CMS Issues Final Rule Significantly Reforming the Requirements for Long-Term Care Facilities Participating in the Medicare and Medicaid Programs[1]

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On October 4, 2016, the Centers for Medicare & Medicaid Services (CMS) published its final "Reform of Requirements for Long-Term Care Facilities"[1] rule in the *Federal Register*, marking the first time since 1991 that the conditions for participation for long-term care facilities have been significantly modified. The final rule revises Part 483 of Title 42 of the *Code of Federal Regulations*.

CMS stated that the rule was "necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety" in the long-term care setting. The final rule implements much of the proposed rule that was released in July 2015, but in some cases, goes even further. While the regulations are effective on November 28, 2016, they can be implemented by providers in phases: Phase 1 must be implemented by November 28, 2016, and Phase 2 and Phase 3 should be implemented by November 28, 2017 and November 28, 2019, respectively. Compliance with the rule will require facilities to devote substantial additional financial and human resources, despite CMS's assertion that the rule will reduce procedural burdens on providers.

Among other things, the final rule includes provisions to address the competency of staff members, strengthen patient rights, and to improve care. The rule allows therapy providers and staff dieticians to write orders in their areas of expertise pursuant to physician delegation, revises requirements related to discharge planning, regulates behavioral health services, revises infection prevention and control standards, and requires certain antibiotic stewardship programs. Following is a short summary of some of the major provisions of the final rule.

Ban on Arbitration Agreements

In the final rule, CMS bans pre-dispute arbitration agreements altogether in order to, as CMS Administrator Andy Slavitt stated in a blog post, "strengthen the rights of residents and families in the event that a dispute arises with a facility." CMS stated in the final rule that it has authority to issue the rule because it does not affect existing agreements, only regulates "the conditions of adoption of such agreements," which it has the power to do in order to regulate participation in the Medicare and Medicaid programs. Thus, binding, pre-dispute arbitration agreements, even if optional, cannot be used by nursing homes after Phase 1 of the rule is implemented on November 28, 2016. Nevertheless, CMS' authority to restrict parties' right to agree to arbitrate remains a likley area of future litigation (as discussed further in a previous article[2]), especially when the agreement is not a precondition to admission.

Quality Assurance and Performance Improvement Programs

The final rule revises the requirements for Quality Assurance and Performance Improvement (QAPI) programs. Facilities will be required to establish and implement a written plan that meets established standards. The new rule also allows for disclosures of QAPI documents to surveyors in order to ensure that facilities have effective QAPI programs. Several commentators were

1 https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities

2 http://www.agg.com/CMS-Federal-Nursing-Home-Arbitration-Agreement-Ban-Is-Not-Likely-to-Remain-Unchallenged-10-04-2016/

concerned that the revisions would weaken the protections afforded to healthcare facilities' QAPI records, which remain confidential in litigation and privileged under 42 U.S.C. §§ 1395i-3(b)(1)(B) & 1396r(b)(1)(B), and may have a chilling effect on facilities' QAPI efforts. The final rule, however, reinforces the privilege and reiterates that its "purpose is neither to inappropriately make documents public nor [] expose facilities to litigation risk." This section will be implemented in Phase 1, with a number of substantive provisions delayed until Phase 2 or 3 in 2017 and 2019.

Infection Control Programs

Long-term care facilities will be required to create an infection prevention and control program (ICPC). Components of this program include an Antibiotic Stewardship program, and designation of at least one Infection Preventionist. Facilities' ICPC must be implemented in Phase 1, but designation of an Infection Preventionist will not be required until Phase 3 in 2019.

Food and Nutrition Services

Under the final rule, a facility must provide each resident with a "nourishing, palatable, well-balanced diet that meets his or her daily nutritional and special dietary needs, taking into consideration the preferences of each resident." This includes sufficient food and nutrition staff, a qualified dietitian, and other specific requirements for feeding and nutrition. Most of these requirements must be in place by Phase 1 in 2016.

Comprehensive Person-Centered Care Planning

The final rule requires facilities to develop and implement a baseline care plan for each resident within 48 hours of admission. The interdisciplinary team tasked to develop resident care plans must now include a nurse aide, as well as a member of the food and nutrition services staff. Additionally, facilities must now use a discharge planning process that focuses on residents' discharge goals and prepares residents to be active in post-discharge care in an effort to reduce re-admissions and hospital admissions. This quality-of-care emphasis implements discharge planning requirements mandated by the 2014 IMPACT Act, and will be implemented in Phase 1, with the baseline care plan provisions taking effect in Phase 2 in 2017.

Deliberate Abuse

CMS refined its definition of abuse in this final rule, stating that "willful infliction of injury" would mean that a facility employee "acted deliberately, not that the individual must have intended to inflict injury or harm." As such, a deliberate act that unintentionally causes harm may be considered abuse. However, citing recent DAB decisions, CMS stated that this definition should not include actions that were "inadvertent or accidental."

Abandoned Proposals

CMS had proposed a new regulation for the provision of therapy services to individuals that do not reside in the facility. After considering the multitude of comments and complex issues involved, CMS decided to forgo adoption of the regulation. As before, providers should continue to comply with the patchwork of state policies on outpatient rehabilitation. CMS had also proposed a regulation requiring a physician or other healthcare professional to conduct an in-person evaluation of a resident prior to an unscheduled transfer to a hospital. CMS determined not to finalize that regulation pending further analysis of the points raised by commenters, which included concerns over expense, burden, and access to care.

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