I. SURVEYORS WILL START ASSESSING COMPLIANCE AND ETHICS PROGRAMS STARTING NOVEMBER 28, 2019

Medicare and Medicaid participating nursing facilities (collectively referred to as "SNFs" or "facilities") have been required to have a compliance and ethics program ("Compliance Program") since March 23, 2013, under Section 6102 of the Affordable Care Act, but to date there has been no regulatory mechanism for the government to enforce this requirement, other than through corporate integrity agreements ("CIAs") imposed by the Office of Inspector General ("OIG") as a condition of settlement of certain federal investigations. The Centers for Medicare and Medicaid Services ("CMS") did not issue final regulations for Compliance Programs until October 4, 2016, with an effective date of November 28, 2019. Starting November 28, 2019, CMS and state survey agencies will be authorized to issue survey deficiencies under federal Ftag F895 to facilities that do not have effective Compliance Programs.

AHCA has been at the forefront of encouraging facilities to implement Compliance Programs and many years ago developed a Compliance Manual and Sample Policies and Procedures for members that is available on its website at: https://www.ahcancal.org/facility_operations/integrity/Pages/Compliance-Programs.aspx. To help members better prepare for the new Compliance Program regulations that appear at 42 C.F.R. § 483.85, AHCA is providing this interim summary of the new requirements. AHCA will update this information as soon as CMS issues further interpretive guidance for F895.[1]

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. 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.

Starting November 28, 2019, surveyors will use the regulations at 42 C.F.R. § 483.85, F895, to determine whether a SNF's Compliance Program is in substantial compliance with the regulations. CMS has not yet issued guidance about how F895 will be interpreted; it is likely CMS will release guidance in an updated State Operations Manual ("SOM"), Appendix PP within the next year or so. It is also possible that CMS will develop a Critical Element Pathway for Compliance Programs at some future date. Facilities should not wait for CMS to release any additional guidance, however, because the regulations require Compliance Programs to be in place and "effective," which means facilities will need to have something in place before November 28, 2019 so that there will be documented evidence of their Programs for the surveyors to assess.

[1] CMS recognizes there are concerns about how surveyors will determine compliance with these requirements. CMS is developing and publishing or disseminating sub-regulatory guidance, including interpretative guidelines, before surveyors begin to survey facilities for these requirements. 81 *Fed. Reg.* 68688, 68813 (Oct. 4, 2016).

II. OVERVIEW OF THE COMPONENTS OF THE COMPLIANCE PROGRAM

This toolkit is designed to help facilities develop and/or revise their Compliance Programs to meet the requirements of the new CMS regulations.

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*[2] 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) (emphasis added).

***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.*

There are eight primary elements of the regulations, and three supplemental ones, plus an annual Compliance Program review. Facilities must establish if they are part of on operating organization with five or more facilities to determine which elements are required (*see,* Section III). Operating organizations with five or more facilities will be required to meet three supplemental components.

Every facility's Compliance Program must contain the following eight primary components, each of which will be discussed more fully in the toolkit.

1. 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.

    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. 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, etc.) with the overall responsibility to oversee compliance with the Compliance Program's standards, policies and procedures.

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

[2] CMS has not yet issued a definition of ''reasonable'' or ''reasonably.'' CMS will be publishing further sub-regulatory guidance on how to determine reasonableness for these requirements at a future date. *Id.*

4. 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.

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

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.

Operating organizations with five or more facilities have to meet three supplemental components.

9. Conducting annual and mandatory program training as explained in 42 CFR § 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 ("CFO") or chief operating officer ("COO")."

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

Additionally, to improve its performance in deterring, reducing, and detecting violations and in promoting quality of care, the operating organization of every facility must review its Compliance Program annually and revise it as needed to reflect changes in all applicable laws or regulations and within the operating organization and its facilities. This means the operating organization should periodically undertake reassessment of its Compliance Program to ensure that changes identified within the organization and its facilities are reflected within the Program.

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

CMS expects all facilities to use their facility assessment to evaluate the needs of their Compliance Programs. Toward that end, CMS encourages operating organizations with four or fewer facilities to incorporate the additional elements that are required for large organizations if their facility assessments indicate that they are necessary to ensure that their compliance and ethics programs are effective. Although this is not an explicit regulatory requirement, it is likely that surveyors may review facility assessments to determine if they address compliance related issues such as resources, training, and staffing to support the Compliance Program.

III. THE "OPERATING ORGANIZATION" IS RESPONSIBLE FOR IMPLEMENTING THE COMPLIANCE PROGRAM

Under the new regulations, the Compliance Program is a program of the "operating organization." An "operating organization" is the individual(s) or entity that operates a facility. 42 C.F.R. § 483.85(a). The Compliance Program of the operating organization for every facility must meet eight components, in addition to an annual review process. Operating organizations with five or more facilities must meet an additional three requirements.

We expect that CMS will issue further guidance about how to determine if an operating organization is one with five or more facilities. The term "with" is as yet undefined, and is not clearly linked to ownership. An operating organization could be a management company if it "operates" a facility, or it could be an administrative services company. At a minimum, facilities that have been identified as part of a chain for cost reporting or similar purposes should assume that the surveyors will expect them to meet the additional three compliance component requirements.

IV. COMPONENT 1: WRITTEN STANDARDS, POLICIES, AND PROCEDURES

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(1).

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, and is the Compliance Program's operational documents. 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.

Surveyors will in all likelihood ask to see these documents, and 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 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.

At its most basic level, the code of conduct should include the organization's mission statement, as well as the eight (or eleven) 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.

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 again in the Component 6, Monitoring and Auditing (s*ee,* Section IX).

A. The Reporting System

It is important to have and publicize a reporting system whereby employees, 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. Consider establishing a compliance, ethics and resident safety hotline with an 800 number, possibly through an external entity. Regardless of what paths you follow, the

reporting mechanisms should be well-publicized. Make use of intranet, internet, posters, newsletters, and admission packets. Don't forget to include families and residents, as well as employees, agents, vendors and volunteers. Consider hanging posters with the compliance hotline near other required postings (such as ombudsman phone numbers). It is always better to have complaints coming to the facility instead of external agencies.

The culture of the organization will dictate the effectiveness of the Compliance Program. To foster a strong culture of compliance, organizations should ensure that their leaders embrace and implement a universal non-retaliation policy. A sample follows:

> **Sample non-retribution policy**: We have a strong Non-Retribution 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.

Another way to improve the culture and encourage reporting is to respond timely to individuals who voice concerns about compliance. Research has shown that many calls that are placed to hotlines relate to employment matters, not necessarily compliance issues. Effective Compliance Programs encourage use of hotlines, regardless of the issues lodged there because it demonstrates a commitment to helping employees, agents, vendors and volunteers "do the right thing."

> ***Tip:*** *Periodically test your 800 hotline. Maintain a log of all calls so you can demonstrate to surveyors that you have a reporting system in place.*

Emphasize that the reporting system can and should be used by employees, 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. The reporting system should work proactively to prevent potential compliance problems.

B. Consistent Disciplinary Standards

Enforcing consistent disciplinary standards related to the Compliance Program requires establishing that employees, agents and volunteers have received and understood the code of conduct. 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 at Section XVI.

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: 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.

C. Standards, Policies and Procedures

The code of conduct does not need to contain all of the facility's policies and procedures but should contain those that support the Compliance Program. They should be readily available to and understood by all employees affected by the policies, as well as physicians, suppliers, agents contractors and volunteers, as applicable. 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 Compliance Program policies and procedures should be supported by other facility-specific policies and procedures for clinical, financial, and administrative functions. 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
    - o Supervisor
    - o Compliance Liaison/Designated Person
    - o Compliance Officer
    - o Hotline
  - ♦ Commitment to a non-retaliatory environment
  - ♦ Attestation to Compliance
- **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
- Resources for Guidance and Reporting Violations
- Non-Retribution Policy
- Internal Investigation of Reports
- Corrective Action
- Discipline
- Internal Audit and Other Monitoring
- 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
- Public Filings and Communications
- Government Investigations
- Compliance Team
- Roles and Responsibilities of High Level Individual, Compliance Liaison and Compliance Officer

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

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(2)

CMS defines "high-level personnel" 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." 42 C.F.R. §483.85(a). When making these assignments, consider the individual's level of authority within the organization. The surveyors will in all likelihood look for job descriptions that tie into the Compliance Program.

For operating organizations with four or fewer facilities, note that they 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 Compliance Program. CMS suggests that these individuals could be the CEO, board members or division directors. Regardless of who is chosen, the specific Compliance Program oversight responsibilities should be included in the job descriptions and should also be referenced in the Compliance Program's core operating documents. The individual(s) with oversight responsibility should have sufficient authority to provide oversight and support to the 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.*

VI. COMPONENT 3: SUFFICIENT RESOURCES AND AUTHORITY

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(3).

CMS has not provided any specific guidance as to how surveyors will interpret sufficient resource and authority. CMS has, however, indicated how it believes operating organizations should explore this issue.

A. Use the Facility Assessment

CMS believes that it has given operating organizations flexibility to design effective Compliance Programs using their resources efficiently. CMS expects that larger organizations, those with five or more facilities, will have more resources available to them than smaller organizations. In the preamble to the final regulations, CMS said:

> [W]e would expect that all operating organizations would also use the facility assessment they developed according to § 483.70(e) in developing and maintaining their programs. For example, the operating organization must provide, among other things, sufficient resources to reasonably assure compliance with the program's standards, policies, and procedures (§ 483.85(c)(3)). . . . Operating organizations should use the facility assessment to determine the resources they need to devote to their compliance and ethics programs to reasonably assure compliance with the requirements finalized in this rule. 81 *Fed. Reg.* 68688, 68813 (Oct. 4, 2016).

Facilities should include their Compliance 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 with the Compliance Program – how much time will be devoted to compliance activities? Is there a compliance budget? Although CMS has not yet issued further guidance, it is likely surveyors will expect to see a line item on the facility assessment that addresses resources.

VII. COMPONENT 4: DUE CARE WITH DELEGATING DISCRETIONARY AUTHORITY

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(4)

In addition to conducting and documenting routine background checks, another way of demonstrating due diligence and compliance with this component is to perform and document monthly exclusion checks.

- SAM (System for Award Management): http://sam.gov
- LEIE (List of Excluded Individuals and Entities): http://oig.hhs.gov/fraud/exclusions/exclusions_list.asp
- State Medicaid sites.

This should be tied into the facility's ongoing obligation to keep residents free from abuse and neglect.

VIII. COMPONENT 5: EFFECTIVE COMMUNICATION

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(5).

This component is reinforced by the training regulation at 42 C.F.R. §483.95(f)(1), F496. The 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 Ftags.

What does it mean to take steps to effectively communicate about your Compliance Program?

- Take steps to communicate effectively standards and procedures to all employees and agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.
- Copies should be provided 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 both 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 Compliance Program entails.
- Have employees, 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, agents and volunteers if and what they know about the facility's Compliance Program. Assign someone the task of conducting compliance interviews with staff, agents and volunteers on a random yet regular basis. We expect that surveyors will have a Critical Elements Pathway related to compliance. Anticipate such questions now and incorporate them into your mock survey process. Ask questions like:
  - ♦ 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?

Tip: *When trying to determine whether you have effectively communicated the essence of your Compliance Program, consider how individuals would respond if presented with a typical government-required CIA attestation such as:*

> *"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [department] with all applicable Federal health care program requirements, obligations of the CIA, and Center policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [department] is in compliance with all applicable Federal health care program requirements and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."*

There should be a mandatory one time training for all new and existing staff, contractors and volunteers, on the Compliance Program that is documented. Operating organizations with five or more facilities will be required to provide this training annually.

Note as well that CMS believes that the facility assessment will 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 Compliance 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. Staff, contractors and volunteers 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 Compliance Program shall be a factor in the annual evaluation of each employee.

IX. COMPONENT 6: MONITORING AND AUDITING

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(6).

Monitoring and auditing are key elements of any Compliance 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 Compliance 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 QAPI programs may be the subject of appropriate auditing and monitoring through the Compliance Program.

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

A. Monitoring Under the 60 Day Rule

The 60 day repayment rule promulgated under Section 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 for 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.

X. COMPONENT 7: CONSISTENT ENFORCEMENT

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(7).

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.

Tip: *Does your employee handbook provide for sanctions for failing to report suspected problems, participating in non-compliant behavior, or encouraging, directing, facilitating or permitting non-compliant behavior? If this is included in your compliance 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.

XI. COMPONENT 8: RESPONSE AND REMEDIATION

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(c)(8).

The Compliance Program should articulate the facility's commitment to correct compliance issues promptly and thoroughly. The organization should indicate that it is committed to investigate all reported concerns promptly 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. The Compliance Program should explicitly state the expectation that all individuals cooperate with investigation efforts.

Regardless of whether a potential violation is discovered through audit, monitoring or an internal investigation, there should be a response and remediation policy to initiate corrective action, including, as appropriate, making prompt restitution of any overpayments amounts, notifying the appropriate governmental agency, instituting whatever disciplinary action is necessary, and implementing systemic changes to prevent a similar violation from recurring in the future.

This may include internal correction plans, reporting to state and/or federal agencies, repayment of known overpayments in accordance with the 60 day repayment rule, and voluntary disclosures. Violations should always be subjected to a root cause analysis so that corrective measures can be implemented and assessed to prevent future non-compliance. Disciplinary action should be taken, if appropriate, in accordance with the discipline policies.

XII. SUPPLEMENTAL COMPONENT 1 FOR OPERATING ORGANIZATIONS OF FIVE OR MORE: ANNUAL TRAINING

The regulation defines this component as follows:

> 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).

Operating organizations with five or more facilities are required to provide annual training to all staff, including contractors and vendors, about the Compliance Program. CMS does not prescribe the content or duration of the training, but it should, at a minimum address all of the components of the Compliance Program, as well as policies and procedures unique to the organization. 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.

XIII. SUPPLEMENTAL COMPONENT 2 FOR OPERATING ORGANIZATIONS OF FIVE OR MORE: DESIGNATED COMPLIANCE OFFICER

The regulation defines this component as follows:

> 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. 42 C.F.R. §483.85(d)(2).

Operating organizations with four or fewer facilities are not required to have a designated compliance officer under the regulations. For operating organizations with five or more facilities, they must have a compliance officer, and compliance must be that person's major responsibility.

When choosing the right person to be 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. 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. CMS has indicated that any further detail on who can and cannot serve as the compliance officer will be provided in the sub-regulatory guidance. In the interim, CMS refers facilities to additional guidance the OIG has published for nursing home compliance programs, ''OIG Supplemental Compliance Program Guidance for Nursing Facilities'' (73 Fr 56832) (https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf).

XIV. SUPPLEMENTAL COMPONENT 3 FOR OPERATING ORGANIZATIONS OF FIVE OR MORE: DESIGNATED COMPLIANCE LIAISONS

The regulation defines this component as follows:

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

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 Compliance Program that is implemented at five or more facilities.

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 at their individual facilities.

XV. TRAINING REQUIREMENTS, 42 C.F.R. § 483.95(F); F496

CMS has yet to provide guidance as to how it will interpret the training requirements for Compliance Programs.

The regulation states:

> (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 -
>
> (1) 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.
>
> (2) Annual training if the operating organization operates five or more facilities.

42 C.F.R. §483.85(f).

Tracking system for all training including in-house, off-site programs, and staff meetings.

XVI. 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 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