



Compliance and Ethics Programs in Nursing Facilities: Overcoming Policy Uncertainty and Logistical Challenges to Build an Effective Program

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Federal Medicare regulations define a nursing facility compliance and ethics program as one that “has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations . . . and in promoting quality of care.”¹ As a sector, the nursing facility industry² faces distinct challenges in implementing compliance programs. Like hospitals and health systems, nursing facilities serve vulnerable populations with acute needs, and they navigate a wide-ranging set of linked state and federal rules (“requirements of participation”) to obtain and retain their certification to participate in Medicare and Medicaid. Like hospitals, health systems, and other institutional providers, nursing facilities are paid by Medicare under complex consolidated billing methodologies. But many nursing facilities operate on leaner margins than other health care institutions.³ Developing and implementing a compliance and ethics program means accounting for myriad risk areas and doing so in a cost-effective manner.

The relatively recent shifting federal regulatory landscape may have complicated the implementation of compliance programs for nursing facilities, but this is not a new concept for the industry. Almost two decades ago, in 2000, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued voluntary compliance program guidance

for nursing facilities.⁴ The Patient Protection and Affordable Care Act (ACA) of 2010 added to federal law a requirement that nursing facilities implement a compliance and ethics program.⁵ The Centers for Medicare & Medicaid Services (CMS) implemented the ACA requirement in CMS’ comprehensive 2016 overhaul of the long term care Conditions of Participation for Medicare and Medicaid, including changing the designation from Conditions of Participation to Requirements of Participation (RoP)⁶ (2016 RoP regulations). But as the nursing facility industry prepared for a November 2019 deadline to implement the compliance program requirements in the RoP regulations, CMS issued a proposed rule that if finalized, would have significantly reduced the requirements, as well as delayed their implementation for another year.

This article provides a historical perspective on this issue, and then reviews the major required components of a nursing facility compliance and ethics program under the 2016 RoP regulations, as well as CMS’ proposed revisions to those requirements. It also offers guidance on general principles for compliance and ethics program implementation, derived from experience working with providers across a variety of sectors, emphasizing ways that nursing facilities can implement an effective program (or expand an existing program) in a cost-efficient manner.

Historical Perspective: Compliance Programs for Long Term Care Entities

In 2000, OIG published voluntary compliance program guidance for nursing facilities (Compliance Program Guidance (CPG)).⁷ The guidance for nursing facilities was part of an OIG initiative to encourage various health care entities (hospitals, home health agencies, hospices, individual and small group physician practices, and others) to develop compliance programs to identify and prevent fraud and abuse. Each CPG identified the elements of a compliance program and compliance risk areas for the specific industry. While the CPGs did not create a mandatory compliance program requirement, many entities developed compliance programs in response to the OIG's guidance, to reduce the risk of unlawful or improper conduct and to mitigate civil penalties and potentially avoid criminal penalties by demonstrating that they had developed an effective compliance program.

In 2008, the OIG issued a supplemental guidance for nursing facilities (Supplemental Guidance)⁸ in response to changes in the nursing facility industry, including changes in care delivery, reimbursement, and federal enforcement priorities. In the Supplemental Guidance, the OIG stated that nursing facilities should “identify and focus their compliance efforts on those risk areas of potential concern or risk that are most relevant to their organizations.”⁹ In the Supplemental Guidance, OIG identified quality of care, submission of accurate claims, and potential violations of the Anti-Kickback Statute in referral and contracting arrangements as key risk areas. Neither the CPG nor the Supplemental Guidance was incorporated into the conditions of participation or conditions of payment for the Medicare or Medicaid programs at that time. As such, adoption or implementation of compliance programs was not widespread throughout the industry at that time, despite the guidance.

In the ACA, Congress added a requirement to the law that nursing facilities, within three years after the law's enactment, have in operation a compliance and ethics program “that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care . . .”¹⁰ The law required HHS to promulgate regulations for an effective compliance and ethics program within two years after the law's enactment.

Requirements for Nursing Facility Compliance Programs in the 2016 RoP Regulations

CMS' sweeping changes in 2016 to the RoP regulations, published on October 4, 2016, constituted the first major revision of those rules since 1991. In addition to generally updating the long term care RoPs to reflect advances in the delivery of care since 1991, the 2016 regulations implemented statutory mandates of the ACA and the Improving Medicare Post-Acute Care Transformation (IMPACT) Act.¹¹ One of the most important statutory changes the 2016 RoP regulations implemented was the requirement in ACA § 6201 (Social Security Act § 1128I) mandating nursing facility compliance and ethics program.

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In response to commenters' concerns about the financial and logistical burdens associated with carrying out the wide-ranging changes to the RoPs, CMS implemented the 2016 regulations in three phases, with Phase 1 regulations taking effect on November 28, 2016; Phase 2 regulations, on November 28, 2017; and Phase 3 regulations, on November 28, 2019.¹² The requirement for the operating organization for each facility to “develop, implement, and maintain an effective compliance and ethics program” was included in the Phase 3 regulations.¹³

Under the regulations, “compliance and ethics program” means, with respect to a facility, a program of the operating organization that—(1) has been reasonably designed, implemented and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and (2) includes, at a minimum, the required components specified under paragraph (c) of this section.¹⁴

Accordingly, surveyors are now trained and have tools to assess whether nursing facilities are properly implementing and following a compliance and ethics program.

The 2016 RoP regulation articulates that the operating organization¹⁵ for each facility must develop, implement, and maintain an effective compliance and ethics program that has, at a minimum, the following components, which substantially restate the requirements in the ACA:¹⁶

- » 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 the 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.¹⁷
- » 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.¹⁸

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- » Sufficient resources and authority for the specific individuals designated to reasonably assure compliance with such standards, policies and procedures.¹⁹
- » Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known, through exercise of due diligence, had a propensity to engage in criminal, civil and administrative violations under the Social Security Act.²⁰
- » Effective communication of 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 42 C.F.R. § 483.95(f) or orientation programs or disseminating information that explains in a practical manner what is required under the program.²¹
- » 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.²²
- » 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.²³
- » 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.²⁴

The 2016 RoP regulations imposed additional compliance program requirements for operating organizations with five or

more facilities. Notably, Social Security Act § 1128I, as amended by the ACA, specifically contemplated the use of more stringent requirements for organizations with five or more facilities, providing that "larger organizations should have a more formal program."²⁵ The additional requirements are the following:

- » A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in § 483.95(f).²⁶
- » 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.²⁷
- » Designated compliance liaisons located at each of the operating organization's facilities.²⁸

As a final requirement under the regulations, the operating organization for each facility is required to 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.²⁹

Proposal to Scale Back the Requirements: July 2019 CMS Proposed Rule

Just as the nursing facility industry braced for the final implementation date of these regulations and began to ensure compliance by November 2019, CMS issued a proposed rule that would significantly revise the 2016 RoP regulation, even before the implementation of the compliance program mandate.³⁰ Specifically, CMS "identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans and states could use to improve and enhance resident health and safety."³¹ As to the implementation of compliance and ethics programs, CMS proposed to "reduce a majority of the burden currently required under the compliance and ethics program that are not required by statute because we believe that the SNF and NF Conditions of Participation would have the appropriate safety and quality standards to support the compliance and ethical requirements with the proposed changes."³²

Based on these considerations, CMS proposed the following changes to the original 2016 RoP regulations:

- » Remove the requirement that each facility designate a compliance officer and a designated compliance liaison for operating organizations with five or more facilities. Instead, such organizations would be required to develop a compliance and ethics program that is appropriate for the complexity of the organization and its facilities and each facility would be required to assign a specific individual within the high-level personnel of the operating organization with the overall responsibility to oversee compliance.³³

- » Remove the annual review requirement and propose that each organization undertake a periodic assessment of its compliance program to identify any necessary changes.³⁴
- » Eliminate the requirement for a “compliance and ethics contact person” to which individuals may report suspected violations. Nursing facilities would no longer be required to specify a designated staff person, but they would nonetheless be required to have a process for reporting, and someone responsible for that process. Note that the facility would still be required to have an alternative method of reporting that allows for anonymous reporting.³⁵
- » Remove the specific language in 42 C.F.R. § 483.85(c)(2) requiring that specific high-level personnel within the organization, “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,” be assigned to oversee compliance with the program’s standards, policies, and procedures. Instead of this prescriptive language, CMS proposed more generally to hold facilities responsible for the effective operation of their compliance programs.³⁶

CMS also proposed to delay the implementation of the compliance program requirements by one year after the date of finalization of the regulation.³⁷ The comment period for the proposed rule closed on September 16, 2019. The Phase 3 regulations took effect on November 28, 2019, and as of this writing, the final rule scaling back the compliance program requirements and delaying their implementation has not been issued. Therefore, long term care facilities are currently bound by the original compliance program requirements that were set forth in the 2016 final rule.

For those used to working with other types of health care facilities, these requirements on their face are similar to those already in place in other industries, but as everyone in the nursing facility industry knows, nursing facilities are different. As a result, the nursing facility industry has been struggling to implement these requirements. There are still a significant number of hoops that nursing facilities will have to navigate to achieve full compliance with these requirements, even if CMS’ proposal to scale back the rules is ultimately finalized.

The organization should develop policies and procedures for the organization’s key risk areas, including quality of care, residents’ rights, billing and cost reporting, employee screening, and kickbacks, inducements, and self-referrals.

Developing and Implementing a Compliance Program

A compliance program, whether required by regulation or recommended as a best practice, helps organizations to identify, prioritize, and respond to risks, including financial risks (fraud and abuse), legal risks (compliance with applicable laws and regulations), and operational risks (inadequate or failed internal processes, people, or systems).

Nursing facilities struggling with developing a compliance program, or with expanding an existing program to include all required components, should focus on addressing their highest-risk areas first. Below are suggestions for developing and implementing a compliance program.

First, organizations should delegate compliance responsibility effectively, and devote appropriate resources to the program. If the organization is considering appointing a current employee to oversee the compliance program, it should consider individuals who are familiar with the organization’s key risk areas (billing, coding, privacy), and who have a reputation for fairness, honesty, and prompt and thorough response to identified issues. It should consider which of the employee’s current duties will be reassigned to provide time for the employee to provide day-to-day oversight of the compliance program.

If, on the other hand, the organization is considering hiring a new employee to oversee the compliance program, organizational leadership should consider what substantive knowledge and “soft skills” the individual must have. Candidates for the position should have an opportunity to meet with senior managers, as well as the CEO, as much of the individual’s work will entail working closely with senior managers.

As for allocation of appropriate resources, the organization should ensure that the the compliance function has dotted-line access to the Board of Directors, reports to the CEO (or designee), and has regular access to senior managers and other employees. The organization should also make sure that senior managers understand that they are responsible for ensuring compliance in their departments, developing meaningful internal audits to measure compliance, and responding to/reporting compliance issues. Senior managers should know that appointing or hiring an individual to oversee the compliance program does not lessen their responsibility for compliance. The organization should consider establishing a staff-level Compliance Committee to identify compliance risks throughout the organization and to assist in implementing a compliance program.

Second, the organization should develop effective written policies and procedures. Compliance-related policies and procedures (including the Code of Conduct) should apply to all individuals affiliated with the organization, including employees, Board members, volunteers, contract providers, etc. The policies and procedures should clearly detail compliance program operations. For example, how should questions and issues be reported and to whom? What are the disciplinary policies related to noncompliance? The policies and procedures should clearly delineate the expectations related to compliance (including reporting compliance issues, training requirements, and participation in compliance investigations).

The organization should develop policies and procedures for the organization's key risk areas, including quality of care, residents' rights, billing and cost reporting, employee screening, and kickbacks, inducements, and self-referrals. The CPG and Supplemental Guidance provide useful guidance on these topics. In identifying risk areas and updating policies and procedures, attention should be paid to areas where the 2016 RoP regulations imposed significant new requirements (for example, comprehensive person-centered care planning, infection control).

In determining what new policies and procedures are needed in each area, the organization should consider whether someone would be able to perform a job in that area in the nursing facility in compliance with applicable laws and regulations based on the available existing written policies and procedures. If not, additional policies, procedures, checklists, etc. may be needed. Also, the organization should consider developing *additional* policies, procedures, and checklists for those working in positions known to be more high risk—for example, documentation, coding, and contracting positions. Based on all these factors, there is no “one-size-fits-all” when developing compliance policies and procedures. Each must be tailored for the specific needs of the given facility and its staff. Regulators will not deem “cookie cutter” policies and procedures sufficient if they are not specifically designed to address the facility's circumstances, including the changes made to the programs as issues have come up and been addressed.

The organization should develop a system to document that affected individuals have received, understand, and agree to comply with the applicable policies and procedures. It should determine how frequently policies and procedures will be reviewed, revised, and distributed to affected individuals.

Third, the organization should develop an effective training program surrounding its compliance program. An organizational training plan should be developed that identifies new employee and annual compliance training requirements, including:

- » General compliance trainings (for all individuals affiliated with the nursing facility) on the compliance program (operations and expectations) and on applicable laws and regulations (False Claims Act, Anti-Kickback Statute)
- » Specific compliance trainings based upon job responsibilities. The staff-level Compliance Committee and/or Senior Management Team can identify positions that would benefit from additional compliance training.

Targeted compliance training should be included in any corrective action following an identified compliance issue.

For training to be effective, the organization should determine the format for compliance training (for example, in person, online learning management system, or written publications). For each format, the organization should consider how knowledge will be assessed and documented (pre- and post-quizzes, discussion of case studies, etc.). The organization should specify which trainings are mandatory and determine how the organization will respond to employees who fail to complete mandatory trainings. Managers should be made aware that they are responsible for ensuring that their employees complete mandatory trainings and are notified of

the expectations when an employee is non-compliant.

Fourth, the organization should focus on developing effective lines of communication. Organizational policies and procedures should explain how employees may report compliance concerns (for example, through the chain of command, versus directly to the Compliance Officer), and how managers should report employee concerns to the Compliance Officer. The organization should develop anonymous and confidential means for reporting, ensuring that anonymous reporting systems do not permit identification (through call logs, camera monitoring of drop boxes, etc.), and that the limits to confidential reporting are clear. For example, in some instances, an individual's identity must be disclosed for purposes of the investigation, including reporting to law enforcement.

The organization should encourage regular communication about and reporting on compliance by the Compliance Officer to employees, senior management, and the Board.

Reported or discovered compliance issues should be documented, steps taken to investigate, and corrective action implemented.

Fifth, the organization should implement self-audit and monitoring protocols. A risk assessment should be conducted to identify the organization's key risk areas. The organization should develop a compliance work plan to address the identified risks. Then, the organization should conduct internal auditing to ensure that compliance “fixes” are still working. For example, is documentation still accurate or have bad habits returned? Is the license expiration spreadsheet up to date, or has this expectation not been communicated to the new HR employee? Audits can help to identify any potential problem areas, patterns, or “hot-spots” of non-compliance in the facility that might need to be addressed through action or additional training.

Audits and monitoring should be meaningful. If the nursing facility or a component department scores perfectly in an internal audit or monitoring activity for six months in a row, consider moving to quarterly audits (then bi-annual, then annual), and adding a new risk-based audit to the organization's compliance work plan.


Sixth, the organization should enforce standards through well-publicized disciplinary policies. Compliance-related examples, as well as clarification that compliance program violations can lead to immediate termination and referral to law enforcement, should be added to the organization's disciplinary policies, when applicable. The policies should clarify that sanctions may apply for failing to report compliance issues, for participation in non-compliant behavior, or (especially relevant for managers) for permitting non-compliant behavior.

From time to time, the organization should conduct an internal audit of personnel records to ensure compliance-related discipline is fair and equitable across the organization (including appropriate discipline for senior managers).

Finally, the organization should respond to detected offenses.

Reported or discovered compliance issues should be documented, steps taken to investigate, and corrective action implemented. The nursing facility should identify trends by department/risk area (coding, billing) and employee type (providers, medical assistants, case managers). The organization should develop compliance work plan activities to assess and respond to related risks.

Conclusion

In our experience, effective compliance programs can be implemented by a wide range of health care organization types, from independent nonprofit providers to large systems. What is important is not having unlimited resources to devote to the endeavor, but instead, harnessing existing resources effectively. As nursing facilities prepare for the implementation of a compliance and ethics program requirement in the RoP regulations, they should ensure that compliance standards are meaningfully enforced through clear policies, effective training, rigorous self-monitoring, and disciplinary and corrective action measures that analyze why the issue arose, modify the policies, as necessary, and implement measures to prevent issues from recurring. 

Endnotes

- 1 42 C.F.R. § 483.85(a).
- 2 The term “nursing facility” is used here to refer collectively to skilled nursing facilities (SNFs) (Medicare-certified facilities that provide extended skilled nursing or rehabilitative care under Medicare Part A) and nursing facilities (NF) (Medicaid-certified facilities). SNFs and NFs are also referred to collectively as “long-term care facilities.”
- 3 Per the Medicare Payment Advisory Commission (MedPAC), “Total margins for nursing homes across all lines of business and all patients are modest and have ranged between 0.6 percent and 3.8 percent since 2001.” MedPAC, *Report to the Congress: Medicare Payment Policy*, p. 208 (Mar. 2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf.
- 4 See OIG, Notice, 65 Fed. Reg. 14289 (Mar. 16, 2000); see also OIG, OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56832 (Sept. 30, 2008).
- 5 Patient Protection and Affordable Care Act (ACA) § 6102, Pub. L. No. 111-48, adding Social Security Act § 1128I.
- 6 See discussion at 81 Fed. Reg. 68693.
- 7 See 65 Fed. Reg. 14289.
- 8 See 73 Fed. Reg. 56832.
- 9 73 Fed. Reg. 56834.
- 10 ACA § 6102, Pub. L. No. 111-48, adding Social Security Act § 1128I(b)(1).
- 11 CMS, Final Rule, Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688 (Oct. 4, 2016).
- 12 81 Fed. Reg. at 68696.
- 13 42 C.F.R. § 483.85.
- 14 See 42 C.F.R. § 483.85(a)(1) and (a)(2).
- 15 Operating Organization means the individual or entity that operates a facility. 42 C.F.R. § 483.85(a)(2).
- 16 42 C.F.R. § 483.85(b).
- 17 42 C.F.R. § 483.85(c)(1).
- 18 42 C.F.R. § 483.85(c)(2).
- 19 42 C.F.R. § 483.85(c)(3).
- 20 42 C.F.R. § 483.85(c)(4).
- 21 42 C.F.R. § 483.85(c)(5).
- 22 42 C.F.R. § 483.85(c)(6).
- 23 42 C.F.R. § 483.85(c)(7).
- 24 42 C.F.R. § 483.85(c)(8).
- 25 Social Security Act § 1128I(b)(2)(B).
- 26 42 C.F.R. § 483.85(d)(1).
- 27 42 C.F.R. § 483.85(d)(2).

28 42 C.F.R. § 483.85(d)(3).

29 42 C.F.R. § 483.85(e).

30 CMS, Proposed Rule, Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities, 84 Fed. Reg. 34,737 (July 18, 2019).

31 *Id.*

32 *Id.* at 34747.

33 *Id.*

34 *Id.*

35 42 C.F.R. § 483.85(d)(2).

36 84 Fed. Reg. at 34747.

37 84 Fed. Reg. at 34752.



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