The CMS Final Rule: Regulatory Changes and Effective Dates

On October 4, 2016, the Centers for Medicare & Medicaid Services published the long awaited Final Rule addressing sweeping changes it had released in its Proposed Rule of July 16, 2015. Med-Net Compliance has prepared the following summary of the key content that lists the areas impacted and the dates when each component becomes effective. For a more detailed understanding of the new information, a link to access the full document as published in the Federal Register is provided at the end of this summary. The provisions covered in this summary primarily will be implemented in Phase 1 of the process, which becomes effective November 28, 2016. Other implementation dates of November 28, 2017 (Phase 2) and November 28, 2019 (Phase 3) are noted where applicable.

Resident Rights (§ 483.10) has retained all existing residents' rights. Language and organization of this section has been updated to improve logical order and readability, clarify where necessary, and update provisions to include advances such as the right to retain and use a cell phone at the resident's own expense, to have access to a telephone including TTY and TDD services, and to access the Internet to the extent available to the facility.

Freedom From Abuse, Neglect, and Exploitation (§ 483.12)
Facilities are required to investigate and report all allegations of abusive conduct. Individuals cannot be employed who have had a disciplinary action taken against their professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of their property. The language of the Elder Justice Act that was part of the Affordable Care Act of 2010 has been added to this section, to include that facility staff "must report immediately, but not later than 2 hours after forming the suspicion, if events that cause the suspicion result in serious bodily injury, or not later than 24 hours if the events that cause the suspicion do not result in serious bodily injury." This section on reporting of crimes will be implemented in Phase 2, which is effective November 28, 2017. Coordination with the QAPI Plan will be required by November 28, 2019.

Admission, Transfer, and Discharge Rights (§ 483.15)
A transfer or discharge must be documented in the medical record, and specific information must be exchanged with the receiving provider or facility when a resident is transferred. Documentation in the medical record must include the basis for the transfer, the specific resident need that cannot be met and necessitates the transfer, attempts to meet the resident's needs, and services available at the receiving facility that can meet that need. This documentation must be made by the resident's physician. Information provided to the receiving facility must include at a minimum contact information of the practitioner responsible for the care of the resident; resident representative information, including contact information; Advance Directive information; all special instructions on precautions for ongoing care, as appropriate; comprehensive care plan goals; and all other necessary information, including a copy of the resident's discharge summary. The detailed documentation portion becomes effective November 28, 2017.

Resident Assessments (§ 483.20)
A facility must make a comprehensive assessment of a resident's needs, *strengths, goals, life history, and preferences*, using the resident assessment instrument (RAI) specified *by CMS*. Discharge Potential Assessment is changed to Discharge Planning. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts. A facility must coordinate assessments with the Preadmission Screening and Resident Review (PASARR) program under Medicaid to the maximum extent practicable to avoid duplicative testing and effort. This includes incorporating recommendations from the PASARR Level II determination and the PASARR evaluation report into a resident's assessment, care planning, and transitions of care. All Level II and other residents with newly evident or possible serious mental disorders, intellectual disabilities, or a related condition must be referred for a Level II review upon a significant change in status assessment. Other new language includes portions inadvertently omitted in previous versions of the regulation. This entire section must be implemented by November 28, 2016.

Comprehensive Person-Centered Care Planning (§ 483.21) *New Section*
This new section requires facilities to develop and implement a baseline care plan for each resident, within 48 hours of their admission, which includes the instructions needed to provide effective and person-centered care that meets professional standards of quality care. This must include initial goals based on admission orders, physician orders, dietary orders, therapy orders, social services, and PASARR recommendations where applicable. The facility must provide the resident and their representative with a summary of the resident's medications and dietary instructions, any services and treatments to be administered, and personal acting on behalf of the facility. A nurse aide and a member of the food and nutrition services staff are added to required members of the interdisciplinary team that develops the comprehensive care plan. Facilities must develop and implement a discharge planning process that focuses on the resident's discharge goals and prepares residents to be active partners in post discharge care, in effective transitions, and in the reduction of factors leading to preventable re-admissions. If a discharge to the community is determined to be not feasible, documentation must state who made the determination and why. This entire section will be implemented by November 28, 2016, with the following exceptions: the baseline care plan will be implemented by November 28, 2017, and the section on trauma informed care will be implemented by November 28, 2019.

Quality of Life (§ 483.24)
Activities of Daily Living (ADLs) and Activities Programing now are combined under Quality of Life. This entire section will be implemented by November 28, 2016.

Quality of Care (§ 483.25)
The Final Rule requires facilities to ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and residents' choices. Quality of Care now includes skin integrity/pressure ulcers; foot care; mobility; accidents; incontinence; colostomy, urostomy, or ileostomy care; assisted nutrition and hydration; parenteral fluids; respiratory care, including tracheostomy care and tracheal suctioning; prostheses; pain management; dialysis; trauma-informed care for trauma survivors; and bed rails. Residents must be assessed for entrapment risk from bed rails prior to their use.

(NOTE: A detailed guide for assessing entrapment risk can be obtained at the following address: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072662.htm) This entire section will be implemented by November 28, 2016, with the exception of the section on trauma-informed care, which will be implemented by November 28, 2019.

Physician Services (§ 483.30)
Attending physicians will be allowed to delegate the writing of dietary orders to qualified dietitians or other clinically qualified nutrition professionals, and delegating therapy orders to therapists under the supervision of the physician, as permitted by state law. This section will be implemented by November 28, 2016.

Nursing Services (§ 483.35)
CMS has added a competency requirement for determining the sufficiency of nursing staff based on a facility assessment, which includes but is not limited to the number of residents, resident acuity, the residents' range of diagnoses, and the content of their individual care plans. Also included under Nursing Services is content about proficiency of nurse aides, and requirements for hiring and use of nursing aides such as: the general rule, non-permanent employees, minimum competency, registry verification, multi-state verification, required retraining, regular in-service training, and waivers. This section will be implemented by November 28, 2016, with the exception of the section on facility-specific assessment to determine sufficient staff and competencies for nursing staff, which will be implemented by November 28, 2017.

Behavioral Health Services (§ 483.40) (Formerly known as Social Services)
A new section to subpart B focuses on the requirement to provide the necessary behavioral health care and services to residents, in accordance with their comprehensive assessment and plan of care. This includes adding ''gerontology'' to the list of possible human services fields from which a bachelor degree could provide the minimum educational requirement for a social worker. This section will be implemented by November 28, 2017, with the exception of trauma-related services by November 28, 2019, and provision of comprehensive assessment and medically related social services to attain or maintain the highest practicable physical, mental and psychosocial well-being by November 28, 2016.

Pharmacy Services (§ 483.45)
Existing requirements regarding ''antipsychotic'' drugs will refer to ''psychotropic'' drugs, now defined as any drug that affects brain activities associated with mental processes and behavior. This includes antipsychotics, antidepressants, antianxiety drugs, and hypnotics. All residents receiving these psychotropic drugs must undergo gradual dose reductions unless contraindicated. Unnecessary Drugs language now falls under Pharmacy Services, as do the two former regulations for Medication Errors. The medical director must receive the pharmacist's drug regimen review reports, in addition to the attending physician and the DON. PRN orders for antipsychotic drugs will be limited to 14 days and cannot be renewed unless the physician or prescribing practitioner evaluates the resident for appropriateness of the medication. A pharmacist will be required to review a resident's medical chart during each monthly drug regimen review. Facilities must develop policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when identifying an irregularity that requires urgent action to

protect the resident. This section will be implemented by November 28, 2016, with the exception of medical chart review and psychotropic drugs by November 28, 2017.

Laboratory, Radiology, and Other Diagnostic Services (§ 483.50) *New Section*
CMS clarified that a physician assistant, nurse practitioner, or clinical nurse specialist may order laboratory, radiology, and other diagnostic services for a resident in accordance with state law, including scope-of-practice laws. This section will be implemented by November 28, 2016.

Dental Services (§ 483.55)
The facility must have a policy identifying those instances when the loss or damage of dentures is the facility's responsibility. NFs must assist residents who are eligible to apply for reimbursement of dental services under the Medicaid state plan, where applicable. Referrals for lost or damaged dentures must be made within 3 business days, unless there is documentation of extenuating circumstances. SNFs and NFs will be prohibited from charging a Medicare resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility. These components of the regulation become effective November 28, 2017.

Food and Nutrition Services (§ 483.60)
This section requires facilities to employ sufficient staff, including a qualified dietitian or other clinically qualified nutrition professional and a director of food and nutrition service, with the appropriate competencies and skills sets to carry out the functions of dietary services while taking into consideration resident assessments and individual plans of care, including diagnoses and acuity, as well as the facility's resident census. The link to the facility assessment information becomes effective November 28, 2017. It also addresses menus and nutritional adequacy, therapeutic diets, frequency of meals, assistive devices, paid feeding assistants, and food safety requirements. Specific details about dietitian requirements and dates of hire become effective at varying periods after the effective date (refer to full document for those details.)

Specialized Rehabilitative Services (§ 483.65)
CMS has added respiratory services to those services identified as specialized rehabilitative services for individuals who have a mental disorder or intellectual disability. Effective date in November 28, 2016.

Administration (§ 483.70)
CMS will require facilities to conduct, document, and annually review a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations and emergencies. Facilities are required to address in this facility assessment the facility's resident population (that is, number of residents, overall types of care and staff competencies required by the residents, and cultural aspects), resources (for example, equipment, and overall personnel), and a facility-based and community-based risk assessment. Facility assessment becomes effective November 28, 2017. Medical records management has been relocated to Administration. Binding Arbitration Agreements are placed under the responsibility of Administration. The Final Rule states that facilities must not enter into an agreement for binding arbitration with a resident or their representative until after a dispute arises between the parties. Arbitration agreements contained in admission agreements signed before the effective

date are unaffected. The Final Rule states that pre-dispute binding arbitration agreements are prohibited and were to be removed from admission agreements beginning 11/28/16; however, a court ruling has halted implementation of this portion of the final rule until the merits of a case seeking to remove this CMS directive can be considered. The Governing Body becomes responsible and accountable for QAPI program effective November 28, 2019.

Quality Assurance and Performance Improvement (QAPI) (§ 483.75)
Quality Assessment and Assurance has been placed under the QAPI regulation. A change to the composition of the QAA committee requires participation of the director of nursing; the medical director or designee; and at least three other members, one of whom must be the administrator, owner, or a board member or other individual with a leadership role effective November 28, 2016. A facility must provide its initial QAPI Plan to the State Agency at annual survey effective November 28, 2017. All LTC facilities are required to develop, implement, and maintain an effective comprehensive, data-driven QAPI program that focuses on systems of care, outcomes of care, and quality of life. The five required elements of the QAPI Program include Program Design and Scope, Program Feedback, Data Systems and Monitoring, Program Systematic Analysis and Systemic Action, Program Activities, and Governance and Leadership. The infection control and prevention officer (ICPO) must participate on the QAA Committee effective November 28, 2019.

Infection Control (§ 483.80)
CMS will require facilities to develop an Infection Prevention and Control Program (IPCP) that includes an Antibiotic Stewardship Program and designate at least one Infection Preventionist (IP). The IP must participate on the QAA Committee. Influenza and pneumococcal immunization programs are placed under Infection Control. Other components include handling, storage, processing, and transport of linens. All facilities will be required to conduct an annual review of their Infection Prevention and Control Program. The facility assessment and antibiotic stewardship become effective November 28, 2017.The Infection Preventionist effective date is November 28, 2019, as is IPCO participation on the QAA Committee.

Compliance and Ethics Program (§ 483.85) *New Section*
CMS will now require that the operating organization for each facility have in effect a compliance and ethics program that has established written compliance and ethics standards, policies and procedures that are capable of reducing the prospect of criminal, civil, and administrative violations in accordance with section 1128I(b) of the Affordable Care Act. This entire section becomes effective November 28, 2019.

Physical Environment (§ 483.90)
Facilities that are constructed, re-constructed, or newly certified after the effective date of this regulation must accommodate no more than two residents in a bedroom, and have a bathroom equipped with at least a commode and sink in each room. Facilities that fall under these categories must include a communication system which relays the calls director to a staff member or to a centralized staff work area. Facilities must also establish safe smoking policies in accordance with state and local laws and regulations, smoking areas, and smoking safety that takes into consideration non-smoking individuals. Smoking requirements are effective November 28, 2017, and call system requirements have an implementation date of November 28, 2019.

Training Requirements (§ 483.95) *New Section*

A new section to subpart B sets forth all the requirements of an effective training program that facilities must develop, implement, and maintain for all new and existing staff, individuals providing services under a contractual arrangement, and volunteers, consistent with their expected roles. Mandatory training includes the following:

- Effective communication for direct care staff
- Resident Rights and Facility Responsibilities
- Abuse, Neglect, and Exploitation
- The elements and goals of the QAPI program
- Infection Control, to include written standards and the facility's policies and procedures
- Compliance and Ethics
- Dementia management for nurse aides
- Providing care for those with cognitive impairment for individuals who work with the cognitively impaired
- Behavioral Health training consistent with the requirements of that section and as determined by the facility's assessment required under Administration.

This entire section is effective November 28, 2019, with the exception of the following sections designated for implementation November 28. 2016: Abuse, Neglect, and Exploitation Training; Dementia Management & Abuse Prevention Training; Care of the Cognitively Impaired; and Training of Feeding Assistants.

Obtain the full text of the Final Rule by visiting the following link:
https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23966.pdf