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CMS proposes delay and revisions to long-term care regulations

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On October 4, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a final rule revising the requirements that long-term care (LTC) facilities must meet to participate in the Medicare and Medicaid programs (the final rule).[1] The effective date of this final rule was November 28, 2016. The requirements set forth in the final rule were initially intended to be implemented in three phases, with the final phase commencing November 28, 2019; however, the breadth of the participation requirements are such that CMS recently proposed a one-year delay in the third and final phase of implementation, as well as revisions to simplify and streamline a variety of the requirements (the proposed rule).[2] Note that the final rule implementing these proposals may be published by CMS prior to the date this article is published.

Background of LTC ROP requirements

The final rule, which contained the most substantial revisions to the Medicare and Medicaid LTC requirements for participation since 1991,[3] was promulgated, in part, as a result of CMS's recognition that the number of individuals accessing LTC has dramatically increased, and the healthcare concerns of individuals residing in these facilities have become increasingly complex.[4] In the final rule, CMS explains that these regulations are referred to as "requirements for participation" instead of "conditions of participation" to reflect the statutory language in the Social Security Act.[5] However, CMS clarifies that there is no meaningful distinction between the two phrases.[6]

Additionally, the Patient Protection and Affordable Care Act of 2010 (ACA)[7] established a variety of new statutory requirements intended to promote certain reforms in LTC facilities.[8] Specifically, the ACA requires LTC facilities to implement an effective compliance and ethics program that detects criminal, civil, and administrative violations; promotes quality of care; and further requires the Secretary of Health and Human Services (the Secretary) to work with the Inspector General of HHS to promulgate regulations for an effective compliance and ethics program.[9] The ACA also requires LTC facilities to implement a Quality Assurance and Performance Improvement (QAPI) program.[10] Based on this mandate in the ACA, in conjunction with the Secretary's authority to promulgate regulations that are "adequate to protect the health, safety, welfare, and rights of residents [in LTC facilities],"[11] CMS significantly revised the LTC requirements for participation, with the goal of "achieving the statutorily mandated outcome of ensuring that each resident is provided care that allows the resident to maintain or attain their highest practicable physical, mental, and psychosocial well-being."[12]

LTC facility requirements for participation, generally

The final rule revised and implemented a significant amount of LTC regulations. Specifically, the final rule addresses LTC resident rights;[13] facility responsibilities;[14] admission, transfer, and discharge rights;[15] resident assessments;[16] comprehensive, person-centered care planning;[17] quality of care and quality of life;[18] physician services;[19] nursing services;[20] behavioral health services;[21] pharmacy services;[22] dental services;[23] food and nutrition services;[24] specialized rehabilitation services;[25] outpatient rehabilitation services;[26] administration requirements;[27] infection control;[28] physical environment;[29] and training requirements.[30]

QAPI program

The final rule also revised the existing LTC quality-related regulations to incorporate the requirements set forth in the ACA that require LTC facilities to establish an effective, comprehensive, and data-driven QAPI program.[31] The QAPI program must be designed to "monitor and evaluate performance of all services and programs of the facility," and requires the facility's governing body to ensure that the QAPI program is "defined, implemented, and maintained" in a manner that continually addresses the facility's identified priorities.[32] The LTC facility must design its QAPI program to be ongoing, comprehensive, and address all systems of care and management practices, including clinical care, quality of life, and resident choice.[33]

The QAPI program must include the ability for direct care workers and other staff, as well as residents, residents' representatives, and residents' families, to provide feedback and input, as well as implement policies and procedures to identify, report, analyze, and prevent adverse and potential adverse events. The facility must establish a methodology under which it takes action to improve performance and tracks the success of such actions. The facility must also establish "performance improvement activities that focus on patient safety; coordination of care; autonomy; choice; and high risk, high volume and/or problem-prone areas identified as a result of the facility assessment." The governing body or executive leadership must ensure that the QAPI program is adequately resourced; prioritizes problems and opportunities based on performance indicator data and resident and staff input; takes corrective action to address identified gaps; and ensures that clear expectations are communicated with respect to resident "safety, quality, rights, choice and respect." Finally, LTC facilities may be required to provide access to certain systems, documents, and information in order to demonstrate compliance with these requirements.[34]

LTC facilities were required to present their QAPI plans to the state survey agency no later than one year after the effective date of the final rule, in the second phase of implementation, which was November 28, 2017.[35] The remaining requirements are required to be implemented in the third phase of implementation, which is three years following the effective date of the final rule, or November 28, 2019.[36]

Compliance and ethics program

ACA also requires the "operating organizations" of LTC facilities[37] to implement a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care.[38] The operating organization of an LTC facility is defined as "the entity that operates the facility," regardless of the facility's legal structure (i.e., whether owned by an entity, an individual, or a small group of individuals).

The final rule requires the operating organization of each facility to develop, implement, and maintain an effective compliance and ethics program that contains several components. Specifically, the organization must

establish written compliance and ethics standards, policies, and procedures designed to prevent and detect criminal, civil, and administrative violations, which must: (1) designate a compliance and ethics program contact to whom individuals may report suspected violations; (2) provide an anonymous, alternative method of reporting without fear of retaliation; and (3) establish consequences for violations. The operating organization must effectively communicate these standards, policies, and procedures to its entire staff, whether through mandatory training or through any other practical and effective method. For purposes of this requirement, "staff" includes any individuals who provide services under a contractual arrangement with the facility, as well as volunteers.[39]

The facility must have a method by which it enforces its compliance standards, policies, and procedures through disciplinary measures, including discipline of "individuals responsible for the failure to detect and report a violation of the appropriate party identified in the operating organization's compliance and ethics program."[40] If a violation is reported or detected, the facility must ensure reasonable steps are taken to appropriately respond, and modify the organization's compliance program to address and further prevent a similar violation, if necessary.

Operating organizations that operate five or more facilities must designate a compliance officer with the overall responsibility to oversee the compliance and ethics program, and who must directly report to the operating organization's governing body.[41] Finally, the final rule requires operating organizations to review their compliance and ethics programs annually, and to revise the program to reflect any changes in applicable laws or organizations, or as necessary based on the facility's performance in "deterring, reducing and detecting" violations.[42]

Pursuant to the final rule, LTC facilities must implement these compliance and ethics program requirements in the third phase of implementation, three years after the effective date of the final rule, or November 28, 2019.[43]

Proposed revisions to LTC requirements and implementation delay

As explained above, the final rule established a three-part phase-in of the LTC requirements to occur over three years, with the purpose of providing LTCs with enough time to effectively incorporate the new requirements into their everyday practices.[44] Phase 1 was implemented on November 28, 2016, and Phase 2 was implemented on November 28, 2017. The third and final phase was set to commence November 28, 2019. However, CMS recently published a proposed rule that would not only modify a variety of the LTC requirements set forth in the final rule, including some requirements that have already been implemented, but would also delay implementation of some of the requirements set to commence in the third implementation phase.[45]

In the proposed rule, CMS proposes to modify existing regulations related to resident rights; admission, transfer, and discharge rights; quality of care; nursing services; behavioral health; pharmacy services; food and nutrition services; administration; and infection control.[46] CMS explains that the purpose of these revisions is to "simplify and streamline the current requirements and thereby increase provider flexibility and reduce excessively burdensome regulations, while also allowing facilities to focus on providing high-quality healthcare to their residents."[47] Additionally, these revisions would purportedly "reduce the frequency of certain required activities" and "remove obsolete, duplicative, or unnecessary requirements."[48]

CMS also proposed substantial revisions to the QAPI program and compliance and ethics program requirements. With respect to the QAPI program, CMS explained that industry stakeholders indicated that the QAPI regulations are "inflexible and too detailed, making it difficult for facilities to identify organizational priorities for

improvement."[49] As such, CMS proposed to eliminate the specific QAPI program design and scope requirements, and to simply maintain the general requirement that QAPI programs be "ongoing, comprehensive and address the full range of care and services provided by the facility."[50] CMS also proposed to eliminate the specific requirements for program feedback, data systems, and monitoring, and to maintain the general requirement that facilities establish and implement written policies and procedures to address feedback and monitoring.[51] Finally, CMS proposed to maintain the requirement that facilities take actions with respect to performance improvement, but to remove the specific requirements regarding development and implementation of policies addressing program systematic analysis and corrective action with respect to performance improvement.[52]

CMS also proposed significant revisions to the compliance and ethics program requirements. For instance, CMS proposed to eliminate the requirement for operating organizations with five or more facilities to designate a compliance officer, and instead proposed that the organizations develop a program "appropriate for the complexity of the organization," which includes tasking a specific individual within "high-level personnel" of the organization with the overall responsibility to oversee compliance.[53] CMS also proposed to remove the requirement that the operating organization conduct an annual review of its compliance program, and instead would only require a "periodic review."[54] Additionally, CMS proposed to remove the requirement that an LTC facility designate a compliance and ethics "contact person" to whom individuals may report suspected violations, but maintained the requirement that facilities have an alternate, anonymous reporting method.[55]

Finally, CMS proposed to delay implementation of the QAPI and compliance and ethics program requirements for one year after the effective date of the finalization of the proposed rule. Comments to the proposed rule were due to CMS no later than September 16, 2019. [56] CMS explained that the purpose of the delay is to "avoid unnecessary work, confusion and burden associated with implementing provisions that are proposed to be changed" in the proposed rule.[57] Specifically, CMS acknowledged that each phase of implementation requires a "significant level of activities, including interpretive guidance drafting and publication, provider education, software development, and surveyor training."[58]

It remains to be seen which, if any, of these proposed revisions will become effective, but LTC facilities should strive toward implementing the requirements set forth in the final rule with respect to QAPI and compliance and ethics programs by November 28, 2019, until such time CMS issues a final rule to the contrary.

Takeaways

- LTC facility requirements for participation were substantially revised in 2016, representing the most significant revisions to these regulations since 1991.
- The revisions were, in part, due to the ACA, which required LTC facilities to implement effective compliance and ethics and quality assurance and performance improvement programs.
- The regulations required LTC facilities to implement these new requirements in three phases, with the third and final phase set to commence November 28, 2019.
- CMS recently proposed substantial revisions to these LTC regulations, including with respect to the compliance and ethics and quality assurance and performance improvement programs requirements.
- CMS also proposed to delay the final phase of implementation, recognizing the additional burden that would result in the event that CMS's proposed revisions become effective.

1 Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Final Rule, 81 Fed. Reg. 68,688 (Oct. 4, 2016).
2 Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency and Transparency; Proposed Rule, 84 Fed. Reg. 34,737, 34,752 (July 18, 2019).
3 Medicare and Medicaid; Requirements for Long-Term Care Facilities; Final Rule, 56 Fed. Reg. 48,826 (Sep. 26, 1991).
4 Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Proposed Rule, 80 Fed. Reg. 42,168, 42,174 (July 16, 2015).
581 Fed. Reg. at 68,693.
6*Id.*
742 U.S.C. § 18001 et seq.
881 Fed. Reg. at 68,690-91; *see also* the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), § 6102.
981 Fed. Reg. at 68,690-91; Section 1128I(b) of the Social Security Act (SSA).
1081 Fed. Reg. at 68,690-91; Section 1128I(c) of the SSA.
1184 Fed. Reg. at 34,739 (quoting Sections 1819(f)(1) and 1919(f)(1) of the SSA).
1281 Fed. Reg. at 68,691.
1381 Fed. Reg. at 68,702; 42 C.F.R. § 483.10.
1481 Fed. Reg. at 68,704; 42 C.F.R. § 483.11.
1581 Fed. Reg. at 68,729; 42 C.F.R. § 483.15.
1681 Fed. Reg. at 68,736; 42 C.F.R. § 483.20.
1781 Fed. Reg. at 68,737; 42 C.F.R. § 483.21.
1881 Fed. Reg. at 68,745; 42 C.F.R. § 483.25.
1981 Fed. Reg. at 68,752; 42 C.F.R. § 483.30.
2081 Fed. Reg. at 68,753; 42 C.F.R. § 483.35.
2181 Fed. Reg. at 68,759; 42 C.F.R. § 483.40.
2281 Fed. Reg. at 68,765; 42 C.F.R. § 483.45.
2381 Fed. Reg. at 68,775; 42 C.F.R. § 483.55.
2481 Fed. Reg. at 68,776; 42 C.F.R. § 483.60.
2581 Fed. Reg. at 68,781; 42 C.F.R. § 483.65.
2681 Fed. Reg. at 68,783; 42 C.F.R. § 483.67.
2781 Fed. Reg. at 68,784; 42 C.F.R. § 483.70.
2881 Fed. Reg. at 68,807; 42 C.F.R. § 483.80.
2981 Fed. Reg. at 68,816; 42 C.F.R. § 483.90.
3081 Fed. Reg. at 68,819; 42 C.F.R. § 483.95.
3181 Fed. Reg. at 68,802; *see* Section 6102 of the ACA, which added Section 1128I(c) to the SSA; codified at 42 C.F.R. § 483.75.
3281 Fed. Reg. at 68,802.
3381 Fed. Reg. at 68,802.
34 81 Fed. Reg.at 68,803.
3581 Fed. Reg. at 68,807, 68,696.
3681 Fed. Reg. at 68,696.
3781 Fed. Reg. at 68,812 (citing Section 1128I(b)(1) of the ACA).
3881 Fed. Reg. at 68,812; *see* Section 6102 of ACA, which added Section 1128I(b) to the SSA, codified at 42 C.F.R. § 483.85.
39 81 Fed. Reg.at 68,813.

40 81 Fed. Reg.at 68,813.
41 81 Fed. Reg.at 68813.
42 81 Fed. Reg.at 68813.
4381 Fed. Reg. at 68697; 42 C.F.R. § 483.85(b).
4481 Fed. Reg. at 68696.
4584 Fed. Reg. 34737.
4684 Fed. Reg. at 34737-38; 34740-45; 34746-47.
4784 Fed. Reg. at 34737.
4884 Fed. Reg. at 34737.
4984 Fed. Reg. at 34745.
5084 Fed. Reg. at 34746. This would remove the requirements set forth in 42 C.F.R. § 483.75(b)(1) through (4).
5184 Fed. Reg. at 34746. This would remove the requirements set forth in 42 C.F.R. § 483.75(c)(1) through (4).
5284 Fed. Reg. at 34746. This would remove the requirements set forth in 42 C.F.R. § 483.75(d)(2).
5384 Fed. Reg. at 34747; 42 C.F.R. § 483.85(d)(1).
5484 Fed. Reg. at 34747; 42 C.F.R. § 483.85(e).
5584 Fed. Reg. at 34747; 42 C.F.R. § 483.85(c)(7).
5684 Fed Reg. at 34752.
5784 Fed Reg. at 34752.
5884 Fed Reg. at 34751.