CMS Proposes a Host of Changes to Nursing Home Requirements for Participation – Part Two

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The Centers for Medicare and Medicaid Services (CMS) proposes a host of changes to the revised Medicare Requirements for Participation ("Requirements for Participation") that it promulgated in 2016 and an extension of the implementation deadline for certain of the Phase 3 requirements for a period of one year following issuance of a final rule. This article explores proposed changes to the facility assessment, quality assurance and performance improvement (QAPI), infection prevention, compliance and ethics, and physical environment requirements. A companion piece examined the proposed resident rights, admission, transfer and discharge rights, quality of care, nursing services, behavioral health, pharmacy services, and food and nutrition services revisions.

■ Administration – Section 483.70

□ Facility Assessment – CMS notes that it received numerous comments from providers and other stakeholders about the facility assessment provisions at Section 483.70(e) because they require information that is similar to information required to be collected under other provisions of the Requirements for Participation. Moreover, providers complained that the requirements rise to the level of micro-managing how facilities conduct their operations, and take away valuable leadership time that can be used for resident care. In response, CMS proposes the following changes to the Facility Assessment provisions:

■ Clarification in the introductory text that data collected for the facility assessment can be utilized to inform policies and procedures for other requirements, such as Sections 483.35 (nursing services), 483.40(a) (behavioral health), 483.60(a) (food and nutrition), and 483.75 (QAPI). It is likely that facilities already are utilizing as much of the facility assessment data as possible for these other requirements, and vice versa, so this revision offers little in the way of burden reduction for providers.

■ Deletion of Section 483.70(e)(3) requiring a facility-based and community-based risk assessment, utilizing an all-hazards approach. This requirement is largely duplicative of the requirement at Section 483.73(a)(1) with respect to emergency preparedness. This proposed change does not eliminate the overall requirement for a facility-based and community-based risk assessment; it merely eliminates the need to include the assessment developed as part of the emergency preparedness requirements in the facility assessment.

■ Decrease in the minimum frequency for conducting a facility assessment from annually to biennially. CMS specifically notes, however, that facilities with high staff turnover should conduct a facility assessment "as frequently as necessary and the issue should be addressed in the QAPI plan." Moreover, the introductory text retains the overall obligation to review and up-

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1 The proposed rule also would make changes to CMS’s Informal Dispute Resolution and Independent Informal Dispute Resolution processes, and would eliminate the requirement for nursing facilities to actively waive their right to a hearing in order to receive a 35 percent reduction in penalty amount. Rather, CMS would institute a constructive waiver process that would operate by default when CMS has not received a timely request for a hearing. AGG Partner, Alan Horowitz, provides further insight into these aspects of the proposed rule here.
Legal Insight

date this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of the assessment. Taken together, the proposed change could be illusory for many facilities that struggle with staff turnover or have frequent changes in resident population or demographics. It at least promises some relief for facilities that experience relative stability in these areas.

■ **Quality Assurance and Performance Improvement (QAPI) Program** – Section 483.75 – In response to comments from the provider community that the QAPI requirements are inflexible and too detailed, and thus hinder the ability of facilities to identify their organizational priorities, CMS proposes to eliminate the subparagraphs under Sections 483.75(b) (program design and scope), (c) (program feedback, data systems and monitoring), and (d) (program systematic analysis and systemic action). All of the subparagraphs presently serve to drill down and establish parameters with respect to a facility’s QAPI program. These changes promise some degree of flexibility for facilities; however, many of the specifics contained in the subparagraphs are natural follow-ons to the generalized requirements that precede them. As a result, providers may find themselves organically incorporating many of the specific elements in their programs anyway.

■ **Infection Control** – Section 483.80 – Presently, Section 483.80(b)(3) requires the infection preventionist to work at least part time at the facility. CMS proposes to eliminate that language because it "could be interpreted in many ways." Instead, if implemented, Section 483.80(b)(3) would require that the infection preventionist have "sufficient time at the facility to achieve the objectives set forth in the facility's [infection prevention control plan]." Despite stating that it believes this is an appropriate standard, CMS is concerned there could be substantial variance in how facilities interpret the requirement, and therefore, is soliciting further comment on the provision. With CMS’s request for additional comments, however, it remains to be seen what the final requirement will look like and whether it will provide any relief or additional flexibility to providers. CMS only recently made on-line training resources for infection preventionists available to providers.

■ **Compliance and Ethics Program** – Section 483.85 – CMS proposes to make the most changes to the compliance and ethics program requirements. Specifically, the agency looks to reduce a majority of the burden associated with requirements not specifically mandated by the underlying statute.²

  □ Required components for all facilities – Section 483.85(c) – The proposed rule would make the following changes:

  ■ While it would retain general language in subparagraph (1) regarding standards, policies, and procedures reasonably capable of reducing the prospect of criminal, civil, and administrative violations, the rule would eliminate the reference to promoting quality of care and the requirements for designation of a program contact to which individuals may report suspected violations, an alternate method of reporting violations anonymously (this provision is moved to newly created subparagraph (9)), and disciplinary standards that set out the consequences for committing violations for staff, individuals providing services under contract, and volunteers.

  ■ It would eliminate the references in subparagraph (2) to specific positions that meet the definition of "high level personnel" to oversee the compliance function.

  ■ In subparagraph (6), it would eliminate the reference to an anonymous reporting system, moving it to newly created subparagraph (9). It also would delete reference to a process for ensuring the integrity of any reported data.

  □ Additional required components for operating organizations with five or more facilities - Section 483.85(d) – CMS proposes to add language to the introductory text to cover not only operating organizations that operative five or more facilities, but also "facilities with corporate level management of multi-unit nursing home chains." The agency does not address the new language in its narrative but it is likely a clarification designed to eliminate any ambiguity. The other changes proposed for Section 483.85(d):

  ■ Eliminates the requirement of subparagraph (1) for a mandatory annual training program, and substitutes a requirement for a "more formal program that includes established written policies

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² 42 U.S.C. § 1320a-7j (Section 1128I of the Social Security Act).
defining the standards and procedures to be followed by its employees.”

- Eliminates the requirement of subparagraph (2) for a designated compliance officer who reports to the operating organization’s governing body, and substitutes a requirement for a program that is “appropriate for the complexity of the operating organization and its facilities.”
- Deletes in its entirety subparagraph (3) requiring compliance liaisons at each facility.

Program Review – Section 483.85(e) – Rather than requiring annual review and revision of the program, CMS proposes a periodic review and revision of the program to identify necessary changes within the organization and its facilities.

While the changes proposed for the compliance and ethics program requirements have the potential to provide significant burden reduction for small, independent facilities, the size and complexity of multi-site providers and large chains will necessarily demand a significantly more robust and formal compliance program. All providers, however, should ensure that their programs are consistent with Department of Health and Human Services, Office of Inspector General guidance available within the agency’s Compliance Resource Portal.

Physical Environment – Section 483.90

- Fire Safety – In 2016, CMS adopted the 2012 edition of the Life Safety Code (LSC). The LSC, in turn, incorporates the 2013 National Fire Protection Association (NFPA) 101A, Guide on Alternative Approaches to Life Safety, which is also known as the 2013 Fire Safety Equivalence System (FSES). An unintended consequence of adopting the newer version of the LSC, and consequently, the 2013 version of the FSES, is that certain older nursing facilities constructed with a wood frame or unprotected steel members could no longer achieve a passing score on the FSES relative to containment, extinguishment, and people movement requirements because the 2013 FSES incorporates a change in scoring on these measures. There are approximately 50 facilities nationwide, but particularly in Pennsylvania and Ohio, that would be forced to completely rebuild, which is cost prohibitive and extremely disruptive to residents, or even close down, if regulatory relief could not be obtained. CMS urged affected providers to avail themselves of a time-limited waiver from the requirements of up to five years while the agency worked on a solution. CMS has included its proposed solution in this rule. Specifically, if implemented, CMS would allow existing facilities certified for Medicare or Medicaid prior to July 5, 2016 to continue to use the older 2001 version of the FSES to determine compliance with containment, extinguishment, and people movement requirements. For affected facilities, this is undoubtedly critical and welcome regulatory relief.

- Resident Rooms and Bathrooms – The existing regulation at Section 483.90(e)(1)(i) requires all newly constructed, re-constructed, or facilities first certified after November 28, 2016, to accommodate no more than two residents in a bedroom. Also, Section 483.90(f) requires newly constructed facilities and those first certified after November 28, 2016, to equip each resident room with its own bathroom having a commode and sink. Industry stakeholders have pointed out to CMS that these requirements discourage building, remodeling, and upgrading facilities, as well as the purchase of older facilities. As a result, despite its assertion that having more than two residents in a bedroom infringes on residents’ privacy and dignity, and presents infection control and resident safety issues, CMS proposes to revise the aforementioned provisions to apply only to newly constructed facilities and newly certified facilities that have not previously been a long-term care facility. CMS, however, is also soliciting comments as to whether it would be appropriate to sunset the exception with respect to facilities that were previously used as a long-term care facility to encourage providers to update them. Accordingly, the regulatory relief occasioned by this exception may prove to be narrowly focused and short-lived.

Finally, the rule would delay for a period of one year following the effective date of the final rule, the implementation deadline for certain of the Phase 3 provisions—generally, QAPI, designation and training of the infection preventionist, and compliance and ethics program. The proposed rule lists the specific citations of the Phase 3 requirements that are subject to the delay. The Phase 3 implementation deadline for provisions not slated for delay by the proposed rule is November 28, 2019.

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3 All nursing facilities are required to be fully sprinklered under Section 483.90(a)(6).
4 See 84 Fed. Reg. 34737 (July 18, 2019), at 34752, Table 2.
Overall, the proposed changes offer a mixed bag for providers. While small facilities, those in rural areas, and those unaffiliated with multi-site providers may see a reduction in their regulatory burden if CMS implements all of the changes in their present form, many of the changes are limited and thus will provide little relief. As a result, this long-awaited rule is likely to be a disappointment to providers who were hoping for large-scale changes to the Requirements for Participation.

Comments to the proposed rule must be submitted no later than 5:00 p.m. Eastern on September 16, 2019. Comments may be submitted electronically via the regulations.gov website. All comments should include reference to file code CMS-3347-P.
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