

Post-Acute Care Compliance

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Are long-term care facilities ready to have an effective compliance program?

On November 28, 2016, the Centers for Medicare & Medicaid Services (CMS) implemented the Final Rule, *Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*, outlining the requirements that long-term care facilities must meet as a Condition of Participation (CoP).¹ The implementation timeframes were broken out into three phases. The third phase of that rule was required to be implemented by November 28, 2019; however, on July 22, 2019, CMS announced a Proposed Rule to amend the 2016 Final Rule to relax or eliminate some of the requirements, titled *Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency*. If finalized, CMS' Proposed Rule may include a one-year extension on the implementation timeframe of certain phase three provisions, including the Compliance and Ethics Program requirements (§483.85). Comments to the Proposed Rule are due no later than September 16, 2019.

While the proposed changes to the Final Rule include additional information, the complexity of the Compliance and Ethics Program requirement deserves some special attention. CMS stated its intent was to “reduce a majority of the burden currently required under the compliance and ethics program that are not required in the statute because [CMS] believe[s] that the SNF and NF CoPs would have the appropriate safety and quality standards to support the compliance and ethics requirements with the proposed changes.”

The good news is that, for the most part, the 2019 Proposed Rule remains aligned with the 2016 Final Rule and more properly aligns LTC CoP Compliance Program requirements with the intentionally vague and less prescriptive language published by the Department of Health and Human Services' Office of the Inspector General (OIG), Department of Justice,

¹ 42 CFR §483: a “long-term care facility” means a skilled nursing facility (SNF) that meets the requirements of §§ 1819(a), (b), (c), and (d) of the Social Security Act, or a nursing facility (NF) that meets the requirements of §§ 1919(a), (b), (c), and (d) of the Act. For Medicare and Medicaid purposes, the “facility” is always the entity that participates in the program, whether that entity is comprised of all of, or a distinct part of, a larger institution.

and Federal Sentencing Guidelines to describe the elements of an effective compliance program.

Additionally, while the 2016 Final Rule referenced it in the comments, the Proposed Rule specifically directs the reader to the OIG March 16, 2000, (65 FR 14289) guidance, titled *Publication Of The OIG Compliance Program Guidance For Nursing Facilities*, and the September 30, 2008, (73 FR 56832) guidance, *OIG Supplemental Compliance Program Guidance For Nursing Facilities*. This is further confirmation that the OIG Compliance Program Guidance can be used as a guide in evaluating the effectiveness of your compliance program.

What Is the Net Effect of the Proposed Compliance Program Changes to Long-Term Care Facilities?

For those who have already implemented their compliance and ethics program to meet the 2016 Final Rule requirements in anticipation of the November 28, 2019, deadline, wait to see whether this new Proposed Rule becomes final before making any changes, keeping in mind to eliminate any potential gaps between your program and the OIG Guidance for Nursing Facilities. The Compliance Program requirements, as described in the CMS 2016 Final Rule (with the inclusion of the OIG Guidance), would align to, or exceed, the 2019 Proposed Rule compliance requirements.

For others who are a bit behind or found the requirements for an executive- or board-level compliance officer and compliance liaisons or frequency of mandatory program reviews overwhelming, they may get lucky and gain relief from those requirements and a potential one-year reprieve if the Proposed Rule becomes final. However, it is clear that whether the deadline to implement an effective compliance program is in 2019 or 2020, you will need to ensure that your organization:

- Complies with all seven elements as referenced in the OIG and CMS Guidance;
- Focuses training and compliance efforts to the entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles; and
- Incorporates compliance training, monitoring and auditing efforts that include, at minimum, the high-risk areas called out by the OIG in its various publications.

The OIG Seven Elements of an Effective Compliance Program for Nursing Facilities include:

1. Designation of a compliance officer and compliance committee;
2. Development of compliance policies and procedures, including standards of conduct;
3. Developing open lines of communication, including an anonymous reporting line;
4. Appropriate training and education/teaching;
5. Internal monitoring and auditing;
6. Response to detected deficiencies; and
7. Enforcement of disciplinary standards.

In their Compliance Guidance, the OIG specifically identified Fraud and Abuse Risk Areas within Nursing Facilities that you should pay particular attention to, along with updated OIG Work Plan Items, when developing your compliance risk assessments and your auditing and monitoring work plans. Those areas include, but are not limited to:

- Quality of care and other risk areas;
- Billing, coding and cost reporting/submission of accurate claims;
- Federal Anti-Kickback Statute;
- HIPAA Privacy and Security Rules;
- Residents' rights;
- Vendor relationships;
- Recordkeeping and documentation;
- Physician self-referrals;
- Anti-supplementation;
- Medicare Part D; and
- Involuntary transfers and discharge (OIG Work Plan, June 2019).

It is also advisable to include any other known compliance risk within the organization discovered through auditing, monitoring, and/or internal or external reporting to meet elements 5 and 6 above. Furthermore, ensuring you've conducted a risk assessment, which is often referred to as the eighth element of an effective compliance program, is also a worthwhile exercise to set your program priorities.

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