📑 HIGHLIGHTS: Overview of Requirements

Under §483.85, facilities are required to develop, implement and maintain a Compliance & Ethics Program (herein known as a C&E Program).

CMS has defined an effective C&E Program as a program that is established by an operating organization 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 under the Act and in promoting quality of care" and includes the minimum required components. An "operating organization" is the individual(s) or entity that operates a facility.

There are eight required components, three additional components for organizations operating five or more facilities, and a required annual review. In addition, training requirements are included under §483.95(f).

📋 REVIEW & ACTION: Compliance and Implementation Checklist

Facilities can use this checklist to ensure their C&E Program has all the required elements. More details are available in the AHCA Compliance and Ethics Implementation Guide.

CMS Requirements	Implementation Strategies	Facility Notes
Establish written compliance and ethics standards, policies and procedures "reasonably capable of" reducing the prospect of criminal, civil and administrative violations and promote quality of care. • Designating an appropriate contact to whom individuals may report suspected violations. • Establishing an alternate method of reporting suspected violations anonymously without fear of retribution. • Disciplinary standards that set out the consequences for committing violations for the entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles	✓ Develop a code of conduct that includes the mission and required elements at §483.85. ✓ Ensure leaders embrace the code of conduct. ✓ Establish a compliance, ethics and resident safety hotline with a toll free number. ✓ Publicize the hotline to all staff, families, residents and contractors. ✓ Respond timely to complaints ✓ Clearly establish discipline for noncompliance.	
Assignment of "high level" individual(s) (e.g., Chief Executive Officer ("CEO"), Board Member, Division Director, etc.) with the overall responsibility to oversee compliance with the C&E Program's standards, policies and procedures.	✓ C&E Program oversight responsibilities should be included in job descriptions and referenced in the C&E Program's core operating documents. ✓ The individual(s) with oversight responsibility should have sufficient authority to provide oversight and support to the C&E Program.	

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Provide sufficient resources and authority to individual(s) overseeing the program to "reasonably assure compliance" with standards, policies and procedures.	✓ Resources devoted should include both human and financial. ✓ Consider facility assessment in in identifying risk areas, developing and maintaining C&E, and determining resources needed for the program. ✓ Facilities should include their C&E Program on their facility assessments because it is likely that the surveyors will look to see if resources are addressed.	
Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.	✓ Document and conduct routine background checks. ✓ Perform and document monthly exclusion screening.	
Effective communication of program standards, policies and procedures to the "entire staff" • 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.	✓ Use your facility assessment to help inform the amount and types of training necessary. ✓ Provide and document mandatory, one-time training for all new and existing staff. ✓ Post your compliance plan or code of conduct on your intranet and internet sites. ✓ Provide copies to vendors/contractors as part of the contracting process and annually thereafter. ✓ Document all training efforts, one time and ongoing.	
Reasonable steps to achieve compliance with the program's standards, policies and procedures, including auditing and monitoring systems, as well as reporting mechanisms and a non-retaliation policy.	✓ Conduct self-assessment or gap analysis to identify risk areas. ✓ Document results in compliance work plan, to be reviewed annually. ✓ Conduct periodic external audits specifically focusing on financial records and quality of care issues.	
Consistent enforcement of the program standards, policies and procedures through appropriate disciplinary mechanisms including, as appropriate, discipline for individual'(s) failure to detect and report a violation to the program contact.	✓ Provide sanctions for failing to report, non-compliant behavior, or encouraging, directing, facilitating or permitting non-compliant. behavior in employee handbook ✓ Require an annual attestation or certification of compliance.	
Ensuring all "reasonable steps" are taken to "respond appropriately" to a violation and to "prevent further similar violations" including any necessary modification to the program.	✓ The C&E Program should explicitly state the expectation that all individuals cooperate with investigation efforts. ✓ Clearly outline the steps taken when a violation is detected. ✓ Identify contingencies for different situations. For example, what to do if	

	the violation is committed by someone identified in the reporting process.	
	✓ Integrate information and data from its compliance and ethics programs into the QAPI program and work together to identify trends or patterns.	
Added Components for Operating Organizations with 5+ Facilities The three added components required of operating organizations with five or more facilities are as follows:		
Conducting annual and mandatory program training that meets the requirements set forth in § 483.95(f).	✓ The annual training program should address all of the components of the C&E Program, as well as policies and procedures unique to the organization. ✓ The annual training program should be reviewed and modified on a regular basis for changes in laws or requirements and the operating organizations performance in prior years. ✓ The operating organization should have a process to ensure those changes are communicated to all staff.	
Designating a compliance officer whose "major responsibility" is to oversee the program, and who reports to the "governing body." Note: The compliance officer cannot be "subordinate to the general counsel, chief financial officer or chief operating officer."	✓ When choosing the compliance officer, the facility should look for someone who has good communication and collaboration skills, as well as an understanding of the organization's operations. ✓ The compliance officer must be both objective and independent. ✓ Consider establishing a compliance and ethics committee to support the compliance and ethics officer and the program.	
Designating a compliance liaison at each of the organization's facilities.	✓ Compliance liaisons should be responsible for assisting the compliance officer with his or her duties under the operating organization's program.	
Annual Review		
The operating organization must also complete an annual review of the compliance and ethics program. The review must 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 improving quality of care. Facilities should make sure to document the annual review, even if no changes or revisions are made.	✓ The program must be modified based on any changes to laws, requirements or the facilities policies ✓ Use past performance to improve its program annually, working with the QAPI committee ✓ Document the annual review, even if changes are not made ✓ Communicate any changes to the entire staff annually	

Training Requirements		
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— • 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. • Annual training if the operating organization operates five or more facilities.	✓ Talk about program issues regularly with staff, contractors and volunteers, and use regular staff meetings as an opportunity to focus on a specific compliance area. ✓ All training should support current scope and standards of practice through curricula which detail learning objectives, performance standards, and evaluation criteria. ✓ Establish a tracking system for all training provided (e.g. in-house, off-site programs, and staff meetings) and who it was provided to.	

Additional Tips:

✓ CMS expects all facilities to take into account their facility assessment to evaluate the needs of their C&E Programs, including identifying risk areas, developing and maintaining the program and determining resources.

✓ The compliance and ethics program should integrate with the Quality Assurance Performance Improvement (QAPI) program.

✓ Be sure facility staff are aware of and can speak to the C&E Program.

RESOURCES: Additional Materials to Help You

For additional information, providers can review these sources:

✓ AHCA Compliance and Ethics Implementation Guide

✓ OIG Compliance Resources: provides support determining best practices, in particular the guidance for nursing facilities published in 2000 and 2008. Specifically, for providers that are now creating their compliance program, the

✓ 2000 OIG Compliance Program Guidance for Nursing Facilities has practical, concrete information about best practices for a compliance program; nursing centers may already be doing many of these items and can repackage existing policies and procedures to demonstrate their program to surveyors.

✓ Measuring Compliance Program Effectiveness: A Resource Guide is another useful tool to help providers assess their program.