

## Compliance Today - February 2020 Revisiting effectiveness of your SNF compliance programs: Thoughts and tips

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The Patient Protection and Affordable Care Act (ACA) of 2010 mandated nursing facilities (NF) and skilled nursing facilities (SNF) adopt compliance and ethics programs. [1] On October 4, 2016, the Centers for Medicare & Medicaid Services (CMS) published a final rule, The Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities (the 2016 final rule), which outlined the requirements for NF and SNF compliance and ethics programs. [2] As Requirements of Participation (RoP) with Medicare, the final rule required NFs and SNFs to have compliance and ethics programs in place on or before November 28, 2019. However, over the past several years, to reduce the regulatory burden for providers and suppliers following the original publication of the 2016 final rule, CMS has revised the Conditions of Participation (CoPs), the Conditions for Coverage (CfCs), and requirements for long-term care (LTC) facilities.

In response, CMS has proposed to delay the implementation of the Compliance and Ethics Program rule (42 C.F.R. § 483.85) and amend certain parts of Phase III requirements, including compliance programs. On July 16, 2019, CMS released a proposed rule regarding the Requirements for States and Long-Term Care Facilities (the 2019 proposed rule). The revisions affected various sections including the Quality Assurance and Performance Improvement (QAPI) program (42 C.F.R. § 483.75) and the compliance and ethics program (42 C.F.R. § 483.80) requirements. Both the changed expectations in the 2019 proposed rule, including the proposed year-long delay, are now putting providers in a state of uncertainty as to what and how much they might have to do next. The comment period for the 2019 proposed rule closed on September 16, 2019, but the final rule is not likely to be published anytime soon. In late November, the 2019 proposed rule was moved from the "proposed rule" category to the "long-term action" category, which means the rule is "under development but for which the agency does not expect to have a regulation action within the 12 months after publication." Therefore, it is still important to revisit the 2016 final rule and stay proactive, putting in place an effective and sustainable compliance program.

## **Proposed changes**

CMS proposed to reduce some of the compliance and ethics program requirements, particularly those applicable to SNFs and NFs with five or more facilities. CMS proposed to remove the requirements that SNFs with five or more facilities:

- Conduct mandatory annual training,
- Have a designated compliance liaison for each facility,
- Conduct annual reviews and make the requirement periodic, and

• Have a compliance officer who oversees all facilities (See Table 1).

| Requirements  | Exact language in final regulation, 42 C.F.R. § 483.85   | Effect of proposed rule  |
|---|--|--|
| Compliance and ethics standards, policies, and procedures   | "Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles." See 42 C.F.R. § 483.85(c)(1). | No change  |
| Assignment of high-level personnel to oversee and be responsible for the compliance program                 | "Assignment of specific individuals within the high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures, such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization." <i>See</i> 42 C.F.R. § 483.85(c)(2).   | Changed<br>definition of<br>high-level<br>personnel <sup>[5]</sup> |
| Sufficient resources and authority  | "Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures." See 42 C.F.R. $\S$ 483.85(c)(3).  | No change  |
| No discretionary<br>authority to<br>individuals with<br>propensity to<br>engage in violations<br>of the Act | "Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act." See 42 C.F.R. § $483.85(c)(4)$ .  | No change  |

| Requirements  | Exact language in final regulation, 42 C.F.R. § 483.85   | Effect of proposed rule |
|---|--|-------------------------|
| Communication of standards, policies, and procedures to staff, contractors, and volunteers via mandatory training, orientation programs, or disseminating information | "The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at $\S$ 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program." See 42 C.F.R. $\S$ 483.85(c)(5).  | No change               |
| Monitoring and auditing, and having an available reporting system.  | "The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data." See 42 C.F.R. § 483.85(c)(6). | No change               |
| Consistent enforcement of standards, policies, and procedures   | "Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program." See 42 C.F.R. $\S$ 483.85(c)(7).  | No change               |
| Response to detected violations and prevention of recurrence  | "After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act." See 42 C.F.R. § $483.85(c)(8)$ .   | No change               |
| 5+ Facilities   |  |                         |

| Requirements                        | Exact language in final regulation, 42 C.F.R. § 483.85  | Effect of proposed rule   |
|-------------------------------------|---|---|
| Mandatory annual training           | "A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in [ $42$ C.F.R. $§$ $483.95(f)$ ]." See $42$ C.F.R. $§$ $483.85(d)$ (1).  | Removal of<br>this<br>requirement <sup>[6]</sup>                      |
| Designated compliance officer       | "A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility. This individual must report directly to the operating organization's governing body and not be subordinate to the general counsel, chief financial officer or chief operating officer." <i>See</i> 42 C.F.R. § 483.85(d)(2).  | Removal of<br>this<br>requirement <sup>[7]</sup>                      |
| Compliance liaisons                 | "Designated compliance liaisons located at each of the operating organization's facilities." See 42 C.F.R. $\S$ 483.85(d)(3).   | Removal of this requirement [8]                                       |
| Annual review of compliance program | "The operating organization for each facility must review its compliance and ethics program annually and revise its program as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities to improve its performance in deterring, reducing, and detecting violations under the Act and in promoting quality of care." See 42 C.F.R. $\S$ 483.85(d)(4). | Review does not have to be annual. Changed to periodic <sup>[9]</sup> |

Table 1. Requirements and changes in the 2016 final rule and the proposed rule

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