American Hospital Association

Regulatory Advisory

October 31, 2016

CMS Revises Long-term Care Facility Requirements

AT A GLANCE

At Issue:

The Centers for Medicare & Medicaid Services (CMS) on Oct. 4 published a final rule to extensively update the regulations that long-term care (LTC) facilities must meet to participate in Medicare and Medicaid. These changes represent the first comprehensive update of Medicare and Medicaid quality and safety requirements for LTC facilities since 1991. Among the changes to current regulations, the final rule:

- Requires facilities to ensure that staff are trained to care for residents with dementia;
- Expands residents' rights, including visitation rights;
- Enhances current infection prevention and control standards by requiring facilities to designate one or more infection preventionists and have antibiotic stewardship programs;
- Prohibits facilities from entering into pre-dispute agreements for binding arbitration with residents or requesting/requiring residents to waive potential facility liability for loss of personal property;
- Allows dietitians and therapy providers to write orders in their areas of expertise when an attending physician who supervises them delegates the responsibility and state law allows;
- Makes substantial changes to pharmacy service requirements and includes standards for the use of psychotrophic medications.

In the final rule, CMS also removed a proposal to require an in-person evaluation of a LTC resident by a physician, physician assistant, nurse practitioner or clinical nurse specialist prior to an unscheduled transfer to a hospital. The final regulations will be phased in over a three-year period beginning Nov. 28. **A detailed summary, prepared for the AHA by Health Policy Alternatives, Inc., is attached.**

Our Take:

The AHA appreciates that CMS is updating the regulations to ensure they reflect current knowledge about safe care delivery and embody high expectations for quality of care. As noted above, the changes are extensive. We are pleased that CMS finalized a staggered implementation schedule, as we urged. However, we remain concerned about the resources needed to meet all of the new requirements. The final rule addressed some, but not all of the AHA's policy concerns, and it remains unclear how some provisions will need to be implemented, such as new behavioral health standards.

What You Can Do:

- ✓ Share this advisory with your leaders involved in the LTC facility services you provide, including any LTC facility administrators, physician and nursing leaders, quality and compliance managers and risk managers.
- ✓ Share your feedback about this final rule with the AHA.

Further Questions or to Provide Feedback on CMS's Proposals:

Please contact the AHA's Evelyn Knolle, senior associate director of policy, at eknolle@aha.org.

Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities
(CMS-3260-F; RIN 0938-AR61)
Summary of Final Rule

The Centers for Medicare & Medicaid Services (CMS) published in the October 4, 2016 *Federal Register* (p. 68688-68867) a final rule "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities" (https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf). Page references given in this summary are to this published document. **Although the regulations are generally effective on November 28, 2016, CMS provides for phased implementation of specific requirements, as discussed below.**

I. Summary Overview

Background: CMS last comprehensively reviewed and updated Medicare and Medicaid requirements for participation for long term care (LTC) facilities in 1991. Since that time, the number of beneficiaries accessing skilled nursing facility services (for Medicare) and nursing facility services (for Medicaid) has grown considerably and the types of people treated in nursing homes has changed. Patient diversity, acuity, and behavioral health services needs have increased, while Medicare has become the primary payer for a larger percentage of patients. Further, the state of knowledge has improved about resident safety, health outcomes, individual choice, and quality assurance and performance improvement. CMS offers the following final rules to improve quality of life, care and services in LTC facilities, to optimize residents' safety, to reflect current professional standards, and to improve the structure of the regulations.

Major changes: Major provisions of the final rule revise minimum health and safety requirements for LTC facilities to align with current clinical practice and allow flexibility to accommodate multiple care delivery models. It requires facilities to assess their capabilities and that of their resident populations and use such information to provide sufficient staff (including registered nurses and qualified dieticians) with necessary competencies. It revises, reorganizes, clarifies and adds to existing resident's rights, updating them to include advancements such as electronic communications. It requires that facilities ensure their staff is properly trained in caring for residents with dementia and in preventing elder abuse and have the proper skill sets for providing person-centered care to residents. It strengthens rules regarding the development of comprehensive care plans, adds a requirement that care plans be developed within 48 hours of admission, and establishes standards for communications regarding transitions of care and for the development of, and documentation required for discharge plans. It includes substantial changes related to pharmacy services and pharmacy reviews, establishes standards for the appropriate use of psychotropic medications, and addresses antibiotic use and its monitoring. It includes requirements that facilities develop a comprehensive, data-driven Quality Assurance and Performance Improvement (QAPI) program. CMS identifies several cross-cutting policy objectives that are incorporated in these rules:

- To reduce unnecessary hospitalizations by improving facilities' planning, assessments, communications between providers, and quality assurance and performance improvement (QAPI) programs;
- To reduce the use of psychotropic medications (not including analgesic opioids) by requiring a comprehensive assessment, extending requirements that currently apply to antipsychotic drugs to all psychotropic drugs, and improving the identification of prescribing irregularities;
- To reduce healthcare associated infections through the use of the comprehensive assessment noted above, establishing standards for infection control programs, and incorporating standards into QAPI processes.

The final rule also incorporates recent legislative changes applicable to LTC facilities. The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) established that certain providers including LTC facilities take into account quality, resource use and other measures in the discharge planning process and account for the treatment preferences

and goals of care for residents. The Affordable Care Act of 2010 (ACA) added requirements for LTC facilities to have an effective compliance and ethics program for preventing and detecting criminal, civil, and administrative violations and promoting quality of care. It also required that dementia management and abuse prevention be included as part of the training requirement for nurse aids.

CMS notes that it sought comments in the development of the updated requirements and has taken them into consideration in drafting the proposed and now final rules.
Many changes in this final rule are intended to improve the logical order of the requirements and to improve readability. As finalized, the rule re-organizes and re-orders existing rules. To guide the reader, CMS includes a table (81 *FR* 68825-68831) which shows the cross references between the existing regulations and where they are moved to in the final rule. The table is not duplicated in this summary.

Impact: CMS estimates that the total projected cost of this rule will be about $821 million (up from $729 million in the proposed rule) in the first year and about $736 million ($638 million in the proposed rule) for subsequent years. It will impact 15,653 separate facilities (updated from the proposed rule's 15,691 to reflect May 2016 data) and cost each of those facilities, on average, $62,900 in year one and $55,000 per year for subsequent years (up from the estimated $46,491 and $40,685 respectively in the proposed rule.) CMS is unable to quantify the benefits of the final rule but says that it will create efficiencies and flexibilities for facilities that are likely to reduce avoidable hospital readmissions, increase the rate of improvement in quality throughout facilities, and create positive business benefits for facilities. The following summary table 5, reproduced from the final rule, provides a section-by-section analysis of the estimated costs for LTC facilities to comply with the requirements of this rule.

TABLE 5—SECTION BY SECTION SUMMARY OF ESTIMATED COST FROM ICR AND RIA TO COMPLY WITH THE REQUIREMENTS CONTAINED IN THIS FINAL RULE

Regulatory section	Number of affected entities	Total 1st year cost to all LTC facilities ($ millions)	Total recurring annual cost to all LTC facilities ($ millions)	Estimated recurring annual cost per facility (rounded to the nearest $)
Resident Rights (§ 483.10)	15,653	$166.87	$166.35	$10,627
Admission, Discharge, and Transfer Rights (§ 483.15)	15,653	2.95	2.95	188
Comprehensive Resident Centered Care Planning (§ 483.21)	15,653	86.36	86.36	5,517
Nursing Services (§ 483.35)	15,653	3.88	3.88	248
Food and Nutrition Services (§ 483.60)	15,653	1.85	1.85	118
QAPI (§ 483.75)	15,653	125.47	50.15	3,204
Infection Control (§ 483.80)	15,653	297.91	297.91	19,032
Compliance and Ethics Program	7,314 (operating organizations).	134.79	114.98	15,721
Training (§ 483.95)	15,653	11.46	11.46	732
Total		831.35	735.90	55,388

A more complete discussion of the economic impact of each of those sections can be found in the Regulatory Impact Analysis which begins at 81 *FR* 68836. In addition, CMS provides the following summary table for the new Information Collection Requirements proposed in the rule. CMS points out that these proposed regulations are not required to include an estimate of the public reporting burden for its information collection requirement because the Omnibus Budget Reconciliation Act (OBRA) of 1987 provides for a waiver under sections 4204(b) and 4214(d)

which CMS believes still applies to the revisions and updates herein. Nonetheless, CMS has estimated the annual reporting and recordkeeping burdens for the new information collection requirements specifically implemented as a result of the ACA. Those burdens are summarized in the following table, and are further discussed at 81 *FR* 68831.

TABLE 3—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
§483.75(a)	0938—New	15,653	15,653	56	876,568	**	75,322,236	75,322,236
§483.75(b)(2)	0938—New	15,653	15,653	40	626,120	**	50,152,212	50,152,212
§483.85(b)	0938—New	7,314	7,314	24	175,536	**	16,266,336	16,266,336
§483.85(c)	0938—New	7,314	7,314	10	73,140	**	6,216,900	6,216,900
§483.85(d)(1)	0938—New	7,314	7,314	8	58,512	**	3,569,232	3,569,232
§483.85(e)	0938—New	7,314	7,314	10	73,140	**	6,216,900	6,216,900
§483.95	0938—New	15,653	15,653	4	62,612	**	3,819,332	3,819,332
Totals		22,967	76,215		1,945,628			161,563,148

** The hourly labor wages are discussed in detail earlier in this section.
There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 3.

II. Provisions of the Final Regulation (and Response to Public Comments on the Proposed Regulation)

In response to the July 16, 2015 proposed rule (80 *FR* 42168), CMS received over 9,800 public comments from a wide range of stakeholders, including many health care professionals. In the preamble to the final rule, CMS first discusses general comments, then addresses its phased-in implementation, and then lays out its responses to specific public comments.

Note that the final regulation text amends or adds new provisions in parts of section 42 of the Code of Federal Regulations as follows:

405 – Federal Health Insurance for the Aged and Disabled
431 – State Organization and General Administration
437 – Payments for Services
482 – Conditions of Participation for Hospitals
483 – Requirements for States and Long Term Care Facilities
485 – Conditions of Participation: Specialized Providers (such as Critical Access Hospitals)
488 – Survey, Certification, and Enforcement Procedures
489 – Provider Agreements and Supplier Approval

CMS notes conforming changes to revise cross-references to part 483 in title 42 in §488.301, §489.53 and §489.55. These were inadvertently not included in the proposed rule. A comparison of the proposed and final rule texts in §485.645(d)(3) and §488.301 indicates additional changes. These relate to definitions (modifies the definitions of "abuse" and "neglect"); it also newly includes the amendments to Part 489.

In addition, CMS renumbered a number of section of the Requirements for States and Long Term Care Facilities. Those renumbered are as follows:

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

Source: 81 *FR* 68861.

A. General Comments

CMS received over 9,800 comments to the proposed rule including from long-term care consumers, advocacy groups, organizations representing providers of long-term care, ombudsman, state survey agencies, health care and legal organizations and individual health care professionals.

Among those were comments expressing support for the proposed changes as well as those expressing opposition. Concerns of commenters opposed to the changes included that they were too broad in scope; would be burdensome and confusing to implement; would require too much paperwork and documentation; and would inhibit weekend and evening discharges. CMS, in response to concerns that the proposed rules were too broad in scope, notes that it is implementing the requirements in a phased-in manner over a period of 3 years and has revised other provisions in response to concerns about burden. Some commenters recommended that CMS ensure that surveyors are well-trained and educated in the new requirements and that stakeholders be included in the development of sub-regulatory materials. In response to commenters' concerns regarding the effect of the rules on LTC facilities in rural areas, CMS notes that the final rules incorporate greater flexibility and do not include certain proposals that would have been especially difficult for facilities to meet.

CMS is particularly troubled by the number of commenters who misunderstood either the pre-existing requirements or the proposed changes. In response to many of those misunderstandings, CMS notes that requirements that residents must be able to choose their attending provider and that a registered nurse (RN) be on the interdisciplinary team have long been in existing regulations. Other misconceptions are addressed on page 81 *FR* 68695 of the final rule.

B. Implementation Date

CMS received many comments on the implementation timeline for the comprehensive rule, with most commenters requesting an extended timeline. In response, CMS will under this final rule phase-in the implementation of the provisions over a period that begins on the effective date of the rule (November 28, 2016) and extends over a three-year period. Those requirements that are

unchanged or modified in only a minor way will be required to be implemented on November 28, 2016. Provisions implemented in phase two, which will have a deadline of one year following the effective date of the final rule, are those with brand new requirements and those requiring more complex revisions. The full year before implementation will allow CMS to change survey processes, update survey guidance, and provide guidance to facilities. Phase three, with a deadline of three years from the effective date of the final rule, will apply to all remaining requirements.

CMS provides, on pages 81 *FR* 68296-68298, a chart of implementation timeframes for the provisions of the final rule. The table is duplicated below.

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

	• Specific usage of the Facility Assessment at § 483.70(e) in the determination of sufficient number and competencies for staff - Implemented in Phase 2.
§ 483.40 Behavioral health services	This section will be implemented in Phase 2 with the following exceptions: • (a)(1) As related to residents with a history of trauma and/or post-traumatic stress disorder - Implemented in Phase 3. • (b)(1), (b)(2), and (d) Comprehensive assessment and medically related social services - Implemented in Phase 1.
§ 483.45 Pharmacy services	This section will be implemented in Phase 1 with the following exceptions: • (c)(2) Medical chart review - Implemented in Phase 2. • (e) Psychotropic drugs - Implemented in Phase 2.
§ 483.50 Laboratory, radiology, and other diagnostic services	This entire section will be implemented in Phase 1.
§ 483.55 Dental services	This section will be implemented in Phase 1 with the following exceptions: • (a)(3) and (a)(5) Loss or damage of dentures and policy for referral - Implemented in Phase 2. • (b)(3) and (b)(4) Referral for dental services regarding loss or damaged dentures - Implemented in Phase 2.
§ 483.60 Food and nutrition services	This section will be implemented in Phase 1 with the following exceptions: • As linked to Facility Assessment at § 483.70(e) - Implemented in Phase 2. • (a)(1)(iv) Dietitians hired or contracted with prior to effective date - Built in implementation date of 5 years following effective date of the final rule. • (a)(2)(i) Director of food & nutrition services designated to serve prior to effective - Built in implementation date of 5 years following the effective date of the final rule. • (a)(2)(i) Dietitians designated to after the effective date - Built in implementation date of 1 year following the effective date of the final rule.
§ 483.65 Specialized rehabilitative services	This entire section will be implemented in Phase 1.
§ 483.70 Administration	This section will be implemented in Phase 1 with the following exceptions: • (d)(3) Governing body responsibility of QAPI program - Implemented in Phase 3. • (e) Facility assessment - Implemented in Phase 2

§ 483.75 Quality assurance and performance improvement	This section will be implemented in Phase 1 with the following exceptions: • (a)(2) Initial QAPI Plan must be provided to State Agency Surveyor at annual survey - Implemented in Phase 2. • (g)(1) QAA committee - All requirements of this section will be implemented in Phase 1 with the exception of subparagraph (iv), the addition of the ICPO, which will be implemented in Phase 3. • (h) Disclosure of information - Implemented in Phase 1. • (i) Sanctions - Implemented in Phase 1.
§ 483.80 Infection control	This section will be implemented in Phase 1 with the following exceptions: • (a) As linked to Facility Assessment at § 483.70(e) - Implemented in Phase 2. • (a)(3) Antibiotic stewardship - Implemented in Phase 2. • (b) Infection preventionist (IP) - Implemented in Phase 3. • (c) IP participation on QAA committee - Implemented in Phase 3.
§ 483.85 Compliance and ethics program	This entire section will be implemented in Phase 3.
§ 483.90 Physical environment	This section will be implemented in Phase 1 with the following exceptions: • (f)(1) Call system from each resident's bedside - Implemented in Phase 3. • (h)(5) Policies regarding smoking - Implemented in Phase 2.
§ 483.95 Training requirements	This entire section will be implemented in Phase 3 with the following exceptions: • (c) Abuse, neglect, and exploitation training - Implemented in Phase 1. • (g)(1) Regarding in-service training, (g)(2) dementia management & abuse prevention training, (g)(4) care of the cognitively impaired—Implemented in Phase 1. • (h) Training of feeding assistants - Implemented in Phase 1.

C. Basis and Scope

CMS adds the following statutory references to the basis for the standards established in §483: sections 1819(f), 1919(f), 1128I, and 1150B of the Social Security Act (SSA).

D. Definitions (§483.5)

CMS finalizes several changes to definitions in §483.5, including revisions to some existing terms for clarity and the addition of new terms. In response to comments, CMS incorporates a number of changes to the proposed definitions and adds an additional term to this section. Those changes are discussed below. CMS notes that additional clarity has been added in the final rule explaining what is meant by "behavioral health" although that discussion is incorporated into the section of the preamble addressing "Behavioral Health" rather than in the discussion of "Definitions."

CMS proposed to add definitions of the following terms: "abuse," "adverse event," "exploitation," "misappropriation of resident property," "neglect," "person-centered care," "resident representative," and "sexual abuse." Definitions for several of these terms are finalized without change. CMS provides for changes in the following:

- The definition for "abuse" is amended to remove the use of the term "presumption" and to be more explicit. CMS disagrees with commenters that the definition should not include the word "willful" and refers readers to two court decisions discussing deliberate actions. CMS notes that it will issue interpretive guidance that will, among other things, provide examples of abuse facilitated through the use of technology. The new definition defines abuse as "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse including abuse facilitated or enabled through the use of technology."
- The definition for "exploitation", which as proposed would have meant "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" is amended in this final rule to remove the term "selfish" from the definition to improve clarity.
- "Neglect" is revised to replace the term "mental disorder" with the term "emotional distress" so that the definition now is "the failure of the facility, its employees or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress."
- CMS conforms the definition of "licensed health professional" with the existing definition in Section 1819(b)(5)(G) by including respiratory therapists/certified respiratory therapy technicians to it.
- The term "resident representative" is changed in the final rule to conform to the existing definition at 45 CFR 1324.1. CMS notes that its intent in defining resident representative is to recognize that a resident has the right to designate an individual or individuals who

can support them in their decision making but not to expand on the scope of authority of any representative nor to supersede state law, regulations or case law regarding residents' surrogate decision makers. In response to a commenter who found the definition to be unclear in a case in which two representatives – one of a resident's choice and one of legal standing – disagree, CMS replies that "Generally speaking, the authority of an individual vested with decision-making power under state law would exceed that of an individual without formal legal recognition." (81 *FR* 68700-68701)

In addition, the final rule includes a new definition for "mistreatment" defined as "inappropriate treatment or exploitation of a resident." CMS also adds a cross-reference in §483.15(b)(1), a section which describes a resident's rights related to transfers and discharges, to the definition of "transfer and discharge" in §483.5.

E. Resident Rights (§483.10**)**

CMS proposed to retain all existing residents' rights but to improve the logical order and readability by clarifying some existing provisions, adding new provisions, and moving some of the residents' rights defined in existing §483.15 into §483.10. In the final rule, however, CMS combines provisions in proposed §483.11 (Facility Responsibilities) into §483.10 to minimize the duplication between the two sections. This is in response to commenters who said that every resident right should have a parallel facility responsibility.

(a) Resident Rights. The general right of a resident to a dignified existence, self-determination, and communications with people and services inside and outside a facility – which had been proposed in the matter preceding §483.10(a), is finalized at §483.10(a). In addition, facility responsibilities with respect to that general right are finalized as §483.10(a)(1) and (2). Paragraph (a)(1) requires the facility to treat each resident with respect and dignity in an environment that maintains or enhances a resident's quality of life. Paragraph (a)(2) requires the facility to provide equal access to quality care regardless of diagnosis severity, condition or payment source. CMS discusses (a)(2) in the preamble in response to commenters' concerns that the provision suggests that every facility must provide care for every individual regardless of a facility's expertise or ability. CMS notes that that was not the intent – rather, the intent was to ensure that once an individual is a resident of the facility, then the facility is obligated to provide equal access to quality care. Should a person's needs change such that the facility no longer has the ability to provide the required care, the person may be transferred or discharged under §483.15.

(b) Exercise of rights. CMS finalizes proposals from §483.10(a)(1) – (5) and §483.11 (a)(1), and (a)(3) - (a)(5) into new paragraph *(b) Exercise of rights*. That section includes:

- In §483.10(b)(1), the requirement that a facility ensure the resident is able to exercise his or her rights without interference, coercion, discrimination or reprisal;
- In (b)(2), the right of the resident to be free from interference, coercion, discrimination or reprisal;
- In (b)(3), the right of a resident who is not judged to be incompetent to retain rights that are not prohibited by a court order. In addition, (b)(3) includes the right to have a same-sex spouse afforded treatment equal to an opposite sex spouse.

- In (b)(4), the requirement that a facility treat the decisions of a resident representative as the decisions of the resident in accordance with applicable law;
- In (b)(5), to not have the representative make decisions beyond the extent required by the court or delegated by the representative;
- In (b)(6), to require the facility to report any concerns if there is reason to believe that a representative is making decisions that are not in the best interest of the resident.
- In (b)(7), to ensure that rights of the resident are devolved to and exercised by the representative to act on the resident's behalf in accordance with state law. CMS made changes to this paragraph to ensure that in the case of a resident representative whose decision-making authority is limited by state law or court appointment, the resident continues to have a right to make decisions that are outside of that limitation.

One commenter recommended that the right to vote be explicitly provided in (b). CMS notes that a number of finalized and existing rights – including the right of a resident to exercise his or her rights as a resident of the facility and as a citizen or resident of the U.S. – sufficiently protect the right to vote, and declines to add specific policies and procedures as being overly prescriptive and burdensome.

CMS received many comments about the rights and roles of a resident's representative and makes several changes in response. The final rule clarifies that CMS did not intend to establish the right of a resident, who is adjudicated incompetent, to revoke a court's delegation of authority to a representative. To clarify that point, CMS incorporates in (b)(3) that the provision applies to those who have ***not*** been determined to be incompetent. CMS mostly declines to make changes in response to requests for additional detail related to what happens when there are multiple representatives or when a court determines that a person is not completely incapacitated. Instead, CMS defers to state law on such matters. CMS states in the preamble that it expects residents' representatives to take into account residents' wishes and preferences in acting on their behalf.

(c) Planning and implementing care. CMS proposed new requirements in §483.10(b) related to planning and implementing care. In the final rule, this paragraph is moved to (c) and combined with proposed §483.11(b). The final (c) now specifies the resident's right to be informed of, and to participate in his or her treatment, including:

(1) To be fully informed in language that he or she can understand of his or her health status and medical condition;
(2) The right to participate in the development and implementation of his or her plan of care including the right to see their plan and sign it following significant changes;
(3) The facility must inform the resident of such rights and support the resident in doing so;
(4) The right to be informed in advance about the care to be furnished and the type of care giver or professional that will provide such care. The proposed rule would have established the right to be informed in advance of the care to be furnished and the "disciplines" that will furnish the care. CMS amended the language to improve clarity.

(5) The right to be informed in advance, about the risks and benefits of proposed care, including alternatives and to choose the alternative or option he or she prefers;
(6) The right to request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive;
(7) The right to self-administer medications if clinically appropriate.
(8) In addition, the final rule states that nothing in this paragraph should be construed as the right of a resident to receive medically unnecessary or inappropriate services.

Commenters made a number of suggestions for additions to residents' rights with respect to planning and implementing care. In many cases, CMS declines to add specificity in this paragraph and instead refers commenters to other sections of the rules where those matters are more thoroughly addressed. For example, in response to recommendations that residents review their own comprehensive care plan and that additional specificity be added about resident involvement in the care planning process, CMS refers commenters to §483.21 – a section establishing standards for the care planning process. In response to a recommendation that antipsychotics may only be provided after obtaining and documenting informed consent and discussing alternatives, CMS refers readers to §483.45 regarding use of antipsychotic medications and §483.10(b)(4) establishing the resident's right to refuse, request or discontinue treatment. In response to a recommendation that additional standards regarding advanced directives are added, CMS refers the commenter to 42 CFR part 489, Subpart I.

The proposed rule would have required that residents have a right to see and sign their plan of care initially and after changes are made to it. In response to concerns that this would be a burdensome requirement as care plans are evolving documents, CMS modifies §483.10(c)(2)(v) so that a signature is only necessary after there are significant changes to the plan of care.

(d) Choice of Attending Physician. CMS incorporates provisions proposed in §483.10(c)(1) and (3) and in §483.11(d) in §483(d)(1)- (5), regarding a resident's right to choose their physicians and facilities' responsibilities with respect to that right. CMS does not finalize proposed §483.10(c)(2) that would have required a physician to meet the facility's credentialing requirements. Commenters' concerns were raised about the lack of a definition of a facility's credentialing requirement and the potential for this requirement to be used to deny a resident's choice of attending physician. Other concerns included the potential time lag before a physician could serve as an attending for a resident while awaiting credentialing and the potential staffing shortages that might be a consequence of requiring covering physicians to be credentialed.

As finalized, the existing right of an individual to choose their own attending physician is expanded so that a resident may choose an attending physician so long as the physician is licensed to practice. If the physician refuses or doesn't meet the nursing home requirements, the facility can seek an alternate physician. The facility is required to inform each resident of the name, specialty, and contact information for the physician and other primary care professionals responsible for their care. If the facility seeks an alternate physician, the facility must discuss the alternative physician with the resident and honor the resident's preferences, if any, among

options. If the resident selects another attending physician who meets the requirements specified in this part of the rules, the facility must honor that choice.

(e) Respect and Dignity. The final rule combines, with additional proposed requirements, a number of existing requirements related to the right of a resident to respect and dignity. The right to be free from physical or chemical restraints, to a reasonable accommodation of needs and preferences, to share a room with a spouse, to receive notice of a change in a room or roommate and to refuse a room transfer are mostly removed from various parts of the pre-existing rules and consolidated into §483.10(e). New rights established and incorporated in this paragraph as proposed are:

- The right of a resident to retain and use personal possessions as space permits unless they present a health or safety risk or infringe on someone else's rights ((e)(2)); and
- The right to share a room with a roommate of choice, *when practicable* ((e)(5)). "When practicable" was added in the final rule to address concerns that such a right could impede the right of a resident who does not approve of the new roommate.

In addition, in response to comment, the final rule adds the right of a resident to refuse transfer to another room in the facility if the purpose of the transfer is solely for the convenience of staff (see (e)(7)(iii)).

(f) Self-Determination. In §483.10(f), CMS consolidates a number of pre-existing rights re-designated from §483.10(c), §483.10(h), §483.10(j), §483.15(b) and §483.15(c) related to protecting residents' funds, their right to receive visitors, to work and to participate in various activities. Proposals that would have been incorporated in §483.10(e) and §483.11(d) are also finalized in §483.10(f).

Visitation Rights (§483.10(f)(4)). CMS expands on the rights of residents to receive visitors by finalizing a number of proposed requirements. Finalized in this rule are requirements that a facility must:

- Provide a resident immediate access to a visit by their representative as well as by a representative of the protection and advocacy system, as designated by the state, and any representative of the agency responsible for the protection and advocacy system for individuals with a mental disorder under the Protection and Advocacy for Mentally Ill Individuals Act of 2000 ((f)(4)(i)(G));
- Have written policies and procedures regarding visitation rights that describe any clinically necessary, safety, or reasonable restrictions ((f)(4)(v)).
- Inform each resident (or representative) of their visitation rights including any restriction or limitation on such rights ((f)(4)(vi)(A));
- Inform each resident of the right to receive the visitors whom he or she designates, including, a spouse, a domestic partner or other family member, or a friend, subject to his or her consent, and his or her right to withdraw or deny such consent at any time ((f)(4)(vi)(B));
- Not restrict, limit, or otherwise deny visiting privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability ((f)(4)(vi)(C)); and

- Ensure that all visitors have full and equal visitation privileges consistent with resident preferences ((f)(4)(vi)(D)).

CMS received many comments about the visitation policies in general as well as the proposed changes. Concerns were raised that the policies would mandate completely open visitation which would result in safety issues and overwhelm facilities that do not have funds to hire additional security. CMS responds that facilities may establish reasonable restrictions although its expectation is that "reasonable restrictions" and "reasonable access" should only be limited by clinical or safety concerns.

Participation in Resident Groups (§483.10(f)(5)). Pre-existing rules establish a right of residents to organize and participate in resident groups in the facility and require facilities to allow staff or visitors to attend those or family group meetings upon invitation. CMS finalizes proposed additions to this paragraph – to ensure that facilities act promptly on any grievances and recommendations of groups regarding resident care. The facility must demonstrate its response to those requests or recommendations but need not implement them. In response to comment, CMS adds "other guests" to those that should be allowed to participate at a group's invitation and establishes that a facility must take reasonable steps with the approval of the group to make residents and family members aware of upcoming meetings. CMS points out in the preamble that the right of family members to participate is a result of, and subordinate to, a resident's right. So where a resident does not want a family member to participate and it would not be appropriate to do so, there is no individual right to attend.

Residents' Financial Affairs (§483.10(f)(10)). CMS finalizes its proposal to consolidate all provisions related to resident's right to manage his or her financial affairs in §483.10(f)(10). The largely pre-existing provisions incorporate several proposed amendments as well as a modification made in the final rule (discussed below) expanding on the existing right of a resident to manage his or her own financial affairs. These provisions were proposed to be moved to §483.11(d)(5) but are finalized at §483.10(f)(10):

- Pre-existing rules prohibit a facility from requiring that residents deposit their personal funds with the facility. In the final rule, if a resident chooses to do this, then the facility must act as a fiduciary of the resident's funds and hold, safeguard, manage, and account for those funds. In response to comments recommending additional financial protections, CMS adds the requirement that the facility act as a fiduciary of a resident's funds. CMS states in the preamble that a fiduciary duty is a legal duty to act solely in another party's interest and the fiduciary may not profit from their relationship with their principals (to whom they owe the duty) unless they have the principals' express informed consent.
- CMS finalizes the requirement that a facility deposit personal funds in excess of $100 in an interest bearing account separate from any of the facility's operating accounts, and credits interest earned to that account. (Pre-existing rules required funds in excess of $50 be deposited for all residents.) For Medicaid recipients, personal funds in excess of $50 must be deposited in an interest bearing account;
- The proposed and final rule require the facility, on the discharge, eviction, or death of a resident, to provide the resident or person administering the resident's estate with the funds, and with a final accounting of those funds within 30 days, in accordance with state law. Pre-existing rules only required these actions upon death of a resident.

Limitations on Charges (§483.10(f)(11)). CMS finalizes several proposed changes to pre-existing provisions (formerly in §483.10(c)(8) and finalized in §483.10(f)(11)) establishing limits on what a facility may charge against the personal funds of a resident. Unless specified below, the requirements are finalized as proposed.

- Services included in Medicare or Medicaid payments. Pre-existing §483.10(c)(8) prohibits facilities from imposing charges against personal funds for items and services for which payment is made under Medicare or Medicaid and lists items and services that are considered to be those included in Medicare or Medicaid payment. CMS finalizes its proposal to add hospice services elected by the resident and paid for under the Medicare Hospice Benefit or by Medicaid to that list, which previously included nursing services, food and nutrition services, required activities programs, routine personal hygiene services, and medically-related social services.
- CMS proposes to add an additional condition on charges against resident's funds, which is that the item or service may not be required to achieve the goals stated in the patient's plan of care.
- CMS incorporates its proposal with a modification that allows facilities to charge a resident for specially prepared or alternative food requested unless ordered by the resident's physician, physician assistant, nurse practitioner or clinical nurse specialist. The proposed rule did not specify the types of providers whose orders would prevent a facility from imposing charges. As finalized, the provision also specifies that when preparing foods and meals, a facility must take into account residents' needs and individual preferences in addition to the overall cultural and religious make-up of the residents.
- CMS finalizes a requirement that a facility may not charge for an item or service that is not requested with an amendment prohibiting a facility from requiring a resident to request an item or service as a condition of admission or continued stay; and requires the facility to inform, orally and in writing, when a resident will be charged for something they are requesting and the amount they will be charged.

(g) Information and Communication. CMS finalizes amendments and additions to existing provisions related to the rights of a resident to information and communications. The final paragraph §483.10(g) incorporates pre-existing provisions from §483.10(b) as well as other existing rules and combines them with provisions that had been proposed at §483.20(f) and (h) and §483.11(e). As finalized, §483.10(g) requires the following:

Access to Information (§483.10(g)(1)). CMS finalizes, as proposed, the right of a resident to be informed of his or her rights and of rules and regulations governing resident conduct and responsibilities.

Personal and Medical Records (§483.10(g)(2)). CMS finalizes its proposal with several changes including one change to the existing right of a resident to have access to medical records. Under the final rule, a facility must provide a resident with access to *medical and personal* records (the proposed rule only addressed *medical* records), upon oral or written request, within 24 hours (excluding weekends and holidays) in the form or format requested by

the resident if it is readily producible, including in electronic form or format when the records are maintained electronically, and if not, in readable hard copy. It retains the pre-existing right of a resident to purchase a copy of the records or a portion of those records with 2 working days advance notice to the facility, and finalizes its proposal that the cost be a reasonable, cost-based fee that only includes the cost of labor for copying the records, the cost of supplies for creating the paper copy or electronic media, and the cost of postage if the resident requested the information by mail.

In response to comments that the fees for a copy of a patient's medical records may be out of reach, CMS notes that its proposal is consistent with HIPAA requirements, guidance for which can be reviewed at www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html. CMS declines to make changes.

The proposed rule would have required a facility to allow a resident to inspect a medical record prior to requesting to purchase a copy. That provision was dropped from the final rule.

Form and Manner of Information (§483.10(g)(3)). The final rule updates cross references but otherwise finalizes CMS' proposed requirement that a facility must ensure that information is provided to each resident in a form and manner the resident can access and understand, including in an alternative format or in a language that the resident can understand. Summaries that translate information described in paragraph (g)(2) can be made available to the patient at their request and expense in accordance with applicable law.

Notices (§483.10(g)(4)). Paragraph (g)(4) clarifies the existing right of a resident to receive notices about their legal rights, the way their personal funds are being protected, information and contact information for advocacy organizations, information about establishing eligibility for Medicaid coverage; and about how to file a complaint or grievance. The final provision clarifies that a resident has a right to receive notices orally and in writing (including in Braille) in a format and a language he or she understands. As proposed, the final provision clarifies that information must be made available for contacting all pertinent state regulatory and informational agencies; provides a more detailed listing of the type of organizations for which information would have to be provided; and clarifies the requirement for information on the right to file a complaint, specifying that a complaint may be filed with the state survey and certification agency concerning any suspected violation of LTC regulations, including resident abuse, neglect, misappropriation of resident property, non-compliance with the advance directives requirements and requests for information regarding the community. CMS adds, in the final rule "exploitation" as one of the reasons, in addition to abuse, neglect, misappropriation of resident property, and non-compliance with advance directives, that the resident may want to file a complaint with a state Survey Agency.

Posting Requirements (§483.10(g)(5)). Paragraph (g)(5) establishes, as proposed, a requirement of a facility to post names, addresses and telephone numbers of all pertinent state agencies and advocacy groups, including Medicaid Fraud Control units and a statement regarding filing complaints with a State Survey Agency.

Access to Telephones (§483.10(g)(6)). CMS finalizes its proposed addition to the existing requirement that a resident have reasonable access to a telephone to include reasonable access to TTY and TDD services and to the internet to the extent available in the facility.

Right to Communicate (§483.10(g)(7)). CMS finalizes proposed changes that establish that the facility must protect and facilitate the resident's right to communicate with individuals and entities inside and external to the facility including to include reasonable access to TTY and TDD services and to the internet to the extent available in the facility. In addition, it incorporates existing §483.10(i)(2), which provides access to stationery, postage, writing implements and the ability to send mail.

Right to Mail (§483.10(g)(8)). CMS finalizes its amendment to the existing right (at §483.10)(i)) of a resident to receive mail by adding that the right applies to letters, packages and other materials delivered to the facility.

Electronic Communications (§483.10(g)(9)). Largely as proposed, the final rule establishes the right of a resident to reasonable access and privacy for electronic communications including email, video, and internet research if available to the facility and at the resident's expense. CMS clarifies in the final rule that use of electronic communications must comply with state and federal law.

Examine Results of Surveys (§483.10(g)(10)). The requirements finalized in (g)(10) include the pre-existing right of a resident to examine the results of recent surveys of the facility, including plans of corrections, to receive information from agencies acting as advocates and to be allowed to contact such agencies.

Post Survey (§483.10(g)(11)). The final rule includes a new requirement that requires a facility to post in a readily accessible place, the result of the most recent survey of the facility and make available for review upon request, reports related to surveys, certification and complaint investigations during the prior 3 years.

Advance Directives. (§483.10(g)(12). CMS finalizes its proposed amendment incorporating current §483.10(b)(8) which requires the facility to comply with requirements in 42 CFR 489, subpart I, related to advance directives. The facility is required to inform all adult residents concerning the right to refuse treatment and, at the resident's option, to formulate an advance directive and include a written description of the facility's policies to implement advance directives and applicable state law. Facilities may contact other entities to furnish the information but will remain legally responsible for assuring that the requirements are met. If an adult is incapacitated at the time of admission, and is unable to receive information or articulate if an advance directive has been executed, the facility is permitted to give advance directive information to the resident's representative in accordance with state law. The facility remains obligated to provide the information to the resident if the resident becomes able to receive the information.

Information for Medicare and Medicaid (§483.10(g)(13)). Existing §483.10(b)(10) regarding the requirement to display information about how to apply for Medicare and Medicaid is moved to (g)(13) in the final rule.

Notification of changes (§483.10(g)(14)). CMS finalizes proposed changes with modifications to pre-existing §483.10(b)(11) related to the requirement that a facility notify a resident or their representative and consult with the resident's physician when there is an accident, a significant change in physical, mental or psychosocial status, or a need to alter treatment significantly or a decision to transfer or discharge the resident and to notify the resident or their representative when there is a change in a room or roommate or in residents' rights. The proposed rule replaced the need to notify the resident's "legal representative or interested family member" with the resident's *"representative"* and added a requirement that the facility ensure that all pertinent information is available and provided on request to the physician. In the proposed rule, CMS described the need to alter treatment significantly as a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment. In the final rule, that need is described as the need to discontinue or *change an* existing form of treatment.

Composite Distinct Part (§483.10(g)(15)). Admission to a composite distinct part, currently §483.10(b)(12) which establishes disclosure requirements in the admission agreement for facilities that are a composite distinct part, are moved to (g)(15).

Notice of Rights and Services (§483.10(g)(16)). Existing §483.(b)(1), regarding the requirement of a facility to provide a notice of rights and services to a resident, is moved to (g)(16) largely as proposed with non-substantive modifications to the language.

Informing Residents Regarding Medicaid Eligibility (§483.10(g)(17)). CMS finalizes minor revisions, as proposed, to current §483.10(b)(5), which requires notification to each Medicaid eligible resident, upon admission and when the resident becomes eligible for Medicaid, about: items and services offered by the facility for which the resident may not be charged; items and services for which the resident may be charged and the amounts of the charges; and of any changes in those items and services.

Informing Residents of Charges (§483.10(g)(18)). CMS incorporates current §483.10(b)(6) requiring that residents be informed of services, and charges for such services, including charges not covered under Medicare or within the facility per diem rate. CMS finalizes its proposal to add new paragraphs (i) through (v) which require the facility to provide notice when changes are made to the items and services covered by Medicare and Medicaid; require notice in writing at least 60 days prior to any change in charges for other items and services; and require refunds, in the case of death, hospitalization, and transfer for charges already paid. Refunds to a resident or resident's representative must be paid within 30 day of the resident's discharge and an admission contract cannot conflict with these requirements.

h. Privacy and confidentiality. CMS finalizes its proposal with several technical changes and one substantive change to incorporate and update the pre-existing §483.10(e) related to a resident's right to privacy and confidentiality. The pre-existing and proposed rule would have

established the right to personal privacy and confidentiality of medical records. In the final rule, CMS adds personal records so that the right extends to the confidentiality of personal and medical records. As proposed, the final rule requires a facility to respect the right to personal privacy, including in verbal, written and electronic communications and incorporates the pre-existing right of a resident to send and receive mail that is unopened. Also as proposed, the final rule includes in that right, the receipt of materials delivered to the facility through a means other than the postal service and clarifies that the facility has to allow representatives of the Office of the State Long-Term Care Ombudsman to examine social and administrative records in accordance with state law, and will no longer require that office to obtain a resident's permission.

i. Safe Environment. CMS incorporates revised pre-existing §483.15(h) as proposed, with one addition, into §483.10(i). CMS finalizes its proposed additional specifications in subparagraphs (1) and (2). Final changes specify that a safe, clean, comfortable and homelike environment includes ensuring that the resident can receive care and services safely, and that the physical layout of the facility maximizes independence and does not pose a safety risk. The final rule adds that the facility must exercise reasonable care for the protection of the resident's property from loss or theft.

j. Grievances. CMS combines proposed §483.10(j) and §483.11(g) and finalizes those provisions related to the resident's right to voice grievances in §483.10(j). In (j)(1), CMS establishes the resident's right to voice grievances without discrimination or reprisal. Grievances under this part can include those related to care and treatment furnished as well as not furnished and the behavior of staff or residents or other concerns regarding the resident's stay. In (j)(2), the facility is required to make prompt efforts to resolve grievances; in (j)(3), the facility is required to make information available to the resident on how to file a grievance or complaint. In (j)(4), the facility must establish a grievance policy which must be provided on request to the resident. The policy must:

(i) Include notification individually or through postings in prominent locations of the right to file a grievance verbally or in writing; the right to make such a filing anonymously; the contact information of the grievance official; a reasonable expected time frame for review of the grievance; the right to a written decision; and the contact information for independent entities with whom grievances may be filed;
(ii) Identify a Grievance Official responsible for overseeing the process, including specific responsibilities that are delineated;
(iii) Describe immediate action that will be taken, as necessary, to prevent further potential violations while an alleged violation is being investigated;
(iv) Provide for immediate reporting of all alleged violations involving neglect, abuse, including injuries of unknown source, and/or misappropriation of resident property, to the administrator and as required by state law;
(v) Ensure that all written grievance decisions include a specified set of information items relevant to the grievance and decision;
(vi) Include that appropriate corrective action is taken in accordance with state law if the alleged violation of patient's rights is confirmed, or an outside entity with jurisdiction confirms a violation; and

(vii) Include that maintaining evidence demonstrating the results of all grievances for at least three years from the time of the grievance decision.

CMS received many recommendations on its proposals related to the resident's right to file a grievance including those recommending timeframes be added, that the requirements be incorporated into Quality Assurance and Performance Improvement (QAPI), that the scope of actionable grievances be expanded, the additional materials be maintained after resolution, etc. CMS expands the scope of actionable grievances in (j)(1) to include grievances related to care and treatment furnished as well as not furnished and the behavior of staff or residents or other concerns regarding the resident's stay.

k. Contact with External Entities. CMS finalizes proposed §483.10(i) as §483.10(k) which provides that a facility cannot prevent or discourage a resident from communicating with federal, state, or local officials, with specification of a number of officials and organizations.

Regulatory Impact. Overall, CMS estimates that the final provisions establishing residents' rights and the related facility responsibilities would affect 15,653 facilities with a total first year cost to all facilities of $166.87 million and about the same amount in annual recurring costs. CMS estimates the average cost per facility to be $10,627 but the costs are not likely to be evenly distributed across facilities so that some will face considerably greater costs and others will face lower costs. The costs are estimated to be driven predominantly by two sets of requirements. The requirements to establish a grievance policy and to identify a grievance official are estimated to cost $153.0 million of that total while requirements that facilities notify residents of changes to their care plans and to have the right to sign their plan of care are estimated to cost an additional $11 million.

F. Facility Responsibilities (Proposed §483.11)

As noted above, CMS does not finalize proposed §483.11 and instead incorporates the responsibilities of facilities into final §483.10.

G. Freedom from Abuse, Neglect, and Exploitation (§483.13 re-designated as §483.12)

CMS finalizes with several changes its proposals to clarify and add to pre-existing rules (previously in §483.13(b)) that prohibit facilities from employing individuals who are unfit for such employment because of past findings of guilt, or actions or incidents of abuse, neglect, or mistreatment by a court of law.[1] CMS finalizes its proposed addition that facilities cannot employ or otherwise engage such individuals and adds that this includes those unfit due to past findings, actions, or incidents of misappropriation of property and, as added in the final rule, past findings, actions, or incidents of exploitation. In describing in this section the individuals that cannot be employed or engaged, CMS includes those who have had a disciplinary action taken

[1] In the preamble to the proposed rule, CMS directs readers to a fuller discussion of these requirements in a June 17, 2011 Survey and Certification Letter to State Survey Agency Directors and in a questions and answers document, both available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter11_30.pdf.

against their professional license by a state licensure body as a result of a finding of abuse, neglect, or mistreatment of residents or misappropriation of resident property.

CMS responds to many comments and recommendations about the employment restrictions. Questions were raised as to the application of these rules to volunteers or others who may have been rehabilitated or whose findings were long in the past or were unrelated to the care of LTC facility patients. CMS adds a provision in §483.12(a)(3)(iii) to allow for some discretion for facilities with respect to an individual's previous disciplinary actions. The provision prevents facilities hiring those who have a disciplinary action *in effect* against his or her professional license by a state licensure body.

Some commenters were concerned that without a centralized registry, a facility would be unable to check for disciplinary action in all states. CMS states that it would expect facilities to exercise reasonable efforts to determine if a state licensing board has taken disciplinary action against an individual. This could include checking websites for states that the person has been known to live or work in.

Under the final rule, facilities must, as proposed, develop and implement written policies and procedures that prohibit and prevent abuse, neglect and exploitation. These policies and procedures must incorporate a process to investigate allegations, to provide for the staff training programs described in §483.95, to coordinate with the facilities' QAPI programs, and ensure the reporting of crimes occurring in federally-funded LTC facilities in accordance with the requirements to do so as described in section 1150B of the Social Security Act (SSA). The following elements are required:

- Annually notifying covered individuals of their obligation to comply with reporting when there is a reasonable suspicion of a crime (in accordance with section 1150B of the SSA.) The reporting must take place *immediately*, but not later than 2 hours after forming the suspicion if there is a possibility of serious bodily injury and no later than 24 hours otherwise. The final rule adds *immediately* to this reporting requirement in response to comment;
- Posting a conspicuous notice of employees' rights; and
- Prohibiting retaliation.

H. Admission, Transfer, and Discharge Rights (§483.12 re-designated as §483.15)

A large number of changes were proposed to the pre-existing section "Admission, Transfer, and Discharge rights." The changes, according to CMS, largely reflect quality concerns related to the care of a resident who is being transitioned between settings. The general matters addressed in this section include admissions, transfers and discharges, bed-hold policies, and therapeutic leave policies. CMS had proposed to change the title of this section to "Transitions of Care," but in response to comment that the new title would make it more difficult for some readers to find information about admissions, transfers, and discharges, CMS does not finalize the title change.

The final provisions add to existing requirements for facilities' admissions policies in §483.15(a) by requiring, as proposed, a facility to have an admissions policy. To the existing prohibition on facilities requesting or requiring residents or potential residents to waive their rights to Medicare

or Medicaid benefits or to any rights conferred by licensing or certification laws, the final rule also prohibits, as proposed, a facility from requesting or requiring residents or potential residents from waiving the facility's liability for loss of personal property.

One commenter raised the concern that some facilities evade a pre-existing requirement in (a)(3) that facilities cannot require a third party guarantee of payment to the facility as a condition of admission, expedited admission or continued stay. Facilities are able to skirt this prohibition by using a contract that requires a resident representative to commit to paying the resident's bill and then suing the representative if it is unpaid. CMS responds that it will investigate this issue and consider it in future notice and comment rule-making.

CMS also finalizes as proposed, an addition to the requirements of a facility's admissions policy that a facility must disclose to residents or potential residents, prior to admission, notice of special characteristics or service limitations of the facility. In the preamble to the proposed rule, CMS explains this to include such characteristics or limitations as religious affiliations that may guide a facility's practices, or its inability to care for those needing psychiatric care. CMS received many comments about this provision, some in opposition, others requesting additional clarification of what is meant by service limitations, and others recommending the addition of protections to ensure the provision does not allow facilities to discriminate in admissions transfers and discharges. CMS makes only one change in the final rule – to ensure that this disclosure occurs prior to admission.

CMS finalizes additions and clarifications to existing requirements for transfer and discharge policies and moves them from §483.12(a) to §483.15(b) and (c). (In the proposed rule, the entire section would have been moved to §483.15(b)). In the final rule, §483.15(b) incorporates pre-existing provisions from §483.12(c) ensuring equal access to quality care for all residents regardless of payment source. CMS finalizes those provisions with updated references and incorporates proposed clarifications as well as an additional cross reference to definitions in §483.5. As proposed, the final rule clarifies that facilities can charge for services for non-Medicaid residents in any amount *unless otherwise limited by state law*.

CMS finalizes its proposed additions to the reasons that a facility can discharge or transfer a resident. Under pre-existing rules, transfers and discharges were permitted when necessary for the resident's welfare or to meet their needs, when a resident's health improves so that services are no longer needed, when the health or safety of individuals at the facility would be endangered, when a resident has failed to pay for their services or when the facility ceased to operate. As proposed, CMS finalizes and makes changes to clarify that discharges made because the safety of individuals in the facility is endangered must be *due to the clinical or behavioral condition of the resident*. CMS also adds to the pre-existing rule that facilities may discharge a resident for failure to pay (or to have paid under Medicare or Medicaid) for their stay. The addition, as proposed, clarifies the meaning of failure to pay by stating that non-payment includes when a resident does not submit the necessary paperwork for the third party payment and when a third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay. As proposed, the final rule also includes new (c)(1)(ii) that prohibits a facility from transferring or discharging a resident while an appeal of the transfer or discharge is pending.

CMS addresses many comments on admissions, discharge and transfer policies (81 *FR* 68730-68735) and incorporates several changes in response to those comments as discussed below.

CMS finalizes several proposed changes to the documentation required in §483.15(c)(2) that must be provided when a facility transfers or discharges a resident. Additions in (c)(2)(i) are intended to ensure that required information is provided to the setting that the resident is being transferred to. Pre-existing rules established a documentation requirement but did not require that the documentation be given to the receiving entity. When the resident is being transferred because of his or her safety or welfare, the facility is, under the final rules, required to include in the documentation the specific needs of the resident that it cannot meet, the attempts it has made to meet those needs, and the services available at the receiving facility that are expected to meet those needs. CMS proposed a list, in §483.15(b)(2)(iii), of items that must be included in such documentation. The extensive list has been shortened in the final rule. In the preamble, in response to comments, CMS points out that the revised list is more flexible than the proposed list. The proposed list would have included demographic information, resident representative information, advance directive information, history, reason for transfer, medical history, active diagnoses, and psychosocial assessment.[2] The finalized list at §483.15(c)(2)(iii), includes contact information of the practitioner responsible for the resident, the resident representative and their contact information, advance directive information, special instructions or precautions for ongoing care, comprehensive care plan goals, and all other necessary information including a copy of the discharge summary and any other documentation needed to ensure a safe and effective transition of care. CMS points out that it expects the discharge summary to include the medication reconciliation, a summary of the resident's stay and status, as well as the post-discharge plan of care.

Contents of the Transfer or Discharge Notice (§483.15(c)(5)). CMS finalizes in §483.15(c)(5), with changes, its proposal to require that the facility send a copy of the transfer notice once the resident's consent for the transfer or discharge is obtained, to the Office of the State Long-Term Care Ombudsman. The final rule removes the requirement for consent to be obtained. CMS declines to revise or remove a requirement that the notice be sent to the Ombudsman despite commenters' concerns that it is unnecessary, unclear what it would achieve, and not likely that such offices will have the resources to act on the notices.

CMS finalizes proposals to require that the notice include information for the resident about how to appeal the transfer, how to obtain an appeals form, and assistance in completing the form and submitting the appeal hearing request. For nursing facility residents with intellectual and developmental disabilities, the notice must also include contact information for 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

[2] In the preamble to the proposed rule, CMS pointed out that several states require or recommend (and the American Medical Directors Association recommends) the use of a universal transfer form and provides resources for further information on utilizing those forms: www.medicare.gov/Pubs/pdf/11376.pdf; and www.innovations.ahrq.gov/content.aspx?id=3285; www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/longtermcare/; http://interact2.net; www.ahrq.gov/professionals/systems/long-term-care/resources/ontime/qualityimprov/index.html; www.healthit.gov/sites/default/files/generalcertexchagneguidance_final_9-9-13.pdf .

2000. Some commenters raised a concern about being obligated to provide assistance with filing appeals. CMS however, responds that such assistance does not need to be extensive, for example, it could be comprised of helping the resident contact the Ombudsman or obtain the appeals form.

In paragraph (b)(5)(iv), CMS finalizes it proposal 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. In final paragraph §483.15(b)(6), CMS requires 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.

Other changes finalized as proposed require in (c)(6), that if the information in the notice changes, residents should be provided with an update as soon as is practicable, and in (c)(7), that the facility provide an orientation for residents to prepare them for the transfer. Finally, in §483.15(c)(9), CMS clarifies that room changes in a composite distinct part are subject to the requirements of final §483.10(e)(7).

With respect to policies that facilities have in place to reserve a residents' bed when the resident is transferred to an acute facility, CMS finalizes an addition to existing rules in §483.15(d) regarding the required notice that must be provided to residents about the facilities' bed-hold policies before the resident is transferred. The final rule requires that the notice describe the reserve bed payment policy in the state plan. Bed-hold policies also need to provide for patients to be readmitted to the facility, to their previous room if available.

I. Resident Assessments (§483.20)

Pre-existing §483.20 describes the comprehensive assessment of each resident's functional capacity that each facility is required to conduct (and periodically update). CMS finalizes as proposed its clarification that the purpose of the assessment is broader than assessing the residents' needs (as under existing rules) and extends the purpose of such assessment to include residents' strengths, goals, life history, and preferences.

In response to a request for clarification of a proposed change to an existing requirement, CMS does not finalize its proposed change to §483.20(b)(1)(xviii). The pre-existing provision ensured that a resident assessment process include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members. CMS had proposed to include "direct access" staff members but the term raised confusion, so CMS does not finalize it.

Preadmission Screening and Resident Review (PASARR) is a federal requirement that all applicants to Medicaid-certified nursing facilities be evaluated for mental illness and intellectual disability. To bring clarity to the existing requirement in §483.20(e) that facilities "coordinate assessments" with PASARR, CMS finalizes its proposal to add paragraphs (e)(1) and (e)(2). Those paragraphs define coordination with Medicaid to mean incorporating recommendations from the PASARR level II determination (for those residents identified in screening as needing a

more in-depth review) and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care; and require the facility to refer all level II residents and all residents with newly evident or possible serious mental illness, intellectual disability or a related condition to level II resident review upon a significant change in their condition.

CMS finalizes without changes new paragraph (k)(2) to provide an exception to the preadmission screening for individuals with mental illness and intellectual disability for admittance to conform to existing statute and new paragraph (k)(4) to require a nursing facility to notify the state mental health authority or state intellectual disability authority when there has been a significant change in a resident's physical or mental condition so that a resident review can be conducted.

Also finalized is CMS' proposal to move paragraphs (k) and (l) to §483.21(b) and (c) as further described below.

J. Comprehensive Person-Centered Care Planning (§483.20(k) and 483.20(l)) re-designated as §483.21)

CMS finalizes with several changes a new section that incorporates certain pre-existing provisions that were in §483.20 and adds new provisions. Unless indicated, the provision was finalized without modification. CMS states that bringing care planning provisions together into their own section of the regulations raises their visibility and reflects the importance of a strong care planning process. Additions and revisions to existing provisions are also intended to address gaps in care planning in LTC facilities as identified in several reports issued by the Office of the Inspector General of the Department of Health and Human Services (HHS).[3]

Baseline care plans. Final §483.21(a) requires facilities to develop *and implement* a "baseline care plan" within 48 hours of a resident's admission. The final rule includes the clarification that such plans must be implemented in addition to being developed. The facility may substitute the comprehensive care plan required under existing §483.20 (moved to §483.21(b)) in this rule) for the baseline plan but only if it is developed within 48 hours of admission. The areas that must be addressed include: initial goals based on admission orders, physician orders, dietary orders, therapy services, social services, and PASARR recommendations. In the preamble to the proposed rule, CMS stated that it expects baseline care plans would be continuously revised and updated as needed until the comprehensive care plan is developed. The final rule adds §483.21(a)(3), requiring a facility to provide the resident and their representative with a summary of the baseline care plan.

Some commenters were concerned about the need for a baseline plan within 48 hours of admission, especially for weekend admissions. CMS asserts that since an RN must be available for at least 8 consecutive hours a day, 7 days a week, there should always be a professional present who can work on such plan even when a resident is admitted on a holiday or weekend.

[3] "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; "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

Other commenters recommended different care planning requirements for short-stay residents versus longer-stay residents. However CMS states that the need for an assessment and plan of care should not be dependent upon the length of time a person is in the facility.

Comprehensive care plans. CMS revises §483.21(b), the new location of existing requirements for facilities to develop a comprehensive patient-centered care plan, to provide clarity, promote resident safety, and encourage person-centered care. In the final rule, CMS adds to the requirement that a facility must develop a comprehensive care plan – requiring it to be *implemented* as well as developed.

New (b)(1)(iii) requires such plans to include a description of any specialized services or specialized rehabilitation services the nursing facility will provide as a result of a PASARR recommendation. If a facility disagrees with the finding of the PASARR, it must indicate the disagreement and the reasons for it in the resident's medical record.

New (b)(1)(iv) requires that discharge plans be included as a part of the comprehensive care plan. Discharge plans must be developed in consultation with the resident and the resident's representative(s), to reflect the resident's goals for admission and their desired outcomes, as well as their preferences for future discharge. Discharge plans must be consistent with requirements in new paragraph (c), described below, where appropriate. Facilities must document whether the resident's desire to return to the community was assessed and whether any referrals to community agencies or other appropriate entities were provided. CMS states that the objective of this requirement is to require facilities to assess a resident's potential for future discharge as early as upon admission, and to maximize a resident's opportunity to attain their highest quality of life through addressing residents' choice.

In re-designated (b)(2), CMS proposed to add to the members of the interdisciplinary team that are required to prepare the comprehensive care plan. Under pre-existing rules (§483.20(k)(2)(ii)), the team that was required to participate included the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff as determined by the resident's needs, and to the extent practicable, the resident, the resident's family or legal representative. CMS proposed to include other appropriate professionals as well as other appropriate staff and to add a nurse aide with responsibility for the resident, a member of the food and nutrition services staff, and a social worker to the list. That team is modified in the final rule to not require the participation of a social worker. Under the final rule, if participation of the resident or their representative is determined to not be practical, the explanation of the reason must be documented in the medical record.

CMS received many comments about the professionals who should or should not be included on the interdisciplinary team. Some recommended the addition of a qualified mental health professional, a member of clergy, or a pharmacist. Others felt that the addition of a mental health professional would be cost prohibitive, and pointed out that many residents invite their own religious leaders to the facility. CMS notes that the team includes "other appropriate staff" so a mental health professional, chaplain, or a pharmacist may be included based on a resident's needs. Other commenters opposed including a nursing assistant with responsibility for the resident and a member of dietary services. They cited concerns that such participation would

remove those staff from direct patient care. CMS points out that there is flexibility for facilities to determine how team members participate. For example, participation could be via teleconference or through other means such as email participation or by contributing written notes.

CMS finalizes its proposal to add a new requirement in (b)(3) requiring that services provided in accordance with such care plans be culturally-competent and trauma-informed.

In response to commenters objecting to the need to document a resident's participation in the care planning process, CMS notes that since a July 2012 report issued by the HHS Office of the Inspector General found that 91% of care plans contained no evidence that a resident or their representative participated, CMS believes this is necessary for facilities to be held accountable for whether or not they actively include the resident and their representatives in care planning.[4] In addition, several commenters requested clarification of what is meant by "trauma-informed care. CMS declines to define the term but provides references (including those provided by other commenters) and notes that interpretive guidance will provide further information.[5]

Discharge planning (§483.21(c)). CMS re-designates, as proposed, §483.20(l) as §483.21(c) and finalizes proposed changes to incorporate requirements of the IMPACT Act, which requires post-acute care (PAC) providers, home health agencies (HHAs), SNFs, inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs) to report standardized patient assessment data, data on quality measures, and data on resource use and other measure. These data must be standardized and interoperable. The IMPACT Act also requires that PAC assessment instruments allow for the submission of standardized patient assessment data and standardized patient data, quality measures, and resource use measures along with patient treatment goals and that patients' preferences be taken into account in discharge planning.[6]

CMS finalizes provisions in §483.21(c)(1)(i) through (vii) to define and require that facilities develop and implement an effective discharge planning process. In the final rule, clarification is added to specify that such a process must be consistent with the discharge rights set forth at §483.15(b). Remaining provisions are finalized largely as proposed: The process must focus on residents' discharge goals and on preparing residents to be active partners in their post-discharge care. As part of the process, the plan must regularly re-evaluate residents to identify changes that require modification of their plans. The interdisciplinary team (IDT) responsible for developing a resident's comprehensive care plan must be involved in the development of the discharge plan. The facility needs to take into account caregiver/ support person availability, and the resident's or

[4] "Skilled Nursing Facilities Often Fail to Meet Care Planning and Discharge Planning Requirements (OEI-02-09-00201).

[5] 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 , The Council on Social Work Education, NASW's standards and indicators for cultural competence (available at http://www.socialworkers.org/practice/standards/index.asp), and The National Standards for Culturally and Linguistically appropriate Services in Health and Health Care (developed by the Office of Minority Health in HHS).

[6] In the preamble to the proposed rule, CMS provided resources for facilities to explore how the use of certified HIT can support their efforts to develop and share standardized discharge summaries at www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf; www.healthit.gov/standards-advisory.

their support persons' capacity and capability to perform any needed care, as part of identifying the resident's discharge needs. The discharge planning process must involve residents and their families and incorporate residents' goals of care and treatment preferences. Facilities are required to document in the discharge plan that a resident had been asked about their interest in receiving information regarding returning to the community, if true, and any referrals to local contact agencies or other appropriate entities made for this purpose. The discharge plan as well as the comprehensive care plan must be updated in response to feedback received from such referrals. If discharge to the community is determined not to be feasible, the facility must document who made the determination and why it was made.[7]

CMS finalizes as proposed, at §483.21(c)(1)(viii), the incorporation of the IMPACT Act requiring LTC facilities to take into account standardized patient assessment data, quality measures and resource use measures to the extent they are available, and other relevant measures specified by the Secretary and to use available data to assist residents who are transferred to another LTC facility or who are discharged to a HHA, IRF, or LTCH, in selecting their providers. 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.

Finally, section §483.21(c)(1)(ix) is finalized, which requires that the evaluation of the resident's discharge needs and discharge plan be documented, completed on a timely basis based on the resident's needs, included in the clinical record, and discussed with the resident or resident's representative. In addition, 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.

In §483.21(c)(2)(i), CMS revises the pre-existing 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.

At §483.21(c)(2)(iii), CMS finalizes it's requirement that facilities reconcile all pre-discharge medications, both prescribed and non-prescription, with residents' post discharge medications and to include this information as part of the discharge summary. The addition of this requirement is to ensure that residents avoid unnecessary medications and prevent adverse drug interactions. In addition, in §483.21(c)(2)(iv), CMS requires that the post-discharge plan be developed with the participation of the resident and, with the resident's consent, with his or her representative and to indicate any arrangements made for the resident's follow up care.

Regulatory Impact. CMS estimates that new requirements in §483.21 related to care planning will affect 15,653 facilities and cost an average of $5,517 per facility. Overall, the costs are estimated to be $86 million per year. The vast majority of those costs, $65 million, is estimated

[7] CMS notes that on May 20, 2016, the HHS Office for Civil rights issued "Guidance and Resource for Long Term Care Facilities: Using the Minimum Data Set to Facilitate Opportunities to Live in the Most Integrated Setting" (see http://www.pasrrassist.org/events/webinar/ocr-guidance-and-resouces-long-term-care-facilities-using-minimum-data-set).

to be attributable to the requirement that a nurse aide and member of nutrition services participate as members on the interdisciplinary care planning team. CMS expects those requirements to add to the duties of those staff members and therefore will increase the staff time necessary to produce care plans.

K. Quality of Care and Quality of Life (§483.24 and §483.25)

CMS proposed to comprehensively revise and re-organize §483.25 to address person-centered, quality care and quality of life. However, many commenters urged that quality of care and quality of life should be addressed independently. In response, CMS has reorganized the provisions into two separate sections: Quality of Life (§483.24) and Qualify of Care (§483.25).

Quality of Life (§483.24). CMS finalizes provisions relating to quality of life at §483.24 instead of §483.25, as proposed. New §483.24, establishes quality of life as a separate overarching principle in the delivery of care to residents of LTC facilities. It includes provisions that were proposed in §483.25(a), (b), and (c) addressing requirements related to activities of daily living, basic life support, and activities programs.

In the text before §483.25(a), CMS establishes the principle applicable to all care and services provided to residents that each resident must receive the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive care plan.

(a) Necessary care and services. In §483.24(a), pre-existing provisions (§483.25(a)(1)) are incorporated with proposed as well as several new changes in the final rule. Consistent with pre-existing rules, facilities must provide necessary care and services to assure that a resident's ability to perform activities of daily living (ADLs) does not diminish, unless it is unavoidable. That care must be based on the comprehensive assessment, and as finalized, the facility's effort must also take into account a resident's needs and choices. The final rule maintains the pre-existing requirements that a resident be given the appropriate treatment and services, and that those unable to carry out ADLs receive necessary services to maintain good nutrition, grooming, and personal and oral hygiene. CMS finalizes its proposed requirement that facility personnel must provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel, subject to the resident's advance directives and adds in the final rule, "subject to physician orders."

(b) Activities of daily living (ADL). CMS finalizes its proposal with an amendment to revise pre-existing §483.25 (a)(1)(i-v) which lists ADLs, but incorporates those provisions into §483.24(b). As finalized, the ADLs are: (1) hygiene, such as bathing, dressing, grooming, and oral care; (2) mobility – transfer and ambulation. CMS adds, in the final rule, walking as a component of mobility; (3) elimination – toileting; (4) dining – eating, including meals and snacks; and (5) communication, including speech, language or other functional communication systems. In the preamble to the proposed rule, CMS noted that communications are not included in standard ADL instruments, but retains them here because it is a vital aspect of an individual's daily life.

(c) Activities. CMS moves and revises pre-existing requirements (at §483.15(f)) related to activities programs. Paragraph §483.24(c) incorporates the existing requirement for an ongoing activities program, based on the comprehensive assessment, to meet the interests of and support the physical, mental and psychosocial well-being of each resident, but adds that the program must also be based on the preferences of the residents. The program must support residents in their choice of activities, include both facility-sponsored, individual and independent activities, and encourage both independence and interaction in the community.

CMS responded to many comments some of which included recommendations for additional quality of life standards. For example, some commenters recommended adding additional requirements for staffing practices or training topics. CMS declines adding additional requirements at this time. In the preamble of the proposed rule, CMS requested comments on whether the pre-existing requirements for the qualifications of an activities program director are appropriate and what minimum requirements for this position should be. Some commenters recommended that CMS should include additional professionals, such as music therapists or those with Masters' degrees in gerontology. CMS declines to make changes at this time but notes that it may further evaluate these requirements in the future.

Quality of Care (§483.25). The final rule establishes the general principle that quality of care applies to all treatment and care provided to facility residents and, similar to qualify of life, must be based on the comprehensive assessment of a resident. Under the final rule, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices and identifies a set of care areas to which those standards apply but are not limited to. The care areas had been identified as "special care issues" in pre-existing and proposed rules. The final list is reordered, "restraints" is removed from this list and instead addressed in §483.12, and several other changes are incorporated as described below:

a) "Vision and hearing" incorporates pre-existing §483.25(b).
b) "Skin integrity" incorporates, with revisions, two pre-existing sections. To "Pressure ulcers" (previously §483.25(c)), CMS adds an additional specification that care be consistent with professional standards of practice. To "Foot care" (previously §483(k)(7)), CMS adds that residents must receive proper treatment and care to maintain mobility and good foot health, consistent with professional standards of practice, including care and treatment to prevent complications from the resident's medical condition. The facility, if necessary, must help the resident make appointments and arrange for transportation.
c) "Mobility" incorporates, with revisions, pre-existing §483.25(e) "Range of Motion." As proposed, CMS adds the requirement that a resident 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.
d) "Accidents" incorporate pre-existing §483.25(h).
e) "Incontinence" incorporates pre-existing §483.25(d), "Urinary incontinence" with additions substantively as proposed: residents with an indwelling urinary catheter must be assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that it is necessary and residents with fecal incontinence must

receive appropriate treatment and services to restore as much normal bowel function as possible.

f) "Colostomy, ureterostomy, or ileostomy care" incorporates pre-existing §483.25(k)(3) and in the final rule, CMS adds that the facility must ensure that residents who require such care receive care that is consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

g) "Assisted nutrition and hydration" incorporates, with proposed revisions, pre-existing §483.25(g), (i), and (j). As proposed "Naso-gastric" tubes includes naso-gastric tubes, gastrostomy tubes, percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids. CMS finalizes the proposed requirements that a resident who is able to eat enough on his or her own or with assistance not be fed by enteral methods unless the clinical condition requires it, the resident consents and a resident fed by enteral means must receive appropriate treatment and services to restore, if possible, oral eating skills, and to prevent complications. The final rule incorporates two changes in response to comment: it removes the requirement that the facility must ensure a resident maintains protein levels and requires the facility to ensure the resident maintains electrolyte balance.

h) "Parenteral Fluids" incorporates pre-existing §483.25(k)(2) and in the final rule, CMS adds that the facility must ensure that residents who require such care receive care that is consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

i) "Respiratory care, including tracheostomy care and tracheal suctioning," incorporates the pre-existing §483.25(k)(4).

j) "Prostheses" incorporates pre-existing §483.25(k)(8) and in the final rule, CMS adds that the facility must ensure that residents who require such care receive care that is consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

k) "Pain management" finalizes a proposed requirement that residents receive necessary and appropriate pain management and, in the final rule, CMS adds that the facility must ensure that residents who require such care receive care that is consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

l) "Dialysis" finalizes its proposed general requirement that residents receive dialysis in accordance with professional standards of practice and resident choices and, in the final rule, CMS adds that the facility must ensure that residents who require such care receive care that is consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

m) "Trauma-informed care" finalizes the proposed standard that residents who are trauma survivors receive culturally-competent, trauma-informed care that meets their special needs, in accordance with professional standards and accounting for residents' experience and preferences in order to eliminate or mitigate triggers that may cause re-traumatization.

n) "Bed rails" finalizes proposed requirements with several changes. Under the final provision, when a facility uses bed rails on a resident's bed the facility must ensure correct installation, use and maintenance, including: first attempting alternatives; assessing resident risk of entrapment; reviewing the risks and benefits of bed rails with

the resident; obtaining informed consent; ensuring that the bed's dimensions are appropriate for the resident's size and weight, and following the manufacturer's recommendations and specifications for installation.

CMS responds to many comments on the list of care issues as proposed. Some commenters supported additional protections for residents whose facility uses bed rails, some commenters felt bed rails should be addressed as if they are restraints. Others felt that their use should be prohibited altogether. Some commenters asked for additional clarity, training or specification for trauma informed care. Some recommended additions to the list of special care issues. For example, some commenters requested adding wheelchair use, dementia care, or worker and resident safety. In response to many of these suggestions, CMS indicated that it may consider further changes in the future.

L. Physician Services (§483.40 re-designated §483.30)

Requirements regarding physician services currently located at §483.40 would be moved to §483.30 with a few additions and modifications. CMS proposed:

- Revise the introductory text of §483.30 to specify that, in addition to a physician's recommendation that the individual be admitted to a facility, a physician, a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS) must provide orders for the resident's immediate care and needs.
- 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 PA, NP, or CNS 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.
- 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. (§483.30(f)(2))
- To provide the physician with the flexibility to delegate to a qualified therapist (defined in proposed §483.65) the task of writing therapy orders, to the extent that the therapist is permitted to do so under state law (§483.30(f)(3)).

In the final rule, CMS is:

- Withdrawing its proposal to require a facility to provide or arrange for an in-person evaluation of a resident prior to the resident being transferred to a hospital.
- Consistent with this change, CMS is withdrawing its proposal to re-designate paragraphs §483.30 (e) and (f) as (f) and (g) in order to accommodate the new paragraph §483.30(e) that would have provided for an in-person evaluation of a resident prior to a transfer to a hospital.
- Finalizing its proposal that a physician may delegate the writing of orders to therapists and registered dieticians (or other qualified nutrition professionals) with a modification to clarify that only the attending physician has the authority to make this delegation.
- Finalizing all other provisions without change.

CMS may revisit the proposal to require a facility to provide or arrange for an in-person evaluation of a resident, prior to the resident being transferred to a hospital, pending further evaluation of the suggestions provided in the comments as well as the second phase of "The Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents" announced on August 27, 2015. This initiative will provide funding to test whether a new payment model for nursing facilities and practitioners, together with the clinical and educational interventions already in place, will improve quality of care by reducing avoidable hospitalizations while also lowering combined Medicare and Medicaid spending. See this report at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/InitiativetoReduceAvoidableHospitalizations/AvoidableHospitalizationsamongNursingFacilityResidents.html.

Public comments and responses can be found on 81 *FR* 68752 – 68753 of the final rule. The majority of the comments disagreed with CMS' proposal to require a facility to provide or arrange for an in-person evaluation of a resident prior to a hospital transfer, citing concern about burden and costs (particularly for small and rural facilities) as well as whether facilities would be able to recruit physicians, NPs, PAs, and CNSs to fill this role among other concerns. Commenters suggested allowing the requirement to be completed through a telehealth mechanism or using registered nurses. CMS withdrew the proposal pending further consideration of the comments and the initiative cited above. CMS received comments both in support of and opposed to allowing the physician to delegate authority to write orders to a qualified dietician or other clinically qualified nutritionist and delegate to a qualified therapist the task of writing therapy orders. CMS finalized its proposal with one modification to clarify that only the attending physician has the authority to make this delegation.

M. Nursing Services (§483.30 re-designated §483.35)

Current regulations at §483.30 address certain aspects of nursing home staffing. CMS says that the current regulations leave gaps such as the competencies of licensed nurses and the need to take into account resident acuity. CMS proposed to relocate the requirements for nursing services from §483.30 to §483.35 and refers readers to the proposed rule for a full discussion of the long-standing interest in increasing the required hours of nurse staffing per day and the various literature surrounding the issue of minimum nurse staffing standard in LTC facilities (See 80 *FR* 42199). In addition, CMS proposed to:

- Require facility to use a competency-based staffing approach to evaluate its population and its resources in accordance with §483.70(e) at least annually, 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.
- Clarify that the facility must take into account its assessment of all residents as well as the skill-sets of individual staff when making staffing decisions.
- Clarify that nurse aides (NA) are included in the term ''other nursing personnel.''

- 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.
- 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.
- Non-permanent caregivers are expected to meet competency, knowledge and skill requirements to the same extent as permanent personnel.
- Add the term ''minimum'' to §483.35(c)(3) to clarify that this paragraph identifies the minimum requirements for hiring a nurse aide.
- To improve the logical order and readability of the nurse staffing regulatory provisions (see 81 *FR* 68754 for a full accounting of those changes).

CMS is finalizing each of the provisions as proposed.

Mandatory Staffing Ratios and 24/7 Presence of a Register Nurse (RN). CMS did not propose mandatory staffing ratios or the 24/7 presence of an RN, the subject of considerable narrative in the final rule. See 81 *FR* 68754 – 68759 for the full detail of these comments.

There was both support and opposition in the public comments for mandatory staff to patient ratios and a requirement for a registered nurse to be on duty 24/7. While CMS is not changing its policy in response to these comments, it agrees that sufficient staffing is necessary, along with the need for that staff to be competent in delivering the care that a resident requires. CMS made the following points in response to comments on this issue:

- §483.35(a)(3) and (c) specifically require that licensed nurses and nurse aides, respectively, have the competencies and skills necessary to provide care to residents in accordance with that resident's needs.
- Noted that it is the facility's responsibility to ensure that the work assigned to a contracted individual is appropriate for his or her competencies and skill sets.
- In response to a comment about whether nurse competencies must be met by each individual nurse or whether the requirement can be collectively met, CMS says that each individual staff member must have the competencies to treat that particular patient's needs.
- In response to a comment that the proposed new standards are no different than the current rules and related comments, CMS indicates that its approach would require that facilities document its assessment and take it into account the number of residents in the facility, and those residents' acuity and diagnoses, when making staffing decisions. CMS states that this approach requires decisions to be made at the facility level precluding staffing decisions from being made at the corporate level and requiring facility and resident specific factors to be taken into consideration.
- It has begun mandatory, payroll-based collection of staffing information from long-term care facilities, to include registered nurses, licensed practical or vocational nurses, certified nursing assistants, or other types of medical personnel as specified by CMS, along with census data, data on agency and contract staff, and information on turnover, tenure and hours of care provided by each category of staff per resident day that could greatly assist in re-evaluating this issue.

- It will consider the commenters' recommendation to examine whether the current methodology for the five-star rating system can be adapted for establishing rules or guidelines providing presumptive levels for facility assessments.
- It would consider phasing in minimum staffing standards if adopted.

Regulatory Impact: CMS believes that the provisions that will require facilities to identify, document, and maintain any training, certification, and similar records in an existing personnel file or training record for direct care personnel will impose an incremental burden of 8 hours per year per facility to identify and add the additional information to existing files (paper or electronic). CMS estimates that this requirement will cost $3,881,944 for all LTC facilities ($31 office assistant hourly wage × 8 hours per facility × 15,653 facilities).

N. Behavioral Health Services (new §483.40)

Current §483.25 sets out requirements for quality of care and quality of life for residents. CMS proposed to add a new §483.40 to address those requirements for behavioral health services. These provisions would work in conjunction with other provisions CMS proposed, including those related to reducing the inappropriate use of psychotropic medications to address the behavioral health care needs for residents.

CMS proposed that §483.40 would require:

- The facility to have sufficient direct care staff with the appropriate competencies and skill 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).
- Based on the comprehensive assessment of a resident, the facility must assure that 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 problem or to attain the highest practical mental and psychosocial well-being.
- A resident whose assessment did not reveal or who does not have a diagnosis of such difficulties will not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the person's clinical condition demonstrates that the pattern was unavoidable.[8]
- If rehabilitative services are required, the facility provide the services or obtain them from an appropriate outside resource.

[8] This language is as it appears in both the proposed and final rules is unclear to us. Health Policy Alternatives has requested clarification from CMS. We believe it is requiring that a mental health intervention may be required even if the patient does not have a mental health diagnosis or an assessment indicating behavioral problems if the patient is demonstrating the behaviors listed and those behaviors are unavoidable because of the patient's clinical condition.)

CMS is finalizing all of these proposals without change and inserting the following definition into §483.40, ''Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.'' CMS is also adding "physical" to §483.40 (d) as shown in bold in the following: '[t]he facility must provide **physical,** medically-related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident.''

Major themes in the comments and CMS' responses are summarized below (and can be found on pages 81 *FR* 68760 – 68765).

Facility Assessment of Patient's Behavioral and Psychiatric Needs. Some comments were concerned about the objectivity of a facility doing a self-assessment of the behavior and psychiatric needs of its residents and suggested that CMS require the assessment be done by an outside source. While CMS acknowledged this concern, it indicates that facilities need the flexibility to determine the best way to perform their facility assessments to comply with this requirement. The facility can certainly perform this assessment itself or it may choose to have an outside entity perform the assessment.

Other comments were concerned that the proposed rule did not provide sufficient specificity regarding how the assessment should be performed. CMS responds that each facility needs to have the flexibility to decide the best manner in which to conduct that assessment, as long as it addresses or includes the factors or items set forth in §483.70(e). CMS will be providing additional subregulatory guidance on this issue.

Non-pharmacological interventions. Commenters noted that cognitive and behavioral conditions have a medical and biological component; others were concerned that the rule would discourage the use of pharmacological interventions. CMS responds to these comments indicating its agreement that cognitive and behavioral conditions have a medical and biological component and that its rules are intending to encourage appropriate care for residents. The final rule indicates that non-pharmacological or behavioral interventions are required in an attempt to reduce or eliminate psychotropic medications, but only if these non- pharmacological methods are not clinically contraindicated for the resident.

Admitting Patients with Behavioral Health Issues. In response to concerns from comments that the proposed rule requires facilities to admit patients with behavioral health issues, CMS indicates that the rules do not require patients with psychiatric diagnoses and behavioral health issues to be admitted but that a facility is required to provide appropriate care for a resident with behavioral health issues if they are admitted.

<u>O. Pharmacy Services (§483.60 re-designated §483.45)</u>

CMS proposed to relocate the LTC requirements for pharmacy services from §483.60 to §483.45. It also proposed:

- The pharmacist be required to review the resident's medical record at least every 6 months or concurrently when the resident is:

1) New to the facility;
2) Returning or being transferred from another facility; or
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 Quality Assessment and Assurance (QAA) Committee has requested be included in the pharmacist's monthly drug review.

The rule uses the broader term "psychotropic drug" in place of "anti-psychotic" drug and explains that a psychotropic drug includes any drug that affects brain activities associated with mental processes and behavior.

- To define "irregularities" that the pharmacist must report as "including, but not limited to, the use of any drug that meets the criteria set forth in proposed paragraph (d) for an unnecessary drug." §483.45(d) defines an unnecessary drug as a drug in one or more of the following categories:
    1) In excessive dose;
    2) For excessive duration;
    3) Without adequate monitoring;
    4) Without adequate indications for its use; or
    5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued.
- To add the medical director to the attending physician and the director of nursing as the individuals to whom the pharmacist reports medication irregularities.
- To require the pharmacist to report irregularities in a written report that is dated, and contains, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist noted.
- To require that the attending physician 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.
- To move the description of "unnecessary drugs" and specific requirements for psychotropic drugs (previously antipsychotic drugs) from §483.25 to §483.45.
- Prescriptions for psychotropic drugs prescribed PRN (as needed) would be prohibited unless that medication was necessary to treat a diagnosed specific condition that was documented in the clinical record.
- PRN orders for psychotropic drugs would be limited to 48 hours and not be continued without justification in the resident's clinical record.

CMS is finalizing these proposals with the following changes:

- Modifying §483.45(c)(2) by requiring that the monthly drug regimen review (DRR) included in current regulations also include a review of the resident's medical record (e.g. the pharmacist's periodic review of the patient's medical record would occur monthly with the DRR instead of every six months or when the patient has been admitted, readmitted or is

taking a psychotropic drug, antibiotic or drug the QAA has requested the pharmacist to include in the monthly DRR).[9]

- Adding a requirement at §483.45(c)(5) that the facility must establish and maintain policies and procedures that addresses the monthly DRR, including but not limited to, timeframes for the various steps in the process and procedures a pharmacist is to take when he or she believes immediate action is required due to potential harm to the resident.
- Modifying the definition of psychotropic drugs at §483.45(c)(3) to read: "A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: (i) Anti-psychotic; (ii) Anti-depressant; (iii) Anti-anxiety; and (iv) Hypnotic." CMS may add other drugs to the definition through subregulatory guidance. This definition excludes "opioid analgesics" from the definition of "psychotropic drug."
- Clarifying that CMS's regulations requiring gradual dose reductions (GDR) for residents on psychotropic drugs is applicable "unless clinically contraindicated." (§483.45(e)(2)).[10]
- Modifying the 48-hour limitation of PRN prescriptions for psychotropic drugs to 14-days except where the attending physician believes a PRN prescription for longer than 14 days is appropriate and documents their rationale in the resident's medical record. The exception to the 14-day limitation will not apply to anti-psychotic drugs.

Public comments and responses to these proposals are at 81 *FR* 68766 – 68774 and are selectively summarized in what follows:

Psychotropic Drugs. Like in the prior section, comments were concerned that CMS' policies were intending to discourage prescriptions for psychotropic drugs. CMS responds that its policy is intended to allow prescription of any medication intended for the benefit of a resident who has been diagnosed [with] a specific condition that requires these medications. The requirements are intended to protect LTC facility residents from drugs that are not being prescribed for their benefit.

There were many commenters concerned that the definition of psychotropic drugs was so expansive as to be unmanageable and would also include drugs that do not warrant the protection safeguards CMS proposed. Other commenters were concerned the inclusion of opioid analgesics in the definition of psychotropic drugs could lead to under treatment of pain. CMS has modified the definition of psychotropic drugs to address these comments but reiterates in the final rule concerns about opioid abuse and activities HHS is undertaking to address this public health issue.

Pharmacy versus Quality of Care. Some commenters indicated a preference for keeping the proposed requirements in the quality of care section rather than the pharmacy section, expressing concern about how this reorganization would affect the surveyor's ability to extend surveys due to a finding of substandard care. CMS responds that changes to the survey process will be managed through subregulatory guidance.

[9] This change in the final rule is described on 81 *FR* 68767 of the final rule but is not included in the summary of final rule changes on 81 *FR* 68774.

[10] This change in the final rule is described on 81 *FR* 68772 of the final rule but is not included in the summary of final rule changes on 81 *FR* 68774.

Drug Regimen Reviews. Some comments requested that CMS require pharmacists to report irregularities to an outside authority if the physician did not take action on them and other commenters requested that CMS require the pharmacist's findings be included in the medical record and the patient be notified of the irregularity. CMS is not making any changes in response to these comments noting that the physician is obligated to record the action, if any, in response to an irregularity in the patient's medical record. The rule indicates it is the responsibility of the physician to determine when to notify a patient about an irregularity.

In response to a variety of other comments requesting specific provisions be included in the rules (e.g. timeframes for reporting and acting upon irregularities, whether the physician is required to repeatedly document the same rationale once a clinically acceptable rationale is provided, etc…), CMS indicates that each facility should have the flexibility to determine the best manner in which to handle these situations.

Limitations on PRN Prescriptions of Psychotropic Drugs. Some commenters suggested that CMS not allow PRN prescriptions at all for psychotropic drugs. Others expressed concern about whether a 48-hour limitation is manageable among physicians and other practitioners that see patients in multiple sites of care. There were comments that were concerned about the impact on patients if a PRN prescription could not be renewed within 48 hours. Commenters suggested longer limitations on PRN prescriptions than 48 hours from 72 hours to 7 days to not having any limitation at all. CMS agreed that the 48-hour limitation was too restrictive and is establishing a 14-day limitation for psychotropic drugs where the attending physician believes a PRN prescription for longer than 14 days is appropriate. The attending physician can extend the prescription beyond 14 days for the resident by documenting their rationale in the resident's medical record. The exception to the 14-day limitation will not apply to anti-psychotic drugs.

<u>P. Laboratory, Radiology, and Other Diagnostic Services (§483.50)</u>

CMS proposed to relocate the LTC requirements for laboratory, radiology and other diagnostic services from §483.75 titled "Administration" to §483.50 under the title "Laboratory, Radiology and Other Diagnostic Services." New §483.50(a) would apply to laboratory services while §483.50(b) would apply to radiology and other diagnostic services. In addition, CMS proposed:

- To allow a facility to provide or obtain laboratory and radiology and other diagnostic services only upon the order of ''a physician, a physician assistant, nurse practitioner, or clinical nurse specialist.'' Prior regulations limited the ordering of a laboratory, radiology and other diagnostic services to the "attending physician." The proposed rule would allow any physician as well as PAs, NPs and CNs to order laboratory, radiology and other diagnostic services.
- 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 to just the physician.
- To clarify in §483.50(a)(2)(ii) that the laboratory would have to promptly notify the ordering professional if results fell outside of clinical reference or expected ''normal''

ranges, unless the orders for the test or the facility's policies and procedures required otherwise.

CMS is finalizing these proposals without change. Public comments and CMS' responses can be found on 81 *FR* 68774- 68775 and largely concerned whether different terminology should be used in place of "prompt" notification and if the notification procedures would result in unnecessary notifications, unwarranted concerns and unnecessary repeated testing. CMS explains why it did not agree with these concerns.

Q. Dental Services (§483.55)

Currently, §483.55 requires that facilities assist residents in obtaining appropriate dental services at the resident's expense for both SNF residents and as covered under the state plan for nursing facility residents. §483.55(a) applies to SNFs while §483.55(b) applies to NFs. Parallel changes would be made for both types of facilities. CMS would retain the requirements related to dental services in §483.55 but make changes to clarify and update this section. CMS proposed to:

- Add new §483.55(a)(3) to clarify that a facility may not charge a resident for loss of or damage of dentures determined in accordance with facility policy to be the facility's responsibility."

- 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.

- Modify new §483.55(a)(4)(ii) and §483.55(a)(5) regarding transportation and referrals for dental services by including a dental clinic or dental school in addition to a dentist's office or, if available, dental services provided within the SNF so long as the facility helped the resident accessing that locale.

- 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.

- Make parallel changes at §483.55(b)(2) and §483.55(b)(3) to apply to nursing facilities and add new §483.55(b)(4) and (5) to prohibit facilities from charging a resident for the loss or damage of dentures determined to be the facility's responsibility and to require that facilities assist residents to apply for reimbursement of dental services as an incurred medical expense under the state plan as appropriate.

CMS is finalizing these provisions as proposed with the following modifications:

- Adding a requirement at §483.55(a)(3) and (b)(4) that the facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility.

- Adding a requirement at §483.55(a)(5) and (b)(3) that the facility must document what they did to ensure that the resident could eat and drink adequately while awaiting dental services.

The comments that led to modifications of the proposed policy in the final rule (81 *FR* 68775-68776) concerned whether the facility could develop a written policy that absolved it from any responsibility for loss or damage of dentures. In response, CMS indicates that any such policy would not be consistent with the regulation and further noted that another provision in the rule (§483.15(a)(2)(iii) prohibits facilities from requesting or requiring residents or potential residents to waive any potential facility liability for losses of personal property. Consistent with the purpose of the proposed policy and in response to a comment, CMS is adding a requirement to ensure that the resident can eat and drink adequately during the timeframe they are awaiting dental services.

R. Food and Nutrition Services (§483.35 re-designated §483.60)

CMS had proposed to make the following changes to existing regulations for dietary standards for residents of LTC facilities:

- Rename "Dietary Services" as "Food and Nutrition services and revise the introductory language to include taking resident preferences into consideration when providing food service.
- 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.
- 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 in §483.60(a)(1).
- Require that a qualified dietitian 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 professional.
- Allow up to 5 years after the effective date of the regulation for dietitians hired or contracted prior to the effective dates of the revised regulations to meet these requirements.
- To continue requiring that, if a qualified dietitian or other clinically qualified nutrition professional was not employed full-time, the facility would have to designate a person to serve as the director of food and nutrition services who would receive frequently scheduled consultation from a qualified dietitian in re-designated §483.60(a)(2).
- To require that the director of food and nutrition services, if hired or designated after the effective date of these regulations, would have to be a certified dietary manager or certified food service manager as evidenced by meeting national certification standards. A certified dietary manager would have to meet the certification standards such as those of the Association of Nutrition and Foodservice Professionals. A certified food manager would have to meet the standards such as those of the International Food Service Executives

Association or have a Food Management Professional certification through the National Restaurant Association.

- If already serving as a director of food and nutrition service on the effective date of the regulations without one of these certifications, the individual must obtain a certification no later than 5 years after the effective date of the rule.
- Provided the following alternative ways of meeting the above requirements:
    - 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.
    - Meeting applicable state requirements to be a food service manager or dietary manager.
- 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 (§483.60(a)(4)).
- Add new §483.60(b) to require that a member of food and nutrition services also participate in the interdisciplinary team (IDT).
- Change ''Recommended Dietary Allowances'' to ''established national guidelines or industry standards'' to calculate daily nutrient recommendations for dietary planning (§483.60(c)(1)).
- 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.
- Make minor revisions to incorporate the addition of drinks (i.e., the facility would have to provide "drinks, including water and other liquids consistent with resident needs and preferences and sufficient to maintain resident hydration" and 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 (§483.60(d)).
- Add new §483.60(e) ''Therapeutic diets,'' that retained the requirement in current §483.35(e) that therapeutic diets be prescribed by the attending physician and 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.
- Modify §483.35(f) in re-designated §483.60(f) to add language that the resident's 3 meals per day at regular times should be served at times in accordance with resident needs, preferences, requests and the plan of care.
- 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 consistent with the resident's preferences, clinical and nutritional needs.
- Require that the facility provide suitable, nourishing alternative meals and snacks for each resident who wants to eat at non-traditional times or outside of the facility's scheduled meal service times, in accordance with their respective plans of care.
- Indicated in the proposed rule that ''suitable, nourishing alternative meals'' would mean that when a resident missed a meal or snack, an alternative of comparable nutritive value to the missed meal or snack would be provided.

- 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.
- Re-designate existing §483.35(h) as new §483.60(h) and retain, with some revisions, provisions for paid feeding assistants, as set out in the 2003 final rule (68 *FR* 55528). Section 483.35(h)(2)(ii) currently requires that, in an emergency, a paid feeding assistant must call a supervisory nurse for help ''on the resident call system.'' The proposed rule would eliminate the reference to "the resident call system."
- Have the IDT make the determination of whether a paid feeding assistant would be appropriate for a resident.
- Clarify in new §483.60(i)(1)(i) that facilities could procure food directly from local producers, farmers or growers, in accordance with state and local laws or regulations.
- Clarify in new §483.60(i)(1)(ii) that the above provision would not prohibit or prevent facilities from using produce grown in facility gardens, subject to compliance with applicable safe growing and handling practices, such as the use of pesticides in accordance with manufacturers' instructions.
- Specify in §483.60(i)(2) that facilities be required to store, prepare, distribute, and serve food in accordance with professional standards for food service safety.
- 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.

CMS is finalizing these provisions as proposed with the following changes:

- Modifies the definition of ''qualified dietitian or other clinically qualified nutrition professional'' at §483.60(a)(1) to more closely align with section 1861(v)(2) of the Act. This change responds to comment that the proposed requirements to be a qualified dietician or other clinically qualified nutrition professional could be lower than the federal statutory requirements. CMS removes the proposed definition and replaces it with:

A qualified dietitian or other clinically qualified nutrition professional is one who: Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose; has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or has a bachelor's degree or higher and has completed at least 900 hours of dietetics practice.

- In response to concerns regarding a potential workforce shortage of certified dietary managers, the final rule allows facilities 12 months from the effective date of the rule for a food service manager, hired after the effective date of this rule, to meet the updated qualifications. (This change can be found in response to the public comments but not with

the summary of final rule changes at the end of the "Food and Nutrition Services" section of the final rule).

- Director of Food and Nutrition Services: Modifies §483.60(a)(2)(i)(D) to specify that the hospitality degree must include food service or restaurant management (e.g. hospitality degrees in programs that do not include a food service or restaurant management component do not meet this requirement).
- Menus and Nutritional Adequacy: Deletes the term ''industry standards'' from the proposal at §483.60(c)(1) that menus must meet the nutritional needs of residents in accordance with established national guidelines.
- Food and Drink: At §483.60(d)(5), CMS replaces the terms ''substitutes'' and ''alternative'' with the terms ''options'' and ''different meal choice.''
- Withdraws the proposal at (f)(2) to delete the requirement that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, or up to 16 hours when a nourishing snack is served at bedtime, and a resident group agrees to this meal span.
- Modifies the regulatory language at §4863.60(f)(3) to state ''Suitable, nourishing meals and snacks must be provided for residents who want to eat at non-traditional times or outside of scheduled meal times, consistent with the plan of care'' to focus on residents actually receiving these snacks or meal options, rather than focusing on the availability of such options. (This is not found in the CMS summary of final rule changes).
- Clarifies §483.60(c)(4) to state that menus should ''reflect, based on a facility's **reasonable efforts**, the religious, cultural and ethnic needs of the resident population, as well as input received from residents and resident groups;'' and defers additional discussion to sub-regulatory guidance. Bolded language is added to reflect CMS' position that the requirement does not mandate that every facility be able to provide every possible religious, cultural, or ethnic diet. (This is not found in the summary of final rule changes).

A summary of selected comments that reflect major themes raised by the public follows (81 *FR* 68777-68782):

- Concerns about the specificity and subjectivity of standards such as "sufficient staff with appropriate competencies and skills." CMS responds that 'sufficient'' staff are enough staff, who have the skills and knowledge to safely and effectively deliver the care that residents need. That is the responsibility of the food and nutrition service. Direct observation and interview questions food and nutrition services can be used to determine if residents are receiving the services they require, in accordance with their individual plan of care, in a safe, timely, and effective manner. Surveyor training on these requirements will be forthcoming. The rule provides examples of questions and criteria on 81 *FR* 68778 a surveyor would use to make evidence-based decisions about whether or not a facility has or does not have sufficient staffing.
- There was strong support for the recognition of resident preferences in proposed food service regulations. Some commenters asked CMS to provide further protection for resident preferences for eating larger or smaller portions consistent with the resident's plan of care. CMS did not make any changes in response to these comments and indicates that the distinctions between requirements on the facility overall and application of the rules to resident-specific needs will accommodate these concerns.

- CMS received comments both in support of and opposed to the proposal to eliminate the requirement that there be no more than 14 hours between meals. Those who objected to removing the requirement felt the proposal was inconsistent with person-centered care and would not further the goal of ensuring that appropriate food is available and provided to residents at reasonable times. CMS responds that the proposal was intended to give facilities some flexibility and to focus their efforts on meeting residents' needs and preferences. Although the response to the comment is confusing, CMS appears to be saying that the requirements for no more than 14 hours between meals is consistent with the policy goal of each resident receiving adequate nutrition and having a say in both what he or she eats. Given the consistency of the requirement with the policy goals in the regulation, CMS has decided to retract its proposal and not eliminate the requirement.

Regulatory Impact:

Requirements for Food Service Directors (§483.60(a)(2)). CMS does not anticipate that many hiring officials will spend additional time recruiting other appropriate candidates, however it assumes that a small percentage will pursue additional candidates and spend time verifying credentials. For purposes of calculating the anticipated cost, CMS estimates that 10 percent of facilities will need to hire a director of food and nutrition services after the effective date of this final rule and this will require an additional hour of the NHA's time beyond their current duties related to hiring staff. Based on this information, CMS estimates that it will cost $133,051 for facilities to comply with this requirement (($85 NHA hourly wage × 1 hour) × (.1 percentage of affected facilities × 15,653 facilities)).

Menu Options (§483.60(c)(4)). CMS anticipates that facilities will have their menus updated by a qualified dietitian or other clinically qualified nutrition professional in the course of routine reviews and updates. Additional time will include the dietitian or other clinically qualified nutrition professional reviewing the facility assessment for pertinent factors and reviewing and updating the menus. CMS anticipates this will require 1 to 4 hours, on average 2 hours, depending on the size of the facility and complexity of resident needs. Based on this information, CMS estimates that it will cost $1,721,830 ($56 dietitian hourly wage × 2 hours × 15,653 facilities) for all LTC facilities to comply with this requirement.

<u>S. Specialized Rehabilitative Services (§483.45 re-designated §483.65)</u>

Current regulations at §483.45 set forth the services that a facility must provide if a resident needs specialized rehabilitative services including, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for a mental disorder. Following the reorganization of part 483 subpart B, CMS proposed to relocate these provisions to §483.65 with minor revisions as follows:

- To add respiratory therapy to the list of specialized rehabilitative services. The addition of this service would explicitly require facilities to provide or obtain these services when necessary and meet the needs of residents facing respiratory issues. However, this addition would not change coverage policy regarding respiratory therapy.

- To clarify that when it is necessary for facilities to obtain these services from an outside source, the provider would have to be a certified Medicare and/or Medicaid provider.
- To clarify the meaning of specialized rehabilitative services in relation to the pre-admission screening and resident review (PASARR) tool. CMS proposed to add to §483.65 a cross reference to the PASARR regulations at §483.120(c) which set out the mental health or intellectual disability services a nursing facility must provide to all residents who need these services.
- To correct a typographical error by deleting the redundant ‘‘mental health’’ before ‘‘rehabilitative services for a mental disorder and intellectual disability.’’

CMS is finalizing these provisions as proposed with the following modifications:

- Withdrawing its proposal to require a facility to use a certified Medicare and/or Medicaid provider when it is necessary for facilities to obtain these services from an outside source. Instead, CMS will require that services obtained from an outside resource must come from a provider that is not excluded from any federally funded health care program.

Significant public comments and CMS' responses included that: (81 *FR* 68782-68783)

- CMS provide a regulatory definition of ‘‘respiratory therapy’’ and a clear discussion of the scope of respiratory therapy services that must be provided. Commenters also requested that the rule provide the qualifications necessary for individuals to furnish these services to help providers better understand how to meet these requirements. CMS responds that regulations at §483.70(f) discuss staff qualifications and specify that the facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of the requirements for LTC facilities including that professional staff must be licensed, certified, or registered in accordance with applicable state laws.
- To address concern about access to respiratory therapy services, one commenter requested that the final rule not require an outside respiratory therapy provider to be a certified Medicare and/or Medicaid provider but only to be not excluded from any federal program. CMS agrees with this comment and has adopted the suggested change in an effort to balance the need to assure the safety of LTC residents against the concerns of facilities regarding obtaining access to providers.

T. Outpatient Rehabilitative Services (§483.67)

CMS proposed to add a new §483.67 ‘‘Outpatient Rehabilitative Services’’ to address facilities that choose to provide outpatient rehabilitative therapy services to individuals that do not reside in the facility. The provision of outpatient rehabilitative services for non-residents is not currently addressed by the requirements for LTC care facilities. CMS proposed to require facilities that provide outpatient rehabilitative therapy services to meet requirements similar to those already established for hospitals, specifically that if the facility provides outpatient rehabilitation, physical therapy, occupational therapy, audiology, or speech-language pathology services:

- The services meet the needs of the patients in accordance with acceptable standards of practice and the facility must meet certain requirements.
- The organization of the service must be appropriate to the scope of the services offered.
- The facility must 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.
- The facility must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered.
- The services 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.
- The 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.
- The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice.

CMS is not these finalizing the proposals and is withdrawing this proposed section in its entirety because "the practice of some LTC facilities providing outpatient rehabilitative services presents several additional complex issues that were not carefully and thoroughly considered." CMS also states that "it is necessary to study the issue further and consider proposals for future rulemaking."

While the majority of commenters indicated support for the addition of the requirements regarding facilities that provide outpatient rehabilitative services, they did raise a number of issues for CMS to address which appears to be the ostensible reason for CMS withdrawing the proposal.

U. Administration (§483.75 re-designated §483.70)

Under existing §483.75, a facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. CMS finalizes its proposals to re-designate and revise a number of the provisions related to this section. CMS also would remove certain subsections and move certain other provisions to different sections of the rule (see 81 *FR* 68784).

Relationship to other HHS regulations. CMS finalizes its proposed changes to this section. In paragraph (c), the term "handicap" has been replaced with "disability" and a reference has been added to HIPPA Privacy, Security and Breach Notification Rules (45 CFR parts 160 and 164). CMS clarifies the end of the paragraph to state that violations of other HHS regulations may result in a finding of non-compliance with this paragraph. In the preamble, CMS notes that violations will be determined by the agency or entity with enforcement authority for those regulations. CMS did not receive comments related to these provisions. CMS also has added 45

CFR part 92 to the regulations specifically referenced in §483.70(c) "Relationship to other HHS regulations."

Governing body (483.70(d)). CMS finalizes its proposed addition of subparagraph (d)(2)(iii) to require the nursing home administrator to report to and be accountable to the governing body. Some commenters urged CMS to withdraw this requirement because many not-for-profit organizations have management structures that include a Chief Executive Officer (CEO) who is not the facility administrator of record and that, in their view, CMS' change would supplant the governance policies of these organizations and undermine the relationship of the CEO to the board of directors. CMS rejects this argument and reaffirms its view that, without this change, the governing body could appoint the administrator but the governing body would not, on an ongoing basis, be required to remain cognizant of the facility's operations and management. CMS intends the change to ensure that the governing body remains informed and knowledgeable about those issues. CMS notes, however, that this new provision does not specify "directly;" thus "a governing body may appoint a designee, such as a CEO, to directly interface with an Administrator. However, the use of a designee does not change the Administrator's accountability to the governing body nor the governing body's responsibility to know and respond to concerns with the operation and management of the facility."

Finalized new paragraph (d)(3) requires the governing body to be responsible and accountable for the QAPI program (see discussion of §483.75 below). However, CMS has withdrawn its proposal to delete the phrase "where licensing is required" from §483.70(d)(2)(i) because it agrees with a comment that this deletion may have created confusion in states where state law allows administrators of hospitals which have a distinct part SNF not to be certified as LTC facility administrators.

Facility assessments (§483.70(e)). CMS has adopted as final its proposed new paragraph (e) to require an annual facility assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. The assessment will have to be updated as necessary, and at least annually; a review and update will also be required whenever there is, or the facility planned for, any change that would require a substantial modification to any part of this assessment. The assessment must address or include certain elements, including its resident population (number, capacity, care needs considering the types of diseases, etc.); staff competencies necessary to provide the level and types of care needed for the resident population; physical environment, equipment, services, and other physical plant considerations necessary to care for this population; and any ethnic, cultural, or religious factors that may potentially affect the care provided including, but not limited to, activities and food and nutrition services. The assessment also must address the facility's resources, broadly defined and specified in the rule. Finally, the annual review must include a facility-based and community-based risk assessment, utilizing an all-hazards approach.

In response to comments that this requirement would be duplicative of existing requirements and thus unnecessary, CMS says that currently, some but not all LTC facilities carry out assessments of their resident populations and the resources required to care for that population. Moreover, some do not perform the assessment that will be required by §483.70(e). Also, most facilities lack documentation of their assessment process. CMS believes that the new provision will enable

each facility to thoroughly assess its resident population and the resources needed to provide for their care and enable it to determine what resources it needs to competently care for its resident population. CMS also states that the assessment documentation requirement will provide a record for staff and management in the future to understand the reasoning for decisions that were made on staffing and other resources as well as a reference point for assessment when deficiencies are noted or when adverse events occur.

In response to other commenters' concerns about a facility being able to rely on its own assessment without there being any enforcement mechanisms or safeguards to ensure that the facility was objectively assessing its residents' needs. CMS says that forthcoming sub-regulatory guidance will provide more compliance information. "If any LTC facility simply writes up a facility assessment to justify the resources it currently has, we believe that will be evident in the facility assessment, as well as in their performance on surveys."

Some commenters criticized the proposed requirement on the basis that CMS did not provide for sufficient detail on what would constitute a compliant assessment, and that the lack of a specified methodology for their review would result in the results not being comparable. Thus, the argument continues, the facility assessments would not provide any valid comparisons or provide any precedent over time sufficient to be beneficial for LTC facilities, advocates, regulators, surveyors, or researchers. Some also questioned whether these assessments could fail to comport with the OBRA '87 requirement that every facility have adequate staff in place to ensure that residents can achieve their maximum well-being. In response, CMS states that the basic elements for the assessment are included, and that the requirements would not be overly burdensome since most facilities already do an assessment. CMS again references forthcoming compliance guidance. With respect to the prospects that assessments will not be standardized or comparable, CMS says that accuracy of the assessments is more important than consistency across facilities and also says that given the significant differences in types of LTC facilities, resident populations, and resources among the LTC facilities, they need the flexibility to determine the best way to comply with this requirement. However, over time, CMS believes that some consistency will likely develop due to facilities sharing what has worked best for them with other facilities and their associations. In addition, a compliant assessment can accurately determine what constitutes sufficient staff for an individual facility, thereby satisfying the requirement in OBRA '87 for sufficient staffing

With respect to commenters' concerns about when assessment updates are needed, CMS says that "as long as the facility assessment encompasses the care and resources needed by the residents, admitting new residents with the same needs should not require an update of the facility assessment. Likewise, hiring new staff or a Director of Nursing or even remodeling should not require an update of the facility assessment, unless these are actions that the facility assessment indicated the facility needed to do. In that case, it should only require notation that the facility has taken the actions to satisfy a need the facility assessment identified."

In response to comments that an assessment should not be required annually, CMS says that the minimal requirement of an annual assessment is needed to ensure that there have not been any substantial changes that will require the facility to update its facility assessment. A facility also may do additional assessments to meet emergency or long-term planning needs.

CMS addresses in the final rule's preamble various other comments related to: the use of facility assessments (e.g., whether, contrary to the spirit of QAPI, they might result in organizational decisions and approaches being specifically directed or managed by CMS); questions on how findings from the assessments would be implemented; preferred alternatives to assessments (e.g., that a stakeholder workgroup be formed to explore whether they or some other process is the best way to proceed); and how the assessments might be used by surveyors (see 81 *FR 68787-8*).

Medical records (§483.70(i)). With respect to the medical record ("clinical record" in the existing text), CMS finalizes its proposal to amend the existing text at §483.75(1) and re-designate it as §483.70(i). The purpose is to better conform to the requirements of the HIPAA Privacy, Security and Breach notification rules at 45 CFR parts 160 and 164. The finalized change also clarifies that the medical record must contain the resident's comprehensive plan of care and physician's and other licensed professional's progress notes.

Transfer agreements (§483.70(j)). CMS adopts as final proposed paragraph (j) (existing paragraph (§483.75(n)) that a practitioner other than an attending physician be able to determine that a hospital transfer is medically appropriate in an emergency and consistent with state law and facility policy. The information exchange requirements are also modified with the intent of improving the exchange of resident information in the event of a transfer and reducing problems that arise in care transitions. CMS received comments in support of these proposals.

Discussion of 483.70(l), (m) and (o). Provisions on disclosure of ownership, facility closure-administrator, facility closure, and hospice services were proposed to be re-designated as paragraphs §483.70(k), (l), (m), and (o) respectively, and the cross-reference in (m) updated, but otherwise unchanged. CMS had proposed to address training of paid feeding assistants in §483.95 "Training requirements." These changes have been finalized.

*Binding arbitration agreements (483.70(n)).*CMS has modified its proposed change to paragraph (1) to <u>prohibit the use of pre-dispute agreements for binding arbitration</u> between any resident or their representative and the facility and allow post-dispute agreements for binding arbitration, if the facility complies with this section. <u>Other provisions of the proposed rule are adopted as final.</u>

<u>Proposed rule.</u> CMS had proposed to require facilities that ask residents to accept binding arbitration to resolve disputes with the facility to meet certain criteria. (Binding arbitration requires that both parties waive the right to any type of judicial review or relief.) CMS noted that although binding arbitration can be a valid agreement when entered into by individuals with equal bargaining power, CMS was concerned that the facilities' superior bargaining power could result in a resident feeling coerced into signing the agreement or that the resident could waive the right to judicial relief without fully understanding what he or she was waiving. Moreover, CMS worried that these increasingly common types of agreements could be detrimental to residents' health and safety and could create barriers for surveyors and other responsible parties to obtain information related to serious quality of care issues. Not only might the resident waive judicial review but confidentiality clauses might be included prohibiting 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.

CMS had further proposed that the facility be required to explain the binding arbitration agreement to the resident in a form, manner and language that he or she understood and have the resident acknowledge that he or she understood it. Language in the agreement that prohibited or discouraged the resident or any other person from communicating with federal, state, or local officials, including, but not limited to, federal and state surveyors, other federal or state health employees regarding any matter, would be prohibited. The explanation would have to state, at a minimum, that the resident was waiving his or her right to judicial relief for any potential cause of action covered by the agreement. The agreement would have to be voluntary on the part of the resident and would have to provide for the selection of a neutral arbitrator and a venue convenient to both the resident and the facility. An agreement would not be considered to have been entered into voluntarily if the facility made it a condition of admission, readmission, or the continuation of the person's residence at the facility. Any agreement for binding arbitration would need to be a separate agreement in which the resident makes an affirmative choice to either accept or reject binding arbitration for disputes between the resident and the facility. Finally, to address concerns about conflict of interest if a resident has a guardian who is affiliated with the facility, the guardian or representative would be prohibited from consenting to an agreement for binding arbitration on the resident's behalf unless that individual was allowed to do so under state law, all of the other requirements in this section were met, and the individual had no interest in the facility. CMS also solicited comments on whether binding arbitration agreements should be prohibited.

Final rule. Because of the interest in this provision, the finalized regulation text is included here:

> (1) A facility must not enter into a pre-dispute agreement for binding arbitration with any resident or resident's representative nor require that a resident sign an arbitration agreement as a condition of admission to the LTC facility.
> (2) If, after a dispute between the facility and a resident arises, and a facility chooses to ask a resident or his or her representative to enter into an agreement for binding arbitration, the facility must comply with all of the requirements in this section.
> (i) The facility must ensure that: (A) The agreement is explained to the resident and their representative in a form and manner that he or she understands, including in a language the resident and their representative understands, and (B) The resident acknowledges that he or she understands the agreement.
> (ii) The agreement must: (A) Be entered into by the resident voluntarily. (B) Provide for the selection of a neutral arbitrator agreed upon by both parties. (C) Provide for selection of a venue convenient to both parties.
> (iii) A resident's continuing right to remain in the facility must not be contingent upon the resident or the resident's representative signing a binding arbitration agreement.
> (iv) The agreement must not contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials, including but not limited to, federal and state surveyors, other federal or state health department employees, and representatives of the Office of the State Long-Term Care Ombudsman, in accordance with §483.10(k).

(v) The agreement may be signed by another individual if: (A) Allowed by state law; (B) All of the requirements in this section are met; and (C) That individual has no interest in the facility.
(vi) When the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee.

In the final rule's preamble, CMS addresses each part of the proposed rule relating to arbitration agreements and the relevant public comments. There were significant disagreements among commenters on whether and when arbitration should be permitted.

Statutory Authority to Regulate Arbitration Agreements. Some commenters argued that the federal government, through the Federal Arbitration Act, favors arbitration and requires that arbitration agreements be enforced unless grounds exist in law or in equity for the revocation of any contract, such as enforcing the agreement would be unconscionable. They also pointed out that both Congress and the courts have repeatedly refused to regulate arbitration agreements between LTC facilities and their residents. They argued that when Congress intends to give an agency authority to prohibit or impose conditions on the use of arbitration agreements, it does so with unambiguous statutory language, and it did not do so in the Social Security Act. They also argued that there was no language in the Act that gave the Secretary statutory authority to interfere in commerce; Congress had, in fact, expressed its opposition to such actions in creating the International Court of Arbitration. Commenters claimed that a previous survey and certification memorandum issued by CMS acknowledged that these agreements were between the facility and resident. In response, CMS notes it disagreement with the claim that CMS lacks authority to issue regulations concerning arbitration agreements contained in LTC facility admissions contracts and enumerates its reasons, including its specific statutory authorities to require LTC facilities to "meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." As CMS discusses, there is significant evidence that pre-dispute arbitration agreements have a deleterious impact on the quality of care for Medicare and Medicaid patients, which warrants its regulatory response. CMS also says that the requirements of this final rule do not contradict its previously published survey and certification letter (see 81 *FR* 68792) and also emphasizes that the rule does not affect any arbitration agreements signed before the effective date of the rule. CMS further notes that if a facility wants to continue to use pre-dispute agreements, it can continue in business without Medicare or Medicaid residents. And it discusses the reasons why arguments that may hold sway with respect to the use of pre-dispute in other settings do not make sense with respect to LTC residents.

Residents' Health, Safety and Well-being. In response to widely diverging views on the effect of pre-dispute arbitration on residents (some commenters saying that they do not have adverse effects; others saying that the proposed requirements were not sufficiently protective), CMS reviews the evidence from a literature review (see 81 *FR* 68793) and concludes that the published research as well as the comments gives it ample justification to draw a connection between the use of pre-dispute arbitration clauses and adverse effects on facility residents.

Arbitration as an Appropriate Forum. CMS addresses the question of whether the use by LTC facilities of alternative dispute resolution has increased, as some commenters suggested, and finds that the literature supports that claim. CMS responds to those commenters who suggested that arbitration is merely a change of the forum for addressing disputes, and therefore, inconsequential by saying that it changes the manner in which a dispute will be resolved by, among other things, waiving the right to a jury trial and providing only limited grounds to appeal the arbitrator's decision. CMS also rejects the idea that judicial review of an arbitrator's decision is adequate protection for beneficiaries. Additional arguments raised by commenters who oppose a prohibition on the use of pre-dispute arbitration are also addressed by CMS, such as potential advantages to both the beneficiary and facility of that process, the effect of a ban on litigation, and whether the government, by prohibiting their use, is unfairly interfering with a matter that is a matter of a private contract between parties.

When, How Arbitration Agreement is Reached. CMS addresses comments addressing issues on the when and how of an arbitration agreement, again concluding that its policy is in the best interest of protecting beneficiaries.

Unequal Bargaining Power. CMS addresses comments that facilities would likely have experience with arbitrations but not residents; that the facility would likely determine which arbitrator to use and that the resident or their representative may not even understand or be aware that they are signing an arbitration agreement. In finalizing a rule that bans pre-dispute arbitration and providing specific notice and other protections, CMS says that these concerns about inequality between the two parties to the dispute should be mitigated.

Confidentiality of Arbitration Process and Decisions. Another issue raised by some commenters is the secrecy surrounding the arbitration process, which can mean that some facilities evade scrutiny and responsibility for substandard care. CMS agrees that this is a substantial concern; in response, it finalizes the proposed requirement at §483.70(n)(4) that the agreement cannot contain any language that prohibits or discourages the resident or anyone else from communicating with federal, state, or local officials. CMS notes that anything that could interfere with federal, state, or local health and regulatory officials or LTC advocates from learning of, or restricting the investigation of, instances of substandard care or other serious instances affects the health and safety of residents. When a surveyor discovers substandard care or another violation of the LTC facility requirements of participation and cites the facility with a deficiency, the surveyor would cite the deficiency on a Form CMS-2567, which is filed with both the state surveyor agency and CMS. This form is available to the public and can be accessed on the LTC Facility Compare website.[11] CMS also requires that when the facility and a resident resolve a dispute with arbitration, a copy of the signed agreement for binding arbitration and the arbitrator's final decision must be retained by the facility for 5 years and be available for inspection upon request by CMS or its designee. This will provide surveyors and CMS the opportunity to learn how often and under what circumstances arbitration is occurring at a facility, as well as the outcomes of any arbitrations. In addition, CMS will be publishing sub-regulatory guidance for surveyors concerning the requirements and it will be monitoring the use of arbitration in LTC facilities through the survey process, not only through the normally scheduled surveys but also through the complaint process.

[11] www.medicare.gov/nursinghomecompare/search.html

CMS addresses additional comments related to the status of residents' rights in the legal process if arbitration is used at 81 FR 68798-68800.

Social Workers (§483.70(p). CMS finalizes its proposals to: (1) relocate the requirement for and qualifications of a social worker from existing §483.15(g)(3) to §483.70(p); and (2) amend the list of human services fields from which a bachelor's degree could provide the minimum educational requirement for a social worker to include "gerontology."

CMS had asked for comments related to qualifications for the social worker, especially whether state licensure should remain the threshold requirement or if additional requirements are appropriate. Commenters were very supportive of social workers and their important roles in LTC facilities. Many of the comments related to the nature of the qualifications, including minimum education requirements. Some wanted to delete the exemption for a full-time social worker in facilities with 120 or fewer beds and require that all LTC facilities, regardless of size, be required to employ a full-time social worker. CMS notes in response that this is a statutory exemption; it also notes that it is a minimum requirement and that facilities may need to provide for more social workers to meet the needs of their residents.

Mandatory Submission of Staffing Information Based on Payroll Data in a Uniform Format (§483.70(q)). In CMS' proposed rule, "Medicare and Medicaid Programs; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016…." (CMS-1622-P) (80 *FR* 22044), published on April 20, 2015, at §483.75(u), it proposed to require that facilities submit staffing information based on payroll data in a uniform format.[12] CMS proposed to re-designate §483.75(u) to §483.70(q). This proposed rule was finalized on August 4, 2015 (80 *FR* 46389) and CMS is finalizing the re-designation at §483.75(u) to §483.70(q) in this final rule.

V. Quality Assurance and Performance Improvement (§483.75)

CMS has adopted, but with some modifications, proposed new section §483.75 to establish programmatic standards required under section 6102 of the ACA, which directs the Secretary to establish and implement a Quality Assurance and Performance Improvement (QAPI) program for SNFs and NFs.

Comments were wide-ranging in terms of concerns about aspects of the proposals. Some stakeholders urged more flexibility in the requirements (including on the number of and specific performance improvement projects (PIPs) or said that they were unnecessary due to current voluntary efforts to improve quality. In contrast, other comments supported more rigorous and specified requirements. Some critiqued CMS' emphasis on certain topics for focus; some said that by emphasizing data and quantitative improvement over other indicators of change, CMS was erring in its focus and urged it to place greater reliance on the use of qualitative reasoning, thinking, and problem solving by facilities to improve the care of their residents. In response,

[12] Section 6106 of the ACA 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.

CMS has eliminated the specific methodologies that it had listed in proposed §487.35(d)(2)(i) as these may be more appropriate in sub-regulatory guidance. It says that its focus on outcomes and data that measures such outcomes is appropriate ("Using data involves critical reasoning and analytical thinking; these are not mutually exclusive.") It agrees with some commenters that not all improvement activities are PIPs and believes that its proposed regulatory language is inclusive of the suggested activities (see §483.75(e)).

In the information collection and regulatory impact sections of the final rule, CMS responds to comments that it had underestimated the financial costs of compliance with the proposed QAPI requirements. CMS responds that because the number, degree and costs of the performance improvement projects are difficult, if not impossible, to quantify, CMS has calculated only the cost of the QAPI information collection requirements ($125.5 million upfront) that will be associated with them. CMS estimates that the ongoing annual cost for each facility to comply with the QAPI requirements will be $3,204 for each facility.

(a) Quality assurance and performance improvement (QAPI) program. CMS proposed and now finalizes with changes that each facility, including one that is part of a multiunit chain, is required to develop, implement and maintain an effective, comprehensive, data-driven QAPI program, reflected in its QAPI plan that focuses on indicators of outcomes of care and quality of life. A facility must maintain and provide documentation and demonstrate evidence of its ongoing QAPI program that meets the requirement of this section. In response to comments, CMS has moved from proposed (h)(2)(i) and (ii) to subparagraph (a)(1) that this information "may include but is not limited to systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities." In addition, the facility must present its QAPI plan to the State Agency no later than one year after the promulgation of this regulation (revised from "at the first annual recertification survey that occurs after the effective date of the regulation") and present an initial and annual recertification survey, upon request, to a State Agency, federal surveyor, or CMS. It must also present documentation and evidence of its ongoing QAPI program's implementation and facility's compliance with requirements of those entities, upon request.

(b) Program design and scope. CMS finalizes its proposal without change to establish requirements for the design of a QAPI program. It has to be ongoing, comprehensive, and address the full range of care and services provided by the facility, including clinical care, quality of life and resident choice; utilize the best available evidence to define goals and measures, processes and outcomes; and reflect the complexities and the unique care provided by a facility.

(c) Program feedback, data systems and monitoring. CMS finalizes with modifications its proposal to require a facility have written policies and procedures for feedback, data collection systems, and monitoring, including adverse event reporting. This includes feedback from direct care staff (changed from "direct care/direct access") workers, other staff, residents and resident representatives; how such feedback will be used to identify high risk, high volume problems and opportunities for improvement; feedback from all departments; development and monitoring and

evaluation of performance indicators; and adverse event monitoring, including how the facility will use the data to prevent adverse events.

(d) Program systematic analysis and systematic action. CMS finalized with changes its proposed requirement that the facility take actions for performance improvement, measure its success, and track performance. In response to comments, CMS has eliminated the parenthetical examples (e.g., root cause analysis and reverse tracer methodology) in paragraph (d)(2)(i).

(e) Program activities. CMS finalizes with one change its proposed requirement that the facility set priorities for performance improvement activities that focus on high-risk, high-volume, or problem-prone areas. It must track medical errors and adverse resident events, analyze their causes and implement preventive activities. The facility also must conduct distinct performance improvement projects. In response to comments, CMS adds in the final rule that the latter requirement is part of the facility's PIPs. The number and frequency of PIPs will have to reflect the scope and complexity of facility services and available resources. At least one project annually will be required to focus on high-risk or problem-prone areas identified through paragraphs (c) and (d).

(f) Governance and leadership. CMS adopts as final with minor changes its proposed requirement that the facility's governing body and/or executive leadership be responsible and accountable for: ensuring that an ongoing QAPI is implemented and maintained, addressing identified priorities; is sustained during leadership and staffing transitions; is adequately resourced with staff time, equipment and technical training; identifies and prioritizes problems; provides for corrective actions that are evaluated; and sets clear expectations for safety, quality, rights, choice, and respect.

(g) Quality assessment and assurance. CMS adopts as final its proposal to incorporate, with revisions, current §483.75(o)(1) and (2), which require a quality assessment and assurance committee. At a minimum, the committee must include the director of nursing services; the Medical Director or his or her designee; at least three other members of the facility's staff (at least one of whom must be the administrator, owner, a board member or other individual in a leadership role); and the infection control and prevention officer. The committee is required to: report to the governing board or designated persons functioning as the governing body; coordinate and evaluate activities under the QAPI program, including the PIPs; and review and analyze data collected under the QAPI program (plus data resulting from drug regimen reviews and reports) acting on available data to make improvements.

(h) Disclosure of information. CMS finalizes with one change its proposed incorporation of current §483.75(o)(3), which provides that a state or the Secretary may not require disclosure of the records of the quality assessment and assurance committee when such disclosure is related to compliance of the committee with the requirements of this section. In response to comments about internal consistency and regulatory overreach, CMS has moved the language in proposed §483.75(h)(2) regarding the information that may be necessary to demonstrate compliance to section (a)(1) and eliminated proposed paragraph (iii) which stated "other documentation considered necessary by a State or Federal surveyor in assessing compliance." Commenters expressed concerns that disclosing quality assurance records to surveyors would expose

providers to increased risk of sanctions and litigation. CMS responds that it has attempted to strike an appropriate balance between concerns about inappropriate use of QAPI materials and its obligation to provide effective oversight of Medicare and Medicaid participating facilities.

(i) Sanctions. CMS finalizes its proposal to incorporate current §483.75(o)(4) which specifies that good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

W. Infection Control (§483.65 re-designated §423.80)

Because of the importance of infection control in the facility setting and the need to update requirements to reflect new standards of practice as well as increasing concerns about antibiotic-resistant infections, CMS proposed, and now finalizes with modifications, significant policy changes to its existing infection control requirements.

CMS finalizes its proposed changes in the introductory language of the regulation text 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. Paragraph (a) is revised to read "Infection prevention and control program" and new §483.80(a)(1), (2) and (3) are added to specify the elements of the IPCP. CMS's changes from the proposed rule in response to comments are described in what follows.

Infection Prevention and Control Program. The facility is required to establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:

(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement, based upon the facility assessment conducted according to §483.70(e) (changed from §483.75(e) in the proposed rule) and following accepted national standards;
(2) Written standards, policies, and procedures for the program, which must include, but are not limited to:

(i) a system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility;
(ii) when and to whom possible incidents of communicable disease or infections should be reported;
(iii) standard and transmission-based precautions to be followed to prevent spread of infections;
(iv) when and how isolation should be used for a resident.

In response to comments that isolation should be the least restrictive as possible for the resident (so, for example, that they can be visited by family conditions permitting), CMS adds to (iv) above, "including but not limited to the: (A) type and duration of the isolation, depending upon the infectious agent or organism involved, and (B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances."

In addition, under finalized (v), the standards and procedures must include 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 under finalized (vi) the hand hygiene procedures to be followed by all staff.

To effectively address the problem of healthcare-associated infections and the need for appropriate use of antibiotics, CMS proposed and now finalizes that the facility's IPCP include an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use. In addition, the facility is required to have a system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility.

Infection Preventionist. CMS finalizes with modifications proposed paragraph (b) to require the facility to designate an infection preventionist (IP) (changed from "Infection Prevention and Control Officer" in the proposed rule). In response to concerns about the proposed rule being too prescriptive in terms in terms of requiring the person to be a clinician for whom infection prevention and control is the major responsibility, CMS requires that the facility designate one or more individuals as the IPs who have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field; be qualified by education, training, experience or certification; work at least part-time at the facility; and have completed specialized training in infection prevention and control. A conforming change is made to the requirement that the IP, or at least one of the individuals if there is more than one IP, participate on the quality and assurance committee and report to the committee on the IPCP on a regular basis.

Regulatory Impact. CMS estimates that the average facility will designate an RN to be the IP and that individual will need to commit about 15% of a full time equivalent (FTE) to his or her responsibilities under the IPCP.

IPCP review. Under a new paragraph (f), the facility will be required to review its IPCP annually and update as necessary.

Other changes. Because it is no longer the standard of care, CMS finalizes its proposal to strike the exception currently at §423.25(v) providing that – based on an assessment and practitioner recommendation – a second pneumococcal immunization 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. As proposed, CMS has also finalized relocating the requirements for influenza and pneumococcal immunizations from existing §483.25(n) to §483.80(d) but uses the term "resident representative" instead of "legal representative," a broader term that encompasses individuals whom the resident has personally identified as their representative. Also as proposed, the requirement concerning linens is moved from existing §483.65(c) to §483.80(e).

Finally, CMS responds to comments about the burden on smaller facilities of complying with the requirements by the proposed deadlines by referring readers to the earlier section (see "B. Implementation Date" on page 5) on the revised implementation deadlines.

Some commenters urged CMS to adopt a minimum staffing standard for LTC facilities, a measure that CMS rejects because it believes that each facility should determine the resources needed to meet infection prevention and control and other requirements. For the same reason, CMS does not incorporate, as recommended by some, the CDC guidelines on infection control although CMS credits those guidelines as an excellent source. It also says that it is exploring with the CDC opportunities to develop and implement infection prevention and control training specific for LTC facility clinical personnel and also related to transitions of care. CMS also advises that sub-regulatory guidance is forthcoming with more specific direction for facilities, surveyors and others concerning compliance with these requirements.

X. Compliance and Ethics Program (§483.85)

Section 6102 of the ACA added a new section 1128I(b) to the Social Security Act requiring SNFs and NFs to have a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care. In the proposed rule, CMS reviewed prior related guidance from the Office of the Inspector General (OIG).[13] It also noted that on September 23, 2010, CMS published a proposed rule "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" (75 *FR* 58204). Section II.E. solicited public comment on seven basic elements of an effective compliance and ethics program required by sections 6102 and 6401(a) of the ACA. In the final version of that rule (76 *FR* 5862), CMS did not adopt any of the proposed compliance and ethics plan requirements, and noted its intent to do so in future rulemaking. In this final rule, CMS finalizes without modification (except to insert effective dates) its proposals implementing requirements under section 6102 of the ACA, which applies only to SNFs and NFs. Section 6401(a), which applies more broadly to all providers and suppliers, including SNFs and NFs, will be addressed in separate rulemaking.

Some commenters were very supportive of the proposed requirements for compliance and ethics programs, especially the components that are required for all facilities. Some appreciated the recognition of the different levels of resources available to smaller and larger operating organizations to develop, implement, and maintain compliance and ethics programs. Some who supported the general outlines of the proposed requirements advocated different specifics such as that certain individuals (e.g., social workers) should be involved in developing and maintaining the facility's compliance and ethics program. In response to CMS' request for definitions on reasonableness (see (a) below), CMS has not adopted a definition but intends to provide sub-regulatory guidance on how to determine reasonableness for these requirements.

[13] "Final Compliance Program Guidance for Nursing Facilities" (March 16, 2000 *Federal Register* (65 *FR* 14289)). This provided voluntary guidance for nursing facilities in developing comprehensive compliance programs promoting adherence to federal health care program requirements as well as private insurance program requirements. "OIG Supplemental Compliance Program Guidance for Nursing Facilities" (September 30, 2008 *Federal Register* (73 *FR* 56832)) provided additional guidance that was again voluntary, setting out basic elements of an effective compliance program that are essentially the same as those provided in 2000.

In response to a comment that the compliance program should be integrated into the QAPI, CMS says that under the rule as finalized, facilities should integrate into their QAPI programs the information and data they collect or arises out of their compliance and ethics programs. Moreover, the requirements for compliance and ethics and the QAPI programs should work together or be coordinated to not only ensure compliance with the requirements in this final rule but also improvements in the quality of care provided to the residents.

(a) Definitions. CMS finalizes its proposed definitions of three terms. "Compliance and ethics program" means a program of the operating organization that 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 includes, at a minimum, the required components specified in paragraph (c). "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. CMS finalizes its proposed policy that all facilities must have in operation a compliance and ethics programs meeting the proposed standards by November 28, 2017, which is one year after the effective date in the final rule.

(c) Required components for all facilities. CMS finalizes its proposed minimum required components for all facilities:

(1) Written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations and promote quality care. Several specific items will have to be included relating to designation of an appropriate compliance and ethics program contact, reporting of suspected violations, and disciplinary standards.
(2) Assignment of specific individuals who are high level personnel with overall responsibility for the compliance and ethics program.
(3) Sufficient resources and authority for the specific individuals assigned responsibility to reasonably assure compliance.
(4) Due care not to delegate discretionary authority to individuals who the organization knew, or should have known, had a propensity to engage in criminal, civil, or administrative violations under the Act.
(5) Steps to effectively communicate the standards, policies, and procedures to the entire staff and to individuals providing services under contractual arrangements, and to volunteers. This includes mandatory participation in training or orientation programs proposed in §483.95 (below) or disseminating information that explains in a practical manner what is required under the program.
(6) Consistent enforcement through appropriate disciplinary mechanisms, including appropriate discipline of individuals responsible for the failure to detect and report a violation.
(7) Reasonable steps, after a violation is detected, to respond appropriately and to prevent further similar violations, including modifications to the program. CMS notes that these reasonable steps should be clearly identified in the organization's program, and it expects that those

steps will differ depending on the size of the organization, the position of the individuals reporting the violation, and the type of violation. CMS expects that ethics compliance be a strong component of each program.

In response to commenters who opposed the inclusion of contract and volunteer personnel in paragraph (5) above as excessive and costly of resources, CMS says that for a compliance and ethics program to be effective, it is crucial that all of the organization's staff, including those who are providing services under contract, and volunteers, consistent with their roles, need to understand the standards, policies and procedures for that program. Also, as set forth in §483.95, "[a] facility must determine the amount and types of training necessary based on a facility assessment as specified at §483.70(e)," thus providing the flexibility for each organization to determine the best way to comply with this requirement, including determining the kind of dissemination of information or training they need to provide to different personnel. Reasonable steps to assure compliance with the program's standards, policies, and procedures, include using monitoring and auditing systems, and reporting systems through which individuals can report violations anonymously within the organization without fear of retaliation.

(d) Additional required components for operating organizations with five or more facilities. CMS finalizes its proposed three additional requirements that operating organizations must include in their compliance and ethics program: a mandatory annual training program meeting the requirements proposed in §483.95(f); a designated compliance officer, for whom compliance is a major responsibility, reporting directly to the governing body and not subordinate to the general counsel, chief financial officer or chief operating officer; and designated compliance liaisons at each of the organization's facilities.

Some commenters were concerned that this proposal would impose additional requirements on certain operating organizations based upon an arbitrary number of facilities; some said that only operating organizations with 15 or more facilities should be required to comply with the additional requirements. CMS, in response, cites the statutory requirement that indicates that the compliance and ethics programs for operating organizations with five or more facilities should be a more formal program or have more elements. In contrast, some commenters not only supported CMS' proposed policy with respect to these organizations but recommended that the additional requirements apply to all operating organizations, regardless of size. Although CMS does not believe that the additional requirements are appropriate for organizations with fewer than five facilities, it encourages those organizations to incorporate the additional elements if their facility assessments indicate they are necessary to ensure that their compliance and ethics programs are effective.

CMS notes comments in support of its proposal to require only the organizations with five or more facilities designate a compliance officer under (d)(2) above for whom compliance is a major responsibility and that smaller organizations have more flexibility in this regard because they may not have the resources to dedicate a full time resource. Although it finalizes this requirement without change, it notes that any further detail on who can and cannot serve as the compliance officer should be provided in sub-regulatory guidance. CMS refers facilities to

additional guidance the OIG has published for nursing home compliance programs[14] "OIG Supplemental Compliance Program Guidance for Nursing Facilities" (73 *FR* 56832) (oig.hhs.gov/compliance/complianceguidanc/docs/complianceguidance/nhg_fr.pdf).

§483.85(e) Annual review. CMS finalizes its proposed requirement that the operating organization conduct an annual review of its compliance and ethics program, and revise the program, if needed, to reflect changes in applicable laws and regulations and to improve its performance in deterring, reducing and detecting violations under the Act and in promoting quality of care.

Some commenters were concerned about the 1-year timeframe for implementation of the compliance and ethics programs and asked for at least two years. As discussed in the section above on implementation dates, CMS is finalizing a phased in delay of the implementation dates. Under the revised timeline, requirements related to a compliance and ethics program must be implemented in Phase 3, or three years from the effective date of the final rule.

Information Collection and Regulatory Impact. CMS estimates that these finalized provisions will affect 395 organizations and that each of the 395 organizations operating 5 or more facilities will commit 30% of a FTE in the compliance program operation, for a total cost of $20,950,800 (30% of FTE × 2080 × $85 × 395). CMS also estimates that in carrying out this program, the compliance liaison (nursing staffs) in each of 6,919 facilities will commit 10 percent of an FTE, at a total cost of $87,788,272 (10% of FTE × 2080 × $61 × 6,919).

Y. Physical Environment (§483.70 re-designated §483.90)

In the proposed rule, CMS indicated that the facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public. Many of these provisions relate to Life Safety Code (LSC) requirements. CMS published a final rule which adopts many provisions of the 2012 LSC "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities," (81 *FR* 26871, May 4, 2016). As part of its comprehensive review and restructuring, the existing provisions of §483.70 are re-designated as new §483.90; however, the language in existing §483.70(a) "Life safety from fire" and §483.70(b) "Emergency power" are unchanged, including new provisions related to the requirement that LTC 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).

Space and equipment. CMS finalizes its proposed new paragraph (c) to require that the resident's individual assessment, including preferences and choices, be included as an element to consider in addition to their plan of care when considering the space and equipment requirements of the facility. The word "essential" has been removed from new §483.90(c)(2) (re-designated from §483.70(c)(2)) because CMS believes that all equipment to which the resident may be exposed,

[14] "OIG Supplemental Compliance Program Guidance for Nursing Facilities" (73 *FR*56832) (oig.hhs.gov/compliance/complianceguidance/docs/complianceguidance/nhg_fr.pdf).

whether deemed essential or not, must be maintained in safe operating condition to ensure resident safety. Proposed new subparagraph (c)(3) is finalized to require facilities to conduct regular inspections of all bed frames, mattresses, and bed rails and to ensure that bed rails, bed frames and mattresses are compatible.

Resident rooms. Existing §483.70(d) allows for bedrooms that accommodate up to four residents. In the proposed rule, CMS said this number is inconsistent with current common practice, is not person-centered or 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. It thus proposed and has now finalized in new subparagraph (d)(1)(i) a requirement that bedrooms in facilities accommodate not more than four residents but that for facilities that receive approval of construction or reconstruction plans by state and local authorities after November 28, 2016, bedrooms must accommodate no more than two residents. (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.) In CMS' view, semi-private rooms are far more supportive of privacy and dignity. (CMS considered but did not propose to require private rooms.) Proposed but not finalized §483.90(d) would have required that the bed size and height be not only convenient for the resident's needs, but also be safe.

In response to comments, some supportive of the semi-private room (some urging that this be required of all LTC facilities) but others opposed for reasons of cost or lack of flexibility, CMS says that this provision represents an appropriate balance among the concerns voiced and is finalizing this requirement as proposed. With regard to the definition of reconstruction, CMS clarifies that, for reconstruction, the requirement applies to the reconstructed area, so that where reconstruction involves a limited area within a building, it would not expect the entire building to upgrade to the new requirements. This should not deter facilities from making needed renovations. CMS defers additional discussion to sub-regulatory guidance.

Bathroom facilities. Existing paragraph (e) requires that each bedroom be equipped with or located near toilet and bathing facilities. CMS proposed and now finalizes a 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 November 28, 2016 (the effective date of this rule), each resident room have their own bathroom ("toilet" in the proposed rule) equipped with at least a commode and sink ("toilet, sink and shower" in the proposed rule). The changes in terminology are in response to comments that "toilet facilities" reflect an institutional mindset. With respect to the proposed shower requirement, CMS was persuaded by the many comments opposing that requirement (e.g., showers are not safe, they go unused, will not fit existing spaces, etc.) and has deleted it in the final rule. CMS notes that facilities continue to have the option to exceed these requirements, in keeping with the health, safety and quality of life of its residents.

Resident call system. Existing paragraph (f) requires a resident call system so as to ensure that a resident can easily call for assistance. CMS noted in the proposed rule that the existing language referencing a "nurse's station" may, in many cases, be outdated. CMS proposed and now finalizes without change that the facility be required to 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.

Dining and resident activities. Existing paragraph (g), which addresses dining and activity rooms, requires a facility to designate non-smoking areas. CMS finalizes with a change its proposal to eliminate "with non-smoking areas identified" as being inconsistent with current practice and state laws and to add new paragraph (h)(5) to require facilities to establish policies, in accordance with applicable federal, state and local laws and regulations, regarding smoking, including tobacco cessation, smoking areas and safety, including but not limited to non-smoking residents. Some commenters opposed the inclusion of tobacco cessation because it would not be appropriate to facilities with a non-smoking policy and CMS has deleted it in the final rule text but says that even in those facilities, smoking cessation support should be offered to residents who smoke and addressed in their person centered plan of care. "Smoking is not addressed as a resident right; rather, we require that facilities have policies and procedures to safeguard residents, whether smoking or non-smoking, if and where smoking occurs." In response to questions about adding electronic cigarettes, CMS says that it will evaluate whether or not electronic cigarettes should be included in this provision in the future.

Regulatory Impact. CMS estimates that the new semi-private room requirement related to resident rooms will affect fewer than 140 facilities annually. It does not have statistics on the number of providers per year who undertake reconstruction and thus cannot quantify the incremental costs of constructing semi-private rooms for those facilities. CMS estimates that the revised requirements related to bathroom facilities will affect fewer than 150 providers per year. Although CMS is aware that ensuring each resident bedroom has an adjacent bathroom may increase construction costs, it is unable to find data regarding either the number of facilities that do not currently have bathrooms adjacent to each resident room or the incremental cost of adding bathrooms adjacent to each resident room in new construction.

Z. Training Requirements (§483.95)

CMS finalizes with some changes proposed new §483.95 requiring facilities to establish a training program for all new and existing staff, individuals providing services under contractual arrangements, and volunteers, consistent with their expected roles. The facility will have to determine the amount and type of training based on the facility assessment under §483.70(e). In its regulatory impact analysis, CMS estimates that it will cost each facility $488 to develop a training program and that the training will be considered part of regular ongoing training for the staff of each facility. CMS also addresses its estimated impact on organizations with fewer than 5 and five or more facilities (81 *FR* 68843-4).

Sections 483.95(a)-(f) would require training programs to include training in:

(a) Communications (the final rule replaces "direct care/access personnel" with "direct care staff");
(b) Resident's rights and facility responsibilities;

(c) Abuse, neglect, and exploitation, including misappropriation of resident funds; procedures for reporting such incidents; and, as added by the final rule in response to comments, dementia management and resident abuse prevention;
(d) The facility's quality assurance and performance improvement program (QAPI);
(e) Infection prevention and control; and
(f) Compliance and ethics standards, policies and procedures, and annual training in the case of organizations operating five or more facilities.

(g) Required in-service training for nurse aides. CMS finalizes without change its proposal to incorporate training requirements at current §483.75(e)(8)(i) – (iii), which require that annual in-service training for nurse aides be sufficient to ensure continuing competence, but no less than 12 hours per year; that the training address areas of weakness in the aide's performance reviews, and may address special needs of residents; and that for nurse aides serving individuals with cognitive impairments, the training address the care of the cognitively impaired.

Section 6121 of the ACA added sections 1819(f)(2)(A)(i)(1) and 1919(f)(2)(A)(i)(1) requiring ongoing training in both dementia management and patient abuse prevention if the Secretary determines it appropriate. In the proposed rule, CMS reviewed the literature and proposed that nurse aide training include such training in dementia management and resident abuse prevention. This provision has been adopted as final as well as the proposed requirement that the training address areas of weakness in facility performance assessments required at §483.70(e), and that for nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

A few commenters recommended increasing the number of on-going in-service training hours for nurse aides. CMS says in response that it agrees that additional consideration should be given to increasing the number of in-service training hours required for nurse aides and that it will continue to review that to determine a minimum number of training hours that will help to enhance the continued competency of staff.

(h) Required training of feeding assistants. CMS finalizes relocating from current §483.75(q) a requirement that facilities may not use any individual as a paid feeding assistant unless that individual has successfully completed a state approved training program, as specified in §483.160.

(i) Behavioral health training. CMS finalizes its proposal to require behavioral health training for the entire staff, based on the facility assessment at proposed §483.70(e).

While commenters supported the training topics named in the proposed rule, many suggested additional topics to be required for all facility staff members who provide services directly to residents. These included such topics as advance care planning, cultural competence, end-of-life care, geriatrics and gerontology, working with young and middle-aged adults, grief and loss, interdisciplinary collaboration, person-centered care, specialized rehabilitative therapy, and intellectual disability. In response, CMS says that given the volume of the requirements that it had proposed and the concerns raised by commenters regarding the time needed to implement them, it would be overly burdensome to increase the number of required training topics at this

time. CMS will continue to evaluate each of the suggested topics and consider them for future rulemaking. In addition, facilities have the flexibility to add more topics to their training programs, in accordance with their facility assessment.

III. Collection of Information Requirements

CMS is ordinarily 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 OBRA 1987 provide for a waiver of Paperwork Reduction Act (PRA) requirements for these regulations. CMS believes that this waiver still applies to those revisions and updates it made to existing requirements in part 483 subpart B. However, CMS provides burden estimates for the new information collection requirements finalized in this rule, specifically those requirements implemented as a result of the ACA. These include ICRs regarding QAPI (§483.75), Compliance and Ethics Programs (§483.85) and Training Requirements (§483.95) (see 81 *FR* 68832 – 68836).

IV. Regulatory Impact Analysis (RIA)

CMS estimates that this regulation is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act and has prepared an RIA.

In response to concerns raised by commenters about the adverse financial burden of compliance with the proposed and now, as revised, final regulations, CMS has provided for and potentially reduced the immediate financial impact by finalizing a phased-in implementation of the requirements over 3 years. It has also removed or made several revisions in this final rule to increase flexibility and avoid creating unintentional consequences for facilities.

Sources of Data Used in Estimates of Burden Hours and Cost Estimates.

CMS includes the following table of values that it used for its burden estimates (information on the sources is at 81 *FR* 68839.

TABLE 4—SUMMARY OF SOURCE INFORMATION USED FOR RIA

Number of LTC Facilities	*15,653
Number of LTC Facilities	*15,653
Number of Operating Organizations with 5 or more facilities	395
Number of Operating Organizations with 5 or less facilities	6,919
Number of Medicare Beneficiaries	** 1,369,700
Hourly pay of a RN	$61
Hourly pay of a Director of Nursing	$85
Hourly pay of a LTC facility Administrator	$85
Hourly pay of a Nurse Aide	$25
Hourly pay of a Social Worker	$47
Hourly pay of an Office Assistant	$31

Note: Hourly pay include a 100% increase for fringe benefits and overhead.
* Source: CASPER Data as of May 1, 2016.
** Source: Long-Term Care Providers and Services Users in the United States: Data From the National Study of Long-Term Care Providers, 2013–2014" *http://www.cdc.gov/nchs/fastats/nursing-home-care.htm.*

CMS also responds to commenters' critiques of its proposed rule RIA for specific sections. These have been noted in the substantive discussion of each section of this summary but for more information, see 81 *FR* 68839-68844.

Regulatory Flexibility Act

CMS does not believe that the required threshold under the Regulatory Flexibility Act will be reached to trigger a required analysis of the impact of the rule on substantial small entities because the impact associated with the provision will be less than 1 percent of the revenue of the nursing facilities (compared with the threshold used by CMS of an impact of more than 3 to 5 percent). CMS observes that with the number of nursing facilities around 15,600, the average annual revenue of a nursing facility is about $10 million. The annual impact on a nursing facility would be around $63,000 in year 1 and $55,000 in year 2 and thereafter. Thus, the average impact on the facility is less than 1 percent of revenue.

In addition, CMS is required 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 (defined as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds). Because this final rule pertains solely to SNFs and NFs, the Secretary has determined that it will not have a significant impact on the operations of a substantial number of small rural hospitals.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately $146 million. This final rule contains mandates that will impose a onetime cost of about $831 million. Thus, CMS has assessed the various costs and benefits of this final rule. It will not mandate any new requirements for state, local or tribal governments. For the private sector facilities, the regulatory impact section, together with the remainder of the preamble, constitutes the analysis required under UMRA.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. CMS' analysis leads it to conclude that the rule does not contain policies that have federalism implications; consequently, a federalism summary impact statement is not required.

Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.