

PUBLICATION

CMS Proposes Rules Requiring LTC Facilities to Implement Compliance and Ethics Programs

November 09, 2015

Under proposed rules issued by the Centers for Medicare and Medicaid Services (CMS), long term care (LTC) facility operators would be required to develop, implement and maintain a comprehensive compliance and ethics program in order to participate in the Medicare and Medicaid programs.¹ If finalized, these new rules would create a burdensome and expensive, but ultimately necessary, set of regulatory requirements for LTC operators.

Historically, the federal regulatory agencies with oversight responsibility for Medicare and Medicaid providers have emphasized the need for a robust compliance program as a "best practice" for providers and suppliers. For example, the Department of Health and Human Services Office of Inspector General (OIG) issued compliance program guidance (CPG) for nursing facilities in 2000 and 2008 that established the OIG's seven basic compliance program elements and identified particular areas of significant risk for LTC providers.² Other examples of the OIG's emphasis on developing a "culture of compliance" can be found throughout the relevant advisory opinions, settlement agreements and public policy statements.

Until recently, the OIG's recommendations for maintaining a corporate compliance program were simply that – recommendations. Section 6102 of the Affordable Care Act (ACA) changed that paradigm, however, by requiring all skilled nursing facilities (SNFs) to develop and implement an effective compliance and ethics program within three years of the ACA's enactment.³ The ACA also required the Secretary of the Department of Health and Human Services (DHHS) to work with the OIG to promulgate regulations for implementing that statutory mandate. Although slightly overdue, the proposed requirement to develop and maintain an effective compliance and ethics program represents the agency's initial attempt at implementing the ACA requirements.

Again, CMS's proposed revisions to the conditions for participation in Medicare and Medicaid would require every LTC facility operator to have a compliance and ethics program in place one year after adoption of the final rule. In addition, every facility's compliance and ethics program would have to include certain specified components drawn largely from the OIG's existing CPG. These program components include:

- The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that cover topics such as reporting suspected violations.
- The assignment of high-level personnel to oversee the compliance and ethics program.
- Communication of the written compliance standards, policies and procedures to the facility's staff, contractors and volunteers.
- Enforcement of the standards, policies and procedures through consistent disciplinary mechanisms.
- Performance of an annual program review in order to update as indicated by changes in applicable laws and regulations.

In addition, operators that have five or more LTC facilities would be required to:

- Conduct a mandatory compliance and ethics training program on an annual basis.
- Designate a compliance officer for whom the compliance and ethics program is a "major responsibility."

- Designate a compliance liaison at each of the operator's facilities.

The costs to implement the proposed rule are expected to be significant. Not only would larger operators be required to prepare an extensive, formal compliance program and designate a compliance officer and compliance liaisons at each facility, but CMS estimates that the new program requirements will cost LTC facilities (collectively) well over \$100 million per year.

Comments to the proposed rule were due to CMS by October 14. Baker Donelson's Long Term Care Industry Service Team will be monitoring these developments closely in the weeks and months ahead.

¹ See generally CMS, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities; Proposed Rule, 80 Fed. Reg. 42168 (Jul. 16, 2015).

² See OIG, Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56832 (Sept. 30, 2008), available at <http://oig.hhs.gov/compliance/compliance-guidance/index.asp> (last visited Oct. 22, 2015); OIG, Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14289 (Mar. 16, 2000), available at <http://oig.hhs.gov/compliance/compliance-guidance/index.asp> (last visited Oct. 22, 2015).

³ See 42 U.S.C. § 1320a-7j(b).