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Skilled nursing facilities: Are you ready to meet federal program mandates?

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Program requirements for long-term care (LTC) facilities participating in Medicare and Medicaid first formally appeared in the federal regulatory landscape through a 1989 final rule of the Health Care Financing Administration, the predecessor of today's Centers for Medicare & Medicaid Services (CMS).[1] The regulations were reviewed in 1991 but left largely untouched until the Social Security Act[2] was amended in conjunction with the passage of the Patient Protection and Affordable Care Act[3] (ACA). The regulations require that operating organizations have "a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations."[4]

The ensuing rulemaking process yielded a final rule on October 4, 2016.[5] Section 483.85 of the final rule defined statutory terms and laid out the new requirements, many of which simply mirrored developments in the field of healthcare compliance. For example:

- The establishment of written standards;
- Designation of a program contact to which individuals could report suspected violations without fear of retribution;
- Disciplinary standards with clear consequences for violations;
- A requirement that the program have sufficient resources and authority to ensure compliance;
- Communication of standards and policies through training and orientation programs;
- The utilization of auditing and monitoring systems;
- The requirement that organizations take all reasonable steps to respond appropriately to violations and prevent similar violations in the future; and
- The requirement that organizations must review compliance and ethics programs annually and revise them as needed.

The final rule, consistent with statutory authority, set different expectations with respect to staffing, depending on the size of the organization. Those organizations with four or fewer facilities could designate "high-level personnel" (e.g., a director or executive officer) to oversee the program in the course of their other duties.

Organizations with five or more facilities would designate a compliance officer who reports directly to the governing board. In addition, they would be required to designate "compliance liaisons" at each facility to assist the compliance officer. The compliance program requirements were scheduled to be implemented in the third and final phase to the final rule's rollout on November 28, 2019.

As one would expect with a regulatory change of this magnitude, public comments came down across a wide spectrum. Commenters expressed concern that the new requirements would take time and resources away from patient care. Some felt that CMS had underestimated the financial burden of the new requirements, which would in turn add financial stress to an industry already stretched thin. There were also concerns over what many saw as overly prescriptive requirements that would needlessly complicate already functioning programs. Other commenters expressed concern over what they saw as critical terms, such as "adequate" and "reasonably," that were inherently ambiguous and not well defined in the rule. Finally, even those who generally favored the new requirements were concerned about the time frame to implementation.