# §483.85 Compliance and Ethics Program Implementation Guide

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## BACKGROUND

Medicare and Medicaid participating nursing facilities have been required to have a Compliance and Ethics (C&E) Program since March 23, 2013, under Section 6102 of the Affordable Care Act. However, there was no regulatory mechanism to enforce the requirement until Centers for Medicare and Medicaid Services (CMS) issued the revised Requirements of Participation (ROP) in 2016, which included the requirements for the Compliance and Ethics Program at §483.85.

Due to the pressures of the pandemic, CMS did not publish the Interpretive Guidance for this, and other phase 2 and 3 requirements from the ROPs, until June 29, 2022.

To give providers and surveyors adequate time to train for and implement these changes, CMS has established an effective date of October 24, 2022. This means that starting October 24, 2022, CMS and state survey agencies will be authorized to issue survey deficiencies under federal F-tag F895 to facilities that do not have effective C&E Programs required at §483.85.

This implementation guide is designed to help facilities develop and/or revise their C&E Programs to meet the requirements of the CMS regulations. This guide includes both a high-level overview of the requirements as well as detailed information, resources and strategies for each component of the required C&E Program.

***Important**: Throughout this guide, you will see references to the "entire staff." CMS defines this term in the regulation as, "includes all staff employed by the facility or operating organization, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles."*

Questions? Please contact us at regulatory@ahca.org.

## OVERVIEW OF COMPLIANCE AND ETHICS PROGRAM REQUIREMENTS AT §483.85

CMS has defined an effective Compliance and Ethics Program (herein known as the "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 of a C&E Program, three additional components for organizations operating five or more facilities, and a required annual review. CMS also 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 necessary resources.

### Primary Components

The eight required components of a C&E Program are as follows:

1. Establish written compliance and ethics standards, policies and procedures "reasonably capable of" reducing the prospect of criminal, civil and administrative violations and promoting quality of care.
    a. Designating an appropriate contact to whom individuals may report suspected violations.
    b. Establishing an alternate method of reporting suspected violations anonymously without fear of retribution.
    c. Developing 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.

2. Assignment of "high level" individual(s) (*e.g.*, Chief Executive Officer ("CEO"), Board Member, Division Director, Chief Compliance Officer, etc.) with the overall responsibility to oversee compliance with the C&E Program's standards, policies and procedures.

3. Provide sufficient resources and authority to individual(s) overseeing the program to "reasonably assure compliance" with standards, policies and procedures.

4. Due care[1] 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.

5. Effective communication of program standards, policies and procedures to the "entire staff"
    a. 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.

6. 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.

7. 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.

8. 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.

**Added Components for Operating Organizations with 5+ Facilities**

The three added components required of operating organizations with five or more facilities are as follows:

9. Conducting annual and mandatory program training that meets the requirements set forth in § 483.95(f).

10. 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."*

11. Designating a compliance liaison at each of the organization's facilities.

[1] Due care is defined by CMS as "generally means the care that a reasonable person would use under the same or similar circumstances."

### Annual Review

The operating organization must also complete an annual review of the compliance and ethics program (for those providers with 5 or more facilities). The review must reflect changes in all applicable laws or regulations and efforts 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.

### Compliance and Ethics Program Risk Areas

Importantly, CMS has identified common and additional risk areas associated with the delivery of health care to nursing facility residents that are part of a C&E Program. These should be considered as facilities are developing or reviewing their C&E Program.

This includes:

- sufficient staffing
- comprehensive care plans
- medication management
- infection prevention
- appropriate use of psychotropic medications
- resident abuse and neglect prevention
- resident safety

Additional risk areas identified 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
- self-referrals

*Tip: If you implemented your C&E Program several years ago, revisit your core documents to make sure they address the common risk areas identified above.*

## COMPONENT 1: WRITTEN STANDARDS, POLICIES AND PROCEDURES

**Regulatory language:**

> 42 C.F.R. §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.

**Overview**:

This component requires written standards, policies and procedures, and emphasizes several key elements that CMS expects facilities to include.

- Standards are the compliance rules an organization must follow
- Policies state the actions necessary for implementing the standards
- Procedures describe the process necessary to comply with the standards and policies

Collectively, this is typically called the code of conduct, although CMS does not use that phrase anywhere in the regulations. The code of conduct sets forth the facility's commitment to compliant and ethical behavior, as well as its expectations for staff's interactions with each other, residents, families, agents, vendors and the government.

At its most basic level, the code of conduct should include the organization's mission statement, as well as the eight (or eleven[2]) components with which the facility must comply. It should also provide information on how to identify compliance issues, guidance on how to communicate compliance issues to compliance personnel/hotline and describe how potential compliance problems are investigated and resolved.

Surveyors will ask to see these documents to support that the facility is meeting the requirement at 483.85(c)(1). They will also ask staff about them (including asking if they know how to access the policies and procedures). Think about what the surveyors will be looking for as you draft, review, and disseminate the code of conduct, policies and

[2] For operating organizations with five facilities or more.

procedures. The documents should be written concisely and at a level that all staff can understand. They should be dated, and reviewed annually, with a revision date to demonstrate the required annual review.

Note that this regulation mentions two specific policies and procedures, one related to the reporting of potential compliance issues, the second concerning standards for discipline. These same elements are repeated in the Component 6, Monitoring and Auditing.

**The Reporting System**

It is important to have and publicize a reporting system whereby staff, contractors/agents, volunteers, families and residents can report suspected concerns and violations by others within the organization without fear of retribution. Operating organizations with four or fewer facilities are not required to have designated compliance officers, but all facilities must have a designated contact to whom people can voice concerns. Make sure you designate someone for this role – it may be your grievance official – and publicize how to reach him or her.

Facilities must also have at least one alternative route for people to report complaints/grievances in an anonymous, confidential, and non-retaliatory manner. The reporting mechanisms should be well-publicized.

<u>Implementation Strategies</u>

- ✓ The culture of the organization will dictate the effectiveness of the C&E Program. To foster a strong culture of compliance, organizations should ensure that their leaders embrace and implement a universal non-retaliation policy. A sample is available in the appendix.
- ✓ Consider establishing a compliance, ethics and resident safety hotline with a toll free number, possibly through an external entity. Effective C&E Programs encourage use of hotlines because it demonstrates a commitment to helping employees, contractors/agents, vendors and volunteers “do the right thing.”
- ✓ Make use of intranet, internet, posters, newsletters, and admission packets to promote the reporting systems. Don’t forget to include families and residents, as well as employees, contractors/agents, vendors and volunteers.
- ✓ Consider hanging posters with the compliance hotline near other required postings (such as ombudsman phone numbers).
- ✓ Emphasize that the reporting system can and should be used by employees, contractors/agents and volunteers to raise questions and seek guidance in a proactive and supportive environment. There should be no such thing as a “stupid question.” When in doubt, staff should be encouraged to ask before acting.

- ✓ Respond timely to individuals who voice concerns about compliance, regardless of whether it's a true compliance issue.
- ✓ If using a hotline, periodically test the hotline and maintain a log of all calls so you can demonstrate to surveyors that you have a reporting system in place

**Consistent Disciplinary Standards**

Enforcing consistent disciplinary standards related to the C&E Program requires establishing that the organizations entire staff have received and understood the code of conduct. Surveyors will be looking for evidence that the entire staff is aware of the consequences of program violations. Consider requiring that all individuals receive the code of conduct on hire, upon major update, and annually, and that they attest in writing that they have received, read, and understood its contents. A sample attestation form is provided in Appendix 1.

Implementation Strategies

- ✓ Compliance must be enforced through appropriate discipline, when necessary.
- ✓ Discipline for noncompliance should be clearly set forth in the code of conduct and cross-referenced in applicable employee handbooks and collective bargaining agreements.
- ✓ Discipline policies should include compliance violations as a basis for discipline, up to and including termination.
- ✓ Discipline policies should:
  - Indicate that discipline will be administered for non-compliant activity;
  - Affirm that employees have an obligation to report suspected non-compliance without retribution;
  - Provide an outline of disciplinary procedures;
  - Identify all parties responsible for appropriate action;
  - Commit that discipline will be fair and consistent.
- ✓ Sample disciplinary language is available in the appendix

**Standards, Policies and Procedures**

The code of conduct does not need to contain all the facility's policies and procedures but should contain those that support the C&E Program. They should be readily available to and understood by the entire staff. Remember that it is likely that surveyors will not only ask to see the standards, policies and procedures, but may also ask specific questions about them.

The C&E Program policies and procedures should be supported by other facility-specific policies and procedures for clinical, financial, and administrative functions.

Implementation Strategies

The code of conduct should address the following issues, including quality of care:

- ✓ Mission and Value Statement
- ✓ Commitment to Ethics and Compliance
  - Mechanisms to Report Compliance Concerns
    - Supervisor
    - Compliance Liaison/Designated Person
    - Compliance Officer
    - Hotline
  - Commitment to a non-retaliatory environment
  - Attestation to Compliance
  - Resources for Guidance and Reporting Violations
  - Non-Retribution Policy
  - Internal Investigation of Reports
  - Corrective Action
  - Discipline
  - Internal Audit and Other Monitoring
  - Compliance Team
  - Roles and Responsibilities of High-Level Individual, Compliance Liaison and Compliance Officer
- ✓ Care Excellence
  - Resident Rights
  - Freedom from Abuse and Neglect
  - Reporting Allegations of Abuse, Neglect and Suspected Crimes
  - Resident Confidentiality (HIPAA and HITECH)
  - Providing Quality Care
  - Gifts from and to Residents
  - Facility Licensure and Certification Surveys
- ✓ Professional Excellence
  - Standards and Responsibility
  - Respectful Behavior
  - Hiring and Employment Practices
  - Compliance as an Element of Performance Evaluation
  - Consistent Disciplinary Enforcement
  - Employee, Vendor, Agent and Volunteer Screening
  - Employee Relations/Workplace Safety
  - Drug and Alcohol Abuse
  - Use of Company Property
  - Computers and the Internet
  - Misappropriation or Inappropriate Disclosure of Proprietary Information
  - Vendor Relationships
  - Marketing and Advertising
- ✓ Regulatory Excellence

- Compliance Education and Training
- Compliance with Federal and State Laws
- False Claims Act, 31 U.S.C. § 3729-3733;
- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b);
- Physician Self-Referral Law (Stark Law), 42 U.S.C.§ 1395nn;
- Exclusion Authorities, 42 U.S.C. § 1320a-7; 42 U.S.C. § 1320c-5; 42 CFR pts. 1001 (Medicare) and 1002 (Medicaid);
- Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; 42 CFR pt. 1003;
- Criminal Health Care Fraud Statute, 18 U.S.C. §§ 1347
- Deficit Reduction Act of 2005 – Applicable if facility receives $5 Million in Medicaid funds
- 60-Day Repayment Rule
- Reporting and Repaying Medicare Overpayments
- Billing Practices
- Professional Affiliations, Referrals and Kickbacks
- Business Courtesies
- Conflicts of Interest
- Copyright Laws
- Financial Practices and Controls
- Competitive Practices and Antitrust Laws
- Securities Trading (as applicable)
- Public Filings and Communications
- Government Investigations

## COMPONENT 2: HIGH-LEVEL INDIVIDUAL TO OVERSEE COMPLIANCE PROGRAM

### Regulatory Language

> 42 C.F.R. §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.

### Overview

CMS defines "high-level personnel" at §483.85(a) as individual(s) who have substantial control over the operating organization or who have a substantial role in the making of policy within the operating organization." In appendix PP of the state operating manual, CMS goes on to say that "The individuals considered ''high-level personnel'' will differ according to each operating organization's structure. Some examples include, but are not limited to, a director; executive officers including the chief executive officer (CEO); 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, as defined in section 1124(a)(3) of the Act."

Operating organizations with four or fewer facilities do not need to have a person with specific "compliance officer" responsibilities or even the job title of compliance officer. All facilities, nonetheless, must make sure that they have one or more specific individuals responsible for overseeing the C&E Program. The specific C&E Program oversight responsibilities should be included in the job descriptions and should also be 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.

### Implementation Strategies

- ✓ When making these assignments, consider the individual's level of authority within the organization. The surveyors may look for job descriptions that tie into the C&E Program.
- ✓ Although not required, best practice would suggest that the oversight responsibility include some degree of coordination with the privacy officer/security officer to ensure proper Health Insurance Portability and Accountability Act (HIPAA) and Health Information Technology for Economic and Clinical Health (HITECH) Act privacy and security controls are in place.

## COMPONENT 3: SUFFICIENT RESOURCES AND AUTHORITY

### Regulatory Language

> 42 C.F.R. §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.

### Overview

CMS indicates that the resources devoted should include both human (e.g. staff time) and financial resources.

In appendix PP of the state operating manual, CMS states *"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."*

### Implementation Strategies

- ✓ 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.
- ✓ Consider who will be involved w
- ✓ ith the C&E Program – how much time will be devoted to compliance activities? Is there a sufficient compliance budget to maintain the Compliance and Ethics Program and process?

## COMPONENT 4: DUE CARE WITH DELEGATING DISCRETIONARY AUTHORITY

### Regulatory Language

> 42 C.F.R. §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.

### Overview

CMS defines "due care" as "generally means the care that a reasonable person would use under the same or similar circumstances."

### Implementation Strategies

- ✓ Document and conduct routine background checks.
- ✓ Perform and document monthly exclusion screening.
  - Exclusion screening is the process of verifying that a current or potential employee is not classified as an excluded individual who is prohibited from participation in any Federal healthcare program. Databases frequently checked during exclusion screening include:
    - System for Award Management (SAM): The SAM system includes individuals and entities found on the OIG exclusion list, and it is necessary for healthcare organizations to continually check this database.
    - List of Excluded Individuals and Entities (LEIE): A list of all individuals and entities currently excluded by the OIG.
    - State Medicaid sites.
    - Other state agencies sites.
  - This should be tied into the facility's ongoing obligation to keep residents free from abuse and neglect.

## COMPONENT 5: EFFECTIVE COMMUNICATION

### Regulatory Language

> 42 C.F.R. §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.

### Overview

This component is reinforced by the training regulation at 42 C.F.R. §483.95(f)(1), F496. So, failure to be able to document and show the surveyors that you have an effective way of communicating with employees, contracted service personnel and volunteers can subject you to deficiencies under two F-tags.

CMS will be looking for the facility assessment to help inform the amount and types of training that will be necessary. The regulations do not specify how the training or dissemination of information is to be performed. CMS encourages flexibility and recognizes that some training could be delegated to contracted agencies.

Remember that staff frequently attend in-services and off-site educational sessions that may touch on the elements of the C&E Program. Invest in a tracking system, paper or electronic, that assures that the facility can show its commitment to effective communication about compliance-related matters. The entire staff should be required to participate in specific training on a periodic basis, related to their job duties or activities. This may include training in Federal and State statutes, regulations and guidelines, the policies of private payers, and training in compliance and ethics. Collectively, tracking this ongoing training and education will help demonstrate the organization’s commitment to compliance with legal requirements and policies.

Attendance and participation in such training programs should be a condition of continued employment and failure to comply with training requirements should result in disciplinary action, including possible termination, when such failure is serious. Adherence to the provisions of the C&E Program shall be a factor in the annual evaluation of each employee.

### Implementation Strategies

Providers should take steps to effectively communicate their C&E Program, such as:

- ✓ Communicate standards and procedures to all employees and contractors/agents by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.
- ✓ Provide copies to vendors/contractors as part of the contracting process and annually thereafter (along with the notice that must be sent regarding the Elder Justice Act).
- ✓ Post your compliance plan or code of conduct on your intranet and internet sites.
- ✓ Require employees to sign annual attestations stating that they have received and read your compliance code of conduct and that they understand what your C&E Program entails.
- ✓ Have employees, contractors/agents and volunteers sign in whenever compliance topics are discussed at in-services or department meetings.
- ✓ If you use electronic learning platforms, have a copy of your compliance modules available for the survey team.
- ✓ Don't rely on paper. Expect surveyors to ask staff, contractors/agents and volunteers if they are aware of the facility's C&E Program, and how it works.
- ✓ Assign someone the task of conducting compliance interviews with staff, contractors/agents and volunteers on a random yet regular basis. Ask questions like:
    - Are you aware of the facility's Compliance and Ethics Program?
    - Is there a method to anonymously report suspected violations?
    - Are you confident in reporting compliance matters without fear of retribution?
- ✓ Provide and document mandatory, one-time training for all new and existing staff, on the C&E Program
    - Operating organizations with five or more facilities will be required to provide this training annually.

## COMPONENT 6: MONITORING AND AUDITING

### Regulatory Language

> 42 C.F.R. §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.

### Overview

Monitoring and auditing are key elements of any C&E Program. The first step is to start with a self-assessment or gap analysis to identify the facility's compliance risk areas, considering both industry-identified as well as facility specific risk areas. The results of the self-assessment should be documented in the facility's compliance work plan, which should be reviewed and updated at least annually or more frequently if the situation warrants.

Auditing and monitoring are important methods to evaluate the effectiveness of the C&E Program documents, training and education, as well as the accuracy of billing and related processes and quality of care and services. If risks or potential risks, deviations or violations are identified, the facility should develop a plan of action to address compliance audit findings and lessen the likelihood of future recurrence.

Auditing can be either proactive or reactive. It is a formal and systematic review intended to help evaluate and improve the effectiveness of processes and systems. In some circumstances, audits should be conducted under the direction of counsel if there is a potential for significant repayments or possible fraud or criminal activity. Monitoring, on the other hand, is more often an internal ongoing process used to determine whether controls and processes are working as intended, and is frequently conducted in real time at the point of action, like when a billing manager reviews claims before submission.

CMS expects periodic external audits specifically focusing on financial records and quality of care issues. CMS also expects that the requirements for compliance and ethics and the QAPI programs should work together or be coordinated to ensure compliance with the regulations but also improve the quality of care provided to the residents. Issues identified in the Quality Assurance and Performance Improvement

(QAPI) programs may be the subject of appropriate auditing and monitoring through the C&E Program. Consider making the QAPI Committee a subcommittee of the Compliance Committee.

Note that CMS again references the need to have a reporting system that employees, contractors/agents and volunteers can access without fear of retribution (s*ee,* Section IV).

Surveyors will be looking for evidence that the facility uses monitoring and auditing systems to detect criminal, civil, and administrative violations by staff.

Monitoring Under the 60 Day Rule

The 60-day repayment rule promulgated under Section 6402(a) of the Patient Protection and Affordable Care Act ("PPACA"), imposes a duty upon facilities to exercise reasonable diligence to determine if a potential overpayment exists. This obligation is met by conducting both proactive compliance activities and reactive investigative activities undertaken in response to receiving credible information about a potential overpayment. Proactive compliance activities must be conducted in good faith by qualified individuals to monitor the receipt of overpayments. Reasonable diligence also includes responding to all credible information produced as a result of ongoing compliance activities. In addition, investigations should be conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment.

## COMPONENT 7: CONSISTENT ENFORCEMENT

### Regulatory Language

> 42 C.F.R. §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.

### Overview

Compliance should be a condition of employment, as well as a factor in job performance and annual competencies and assessments. Policies and procedures should set out expectations for reporting compliance issues and for assisting in their resolution. CMS expects that facilities will require mandatory reporting of potential compliance concerns. Most importantly, facilities must apply discipline fairly and consistently regardless of the perpetrator's position.

### Implementation Strategies

- ✓ Provide sanctions for failing to report suspected problems, participating in non-compliant behavior, or encouraging, directing, facilitating or permitting non-compliant behavior in your employee handbook.
- ✓ If this is included in your C&E Program, make sure that there is consistency with the facility's other core documents, including any collective bargaining agreements, for example.
- ✓ Consider requiring an annual attestation or certification of compliance. See, Section XVI for sample language.

## COMPONENT 8: RESPONSE AND REMEDIATION

### Regulatory Language

> 42 C.F.R. §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.

### Overview

The C&E Program should articulate the facility's commitment to investigate and address all reported compliance issues promptly, thoroughly and confidentially to the extent possible. The Compliance Officer or designated person should coordinate any findings from the investigations and immediately recommend corrective action or changes that need to be made. Violations should always be subjected to a root cause analysis so that corrective measures can be implemented and assessed to prevent future non-compliance. Facilities should integrate this information and data into their QAPI program as required at 483.7 (g)(2)(iii) and determine any trends and patterns of systemic problems.

The reporting process should also include an alternative approach if the reporting process involves the person who has committed the violation, such as reporting to the organization's hotline or compliance line (if available), an executive officer of the organization, the Ombudsman or another appropriate agency.

Disciplinary action should be taken, if appropriate, in accordance with the Human Resources discipline policies, which should be consistent with the Employee Handbook.

### Implementation Strategies

- ✓ The C&E Program should explicitly state the expectation that all individuals cooperate with investigation efforts.
- ✓ The organizations program should clearly outline the steps taken when a violation is detected. Such steps may include:
  - Corrective action plan
  - Return of overpayments
  - Report to the government and/or a referral to criminal and/or civil law enforcement authorities
  - Instituting whatever disciplinary action is necessary

- Implementing systemic changes to prevent a similar violation from recurring in the future.

✓ The organization's program should also identify contingencies for different situations. For example, what to do if the violation is committed by someone identified in the reporting process.

✓ The organizations program must integrate information and data from its Compliance and Ethics Program into their QAPI program. The QAPI committee should work with the compliance officer to identify trends or patterns.

## COMPONENT 9 FOR OPERATING ORGANIZATIONS WITH 5+ FACILITIES: ANNUAL TRAINING

### Regulatory Language

> A mandatory annual training program on the operating organization's compliance and ethics program that meets the requirements set forth in § 483.95(f). 42 C.F.R. §483.85(d)(1).

### Overview

Operating organizations with five or more facilities are required to provide annual training to all staff, including contractors and vendors, about the C&E Program. CMS does not prescribe the content or duration of the training, but instead states that 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 in 483.95(f)."

CMS expects that in large organizations the training will be developed by the Compliance Officer, who is located within the operating organization, and not at the individual facilities.

### Implementation Strategies

- ✓ The annual training program should, at a minimum, 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.
  - The operating organizations performance in prior years.
  - Issues identified in risk assessments.
- ✓ The operating organization should have a process to ensure those changes are communicated to all staff.

## COMPONENT 10 FOR OPERATING ORGANIZATIONS WITH 5+ FACILITIES: DESIGNATED COMPLIANCE OFFICER

### Regulatory Language

> 42 C.F.R. §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.

### Overview

Operating organizations with five or more facilities, must have a compliance officer, and overseeing compliance must be that person's major responsibility. *Note: Operating organizations with four or fewer facilities are not required to have a designated compliance officer under the regulations but still must designate a high-level person with compliance accountability as discussed above.*

CMS expects this program to be appropriate for the complexity of the organization and facilities they operate.

The regulations are explicit that the compliance officer cannot be subordinate to the general counsel, CFO, or COO. Expect surveyors to ask for the facility's organizational chart to verify that there is no improper subordination.

CMS believes that the compliance officer would be within the operating organization's staff and not located at an individual facility to avoid any interference or influence of the compliance officer by an administrator. The compliance officer must be able to communicate with the governing body without being subject to any coercion or intimidation.

The compliance officer must also have sufficient time and resources to fulfill all of their responsibilities under the operating organization's Compliance and Ethics Program.

While it is not required, a compliance and ethics committee is a best practice to support the compliance officer with developing/sustaining the program, including its related policies and procedures. The committee would support, among other things: conducting annual risk assessments, reviewing the annual monitoring and auditing plan, and offering recommendations based on the results. Who serves on the compliance committee will depend on staffing and expertise. Typically, this committee would include the Compliance Officer (or high-level personnel overseeing compliance) and other senior management of departments such as billing, clinical, human resources, audit, and operations. Providers may find efficiencies by coordinating compliance

workstreams with the Quality Assessment and Assurance Committee and staff implementing the Patient Driven Payment Model. For example, all of these groups would be involved in assessing systemic policies for therapy utilization/billing under the new payment system.

**Implementation Strategies**

- ✓ 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.

## COMPONENT 11 FOR OPERATING ORGANIZATIONS WITH 5+ FACILITIES: DESIGNATED COMPLIANCE LIAISONS

### Regulatory Language

> 42 C.F.R. §483.85(d)(3). Designated compliance liaisons located at each of the operating organization's facilities.

### Overview

A compliance liaison is not the same as the compliance officer. The compliance liaison is an adjunct to the compliance officer and is not responsible for the organization's overarching C&E Program.

While not defining the term "compliance liaisons" in the regulation, CMS states that an organization that is required to have site liaisons "will develop its own definition for the position 'designated compliance liaison' and determine the qualification, duties and responsibilities for the individuals in this position." At a minimum, these liaisons should be responsible for assisting the compliance officer with his or her duties under the operating organization's program.

## ANNUAL REVIEW

### Regulatory Language

42 C.F.R. §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.

### Overview

The operating organization is required to update their Compliance and Ethics Program annually, based on laws, requirements or the facility or organization itself. Past performance should also be evaluated during the annual review and used to make improvements as necessary. As an operating organization revises its program, it should ensure that those changes are communicated to its entire staff. Surveyors will be looking for evidence that the program has been reviewed annually.

### Implementation Strategies

- ✓ 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 entire staff annually

## TRAINING REQUIREMENTS

### Regulatory Language

42 C.F.R. §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.

### Overview

This section is covered under the training requirements of the requirements of participation.

For the purposes of this section, CMS defines the term staff as *"all new and existing staff (direct and indirect care functions); individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles (see requirements in §483.95)."*

Surveyors will be looking for evidence that shows the facility provides training or effectively communicates, in some manner, the facility's standards, policies and procedures of the compliance and ethics program. They will also be looking for a system to track attendance at required trainings. And for organizations with five or more facilities, they will look to determine if annual compliance and ethics training is conducted.

### Implementation Strategies

- ✓ 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 whom it was provided to.

# APPENDIX I SAMPLE LANGUAGE

## Sample Non-Retaliation Policy

We have a strong Non-Retaliation Policy covering anyone who reports a compliance concern in good faith through any channel. No supervisor, manager or employee is permitted to engage in retaliation, retribution or any form of harassment directed against an employee who reports a concern in good faith. All reported concerns are presumed to be made in good faith. Only if investigation reveals strong evidence that someone reported a concern that had no factual basis, and the concern was reported to embarrass or otherwise defame an employee or other entity, might adverse action be appropriate. Any manager, supervisor or employee who engages in retribution, retaliation or harassment is subject to discipline up to and including dismissal on the first offense.

## Sample Attestation Provisions

**ANNUAL ATTESTATION OF _____**

**[OPTION 1:**

I attest that I have read my organization's Compliance and Ethics Plan and that I have had the opportunity to ask questions about anything in the Compliance and Ethics Plan that I did not understand. I am committed to honoring [upholding] the Compliance and Ethics Plan, and I have followed [adhered to] it during the past year of my employment at _____. I further state that in the past year, I have not experienced any sexual, racial or other harassment or discrimination at _____.**]**

**[OPTION 2:**

I attest that I have read and understood my organization's Compliance and Ethics Plan, and that I have adhered to it during the past year of my employment at _____. During the last year, I have not violated the Compliance and Ethics Plan, nor have I engaged in any illegal activity related to the operations of _____. I further state that in the past year, I have not experienced any sexual, racial or other harassment or discrimination at _____.

I understand that my organization encourages all employees to express any issues or concerns they may have related to compliance, without fear of retaliation. I have either brought any concerns I may have had during the past year to my supervisor's or management's attention, or I have had no concerns other than those stated below.

Please use the space below to write any comments or information of which you wish to advise us.**]**

_____ _____

Employee Signature Date

_____ _____

Employee Name (Print) Department

### Sample Disciplinary Language:

Every team member is responsible for ensuring that he or she complies with the code of conduct and all policies and procedures. Any team member who violates any of these standards and/or policies and procedures is subject to discipline up to and including termination.

## APPENDIX II EXTERNAL RESOURCES

For additional information, providers can review these sources:

- ✓ 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.