



# AHCA Compliance and Ethics Toolkit

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## PURPOSE

- The purpose of this presentation is to increase your understanding of the elements of the new Compliance and Ethics Program that will be implemented as part of Phase 3 of the Requirements of Participation.

**DISCLAIMER: INFORMATION CONTAINED WITHIN THIS PRESENTATION IS FROM THE AHCA COMPLIANCE AND ETHICS TOOLKIT AND USED WITH EXPRESS PERMISSION FROM AHCA**

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## INTRODUCTION

- ▶ AHCA has developed a Compliance and Ethics Toolkit. This toolkit is designed to help facilities develop and/or revise their Compliance Programs to meet the requirements of the new CMS regulations.

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## INTRODUCTION

- ▶ Starting November 28, 2019, CMS and state survey agencies will be authorized to issue survey deficiencies under federal F-tag F895 to facilities that do not have effective Compliance Programs.

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## INTRODUCTION

- Facilities that **do not** already have a Compliance Program should begin putting one in place so that they are ready for survey enforcement.
- Facilities that **have implemented** Compliance Programs should review the new requirements against their existing programs and revise as necessary.

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## INTRODUCTION

- The goal is to have an **effective** Compliance Program, with **sufficient documentary evidence** in place, to show surveyors who will be assessing the Compliance Program for substantial compliance with the new CMS regulations at 42 C.F.R. § 483.85, F895

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## IMPORTANT DISCLAIMER

- CMS has not released guidance about how F895 will be interpreted.
- CMS will likely release guidance in an updated State Operations Manual, Appendix PP
- CMS may also develop a Critical Element Pathway for Compliance Programs.

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# DON'T WAIT



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## OVERVIEW OF THE COMPLIANCE PROGRAM

### ► What is an effective program?

- CMS has defined an **effective** Compliance and Ethics Program as a program that is established by an operating organization that includes the minimum components of the regulations and “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.*”

- 42 C.F.R. § 483.85(a)

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## OVERVIEW OF THE COMPLIANCE PROGRAM

CMS has defined an effective Compliance and Ethics Program as a program that:

1. **is established by an operating organization;**
2. **that includes the minimum components of the regulations;**
3. and “has been reasonably designed, implemented, and enforced;
4. so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations;
5. under the Act and in promoting quality of care.”

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## OVERVIEW OF THE COMPLIANCE PROGRAM

- ▀ What is an Operating Organization?
  - ▀ An “operating organization” is the individual(s) or entity that operates a facility.

**The Compliance Program is a program of the “operating organization.”**

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## OVERVIEW OF THE COMPLIANCE PROGRAM

- ▀ What are the minimum components of the regulations?
  - ▀ There are **eight primary elements** of the regulations, **three supplemental elements**, plus an annual Compliance Program review.

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## OVERVIEW OF THE COMPLIANCE PROGRAM **8 PRIMARY COMPONENTS**

- Written Standards, Policies, and Procedures
- Assign High-Level Personnel to Oversee the Program
- Allocate Sufficient Resources and Authority
- Exercise Due Care Not to Ensure Overseer Is Not Predisposed to Engage in Illegal Behavior
- Effective Communication of Standards, Policies, Procedures
- Incorporate Monitoring and Auditing System
- Consistent Enforcement of Standards, Policies, Procedures
- Incorporate Remediation and Program Modification

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## OVERVIEW OF THE COMPLIANCE PROGRAM **3 SUPPLEMENTAL COMPONENTS**

- Conduct Annual and Mandatory Program Training
- Designate a Compliance Officer whose Primary Responsibility is to Oversee the Program.
- Designate a Compliance Liaison at each of the Organizations Centers.

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## OVERVIEW OF THE COMPLIANCE PROGRAM

- All facilities are required to comply with the 8 primary elements and the annual Compliance Program Review
- Facilities that are part of an operating organization with **5 or more facilities** are also required to meet three supplemental components.

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## OVERVIEW OF THE COMPLIANCE PROGRAM

- CMS has not defined how to determine whether an operating organization is one with **5 or more facilities**
  - It is not clearly linked to ownership
  - It is possible it could include a "management company" if it operates a facility.
  - It is also possible it could be an administrative services company

**At a minimum, facilities that have been identified as part of a chain should assume that surveyors will expect them to comply with the 3 additional supplemental components.**

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## OVERVIEW OF THE COMPLIANCE PROGRAM

- **Tip:** If you implemented your Compliance Program several years ago, **revisit your core documents** to make sure they **address quality of care**. Older compliance plans typically concentrated on preventing and detecting billing and documentation errors and did not include quality of care, which tended to be within the purview of quality assurance or other operational committees.

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

- Focuses on the **development and implementation** of the Compliance Program.
- Emphasizes **three key elements** that CMS expects facilities to include:
  - The Reporting System
  - Consistent Disciplinary Standards
  - Standards, Policies and Procedures

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

### ■ The Reporting System

- Designating an appropriate contact to whom individuals may report suspected violations.



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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

- Establish an **alternate method** of reporting suspected violations **anonymously** without fear of retribution.



**ALTERNATIVE ROUTES**

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

Using a 1-3 scale, with 1 the highest, evaluate the presenter's oral presentation and accompanying visual aids. For example, the presenter used visual aids that were helpful and easy to understand. If they were not particularly helpful, check the "not helpful" column.

Date:	Start time:	End time:	Total:
Presenter's name:			
Presenter's topic:			
Evaluation category	Yes/No	Rating	
Began with an explanation of audience situation (topic) before starting the actual presentation?			
Began the actual presentation with an introduction?			
Introduction indicated topic?			
Introduction indicated purpose?			
Introduction gave context?			
Introduction attempted to motivate interest?			
Used one or more visuals?			
Visuals were effective?			
Referenced important visuals?			
Used verbal headings?			
Presentation was organized?			
Explained technical information clearly?			
Timing which was very well effective?			
Held my attention?			
Spoke with a real conviction?			
Presentation was the expected length?			
Presentation was adequate (overall rating):			
Comments:			

**Compliance  
Program  
Poster**



**ALTERNATIVE ROUTES**



**1-800-COMPLIANCE**



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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

**If asked, what  
would they say....**



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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

- Key Elements of An **Effective** Compliance Program
  - Universal Non-Retaliation Policy
  - Timely Response to Reports
  - Encourage Use of Hotlines and Other Reporting Mechanisms
  - Periodic Testing of Reporting Mechanism
  - Emphasize Use of Compliance Program by EVERYONE

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

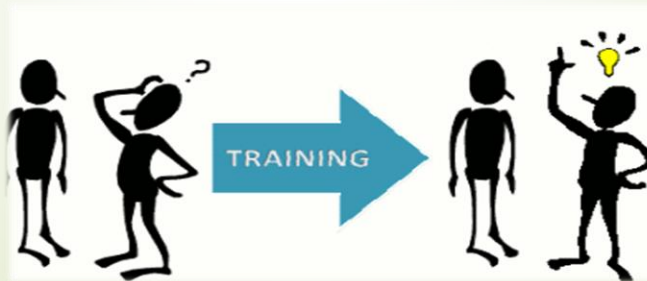
- **Consistent Disciplinary Standards**
  - Disciplinary **standards** that set out the consequences for committing violations for the entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles.

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

### ■ Enforcement

- Establish Employees, Agents and Volunteers **Receive and Understand** the Code of Conduct



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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

- Discipline for Noncompliance should be clearly set forth in the:
  - Code of conduct;
  - Cross-referenced in employee handbooks;
  - Included in any collective bargaining agreements

**Compliance must be enforced through the appropriate discipline, when necessary.**

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

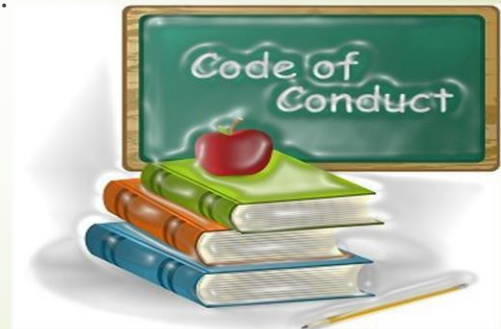
- Discipline Policies should:
  - Indicate **discipline for non-compliant** activity;
  - Re-enforce **employee obligation to report** w/o retribution;
  - Provide an **outline of disciplinary procedures**;
  - **Identify all parties responsible** for appropriate action;
  - Commit that **discipline will be fair** and consistent.

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

- Written compliance and ethics standards, policies and procedures "**likely to be effective**" to reduce the prospect of criminal, civil and administrative violations and promote quality of care.

- **STANDARDS**
- **POLICIES**
- **PROCEDURES**



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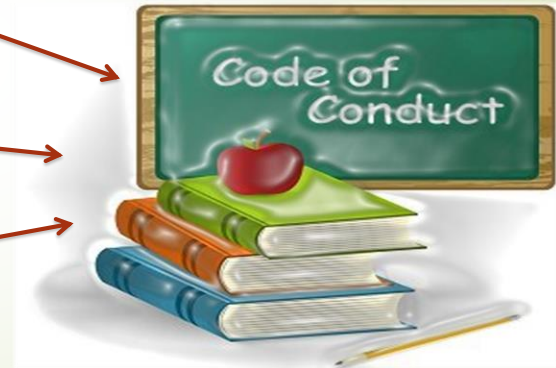


## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

➤ STANDARDS

➤ POLICIES

➤ PROCEDURES



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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

➤ **Standards, Policies and Procedures**

➤ **Code of Conduct:**

- Contains facility P&P's that support the Compliance Program
- Are readily available and understood by all individuals\* affected by the policies

\*employees, physicians, suppliers, agent contractors, volunteers

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

**Compliance Program policies and procedures should be supported by other facility-specific policies and procedures for clinical, financial, and administrative functions.**

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

- Code of Conduct should address the following issues:
  - Commitment to Ethics and Compliance
  - Care Excellence
  - Professional Excellence
  - Regulatory Excellence
- It should also contain:
  - Mission and Value Statement

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

### Commitment to Ethics and Compliance

- Mechanisms to Report Compliance Concerns
- Commitment to a non-retaliatory environment
- Attestation to Compliance

### Care Excellence

- Resident Rights
- Freedom from Abuse & Neglect
- Reporting Allegations of Abuse, Neglect and Suspected Crimes
- Resident Confidentiality
- Providing Quality Care

See AHCA Ethics and Compliance Toolkit for a Complete List of P&P

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## COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

### Professional Excellence

- Standards and Responsibility
- Respectful Behavior
- Hiring and Employment Practices
- Compliance as an Element of Performance Evaluation
- Consistent Disciplinary Enforcement
- Drug and Alcohol Abuse

### 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);

See AHCA Ethics and Compliance Toolkit for a Complete List of P&P

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## COMPONENT 2: ASSIGNMENT OF HIGH LEVEL INDIVIDUAL TO OVERSEE COMPLIANCE PROGRAM

- Assignment of “high level” individual(s) with the overall responsibility to oversee compliance within the Compliance Program's standards, policies and procedures.
- Examples:
  - Chief Operating Officer
  - Board Member
  - Divisional or Regional Director



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## COMPONENT 2: ASSIGNMENT OF HIGH LEVEL INDIVIDUAL TO OVERSEE COMPLIANCE PROGRAM

- CMS defines “high-level Personnel” as an individual who has substantial **control over the operating organization** or who has a substantial **role in policy making** within the organization.

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## COMPONENT 2: ASSIGNMENT OF HIGH LEVEL INDIVIDUAL TO OVERSEE COMPLIANCE PROGRAM

- Operating Organization with **4 or fewer facilities** are not required to have a specific person designated with a title of "Compliance Officer"
- **ALL** Facilities must have at least one individual responsible for overseeing the Compliance Program.
- CMS suggests this individual be the Chief Executive Officer, A Board Member, a Divisional Director
  - Designated individual **must have sufficient authority** to provide oversight and support of the Compliance Program

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## COMPONENT 2: ASSIGNMENT OF HIGH LEVEL INDIVIDUAL TO OVERSEE COMPLIANCE PROGRAM



- The Specific Compliance Program Oversight Responsibilities should be:
  - Included in the job description
  - Referenced in the Compliance Programs Core Operating documents

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## COMPONENT 2: ASSIGNMENT OF HIGH LEVEL INDIVIDUAL TO OVERSEE COMPLIANCE PROGRAM

- **Tip:** 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.



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## COMPONENT 3: SUFFICIENT RESOURCES AND AUTHORITY

- **Sufficient Resources And Authority**
  - **Sufficient resources and authority** to individual(s) designated to oversee the Compliance Program to “**reasonably assure compliance**” with standards, policies and procedures.

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## COMPONENT 3: SUFFICIENT RESOURCES AND AUTHORITY

- How To “Reasonably Assure Compliance”
  - Use the Facility Assessment
    - Determine the resources needed
    - Include the Compliance Program in the facility assessment
      - How much time is devoted to compliance activities?
      - Is there a compliance budget?



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## COMPONENT 3: SUFFICIENT RESOURCES AND AUTHORITY

**What Does It Mean to Have An Individual w/ Sufficient Authority to Provide Oversight?**



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## COMPONENT 4: DUE CARE WITH DELEGATING DISCRETIONARY AUTHORITY

### ► Due Care With Delegating Discretionary Authority

- Documentation of due diligence to ensure individual(s) overseeing the program do not have the “propensity” to **engage in criminal, or improper civil or regulatory behavior.**

**EXERCISE  
OF DUE  
DILIGENCE**

**+ DOCUMENT =**



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## COMPONENT 4: DUE CARE WITH DELEGATING DISCRETIONARY AUTHORITY

### ► Exercise Due Diligence

- Conducting Background checks
- Performing Monthly Exclusion Checks
  - System for Award Management
  - OIG List of Excluded Individuals and Entities
  - State Medicaid Sites

**EXERCISE  
OF DUE  
DILIGENCE**

**+ DOCUMENT =**



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## COMPONENT 5: EFFECTIVE COMMUNICATION

### ► Effective Communication

- Effective communication of program standards, policies and procedures to staff, contractors and volunteers.



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## COMPONENT 5: EFFECTIVE COMMUNICATION

- What does it mean to take steps to **effectively communicate** about your Compliance Program?
  - Explain Requirements in a "Practical Manner"
  - Participation in Training Programs
  - Disseminating Publications
  - Post Code of Conduct on intranet and internet sites
- How do you **demonstrate effective communication** about your Compliance Program?
  - Signatures on Annual Attestation Forms
  - In-service sign-in Sheets
  - Printed Validation Reports from Electronic Learning Platforms

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## COMPONENT 5: EFFECTIVE COMMUNICATION

Do you know if this facility has a Compliance Program?

What are you supposed to do if you have concerns?

To whom should you report concerns?



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## COMPONENT 6: MONITORING AND AUDITING

### ► Monitoring And Auditing

- **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.

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## COMPONENT 6: MONITORING AND AUDITING

Such steps include, but are not limited to:

**Use of monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations...**

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## COMPONENT 6: MONITORING AND AUDITING

### Monitoring And Auditing

1. Self assessment or gap analysis to identify compliance risk areas
2. Document results in facility's compliance work plan
3. Review and update compliance work plan at least annually

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## COMPONENT 6: MONITORING AND AUDITING

- Purpose of Auditing
  - Evaluate effectiveness of the Compliance Program
  - Evaluate accuracy of billing and related processes
  - Evaluate the Quality of Care and Services Provided

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## COMPONENT 6: MONITORING AND AUDITING

- Expectations
  - Periodic external audits
  - Coordination of the Compliance Program and the QAPI Program
  - Emphasis on ensuring a retribution free reporting system

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## COMPONENT 6: MONITORING AND AUDITING

- 60 Day Repayment Rule
  - Imposes a duty on facilities to exercise reasonable diligence to determine if a potential overpayment exists.
  - Duty fulfilled by conducting **proactive** compliance activities and **reactive** investigative activities.

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## COMPONENT 7: CONSISTENT ENFORCEMENT

- **Consistent Enforcement**
  - 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.

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## COMPONENT 7: CONSISTENT ENFORCEMENT

- Ethics and Compliance Program Expectations
  - Condition of Employment
  - Factor in Job Performance Evaluations
  - Factor in Annual Competences and Assessments
  - Mandatory Reporting of Compliance Issues
  - Fair and Consistent Discipline for Failure to Report or Comply with any aspect of the program.

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## COMPONENT 7: CONSISTENT ENFORCEMENT

***Tip: Make sure your employee handbook addresses sanctions for failing to report suspected problems, participating in non-compliant behavior, or encouraging, directing, facilitating or permitting non-compliant behavior?***

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## COMPONENT 8: RESPONSE AND REMEDIATION

- 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.

**“What did you do after a violation was detected?”**

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## COMPONENT 8: RESPONSE AND REMEDIATION

### Response and Remediation Policy

- Coordinate Investigative Findings
- Emphasize Expectation of Cooperation with Investigative Efforts
- Recommend Corrective Action
  - Make prompt restitution, as appropriate
  - Notification of appropriate Government agency
  - Instituting appropriate Disciplinary action
  - Implementing system changes to prevent future violations

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## ANNUAL REVIEW

- All facilities will be required to **REVIEW and REVISE** their Ethics and Compliance Program annually.
  - Purpose:
    - Improve efficacy of the program
      - Deterring →
      - Reducing →
      - Detecting →
- VIOLATIONS**
- Promoting QUALITY OF CARE**

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## ANNUAL REVIEW

- Periodic updates may also be needed to ensure that any major organizational changes are also incorporated into the program.

**DOCUMENT, DOCUMENT, DOCUMENT**

**Make sure to document the annual review, even if no changes or revisions are made.**

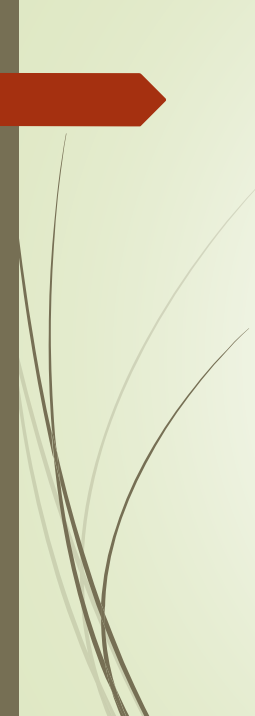
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## **SUPPLEMENTAL COMPONENTS**

**APPLIES TO ORGANZATIONS WITH FIVE OR MORE FACILITIES**

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### **SUPPLEMENTAL COMPONENT 1: ANNUAL TRAINING**

**Operating organizations with five or more facilities are required to provide annual training to all staff, including contractors and vendors, about the Compliance Program.**

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## **SUPPLEMENTAL COMPONENT 2: DESIGNATED COMPLIANCE OFFICER**

**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.**

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## **SUPPLEMENTAL COMPONENT 3: DESIGNATED COMPLIANCE LIAISONS**

**Designated compliance liaisons located at each of the operating organization's facilities.**

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## TRAINING REQUIREMENTS

- The regulation states:
  - Compliance and ethics. The operating organization for each facility must include as part of its compliance and ethics program:
    - An effective way to communicate that 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.

**42 C.F.R. §483.85(f)**

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## TRAINING REQUIREMENTS

- All facilities are required to perform a mandatory one time training for all new and existing staff, contractors and volunteers, on the Compliance Program that is documented.
- Operating organizations with 5 or more facilities are required to provide training on the Compliance Program annually.
- 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 Compliance Program.

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## TRAINING REQUIREMENTS

**Facility Assessment will help inform a facility of the amount and type of training that will be necessary.**

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## ATTESTATION PROVISIONS

- As part of meeting the requirements of the regulation an **organization must be able to demonstrate** they have an effective compliance program.
- The AHCA Compliance and Ethics Toolkit includes several sample attestation provisions that can be integrated into your employee handbooks, in-service trainings, annual competency materials or other training materials to help demonstrate an individuals participation and understanding of your organizations Compliance and Ethics Programs.

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## RESOURCE

- The Compliance and Ethics Toolkit  
<https://educate.ahcancal.org/products/ahca-toolkit-rop-compliance-and-ethics-program>
- A Compliance Manual and Sample Policies and Procedures are available on the AHCA/NCAL website at:  
[https://www.ahcancal.org/facility\\_operations/integrity/Pages/Compliance-Programs.aspx](https://www.ahcancal.org/facility_operations/integrity/Pages/Compliance-Programs.aspx) .