



483.85 Compliance and Ethics Program



Phase 3 Requirements

Division of Nursing Homes

Welcome, today we will discuss the new Compliance and Ethics Program guidance for the requirements in §483.85.

Overview

- New Compliance and Ethics Program requirements in F895
- Intent and definitions
- Requirements for all facilities and additional requirements for operating organizations with five or more facilities
- Questions surveyors should consider when investigating F895
- Potential tags for additional consideration
- Compliance and Ethics training requirements

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Specifically, we will review the requirements of new F-tag F895 for the Compliance and Ethics Program, we will also review the intent of these requirements, pertinent definitions, requirements that apply to all facilities as well as additional requirements that apply to operating organizations with 5 or more facilities, investigative procedures for surveyors and training requirements.

Compliance and Ethics Program - Intent

To ensure that facilities have in operation an effective compliance and ethics program that uses internal controls to more efficiently monitor adherence to applicable statutes, regulations and program requirements to deter criminal, civil and administrative violations and promote quality of care for nursing home residents.

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The intent of the new compliance and ethics program requirements at F895 is to ensure the facility has an effective system to deter any criminal, civil and administrative violations, which ultimately promotes the quality of care for nursing home residents.

On March 16, 2000, the Department of Health and Human Services, Office of the Inspector General also known as OIG, released Compliance Program Guidance for Nursing Facilities to promote “a higher level of ethical and lawful conduct throughout the entire health care industry”. The OIG previously issued guidance for other segments of the health care industry based on the belief that “a health care provider can use internal controls to more efficiently monitor adherence to applicable statutes, regulations, and program requirements.” This guidance also provided the basis for the Patient Protection and Affordable Care Act which amended a section of the Social Security requiring Medicare skilled nursing facilities and Medicaid nursing facilities to have a compliance and ethics program. The OIG guidance recommended seven elements which should be included in an effective, comprehensive compliance and ethics program:

1. Implementing written policies, procedures and standards of conduct
2. Designation of a compliance officer and compliance committee
3. Conducting effective training and education
4. Developing effective lines of communication
5. Enforcing standards through well-publicized disciplinary guidelines

6. Conducting internal monitoring and auditing
7. Responding promptly to detected violations and corrective action

There are a number of common risk areas which are mostly associated with the delivery of health care to nursing facility residents. Some of them include sufficient staffing, comprehensive care plans, medication management, infection prevention, appropriate use of psychotropic medications and resident abuse, neglect and safety.

Additional risk areas include resident rights, fraud prevention, billing and cost reporting, employee screening, resident assessment accuracy, creation and retention of records, falsification and modification of documentation, conflicts of interest, kickbacks, inducements and self-referrals.

Regulatory Definitions

High-level personnel - an individual(s) who has substantial control over the operating organization or who has a substantial role in the making of policy within the operating organization.

Operating organization - the individual(s) or entity that operates a facility

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In the requirements, there are two specific regulatory definitions we want to highlight. The first is high level personnel which is the person or people who have substantial control over the organization or who has a substantial role in making policies in the operating organization.

The second definition clarifies that an operating organization is one or more individuals or entity that operates a facility.

Requirements for All Facilities

- §483.85(c) Required components for all facilities.
The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

The operating organization of each facility must have a compliance and ethics program that has been reasonably designed, implemented, maintained and enforced, so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Social Security Act and in promoting quality of care.

It is important for the facility to consider their facility assessment developed according to §483.70(e) in identifying risk areas, developing and maintaining their compliance and ethics program, and determining resources needed for the program.

Next we will discuss the required components.

Requirements for All Facilities

- §483.85(c)(1) 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 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.

The operating organization must have written standards, policies and procedures for its compliance and ethics program, which include at a minimum:

- Designation of an appropriate compliance and ethics program contact to whom an individual can report suspected violations;
- An alternate method of reporting suspected violations anonymously without fear of retribution; and
- Disciplinary standards that describe the consequences for committing violations for the entire staff.

Requirements for All Facilities

- §483.85(c)(2) 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.
- §483.85(c)(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

The operating organization must assign specific individuals within the high-level personnel of the organization with the overall responsibility of overseeing adherence to the compliance and ethics program's standards, policies, and procedures.

High-level personnel means individuals who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization. The individuals considered "high-level personnel" will differ according to each operating organization's structure. Some examples include,, a director; executive officers including the chief executive officer; members of the board of directors; an individual in charge of a major business or functional unit of the operating organization; or an individual with a substantial ownership interest in the operating organization.

The program must also include provisions ensuring that the specific individual designated with oversight responsibility has sufficient resources and authority to assure compliance with program standards, policies, and procedures. The resources devoted should include both human and financial resources.

Requirements for All Facilities

- §483.85(c)(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.
- §483.85(c)(5) The facility takes steps to effectively communicate 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 §483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

Organizations must exercise the care that a reasonable person would use under the same circumstances when delegating substantial discretionary authority to individuals, to ensure that the delegation is not made to an individual who the operating organization knew, or should have known, through the exercise of due diligence, had engaged in or had the predisposition to engage in unethical acts, or potential criminal, civil and/or administrative violations of the Act.

The facility is also required to effectively communicate to the entire staff, the standards, policies and procedures of the compliance and ethics program. Requirements include, mandatory participation in training, orientation programs, and/or dissemination of information that explains what is required under the program, in a practical manner.

Requirements for All Facilities

- §483.85(c)(6) 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.

Under 483.85(c)(6),

The facility must take reasonable steps to achieve compliance with the program's standards, policies and procedures. These steps include:

- Utilizing monitoring and auditing systems to detect criminal, civil, and administrative violations under the Social Security Act, by any of the facility's staff.
- Publicizing a reporting system whereby any of the organization's entire staff could report violations anonymously within the operating organization without fear of retaliation, and
- Having a process for ensuring the integrity of any reported data.

Requirements for All Facilities

- §483.85(c)(7) 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.

The compliance and ethics program must establish appropriate disciplinary mechanisms and effectively communicate those mechanisms, so that the operating organization's entire staff is clearly aware of the consequences of program violations.

The operating organization is required to consistently enforce its standards, policies, and procedures through appropriate disciplinary mechanisms which may include, discipline of individuals who fail to detect and report a violation to the appropriate party identified in the organization's compliance and ethics program.

Requirements for All Facilities

- §483.85(c)(8) 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.

After an operating organization detects a violation, it must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations. This includes any necessary modification to the organization's program.

The program should clearly identify the reasonable steps to take when a violation is detected. Such steps may include a corrective action plan, the return of overpayments, a report to the government and/or or a referral to criminal and/or civil law enforcement authorities. The steps will differ depending upon the size of the operating organization, the position of the individual reporting the violation, and the type of violation. For example, an operating organization's program may state that a staff member should immediately notify their immediate superior when he or she detects a violation. However, if it is the immediate superior or the operating organization's management whom the staff member believes is committing the violation, the staff member should have an alternative process to report the violation, such as, an executive officer of the organization, the Office of the State Long-Term Care Ombudsman or other appropriate agency or law enforcement authority.

Facilities should integrate the information and data from their compliance and ethics programs into their Quality Assurance and Performance Improvement, also known as QAPI

program. The QAPI committee should work with the compliance officer to determine if there are trends or patterns of systemic problems.

Requirements for All Facilities

- §483.85(e) Annual review.

The operating organization for each facility must 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.

The operating organization for each facility must review its compliance and ethics annually.

Additionally, as an operating organization becomes aware of changes in laws or requirements, it should modify its program to ensure it is current with requirements.

The operating organization's performance in prior years should also be used to improve its program. As an operating organization revises its program, it should ensure that those changes are communicated to its entire staff.

Additional Requirements for Operating Organizations with Five or more Facilities

- §483.85(d) Additional required components for operating organizations with five or more facilities. In addition to all of the other requirements in paragraphs (a), (b), (c), and (e) of this section, operating organizations that operate five or more facilities must also include, at a minimum, the following components in their compliance and ethics program:
- §483.85(d)(1) A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in §483.95(f).

There are additional requirements for operating organizations with five or more facilities.

These organizations must have a more formal compliance and ethics program that includes written policies which define the standards and procedures their employees must follow; and

They must develop a compliance and ethics program that is appropriate for the complexity of their organization and the facilities they operate.

Additionally, operating organizations with five or more facilities must have a mandatory annual training program. The annual training should be delivered in a practical manner based on its resources, the complexity of the operating organization and its facilities and in accordance with compliance and ethics training requirements found at F946.

Additional Requirements for Operating Organizations with Five or more Facilities

- §483.85(d)(2) 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.
- §483.85(d)(3) Designated compliance liaisons located at each of the operating organization's facilities.

Operating organizations with 5 or more facilities must designate a compliance officer for whom the compliance and ethics program is a major responsibility.

The operating organization should ensure that the assigned compliance officer has sufficient time and other resources to fulfill all of his or her responsibilities under the operating organization's compliance and ethics program.

The compliance officer should be able to communicate with the governing body without being subject to any coercion or intimidation. This ensures that the compliance officer is not unduly influenced by other managers or executive officers, such as the general counsel, chief financial officer or chief operating officer.

Additionally, the designated compliance liaison must be located at each of the operating organization's facilities. At a minimum, the facility-based liaison should be responsible for assisting the compliance officer with his or her duties under the operating organization's program at their individual facilities.

Questions Surveyors Should Consider

- When investigating concerns related to a criminal, civil and administrative violation in the facility, surveyors should review the facility's written standards, policies and procedures for the compliance and ethics program and interview high-level personnel, who are designated to oversee the program and staff.
- The guidance also contains probes in F895 to consider during investigation and when making compliance determinations. Examples include:
 - When reports or reasonable suspicions of violations are identified, did the organization take prompt action to respond to the violations and prevent further occurrences?
 - Does the operating organization review the program annually and as needed, and in response to organization, facility and/or regulatory changes?

When investigating concerns related to a criminal, civil and administrative violation in the facility, surveyors should review the facility's written standards, policies and procedures for the compliance and ethics program and interview high-level personnel, who are designated to oversee the program and staff. The guidance contains probes in F895 to consider during investigation and when making compliance determinations. Some of the probes include:

- Does the operating organization have written standards, policies and procedures for the compliance and ethics program that are reasonably capable of reducing the possibility of criminal, civil and administrative violations under the Act?
- Interview high-level personnel designated to oversee the organization's compliance and ethics program about their involvement in the program to determine:
 - how the facility uses monitoring and auditing systems to detect criminal, civil, and administrative violations by staff;
 - if they are aware of the potential violation under investigation and what was their response.
- Ask staff if :
 - they are aware of the facility's compliance and ethics program;
 - there is a method for staff to anonymously report suspected violations;
 - they are confident in reporting compliance matters without fear of retaliation.
- **If the operating organization has five or more facilities, have a compliance officer and a facility-based compliance liaison been designated?**

Potential Tags for Additional Consideration

If a negative or potentially negative resident outcome is determined to be related to the facility's failure to meet compliance and ethics requirements, it should also be investigated under the appropriate quality of care or other relevant requirement.

For concerns related to systems of care and management practices, written policies and procedures for feedback, data collection systems, monitoring, analyzing and acting on available data to make improvements, see Quality Assurance and Performance Improvement (QAPI) requirements in §483.75.

As part of this training, we want to emphasize that surveyors should always investigate the appropriate quality of care requirements when a determination is made related to the facility's failure to meet the requirements of F895.

In regards to concerns that are related to the facility's systems of care and management practices, written policies and procedures for feedback, data collection systems, monitoring, analyzing and acting on available data, surveyors should also consider the requirements in F867 Quality Assurance and Performance Improvement.

483.95 Training Requirements

F946 Compliance and Ethics Training

- §483.95(f) Compliance and ethics.
The operating organization for each facility must include as part of its compliance and ethics program, as set forth at §483.85—
- §483.95(f)(1) An effective way to communicate the program's standards, policies, and procedures through a training program or in another practical manner which explains the requirements under the program.
- §483.95(f)(2) Annual training if the operating organization operates five or more facilities.

We want to remind you about the Compliance and Ethics Training requirements in F946. Please view the CMS Training presentation and Appendix PP of the SOM for additional information on the training requirements.

Thank You

Thank you for your continued efforts towards our shared goal in providing quality care to America's nursing home residents

Submit questions about §483.85 Compliance and Ethics Program to the DNH Triage mailbox:

DNH_TriageTeam@cms.hhs.gov



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If you have questions about the Compliance and Ethics Program requirements at F895, please send them to the DNH Triage mailbox at: DNH_TriageTeam@cms.hhs.gov

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