

PUBLICATION

Fundamentals of CMS Updates to Appendix PP of the State Operations Manual: Compliance and Ethics Program

October 24, 2022

F895: Compliance and Ethics Program

F895 is a new tag that was made effective in November 2019 and requires each facility to have a compliance and ethics program that is governed by written standards and policies. The program must also have effective leadership and sufficient human and financial resources to operate effectively. The regulation governing the tag is designed to ensure that facilities have an effective compliance and ethics program in operation that uses internal controls to monitor adherence to statutes, regulations, and program requirements more efficiently. The goal of the regulation is to require facilities to develop the tools to deter criminal, civil, and administrative violations and promote quality of care for nursing home residents.

SOM Provides Guidance Regarding Compliance and Ethics Program Design, Resources, and Implementation

Under the new guidance, a facility must have a compliance and ethics program that has been "reasonably designed, implemented, maintained, and enforced" so it is likely to be effective in (1) preventing and detecting criminal, civil, and administrative violations; and (2) promoting quality of care for residents. The program must be structured through written standards, policies, and procedures that are communicated effectively to the entire staff. The facility must assign overall responsibility for overseeing adherence to the program's standards, policies, and procedures to a high-level individual who has substantial control over or a substantial role in making policy within the operating organization, and the program must be supported by sufficient human and financial resources. The program must also employ disciplinary measures to consistently enforce guidelines in response to violations and take "all reasonable steps" to respond to any occurring violations and prevent future violations. Lastly, the facility must conduct a review of the program at least annually.

Operating organizations that operate five or more facilities must meet additional requirements for their compliance and ethics programs. The operating organization must designate a compliance officer for whom the program is a major responsibility. The compliance officer should be able to communicate with the governing body and must not be unduly influenced by other managers or executive officers, such as the general counsel, chief financial officer, or chief operating officer. The operating organization must also place a designated compliance liaison at each of its facilities who will be responsible for assisting the compliance officer in fulfilling their duties at the individual facility. In addition, the organization must have a mandatory annual training program.

Key Takeaways

The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued compliance program guidance for nursing homes in March 2000, after the release of similar guidance for other segments of the health care industry. Supplemental guidance was released in September 2008. This revision to the SOM operationalizes the OIG's guidance to give facilities concrete steps to follow to increase the efficacy of their existing compliance programs, or new structure for facilities that may not have previously established robust compliance and ethics programs. In addition, HHS now has another, interim tool for enforcement of its expectations for compliance through the survey process.

For specific guidance or more information about this alert, please contact [Howard Sollins](#), [Stefanie Doyle](#), or any other member of [Baker Donelson's Long Term Care Team](#).