As a result of CMS recently publishing the biggest overhaul to federal long-term care regulations in 25 years, affected facilities should act now to ensure they are prepared for the upcoming changes. CMS will implement the new and revised regulations in three phases, with Phase 1 regulations having an implementation date as early as Nov. 28 and Phase 3 three years later on Nov. 28, 2019.

To see a copy of the Final Rule, click [here](#).

**Executive Summary of Changes to Clinical Requirements for Long-Term Care Facilities**

The Final Rule introduces a number of revisions and new sections regarding the clinical requirements for long-term care facilities that participate in Medicare and Medicaid.

**Resident Assessment – 42 C.F.R. § 483.20.**

CMS added general areas that facilities must assess when completing comprehensive assessments for residents. Now, instead of taking into consideration just a resident’s needs, facilities must also consider, and should make their best attempts to obtain information on, the resident’s strengths, goals, life history, and preferences. Further, in an effort to encourage facilities to move the discussion of possible discharge away from a facility’s judgment and towards resident preference and expectation, CMS revised the requirement that the assessment address “discharge potential” to instead address “discharge planning.” CMS also clarified that the assessment process includes communication with direct care staff, which...
CMS defines as those staff who provide care and services to allow residents to attain or maintain their well-being through interpersonal contact with residents or resident care management. Thus, staff whose primary duty is to maintain the facility’s physical environment are not part of the resident assessment process.

Regarding the current requirement that facilities coordinate assessments with Medicaid’s Preadmission Screening and Resident Review (PASARR) program, CMS clarified that this includes: (1) incorporating recommendations from PASARR level II determinations and the PASARR evaluation report into a resident’s assessment, care planning, and care transitions, and (2) referring all level II residents and residents with newly evident or possible serious mental disorders, intellectual disabilities, or related conditions for level II review upon a decline or improvement in a resident’s status.

In addition to these substantive revisions, CMS made a few technical corrections to the resident assessment regulation, admitting that CMS inadvertently left out certain statutory requirements already in effect. Specifically, CMS added content regarding exceptions to the preadmission screening program for individuals with a mental disorder or intellectual disability and notification to state mental health or intellectual disability authorities of significant changes in a resident’s condition with a mental disorder or intellectual disability.

**Implementation Date:** These revisions will be implemented in Phase 1 on Nov. 28, 2016.

**Recommended Action Item:** Facilities should review their processes for conducting resident assessments to ensure that direct care staff gather appropriate information on residents. Facilities should keep in mind, and educate staff, that the purpose of the resident assessment is no longer to simply understand resident needs but also to understand residents’ strengths, goals, life history, and preferences, including those preferences for discharge.

**Comprehensive Person-Centered Care Planning – 42 C.F.R. § 483.21.**

CMS created this new section on comprehensive person-centered care planning, by relocating existing provisions on care plans and discharge planning and adding in the following new provisions:

- **Baseline Interim Care Plan.** CMS will require facilities to complete a baseline interim care plan, or alternatively the comprehensive care plan, for each resident within 48 hours after admission. Recognizing that certain types of information are necessary to provide appropriate care immediately, CMS requires facilities to include, at a minimum, the following information in the baseline interim care plan: (i) initial goals based on admission orders; (ii) physician orders; (iii) dietary orders; (iv) therapy services; (v) social services, and (vi) PASARR recommendation, if applicable. After developing the plan, facilities must also provide the resident and resident representative with a summary of the interim care plan.

- **Comprehensive Care Plan.** In developing the comprehensive care plan, CMS reiterated that it should be person-centered and focused on the resident as the locus of control. In the comprehensive care plan, facilities must now consider and document a resident’s preference and potential for future discharge and return to the community, along with any referrals to local agencies or entities for this purpose. Facilities must also include any specialized services provided pursuant to a PASARR recommendation or otherwise explain the facilities’
disagreement with the PASARR recommendation. Further, all services provided or arranged for as outlined in the care plan need to be culturally-competent and trauma-informed. In terms of those individuals that participate in the comprehensive care planning process, CMS added several persons to the make-up of the interdisciplinary team (IDT): (i) a nurse aide with responsibility for the resident; (ii) a member of the food and nutrition services staff; and (iii) “other appropriate staff or professionals,” identified based on the resident’s specific needs or at the resident’s request. Further, if the facility does not include the resident and/or resident representative in development of the care plan or if these individuals refuse to participate, the facility must include an explanation in the resident’s medical record.

- **Discharge Planning.** In an effort to improve discharge planning, CMS will require facilities to develop and implement an effective discharge planning process, with the involvement of the IDT responsible for the resident’s comprehensive care plan. The discharge plan for each resident involves the regular re-evaluation of the resident’s discharge needs and modification of the plan as needed, along with discussing the evaluation with the resident or resident’s representative. CMS sets forth specific types of information to consider and actions to take throughout the discharge planning process, including: (i) the availability of caregivers / support persons and their capacity and capability, along with the resident’s, to perform required care post-discharge; (ii) resident’s goals of care and treatment preferences; (iii) helping residents select post-acute providers by using standardized patient assessment data, quality measures, and resource use measures, which skilled nursing facilities, home health agencies, long-term care hospitals, and inpatient rehabilitation facilities must already report on; (iv) the resident’s interest in receiving information about returning to the community and the provision of referrals to appropriate entities made for this purpose (and, if discharge to the community is not feasible, then the facility must document who made the determination and the reasons for such).

CMS also revised the current requirements for the contents of post-discharge summary. CMS specified that a recapitulation of a resident’s stay in the summary must include at least: diagnoses; course of illness/treatment or therapy; and pertinent lab, radiology, and consultation results. The summary must also now include arrangements made with other providers for the resident’s follow-up care, any post-discharge medical and non-medical services as needed, and a reconciliation of all pre-discharge and post-discharge medications.

**Implementation Date:** This section will be implemented in Phase 1 on Nov. 28, 2016 with two exceptions. Requirements related to baseline care plans (42 C.F.R. § 483.21(a)) will be implemented in Phase 2 on Nov. 28, 2017. The provision regarding trauma informed care (42 C.F.R. § 483.21(b)(3)(iii)) will be implemented in Phase 3 on Nov. 28, 2019.

**Recommended Action Item:** Facilities should review whether their care plans as written, and the underlying development of such, support the person-centered concept of care planning. For comprehensive care plans developed or revised as of Nov. 28, 2016, facilities must ensure that the IDT is comprised of the appropriate staff members and may
need to revise staffing schedules and training to accommodate for additional participation in the IDT by facility staff. IDT members and other appropriate staff should also be educated on the new requirements for comprehensive care plans and discharge plans. In the coming months, facilities should begin to determine how to meet the 48-hour deadline for completing a baseline care plan and train staff accordingly on the minimum requirements for information to be included in the baseline care plan.

**Nursing Services – 42 C.F.R. § 483.35.**

CMS acknowledged gaps in previous regulations regarding competencies of licensed nurses and nurse aides and the need to take into account resident acuity when making staffing decisions. Accordingly, CMS implemented new requirements for nursing services to address these gaps. For instance, facilities now must follow a competency-based staffing approach. This requires facilities to base their nurse staffing decisions on an evaluation of the number and acuity of residents, range of diagnoses and resident needs, and training, experience and skill sets of facility staff in accordance with the new annual self-assessments required of facilities. CMS clarified that facilities must ensure that the individual providing care to a resident has the skills and competencies necessary to deliver that care—it is not sufficient that facility staff as a whole have the competencies and skills sets necessary to provide care. CMS also clarified that it expects non-permanent caregivers to meet competency, knowledge, and skill requirements to the same extent as permanent personnel. Notably, CMS expressly declined to impose any minimum staffing levels or ratios for nursing staff when making the above mentioned revisions.

**Implementation Date:** This section will be implemented in Phase 1 on Nov. 28, 2016 with one exception. Specific usage of the facility’s annual self-assessment (as required at 42 C.F.R. § 483.70(e)) in determining the sufficient number and competencies of staff will be implemented in Phase 2 on Nov. 28, 2017.

**Recommended Action Item:** For nursing and direct care staff, facilities should review their staffing levels and evaluate individual competencies. While use of the facility self-assessment as a basis for nursing staff decisions is not required until Nov. 28, 2017, facilities must nonetheless ensure they are appropriately staffed and each individual providing care to residents is competent to do so in the meantime.

**Pharmacy Services – 42 C.F.R. § 483.45**

CMS revised the requirements related to monthly drug regimen reviews (DRR) for each resident. Now, a pharmacist is required to concurrently review the resident’s medical record with the DRR. After conducting the DRR, currently a pharmacist is required to report any “irregularities” to the attending physician and director or nursing. In the Final Rule, CMS defined irregularities as including, but not limited to, the use of any unnecessary drug (as defined in 42 C.F.R. § 483.45(d)). If identified, the pharmacist must now also report the irregularities to the facility’s medical director and create a written, dated report of the irregularities. The resident’s attending physician then must document in the resident’s medical record his/her review of the report and actions to be taken, if any, to address it. Keeping in mind the above requirements, facilities must develop and maintain policies and procedures for the monthly DRRs that include timeframes for the various steps in the DRR process and procedures pharmacists must take if immediate action is required to protect the resident.

In addition, CMS implemented a few revisions specific to psychotropic drug use. Previously, regulations provided specific safeguards for the use of antipsychotic drugs, which prohibited their use unless necessary to treat a diagnosed and documented condition and required gradual reduction of antipsychotic drug dosages. Now, these safeguards apply to an expanded list of drugs, which CMS classifies as psychotropic medications and includes, for example, anti-psychotics, anti-depressants, anti-anxiety, and hypnotic medications. CMS imposed further
limitations on psychotropic drug use as well. Facilities must ensure that residents do not receive psychotropic drugs pursuant to a PRN order unless necessary to treat a diagnosed specific condition documented in the resident’s clinical record. Further, every such PRN order must be limited to 14 days and cannot be continued beyond that unless the resident’s attending physician or prescribing practitioner evaluates the resident and documents the rationale for continuation of the order.

**Implementation Date:** This section will be implemented in Phase 1 on Nov. 28, 2016 with two exceptions. Medical chart reviews (42 C.F.R. § 483.45(c)(2)) and requirements related to psychotropic medications (42 C.F.R. § 483.45(e)) will be implemented in Phase 2 on Nov. 28, 2017.

**Recommended Action Item:** Facilities must create and/or update their policies and procedures on monthly DRRs to confirm with CMS’ new requirements. Facilities should also educate pharmacists on the new DRR requirements and inform any attending physicians of their responsibility to document review of any reports of identified irregularities created by the pharmacist. In the coming months, facilities may wish to update or develop protocols on psychotropic drugs to ensure their use is appropriate and in compliance with regulations.

**Infection Control – 42 C.F.R. § 483.80**

CMS modified prior regulatory language on infection control programs to include infection prevention in addition to control and clarify that the infection prevention and control program (“IPCP”) must help prevent the development and transmission of communicable diseases, not just infections. Facilities must establish an IPCP that includes the following elements: (i) a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and contractors based on the facility’s annual self-assessment and accepted national standards; (ii) written standards, policies, and procedures that meet certain specified requirements; (iii) an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use; and (iv) a system for recording incidents identified under the IPCP and corrective actions taken by the facility. As part of the IPCP, facilities will designate at least one person as an “Infection Preventionist” who is responsible for the program and meets CMS’ qualifications for the role. The Infection Preventionist must also be a member of the facility’s QAA committee and regularly report to the committee on the IPCP. CMS requires annual review, and update if applicable, of the IPCP.

**Implementation Date:** This section will be implemented in Phase 1 on Nov. 28, 2016 with a few exceptions. The requirements that the IPCP be based on the facility’s annual self-assessment (see 42 C.F.R. § 483.80(a)) and include an antibiotic stewardship program (42 C.F.R. § 483.90(a)(3)) will be implemented in Phase 2 on Nov. 28, 2017. Provisions regarding the designation of the Infection Preventionist and his/her participation in the QAA committee (42 C.F.R. § 483.80(b)-(c)) will be implemented in Phase 3 on Nov. 28, 2019.

**Recommended Action Item:** Requirements for the IPCP are more robust that current requirements for Infection Control Programs. As a result, facilities must review and analyze their Infection Control Programs to identify deficiencies, initiate appropriate corrective action, and create/amend written standards, policies, and procedures regarding infection and disease prevention and control.

**Upcoming Information for You**

This alert is the last in a serious of four communications regarding the Final Rule. Please join us on Nov. 2, 2016, at 12 p.m. CT for the last of our three webinars. The webinar will provide a more in-depth analysis of the aspects of the Final Rule mentioned above, discuss how the Final Rule will affect your facility’s operations, and identify steps you should take to prepare for implementation of the Final Rule. See more [here](#).
For More Information

For questions regarding this information, please contact one of the authors below, a member of Polsinelli’s Health Care practice, or your Polsinelli attorney.

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