

We have proposed to require that each facility develop a QAPI program. In addition to the QAPI requirement related ICR costs discussed in the COI section, we expect that facilities would incur additional costs that would be dependent upon the projects they selected for their quality improvement activities. In turn, the projects would be dependent upon resident needs, and the type, complexity, and quality of services already provided by the facility. Facilities would 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 (\$118,419,977 upfront) that would be associated with the QAPI requirements (discussed in the COI section of the preamble). However, we encourage the public to comment on the

potential costs for facilities of their quality improvement projects. We estimate that the ongoing annual cost for each facility to comply with the QAPI requirements would be \$3,021 for each facility and for all facilities would be \$47,402,511 ($\$3,021 \times 15,691$). (This discussion is detailed in the COI section.)

Infection Control (§ 483.80)

Infection Prevention and Control Officer (§ 483.80(b))

Facilities and their staffs are currently required to have an infection control program (§ 483.65). In this rule, we are proposing that each facility must also designate one individual as the infection prevention and control officer (IPCO) for whom the infection prevention and control program (IPCP) is a major responsibility. The IPCO would be 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 would also be required to be a member of the facility's QAA committee. The percentage of the RN FTE that would be required at each facility will vary greatly. We believe that each facility would have to determine the appropriate percentage based upon its facility assessment, especially its assessment of the acuity of its resident population. A facility with a generally healthy population of elderly individuals would likely require many fewer hours than a facility with a large percentage of subacute residents or residents that are on ventilators. For the purposes of determining an estimate, we believe that the average facility would designate a registered nurse (RN) to be the IPCO and that individual would need to commit about 15 percent of a full time equivalent position (FTE) to his or her responsibilities under the IPCP. We estimate that this would require 15 percent of one RN FTE for each of the 15,691 facilities for a total cost of \$283,944,336 (15% of an RN FTE \times \$58 average hourly wage for an RN \times 2,080 hours (40 hours a week \times 52 weeks = 2,080 hours) \times 15,691 facilities = \$283,944,336). We request comment on the time and other costs that would be associated with rule-induced improvements in infection control procedures if any, put into practice by facility personnel other than the IPCO.

Compliance and Ethics Program (§ 483.85)

Compliance Officer and Compliance Liaison Activities (§ 483.85)

We propose 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 \$24,985,420. We estimate that in carrying out this program the compliance officer (similar to an administrator) in each of the 387 organizations operating 5 or more facilities would commit 30 percent of an full time equivalent (FTE) in the compliance program operation, for a total cost of \$19,319,040 (30% of FTE \times 2080 \times \$80 \times 387). We also estimate that in carrying out this program the compliance liaison (nursing staffs) in each of 7,879 facilities would commit 10 percent of an FTE, at a total cost of \$95,052,256 (10% of FTE \times 2080 \times \$58 \times 7879).

Annual Review of Program (483.85(e))

As detailed in the COI section, we propose to require each facility 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 would cost an estimated \$5,956,000.

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, we would 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 requirements similar to those proposed 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. Although we know that semi-private rooms will increase

constructions costs, we were unable to find data regarding the incremental increased cost to the facility of semi-private rooms versus configurations that accommodate up to four residents. We welcome data on this issue and on the question of whether this provision of the rule creates an incentive for facilities to avoid or delay otherwise beneficial renovations.

Toilet Facilities (§ 483.90(e))

For resident rooms newly constructed or undergoing reconstruction, we would require that each room have its own bathroom equipped with at least a toilet, sink and shower. 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. We do not have statistics on the number of providers per year who undertake reconstruction. Although 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 or reconstruction. We welcome data on this issue and on the question of whether this provision of the rule creates an incentive for facilities to avoid or delay otherwise beneficial renovations.

Training Requirements (§ 483.95)

General Training Topics (§ 483.95a)

We are proposing that facilities 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 would 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 would 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 nursing home staff on key patient safety concepts to improve the safety of nursing home 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 would 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 would need to compare their training programs to their facilities assessments as required at proposed § 483.70(e) and ensure they cover the above training topics. We expect that complying with this requirement would require the involvement of a RN and the infection control and prevention officer (ICPO). We expect that a RN would spend more time reviewing, revising and/or developing new sections for the training program. The ICPO would need to weigh in on the infection control training related topics. We estimate that it would require 8 (6 for the RN (\$58/hr) and 2 for the ICPO (\$58/hr)) burden hours for each facility to develop a training program at a cost of \$464. Thus, for all facilities to comply, it would cost an estimated \$7,280,624 (\$464 estimated cost for each facility × 15,691 facilities). We believe that the training would be considered part of regular on-going 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. Our rule proposes, 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 would 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 × \$58 average hourly wage for a RN = \$900,740). For the training in operating organizations with 1 to 4 facilities, we expect that operating organizations would 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 5 or more facilities would 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 × \$80 = \$61,920) and 2 hours of time of a compliance liaison (similar to an RN) at the facility level (7,879 facilities × 2 × \$58 = \$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 proposed rule would 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. Facilities would 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 would 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 would need to acquire training materials to either update or supplement what they are currently using to train NAs. 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 nursing homes 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 nursing homes 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 would cost facilities an estimated \$3,640,312 to review and update their current in-service training material.

D. Summary of Impacts

Table 2 below presents a summary of the section by section estimated costs to comply with the requirements of this proposed rule.

TABLE 2—SECTION BY SECTION SUMMARY OF ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS PROPOSED RULE

Regulatory area	Section	First year total cost	Total cost in year 2 and thereafter
Resident Rights	483.10	\$10,436,051	\$10,436,051
Facility Obligations	483.11	1,935,785	999,345
Transitions of Care	483.15	3,331,225	3,331,225
Comprehensive Resident Centered Care Planning	483.21	118,184,092	118,184,092
Physician Services	483.30	35,660,786	35,660,786

TABLE 2—SECTION BY SECTION SUMMARY OF ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS PROPOSED RULE—Continued

Regulatory area	Section	First year total cost	Total cost in year 2 and thereafter
Nursing Services	483.35	3,640,312	3,640,312
Food and Nutrition Services	483.60	1,788,774	1,663,246
QAPI	483.75	118,419,977	47,402,511
Infection Control	483.80	283,944,336	283,944,336
Compliance and Ethics Program	483.85	139,356,716	120,327,296
Training	483.95		
General Training Topics	483.95(a)	7,280,624	7,280,624
Compliance and Ethics Training	483.95(f)	1,876,624	1,876,624
Dementia Management and Abuse Training	483.95(g)	3,640,312	3,640,312
Total		729,495,614	638,386,760

E. Alternatives Considered

The requirements for long-term care facilities have not been comprehensively updated in many years. The effective and efficient delivery of health care services has changed substantially in that time. We believe the changes we have proposed are necessary to ensure the requirements are consistent with current standards of practice and continue to meet statutory obligations and ensure that residents receive care that maintains or enhances each resident's quality of life and attains or maintains the resident's highest practicable physical, mental, and psychosocial well-being. Below we discuss the alternatives that we considered when developing this proposed rule.

1. Scope of Proposed Revisions

We considered only proposing those requirements that are required by statute. Specifically, the Affordable Care Act included provisions regarding dementia and abuse training, QAPI program, and compliance and ethics program, and the IMPACT Act requires that we issue regulations regarding discharge planning. Taking this approach would be less burdensome on the LTC community overall. 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. Our proposed revisions address several issues, such as avoidable hospitalizations, staffing concerns, infection control, and behavioral health. In addition, we believed that it was necessary to modernize the regulations to reflect advances such as electronic communications and health information technology. Overall, we believe that a general reorganization and comprehensive revision would ensure 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. We believe the changes we have proposed are necessary to ensure that residents receive care that maintains or enhances each resident's quality of life and attains or maintains the resident's highest practicable physical, mental, and psychosocial well-being. Therefore, we determined it would be most effective to make comprehensive changes at this time.

2. Psychotropic Drugs

We considered not proposing to revise the existing requirements that apply to antipsychotic drugs to psychotropic drugs. This approach would be less burdensome for nursing homes. However, we are concerned that the current requirements are insufficient to protect the health and safety of nursing home residents. We learned that while some residents are being taken off of anti-psychotics, they are then prescribed other medications that are continuing to affect their mental processes and behavior. We are also concerned that drugs, other than anti-psychotics, that affect mental processes or behavior can be prescribed in ways that benefit of the staff and not necessarily the resident's health. In addition, in cases where medication is originally prescribed for the resident's benefit, we are concerned that the resident could remain on these types of medications even after non-pharmacological interventions or gradual reductions in the medication could have either eliminated the reason for the medication or at least reduced the amount of medication required by the resident. Thus, we believe that all psychotropic medications should be subject to the proposed requirements to protect the health and safety of nursing home residents.

We also considered various definitions for psychotropic drugs. The definition would determine the types of medications that specific requirements in this proposed rule would apply to and the burden they would place on the LTC facilities and health care providers. After reviewing different definitions, we are proposing to define a psychotropic drug as any drug that affects brain activities associated with mental processes and behavior. We have included a list of drug categories that are typically considered psychotropic drugs in the literature, that is, anti-psychotic, anti-depressant, anti-anxiety, hypnotic, and opioid analgesics. We have also included any other drugs that have effects similar to those drugs in these categories. We believe that this provision is necessary so that drugs used for "off-label" use would be subject to the regulatory requirements. We acknowledge that this is a broad definition and may result in additional burden for the facilities. However, we also believe this definition encompasses all of the drugs that could be used to control a resident's mental processes and behavior. We are specifically requesting comments on the scope of our proposal.

3. Binding Arbitration

We considered not proposing any requirements concerning binding arbitration agreements. Taking this approach would certainly be less burdensome to the facilities. However, stakeholders raised specific concerns about nursing homes either requiring or pressuring nursing home residents to sign these agreements and, therefore, waiving the right to pursue resolution of a dispute with the nursing home in court. We share the stakeholders' concern that some nursing homes may be requiring residents to sign agreements for binding arbitration as a requirement for admission into the facility. In addition, if the nursing home

is not requiring the agreement as a condition of admission, some facilities may be requesting the resident to sign the agreement without fully explaining the rights the resident is waiving and the consequences of that waiver. We believe that nursing home residents need to be fully aware of the right they are waiving (the right to seek relief in a court for a dispute between the resident and the facility) if a nursing home requests they sign an agreement for binding arbitration. Thus, we have proposed specific requirements if a nursing home chooses to request that a resident sign an agreement for binding arbitration. These requirements include, among other things, that the nursing home must explain the agreement to the resident in a form and manner that he or she understands, and that the resident acknowledge that they understand the agreement. We have also proposed specific requirements for the agreement, including that admission to the facility cannot be contingent upon the resident signing the agreement, the agreement must be entered into voluntarily, and the arbitration must be conducted by a neutral arbitrator in a venue convenient to both parties. In addition, we have also proposed that the agreement 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 surveyors, health department employees, and representatives of the Office of the State Long-Term Care Ombudsman. We believe this requirement is essential so that residents and others who have knowledge of their care are not discouraged from speaking with surveyors and others from whom the resident can seek assistance. In addition, another individual can sign the agreement for the resident only if allowed by state law and the individual has no interest in the facility. Thus, we believe these comprehensive requirements are needed so that residents understand the right they are waiving by signing an agreement for binding arbitration and that the arbitration will be conducted in a neutral and fair manner.

We also considered prohibiting binding arbitration agreements. This would be more burdensome to the LTC facilities. However, it would remove the choice to agree to binding arbitration from the resident. Alternative dispute resolution, which includes arbitration, is favored by the courts and provides both parties, the resident and the nursing home, with advantages. Arbitration can result in disputes being

resolved faster and in a less burdensome manner for both parties. There have also been court decisions that have upheld these agreements in cases involving nursing home residents. However, we are concerned that despite the protections we have proposed in this rule, some nursing home residents and potential residents may feel pressured to sign these agreements. For example, in cases where a potential resident or their family have the time to do research and visit multiple homes, a resident may feel he or she can more easily refuse to sign an agreement for binding arbitration. However, if the resident is hospitalized and needs to locate a facility quickly, they may feel more pressure to accept such an agreement. Thus, we have also requested comments on whether agreements for binding arbitration should be prohibited.

4. In-Person Physician Evaluation Before Transfer

We considered not proposing to require an in-person evaluation of a resident prior to an unscheduled, non-emergency transfer of a resident to a hospital. However, in concert with improved communication requirements, an evaluation of a resident by a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist prior to a resident's transfer may identify options that could allow some residents to be treated in place and avoid unnecessary hospitalizations.

5. Additional Changes

We also considered proposing additional changes. In some cases, we determined that an issue was not adequately developed for us to make an evidenced-based proposal. In several of these cases, we have specifically solicited comments so that we are better informed. For example, we considered requiring all facilities to implement a hazard analysis and critical control point program for food and nutrition services, but instead chose to request comments so that we better understand the potential benefits and impact, particularly on small facilities. We may consider these topics in future rule-making.

We also considered more prescriptive changes in several areas. Throughout this rule, we focused on supporting person-centered approaches and innovative care delivery models. This requires that we allow flexibility in the regulatory language. Where possible, we chose a more flexible option to ensure that proposed regulatory requirements could be accommodated across the spectrum of facility sizes and resident populations. This particularly applied

in our consideration of options to address nurse staffing. In that area, we specifically considered establishing minimum nurse hours per resident day, establishing minimum nurse to resident ratios, requiring that an RN be present in every facility either 24 hours a day or 16 hours a day, and requiring that an RN be on-call whenever an RN is not present in the facility instead of or in addition to imposing a competency-based staffing requirement that takes into consideration the acuity, diagnoses, and number of residents in the facility. All of the options not chosen had high associated burdens, with options for RN staffing changes ranging from in excess of \$1,000,000,000 to over \$5,000,000,000 total to implement across likely affected facilities, based on the current statutory minimum staffing requirements. Earlier in this preamble, we specifically invited comments on the costs of mandating a 24 hour RN presence, the benefits of a mandatory 24 hour RN presence, including cost savings and improved resident outcomes, as well as any unintended consequences of implementing this requirement. We will reconsider these options in light of future research, recommendations, and the availability of more valid and reliable payroll-based staffing data.

We also considered adding more requirements to the qualifications for a social worker in § 483.70(p). We considered requiring a masters of social work (MSW) for the social worker. We also considered requiring that the social worker also have a certification related to clinical work or gerontology. We did not propose these requirements because we are concerned that increasing the qualifications for social workers in nursing homes may result in access issues. We have received input that some nursing homes already have difficulty in hiring qualified social workers. We would welcome comments related to qualification for the social worker, especially whether state licensure should remain the threshold requirement or if additional requirements are appropriate.

F. Benefits of Proposed Rule

This proposed rule would implement comprehensive changes intended to update the current requirements for long-term care 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 we propose 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 would change their policies even in the absence of this rulemaking.

In addition to proposing changes that are likely to have long-term positive impacts on quality of life and quality of care, we have proposed several changes that may mitigate the costs associated with implementing some of our proposed 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. We do not have data on how many medical records requests are made each year, nor do we have empirical data on the time difference, thus we have no way to estimate the magnitude of these savings. However, to understand the possible magnitude of the savings, let us assume that 2 percent of residents request their record each year (27,644). We further assume that, on average, it takes an office clerk 15 minutes to make a page by page copy of a medical record. If twenty-five percent of residents (6,911) requesting a copy of their medical record accept an electronic copy in lieu of a paper record or if the paper copy can be printed from an electronic record rather than copied page by page and it takes an office clerk 5 minutes to make an electronic copy, the facility saves 10 minutes of clerk time per record. The annual savings would be \$24,189. We believe this is likely a conservative estimate.

Another area that may produce substantial savings is our proposal to allow 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 further believe that dietitians or other clinically qualified

nutrition professional are already performing resident dietary assessments and making dietary recommendations to the physician who then evaluates the recommendations and writes orders to implement them. We do not currently have data to estimate the savings that this could produce in SNFs and NFs. However, we believe that it will allow for better use of both physician and dietitian time.

We also propose to 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 propose to modify 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. Furthermore, reducing the number of hospitalization through these preventative actions would also reduce our estimated burden for requiring practitioner evaluation of a resident prior to a hospital transfer. Finally, improved dental care and oral hygiene would likely result in improved quality of life. However, we have no basis on which to calculate these savings and therefore do not quantify them.

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. Proposed improvements in food and nutrition services have the potential to improve resident quality of life. They may also result in a reduced incidence of food-borne illness, which could result in substantial savings. We invite comment, data and analysis on this issue, including the related question of whether the activities for which costs were estimated in the cost section, above, are sufficient to generate the benefits discussed here.²

We are concurrently proposing to strengthen requirements related to infection control. While a reduction in the incidence of healthcare associated infections would 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 nursing homes. 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 two to three 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/ManagementofNorovirusInfectionOutbreaksinHospitalsand>

² 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.

NursingHomes.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 invite comment, data and analysis on this issue, including on the question of how actions of a facility's infection prevention and control officer affect the practices of other facility personnel, and whether such effects are sufficient to yield infection control benefits.

We note that we made several changes that target reducing avoidable or unnecessary hospitalizations. We make proposals regarding improved communication of critical information, in-person evaluation or residents prior to transfer, 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, however, we have not quantified potential savings.

Currently, the regulations require that the nurse's station be equipped to receive resident calls. Our proposal to require a communications system that allows residents to call for assistance through a communications system that relays the call directly to a staff person or centralized staff area from each bedside and from toilet and bathing facilities provides added flexibility and efficiency. Eliminating the requirement for a "nurses' station" better accommodates a decentralized care model, better reflects current practice, and may improve response times. However, we have no basis upon which to calculate specific cost savings that this flexibility would provide.

This does not take into account dollar amounts from improved resident quality of life or improved staff work life. Reduced costs from improved staff satisfaction resulting in reduced turnover, decreased use of agency labor and decreased worker compensation costs could be substantial. The cost of turnover among nurse aides was estimated at \$2,500 per occurrence in 2008 (Frampton, Susan, et al. "Making the Case for Change" Long-Term Care Improvement Guide 2010, retrieved from <http://www.residentcenteredcare.org/Pages/About%20the%20guide.html>).

According to 2014 BLS statistics, there are over 1.4 million nurse aides employed in the United States; over 616,000 are employed in nursing facilities. AHCA reported in 2010 that the national turnover rate for certified nurse assistants (nurse aides) was 43 percent.

According to the American Nurses Association, the cost of recruiting and replacing an RN is 1.1 to 1.6 times an annual nurse's salary (<http://www.nursingworld.org/SafeStaffingFactsheet.aspx>). According to a 2009 survey by the American Health Care Association (http://www.ahcancal.org/research_data/staffing/Documents/staffsurvey_2009_full_report.pdf), the turnover rate for staff RNs was 46.7 percent and for administrative RNs was 36.3 percent. 2014 BLS data shows that over 140,000 RNs are employed in nursing care facilities at an annual mean wage of \$62,440. Additional savings would accrue as a result of reduced turnover of other personnel such as licensed practical or vocational nurses, reduced use of agency staff and decreased worker compensation costs. One 2012 study found that over 60 percent of all nurse aides working in the United States reported being injured once in the study year. Further, the report found that certain workers were more likely to

have a workplace injury, including those who were new, changed jobs more frequently, reported poor job preparation, and who had inadequate time to provide personal care. Khatutsky, G., Wiener, J. M., Anderson, W. L., & Porell, F.W. (2012). Work-related injuries among certified nursing assistants working in U.S. nursing homes. RTI Press publication No. RR-0017-1204. Research Triangle Park, NC: RTI Press. Retrieved from www.rti.org/rtipress). Some of our proposals, such as nurse aide training and competency requirements, would address some of these issues. However, the savings are not easily estimated. Cumulative, modest impacts from proposed changes could result in savings, in addition to the improvements in quality of life for residents. In addition to the more specific requests related to food service and infection control, we invite general comment, data and analysis on whether the actions whose costs are estimated elsewhere in the regulatory impact analysis are sufficient to yield the benefits discussed in this section.

G. Cost to the Federal Government

If these requirements are finalized, CMS will update the interpretive guidance, update the survey process, and make IT systems changes. In order to implement these new standards, we anticipate initial federal start-up costs between \$15 to20 million. Once implemented, improved surveys to review the new requirements will require an estimated \$15 to20 million annually in federal costs. CMS will continue to examine and seeks comment on the potential impacts to both Medicare and Medicaid.

H. Accounting Statement

As required by OMB Circular A-4 (available at <http://www.whitehouse.gov/omb/circular/a004/a-4.pdf>), we have prepared an accounting statement.

TABLE 3—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)	659	2015	7%	2016–2020
	658	2015	3%	2016–2020
Qualitative	Unquantified possible cost associated with the toilet 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 nursing homes 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>). Therefore, the Secretary has determined that this proposed rule will have a significant economic impact on a substantial number of small entities.

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 proposed rule pertains solely to SNFs and NFs. Therefore, the Secretary has determined that this proposed 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 2014, that is approximately \$141 million. This proposed rule contains mandates that would impose a one-time net cost of approximately \$766,822,783 (after including savings of \$24,189). Thus, we have assessed the various costs and benefits of this proposed rule. This proposed rule would 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 proposed rule (and subsequent 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 proposed 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 proposed 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.

I. Conclusion

The proposed requirements in this proposed rule would update the existing requirements for long-term care facilities to reflect current standards of practice. In addition, proposed changes would 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.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 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 and paragraph (b)(9) is added 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), and (h)(3)).
(2) Facility responsibilities (§ 483.11(d)(1)(i), (d)(1)(iii), (d)(4), (e)(11), (e)(12), (e)(14)(iii), and (f)(1)(i)).
(3) Transitions of care (§ 483.5(n), § 483.15(b)(1), (b)(2), (b)(3)(i) through(iii), (b)(4), (b)(5)(i) through (vii), and (b)(7)).
(4) Freedom from abuse, neglect and exploitation (§ 483.12).
(5) Patient activities (§ 483.25(c)).
(6) Social services (§ 483.40(d) and § 483.75(p)).
(7) Discharge planning (§ 483.20(e)).
(8) Specialized rehabilitative services (§ 483.65).
(9) Dental services (§ 483.55).

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-7), 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 facilities 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”, “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. This presumes that 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. Means 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.

* * * * *

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.

* * * * *

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.

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 mental illness.

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 an individual of the resident's choice who has access to information and participates in healthcare discussions or a personal representative with legal standing, such as a power of attorney, legal guardian, or health care surrogate appointed or designated in accordance with state law. If selected as the resident representative, 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.

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.

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.

(a) *Exercise of rights.* (1) 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.

(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) A resident has the right to designate a representative, in accordance with State law.

(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) 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.

(i) The resident may exercise his or her rights to the extent not prohibited by court order.

(ii) 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.

(iii) The resident's wishes and preferences must be considered in the exercise of rights by the representative.

(iv) To the extent practicable, the resident must be provided with opportunities to participate in the care planning process.

(5) In the case of a resident who has not been adjudged incompetent by the state court, any legal surrogate designated in accordance with state law 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.

(b) *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 be informed, in advance, of the care to be furnished and the disciplines that will furnish care.

(3) The right to be informed in advance 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.

(4) 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 as specified in § 483.11(e)(6).

(5) 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 changes to the plan of care.

(6) The right to self-administer medications if the interdisciplinary team has determined that this practice is clinically appropriate in accordance with § 483.11(b)(2).

(7) 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.

(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 requirements of the facility.

(3) 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 § 483.11(c) to assure provision of appropriate and adequate care and treatment.

(d) *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.

(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 notice 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 to relocate:

(i) 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) 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.

(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.

(e) *Self-determination.* The resident has the right to self-determination, including but not limited to the right to—

(1) Choose activities, schedules (including sleeping and waking times), health care and providers of health care services consistent with his or her interests, assessments, and plan of care;

(2) Interact with members of the community and participate in community activities both inside and outside the facility;

(3) Receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation, and in a manner that does not impose on the rights of another resident, including the individuals specified in § 483.11(d);

(4) Organize and participate in resident groups in the facility;

(5) Participate in family groups;

(6) 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;

(7) Participate in other activities, including social, religious, and community activities that do not interfere with the rights of other residents in the facility;

(8) Choose to or refuse to perform services for the facility subject to the facility requirements in § 483.11(d)(4);

(9) 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 as specified in § 483.11(d)(6)(ii);

(10) Make choices about aspects of his or her life in the facility that are significant to the resident.

(f) *Access to information.* (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 receive notices verbally (meaning spoken) and in writing (including Braille) in a format and a language he or she understands, including

(i) Required notices as specified in § 483.11(e);

(ii) Information and contact information for State and local advocacy organizations, including but not limited to the State Long-Term Care Ombudsman program (established under section 712 of the Older Americans Act of 1965, as amended 2006 (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 about abuse, neglect, misappropriation of resident property in the facility, and non-compliance with § 489.102 of this chapter.

(3) The resident has the right to access medical records pertaining to him or herself,—

(i) 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 medical 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, including current medical records, within 24 hours (excluding weekends and holidays); and

(ii) 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 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 medical 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.

(4) 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.

(g) *Privacy and confidentiality.* The resident has a right to personal privacy and confidentiality of his or her personal and medical records.

(1) This includes the right to privacy in his or her verbal (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.

(2) 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;

(3) The resident has a right to a secure and confidential medical record.

(4) 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.

(h) *Communication.* (1) 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.

(2) 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.

(3) 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 paragraph (g)(1) of this section; and

(ii) Access to stationery, postage, and writing implements at the resident's own expense.

(i) *Safe environment.* The resident has a right to a safe, clean, comfortable and homelike environment in accordance with § 483.11(g), including but not limited to receiving treatment and supports for daily living safely.

(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.

(2) The resident has the right to prompt efforts by the facility to resolve grievances in accordance with § 483.11(h).

■ 14. Section 483.11 is added to subpart B to read as follows:

§ 483.11 Facility responsibilities.

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 as specified in § 483.10, including, but not limited to the following obligations:

(a) *Exercise of rights.* (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 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.

(3) 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.

(4) 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.

(5) 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 may report such concerns as permitted and shall report such concerns when and in the manner required under State law.

(b) *Planning and implementing care.*

(1) The facility shall inform the resident of the right to participate in his or her treatment and shall support the resident in this right, consistent with § 483.10(b). The planning process must:

(i) Facilitate the inclusion of the resident 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.

(2) The interdisciplinary team, as defined by § 483.21(b)(2)(ii), is responsible for determining if resident self-administration of medications is clinically appropriate.

(c) *Attending physician.* (1) 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.

(2) 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.

(3) If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.

(d) *Self-determination.* The facility must promote and facilitate resident self-determination through support of resident choice as specified in § 483.10(e) and as follows:

(1) The facility must:

(i) 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 2006 (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 mental illness (established under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 (42 U.S.C. 10802); and

(G) The resident representative.

(ii) 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) 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) 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

(2) 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 that the facility may need to place on such rights and the reasons for the clinical or safety restriction or limitation. A facility must meet the following requirements:

(i) Inform each resident (or resident representative, where appropriate) of his or her visitation rights, including any clinical or safety restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

(ii) 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.

(iii) Not restrict, limit, or otherwise deny visitation privileges on the basis of

race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(iv) Ensure that all visitors enjoy full and equal visitation privileges consistent with resident preferences.

(3) The facility must provide a resident or family group, if one exists, with private space; and

(i) Staff or visitors may attend meetings only at the group's invitation;

(ii) 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;

(iii) The facility must consider the views of a resident or family group and act upon the grievances and recommendations of such groups concerning issues of resident care and life in the facility.

(A) This should not be construed to mean that the facility must implement as recommended every request of the resident or family group.

(B) The facility must be able to demonstrate their response and rationale for such response.

(4) 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.

(5) 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, the facility must adhere to the following requirements.

(i) *Management of personal funds.*

Upon written authorization of a resident, the facility must 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:

(1) Except as set out in paragraph (d)(5)(ii)(B)(1) 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.)

(2) 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:

(1) 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.)

(2) 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.

(6) 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 may 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 § 483.25(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.* Listed below in paragraphs (d)(6)(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 § 483.25(c).

(J) Noncovered 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 below, 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 health care provider, as these are included per § 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 noncovered 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.

(e) *Information and communication.*

(1) With the exception of information described in paragraph (e)(2) 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 (e)(2) of this section may be made available to the patient at their request and expense in accordance with applicable law.

(2) The facility must:

(i) Provide the resident with access to 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 medical 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) Allow the resident to purchase, after receipt of his or her medical records for inspection, 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 working days advance notice to the facility.

(iii) The facility may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(A) Labor for copying the medical 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) The facility must make reports with respect to any surveys, certifications, and complaint investigations conducted by Federal or State surveyors during the 3 preceding years available for any individual to review upon request and any plan of correction in effect with respect to the facility available for examination in a place readily accessible to and in a form understandable by residents, and must post a notice of its availability.

(4) The facility must post, in a form and manner accessible and understandable to residents, resident representatives and support person:

(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 and certification 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 and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the requirements specified in 42 CFR part 489 subpart I (Advance Directives).

(5) 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.

(6) 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.

(7) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and notify 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 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(b)(1)(ii).

(ii) When making notification under paragraph (e)(7)(i) of this section, the facility must ensure that all pertinent information specified in § 483.15(b)(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(d)(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).

(8) *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(b)(9).

(9) 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;

(10) 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 paragraphs (e)(10)(i)(A) and (B) of this section.

(11) 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 thirty days from the resident's date of discharge from the facility.

(v) Where the facility requires the execution of an admission contract by or on behalf of an individual seeking admission to the facility, the terms of the contract must not conflict with the requirements of these regulations.

(12) The facility must furnish to each resident a written description of legal rights which includes—

(i) A description of the manner of protecting personal funds, under paragraph (d)(5) of this section;

(ii) 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.

(iii) 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 and certification 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

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning any suspected violation of state or federal nursing facility regulations, 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.

(13) The facility must protect and facilitate that resident's right to communicate with individuals and entities within and external to the facility, consistent with § 483.10(h), 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.

(f) *Privacy and confidentiality.* (1) The facility must respect the resident's right to personal privacy, including privacy in his or her verbal (meaning spoken), written and electronic communications.

(i) This includes ensuring that a resident can send and promptly receive mail that is unopened; as well as receive, unopened, letters, packages and other materials delivered to the facility for the resident through a means other than a postal service.

(ii) 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 comply with the residents' rights in § 483.10(g)(3) regarding his or her medical records.

(3) 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.

(g) *Safe environment.* 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. This includes ensuring:

(i) That the resident can receive care and services safely.

(ii) That the physical layout of the facility maximizes independence and does not pose a safety risk.

(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 71–81 °F; and

(7) For the maintenance of comfortable sound levels.

(h) *Grievances.* (1) The facility must make information on how to file a grievance or complaint available to the resident, including the information required under paragraph (f)(2) of this section.

(2) The facility must make prompt efforts to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(3) The facility must establish a grievance policy to ensure the prompt resolution of all grievances regarding the residents' rights contained in § 483.10. 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 verbally (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 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) 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 and certification 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 three years from the issuance of the grievance decision.

(i) *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 of the protection and advocacy system, regarding any matter, whether or not subject to arbitration or any other type of judicial or regulatory action.

■ 15. 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) Not employ or otherwise engage individuals who—

(i) Have been found guilty of abuse, neglect, 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, mistreatment of residents or misappropriation of their property; or

(iii) Have had a disciplinary action taken against a professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of resident property.

(3) 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 Social Security 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 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 to the administrator of the facility and to other officials (including to the State survey and certification 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 resident representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

§ 483.13 [Removed]

■ 16. Remove § 483.13.

■ 17. Section 483.15 is revised to read as follows:

§ 483.15 Transitions of care.

Transitions of care include admissions to and discharges or transfers to or from a SNF or NF. This section also addresses bed-hold policies and therapeutic leave.

(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, at or 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(c) 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) *Transfer and discharge—(1) Facility requirements—(i) Equal access to quality care.* (A) A facility must establish, maintain and implement identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment;

(B) 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 § 483.11(e)(11)(i) and (e)(12) describing the charges; and

(C) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(ii) 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 does not apply unless the resident does not submit the necessary paperwork for third party payment or until 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.

(iii) 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.

(2) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (b)(1)(i)(A) through (F) of

this section, the facility must ensure that the transfer or discharge is documented in the resident's clinical record and appropriate information is communicated to the receiving health care institution or provider.

(i) Documentation in the resident's clinical record must include:

(A) The basis for the transfer per paragraph (b)(1)(ii).

(B) In the case of paragraph (b)(1)(ii)(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 must be made by—

(A) The resident's physician when transfer or discharge is necessary under paragraph (b)(1)(i)(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) Demographic information including but not limited to name, sex, date of birth, race, ethnicity, and preferred language.

(B) Resident representative information including contact information.

(C) Advance Directive information.

(D) History of present illness/reason for transfer including primary care team contact information.

(E) Past medical/surgical history, including procedures.

(F) Active diagnoses/Current problem list and status.

(G) Laboratory tests and the results of pertinent laboratory and other diagnostic testing.

(H) Functional status.

(I) Psychosocial assessment, including cognitive status.

(J) Social Supports

(K) Behavioral Health Issues

(L) Medications.

(M) Allergies, including medication allergies.

(N) Immunizations.

(O) Smoking status.

(P) Vital signs.

(Q) Unique device identifier(s) for a patient's implantable device(s), if any.

(R) Comprehensive Care plan goals, including health concerns, assessment and plan, resident preferences, interventions, including efforts to meet resident needs, and resident status.

(iv) This requirement may be satisfied by the discharge summary providing it meets the requirements of § 483.21(c) and includes at a minimum the information specified in paragraph (b)(2)(iii) of this section.

(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. Subject to the resident's agreement, 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 clinical record in accordance with paragraph (b)(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 expected to be transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State, the name, address (mailing and email), and telephone number of the State 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, 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 (42 U.S.C. 10802); and

(vii) For nursing facility residents with mental illness, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with mental illness 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 of the residents or other responsible parties, 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(d)(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.

(c) *Notice of bed-hold policy and readmission—*(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.

(3) *Permitting resident to return to facility.* A nursing 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, is readmitted 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 Medicaid nursing facility services.

(ii) 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 information specified in paragraphs (b)(5)(iv) through (vii) of this section.

(4) *Readmission to a composite distinct part.* When the nursing facility to which a resident is readmitted 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 readmission, the resident must be given the option to return to that location upon the first availability of a bed there.

§ 483.20 [Amended]

■ 18. 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/direct access 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 illness, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.

* * * * *

(k) *Preadmission screening for individuals with mental illness and individuals with intellectual disability.*

(1) A nursing facility must not admit, on or after January 1, 1989, any new resident with—

(i) Mental illness 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 mental illness if the individual has a serious mental illness 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 mental illness or intellectual disability for resident review.

■ 19. 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 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).

(b) *Comprehensive care plans.* (1) The facility must develop a comprehensive person-centered care plan for each resident, consistent with § 483.10(b)(1) and § 483.11(b)(1), that includes measurable objectives and timetables 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 § 483.25 or § 483.40; and

(ii) Any services that would otherwise be required under § 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(b)(4).

(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) A social worker.

(F) 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.

(G) 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 and preparing residents to be active partners in post-discharge care, effective transition of the resident from SNF to post-SNF care, and the reduction of factors leading to preventable readmissions. The facility's discharge planning process must—

(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 § 483.20(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, his or her family, 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.

■ 20. Section 483.25 is revised to read as follows:

§ 483.25 Quality of care and quality of life.

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 the resident's advance directives.

(b) *Activities of daily living.* (1) Hygiene—bathing, dressing, grooming, and oral care,

(2) Mobility—transfer and ambulation,

(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, 1 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.

(d) *Special care issues.* 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 and the residents choices, related to the following special concerns—

(1) *Restraints.* The facility must 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.

(2) *Bed rails.* The facility must ensure correct installation, use and maintenance of bed rails, including but not limited to the following elements.

(i) Attempt to use alternatives prior to installing a side or bed rail.

(ii) Assess resident for risk of entrapment from bed rails prior to installation.

(iii) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation

(iv) Ensure that the resident's size and weight are appropriate for the bed's dimensions.

(v) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.

(3) *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—

(i) In making appointments, and

(ii) 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.

(4) *Skin integrity—(i) Pressure ulcers.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(A) 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

(B) 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.

(ii) *Foot care.* To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must:

(A) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(B) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from such appointments.

(5) *Mobility.* (i) 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

(ii) 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.

(iii) 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.

(6) *Incontinence.* (i) The facility must ensure that 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.

(ii) For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—

(A) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(B) 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

(C) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(iii) 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.

(7) *Colostomy, ureterostomy, or ileostomy care.*

(8) *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—

(i) 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 or resident preferences indicate otherwise;

(ii) Is offered sufficient fluid intake to maintain proper hydration and health; and

(iii) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.

(iv) 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

(v) 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.

(9) *Parenteral fluids.*

(10) *Accidents.* The facility must ensure that—

(i) The resident environment remains as free of accident hazards as is possible; and

(ii) Each resident receives adequate supervision and assistance devices to prevent accidents.

(11) *Respiratory care, including tracheostomy care and tracheal suctioning.* See § 483.65 re: Specialized rehabilitative services.

(12) *Prostheses.*

(13) *Pain management.*

(14) *Dialysis.*

(15) *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.

■ 21. In the table below, each section and paragraph indicated in the first column is redesignated as the section and paragraph 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. Redesignate paragraphs (e) and (f) as paragraphs (f) and (g), respectively.

■ d. Amend newly designated paragraph (f)(1) introductory text by

removing the reference “paragraph (e)(2)” and adding in its place the reference “paragraph (f)(4)”.

■ e. Add a new paragraph (e).

■ f. Amend newly redesignated paragraph (f) by further redesignating paragraph (f)(2) as paragraph (f)(4).

■ g. Add new paragraphs (f)(2) and (f)(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) *Availability of a physician, physician assistant, nurse practitioner, or clinical nurse specialist to evaluate resident for non-emergent transfer to a hospital.* The facility must provide or arrange for an in-person evaluation of a resident by a physician, a physician assistant, nurse practitioner, or clinical nurse specialist prior to transferring the resident to a hospital.

(1) The evaluation must occur expeditiously once the potential need for a transfer is identified.

(2) This requirement does not apply in emergency situations where the health or safety of the individual would be endangered.

(f) * * *

(2) A 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 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 redesignated paragraphs (e)(6) and (7).
- i. Revise 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 developmental disabilities or mental illnesses; 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 illnesses; and

(v) The facility that is granted such a waiver notifies residents of the facility and their resident representatives of the waiver.

* * * * *

■ 24. Section 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.

(a) The facility must have sufficient direct care/direct access 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 § 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 illnesses 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 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, and

(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.

(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental illness 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 § 483.45; or

(2) Obtain the required services from an outside resource (in accordance with § 483.75(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 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 at least every 6 months and:

(i) When the resident is new, that is the individual has not previously been a resident in that facility; or

(ii) When the resident returns or is transferred from a hospital or other facility; and

(iii) 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.

(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;

(iv) Hypnotic;

(v) Opioid analgesic; and

(vi) Any other drug that results in effects similar to the drugs listed in paragraphs (c)(3)(i) through (v) of this section.

(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.

(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 48 hours and cannot be continued beyond that time unless the resident's physician or primary care provider documents the rationale for this continuation in the resident's clinical record.

(f) *Medication errors.* The facility must ensure that its—

(1) Medication error rates are not five percent or greater; and

(2) Residents are free of any significant medication errors.

* * * * *

■ 26. A new § 483.50 is added and is amended as follows:

■ a. Section heading is added.

■ b. New paragraphs (a) and (b) are redesignated from paragraphs (j) and (k) of newly redesignated § 483.70.

■ c. Newly designated paragraphs (a)(2)(i), (a)(2)(ii), (b)(2)(i) and (b)(2)(ii) are revised.

The additions and revisions read as follows:

§ 483.50 Laboratory, radiology, and other diagnostic services.

(a) * * *

(2) * * *

(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.

* * * * *

- (b) * * *
(2) * * *

(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.

* * * * *

■ 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) 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) Promptly, within three days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within three days, the facility must provide documentation of 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 three days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within three days, the facility must provide documentation of the extenuating circumstances that led to the delay;

(4) 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 is qualified based on:

(i) Meeting State requirements to practice dietetics, including licensure or certification, or

(ii) If the state does not have requirements, registration by the Commission on Dietetic Registration of the Academy of Nutrition and Dietetics, or

(iii) For dietitians hired or contracted with prior to [effective date of final rule], meets these requirements no later than 5 years after [effective date of final rule] 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 [effective date of final rule], meets the following requirements no later than 5 years after [effective date of final rule], 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 hospitality from an accredited institution of higher learning; or

(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 or industry standards; ;

(2) Be prepared in advance;

(3) Be followed;

(4) Reflect the religious, cultural and ethnic needs of the residents, 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 substitutes of similar nutritive value to residents who choose not to eat food that is initially served or who request an alternative meal; 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) Suitable, nourishing alternative meals and snacks must be available for residents who want to eat at non-traditional times or outside of scheduled meal service times and in accordance 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 mental illness 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) Obtain the required services from an outside resource (in accordance with § 483.70(g)) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

* * * * *

■ 30. Section 483.67 is added to read as follows:

§ 483.67 Outpatient rehabilitation services.

If the facility provides outpatient rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must meet the needs of the patients in accordance with acceptable standards of practice and the facility must meet the following requirements.

(a) *Organization and staffing.* (1) The organization of the service must be appropriate to the scope of the services offered.

(2) The facility must ensure the services are organized and staffed to

ensure the health and safety of residents.

(b) *Personnel.* (1) The facility must assign one or more individuals to be responsible for outpatient rehabilitative services. The individual responsible for the outpatient rehabilitative services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) The facility must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) 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.

(c) *Delivery of services.* (1) 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.

(2) 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).

(3) The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

■ 31. 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), and (t) as paragraphs (f), (g), (h), (i), (j), (k), (l), (m), and (o), 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 and second columns, remove the reference indicated in the third column and add the reference indicated in the fourth column.

Paragraphs	Remove	Add
(g)(1)	(h)(2)	(g)(2).

Paragraphs	Remove	Add
(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); 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;
 (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 LTC 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, three 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(b)(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.* If the facility enters into an agreement for binding arbitration with its residents:

- (1) The facility must ensure that:
 - (i) The agreement is explained to the resident in a form and manner that he

or she understands, including in a language the resident understands, and

(ii) The resident acknowledges that he or she understands the agreement.

(2) The agreement must:

(i) Be entered into by the resident voluntarily;

(ii) Provide for the selection of a neutral arbiter;

(iii) Provide for selection of a venue convenient to both parties.

(3) Admission to the facility must not be contingent upon the resident or the resident representative signing a binding arbitration agreement.

(4) 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 § 483.11(i).

(5) The agreement may be signed by another individual if:

(i) Allowed by state law;

(ii) All of the requirements in this section are met; and

(iii) That individual has no interest in the facility.

* * * * *

(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.

■ 32. 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;

(2) Present its QAPI plan to the State Agency Surveyor at the first annual recertification survey that occurs after [the effective date of this regulation];

(3) Present its QAPI plan to a State 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 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/direct access workers, 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 from all departments, including but not limited to the facility assessment required at § 483.75(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 (such as root cause analysis, reverse tracer methodology, or health care failure and effects analysis) to determine underlying causes of problems impacting larger systems;

(ii) Development of 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) 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 based on performance indicator data, and resident and staff input that reflects organizational processes, functions, and services provided to residents.

(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/her designee;

(iii) At least 3 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.* (1) 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.

(2) Demonstration of compliance with the requirements of this section may require State or Federal surveyor access to:

(i) Systems and reports demonstrating systematic identification, reporting,

investigation, analysis, and prevention of adverse events;

(ii) Documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities; and

(iii) Other documentation considered necessary by a State or Federal surveyor in assessing compliance.

(i) *Sanctions.* Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

■ 33. 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 § 483.75(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 isolation should be used for a resident;

(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 prevention and control officer.* The facility must designate one individual as the infection prevention and control officer (IPCO) for whom the IPCP at that facility is a major responsibility. The IPCO must:

(1) Be a clinician who works at least part-time at the facility, and

(2) Have specialized training in infection prevention and control beyond their initial professional degree.

(c) *IPCO participation on quality assessment and assurance committee.* The person designated as the IPCO 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. ■ 34. 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—

(i) 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

(ii) 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 [1 year after the effective date of the final rule], 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 Social Security 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 Act and in promoting quality of care.

■ 35. In newly redesignated § 483.90—

■ a. Revise paragraph (c).

■ b. Revise paragraphs (d)(1)(i) and (d)(2)(i).

■ c. Revise paragraph (e).

■ d. Revise paragraphs (f) introductory text and (f)(1).

■ e. Revise paragraph (g)(2).

■ f. Add paragraph (h)(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.

(d) * * *

(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 [effective date of final rule], 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;

* * * * *

(e) *Toilet facilities.* Each resident room must be equipped with or located near toilet and bathing facilities. For facilities that receive approval of construction or reconstruction plans from State and local authorities or are newly certified after [effective date of the final rule], each resident room must have its own bathroom equipped with at least a toilet, sink and shower.

(f) *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

* * * * *

(g) * * *

(2) Be well ventilated;

* * * * *

(h) * * *

(5) 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.

■ 36. 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/direct access personnel.

(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 and § 483.11, 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.

(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]

■ 37. 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]

■ 38. 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]

■ 39. 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]

■ 40. 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]

■ 41. 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]

■ 42. 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

■ 43. 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]

■ 44. 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)”.

■ 45. 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)).

(2) Facility responsibilities (§ 483.11(d)(1)(i), (d)(1)(iii), (d)(4), (e)(11), (e)(12), (e)(14)(iii), and (f)(1)(i)).

(3) Transitions of care (§ 483.5(n), § 483.15(b)(1), (b)(2), (b)(3)(i) through (iii), (b)(4), (b)(5)(i) through (vii), and (b)(7)).

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

(5) Patient activities (§ 483.25(c)), 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)).

(7) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), and § 483.21(b) and (c)), 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).

(9) Dental services (§ 483.55).

(10) Nutrition (§ 483.25(d)(8) of this chapter).

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 46. 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]

■ 47. In § 488.56, paragraph (a) introductory text is amended by removing the reference “§ 483.30” and adding in its place the reference “§ 483.35”.

■ 48. Section 488.301 is amended by revising the definitions of “nurse aide”, “paid feeding assistant”, and “substandard quality of care” to read as follows:

§ 488.301 Definitions.

* * * * *

Nurse aide means an individual, as defined in § 483.5(n) 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.

* * * * *

Standard quality of care means one or more deficiencies related to participation requirements under § 483.10 “Resident rights”, paragraphs (d) and (e); § 483.11 “Facility Responsibilities”, paragraphs (d) and (g); § 483.12 “Freedom from abuse, neglect, and exploitation”; § 483.25 “Quality of care, and quality of life”; § 483.40 “Behavioral health services”, paragraphs (b) and (d); § 483.45 “Pharmacy services”, paragraphs (d), (e), and (f); 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]

■ 49. 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]

■ 50. 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)”.

Dated: May 12, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 8, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015-17207 Filed 7-13-15; 8:45 am]

BILLING CODE 4120-01-P