



# **Comprehensive Compliance and Ethics Program Manual & Resources**

## Introduction

The Centers for Medicare and Medicaid Services (CMS) require providers who receive Medicare and Medicaid funding to establish a comprehensive compliance and ethics program. CMS notes that the Office of Inspector General (OIG) issued a Compliance Program Guidance for Nursing Facilities in March 2000, to promote “a higher level of ethical and lawful conduct throughout the entire health care industry”. The Compliance Program Guidance for Nursing Facilities outlined seven elements that should be included in an effective, comprehensive compliance and ethics program ranging from developing and implementing policies and procedures to responding to violations and initiating corrective action.

While the regulatory requirements outlined by CMS are focused on the care of older adults, there are additional considerations when developing a comprehensive compliance and ethics program such as antitrust laws. This manual will provide required and optional elements that can be considered when reviewing your compliance and ethics program.

Assisted Living and other post-acute care providers outside of those accepting Medicare and Medicaid funding may find this manual resourceful and may use any part of it to establish a compliance and ethics program. However, given the philosophy of other provider settings, not all content may be relevant.

You can access resources throughout the manual by using the QR codes or clicking on the links.

## Definitions

Due Care generally means the care that a reasonable person would use under the same or similar circumstances.

Entire Staff include all staff employed by the organization, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers’ expected roles.

## CMS Compliance and Ethics Requirements



[Appendix PP](#) in the State Operations Manual (SOM) issued by CMS includes required elements within the compliance and ethics program that are outlined below and described in additional detail throughout the manual.

- Designation of an individual to receive information regarding potential violations or a compliance officer depending on the size of the organization.
- Written policy and procedure on methods of reporting suspected violations, including anonymous reporting methods without fear of retribution for reporting.

- Written policy and procedure on disciplinary standards and the consequences for committing violations by staff.
- The organization must allow for sufficient resources and authority to assure compliance with the program standards, policies, and procedures.
- Effectively communicate and educate the entire staff on the compliance and ethics program policies, procedures, and standards.
- Taking reasonable steps to achieve compliance by using monitoring and auditing systems, reporting, and ensuring the integrity and accuracy of reported data.
- Establishing a response to detected violations of the compliance and ethics program.
- Reviewing and modifying the program based on the facility assessment, violations, updated laws, among other factors.

## Designation of a Compliance Officer

Organizations with fewer than five nursing homes are required to designate an individual to receive information regarding potential violations of the compliance and ethics program.

Organizations with five or more nursing homes must designate a compliance officer with the compliance and ethics program being a major responsibility in their job duties. In addition, each nursing home must have a compliance liaison who is responsible for assisting the compliance officer with the compliance and ethics program in their designated buildings.

The compliance officer must report directly to the governing body of the organization and should not have interference by other employees such as general counsel, financial or operating officers.

You can view/use the [Sample Compliance Officer Job Description](#) available on our website. In general, the Compliance Officer should assist with:

- Maintaining, investigating, responding to complaints about potential compliance and ethical concerns.
- Participate in the QAPI process.
- Audit or ensure appropriate coding and billing practices occur.
- Assist in planning and providing staff education.
- Developing policies and procedures to prevent and quickly identify compliance and ethics violations.
- Ensure that organizational policies and procedures are followed.



## Reporting Suspected Compliance & Ethics Violations

You must establish and implement a policy and procedure on reporting suspected compliance and ethics violations. To make the most accessible, you should allow these concerns to be reported in a variety of ways such as:

- In writing which could include developing a form for grievances or concerns.
- Via phone, which should include leaving voice messages as the designated Compliance Officer may not be available at all hours. Ensure that phone numbers are posted in readily accessible areas throughout your building, including individuals in wheelchairs.
- By email, again ensuring that the email address is readily accessible throughout your building.

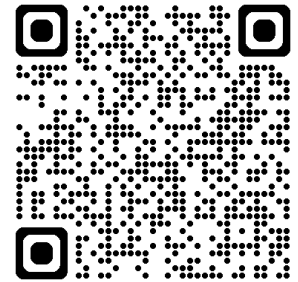
In addition, you must have a process for individuals to anonymously report concerns. This could be done in a variety of ways such as posting contact information for the long-term care ombudsman, state survey agencies, or others who may accept concerns or complaints on behalf of advocacy agencies.

Another method for anonymous reporting is establishing a compliance and ethics hotline. Vendors provide a telephone number for individuals to report concerns, and the information is disseminated to you to follow up on. LeadingAge Illinois and Iowa partner with several businesses that may offer these services. Current business partners for both states can be found in the links or the QR code on the right.

The policy and procedures must include that individuals will not be retaliated against for any reported concerns. While the presentation is specific to employer and employee relationships, you can find ideas for [best practices to prevent retaliation](#) from the Department of Labor.

All reported concerns should be investigated for potential compliance and ethics violations. Based on the results of the investigation, you may need to reference the disciplinary policy discussed later in this manual.

You can access  
[LeadingAge IL  
Business  
Partners here:](#)



and  
[LeadingAge IA  
Business  
Partners here:](#)



## **Disciplinary Standards & Consequences of Compliance and Ethics Violations**

The compliance and ethics program must incorporate a policy and procedure on disciplinary standards for staff who violate the program requirements. Disciplinary actions based on violation are likely very specific to the organizational practices for employee discipline.

In the [General Compliance Program Guidance](#), the OIG encourages providers to include individuals that are involved in the decision-making process for violations within the policy and procedure and that disciplinary action or remedial consequences shall be made on a fair and equitable basis. The Compliance Officer should monitor the investigations conducted and resulting discipline to ensure consistency and that appropriate procedures are followed.

With the requirement for providers to educate staff on the policies and procedures included in the Compliance and Ethics program, it may be best to incorporate examples of disciplinary actions that may result from specific types of violations. For example, you may have a progressive disciplinary practice where an individual first receives a verbal warning or coaching on the infraction/violation and then if the violations continue, additional disciplinary action is taken. However, with compliance and ethics there are likely circumstances that could result in termination of employment without a progressive disciplinary process, such as an incident of abuse, neglect, or misappropriation of a resident's property.

Consideration of establishing a code of conduct policy and procedures may also be beneficial for the provider to establish a commitment to comply with Federal and State laws and regulations.

Consequences of violations may also result in reporting individuals to the appropriate professional licensure board as necessary. For example, if a nurse working in a nursing home is caught taking a resident's opioid medication, the incident could result in immediate termination depending on the organizational procedures, would require reporting to local law enforcement and the state survey agency according to CMS regulations, and the nursing home would report the incident to the board of nursing.

### **Sufficient Resources & Authority**

The compliance and ethics program is required to have enough dedicated provisions to ensure that the Compliance Officer is able to sufficiently carry out the program. This includes workforce to complete all of the steps outlined in the compliance and ethics program as well as financial resources. The regulation does not indicate that a specific policy and procedure must be developed for allocating resources to the program. However, surveyors will likely review the program elements to ensure that they are functioning as outlined. If they are not, they may question individuals if there are adequate resources available or if this is a contributing factor to the identified concerns.

In addition, the Compliance Officer must have sufficient authority to carry out the program. As outlined in the regulation, this person should report directly to the governing board.

## Communication & Education

Providers are required to communicate all policies and procedures on compliance and ethics to the entire staff, which include volunteers and contractors based on their designated roles.

The regulation includes that the training should support current scope and standards of practice for education including objectives, performance standards, and evaluation criteria as well as tracking staff participation in the required training.

At a minimum, providers must conduct this training upon hire for new staff. Organizations that have five or more sites must complete this training on an annual basis. Even though it is not required for providers with fewer than five sites, it is best practice to incorporate compliance and ethics into the training program.

The OIG includes that material addressing concerns identified in audits and investigations, should be incorporated into the training and education program as well as describing the provider's commitment to compliance. The OIG also recommends including:

- The identity and role of the compliance officer.
- The role of the Compliance Committee (if applicable).
- The importance of open communication with the compliance officer.
- The various ways individuals can raise compliance questions and concerns.
- Nonretaliation for disclosing or raising compliance concerns.
- The means through which the entity enforces written policies and procedures equitably and impartially.

## Monitoring & Analyzing

The next principle to incorporate into the compliance and ethics program is how the provider will monitor for compliance and analyze data. This can be done in a variety of ways, depending on what aspect providers are monitoring.

Monitoring can include but is not limited to:

- Monitoring specific problematic or high-risk areas for compliance. The SOM outlines areas of high-risk such as sufficient staffing, care plans, medication management, infection prevention, psychotropic medications, and abuse. These specific areas should already be incorporated into your quality assurance program to ensure that the nursing home is maintaining compliance with the required regulations.

- Monitoring reimbursement practices such as coding the MDS to ensure that items are being coded correctly, services are necessary based on the resident's medical conditions, etc.
- Monitoring non-regulatory standards such as HIPAA violations. This could also be completed in a variety of methods such as examining workstations to ensure electronic equipment is secure, emails are encrypted that contain protected health information, and the information technology (IT) systems are working appropriately, and tests are conducted as required.
- Monitoring that the compliance and ethics policies and procedures are implemented appropriately such as thorough investigations of alleged violations with appropriate disciplinary action based on the results of the investigation.

**Access the  
OIG's  
Compliance  
Program  
Guide [Here:](#)**



This monitoring should lead to establishing data points that can be analyzed for compliance. Take one of the high-risk areas as an example - eight residents in the nursing home are on psychotropic medications and through a review seven residents have an appropriate indication for psychotropic medication use. This would provide you with adequate data to monitor compliance with this requirement as well as trend improvement or worsening in specific compliance measures.

Both monitoring and analyzing the data should be included in the provider's quality assurance and performance improvement (QAPI) program.

According to the OIG's Compliance Guide, additional areas that you may consider as part of a monitoring and analyzing system can include:

- Analyzing applicable legal requirements.
- Assessing, developing, and regularly reviewing policies and procedures.
- Monitoring and recommending internal systems and controls.
- Assessing education and training needs and effectiveness.
- Regularly reviewing required training.
- Conducting annual risk assessments.
- Evaluating the effectiveness of the compliance workplan and any action plans for risk remediation.
- Evaluating the effectiveness of the compliance program.

## **Detecting & Responding to Violations**

When a violation is detected, the organization must ensure that all reasonable steps identified in the program are taken to respond appropriately and prevent similar violations. This includes analyzing the violations and determining root causes with

implementing new interventions and processes to prevent additional violations from occurring. Based on the analysis, the organization's compliance and ethics program may need modification. The SOM includes steps the organization should include when responding to a violation such as:

- Immediately notifying the immediate supervisor when a violation is detected
- Corrective action plans
- Return of overpayments
- Reporting to the appropriate state agencies such as law enforcement, state survey agencies, etc.

The OIG Compliance Guide expands optional items that could be included in the compliance and ethics program such as investigating and documenting violations.

Completing internal investigations will likely include interviews and documentation review. However, additional steps such as data review, email searches, and audits may be necessary to complete a thorough investigation. Based on the results of the investigation, it may be important to contact legal counsel, auditors, or additional experts that can aid the investigation.

Regardless of the size or severity of the violation, the organization should maintain documentation of the response to the violation. This can include:

- Description of the alleged violation
- Results of investigation including interview notes and documentation copies
- Documentation of who and when reporting was completed
- Disciplinary action or corrective action implemented

## **Review & Modification of the Program**

The compliance and ethics program should be routinely reviewed. The SOM indicates that annual review of the program as well as when there are changes in laws and/or requirements. As outlined in various components of the program, there are additional reviews that should be conducted such as corrective action plans.

The SOM also indicates that performance in the previous year should be considered in attempts to improve the compliance and ethics program. Any changes to the compliance and ethics program should be communicated to the entire staff to ensure compliance.

## **Optional Program Considerations**

Compliance with the following laws is necessary, however, they are not required to be included in the compliance and ethics program. Incorporating them into the compliance and ethics program could ensure that the organization is complying, analyzing, and monitoring these applicable laws.



## Anti-Kickback Statute

The Federal anti-kickback statute prohibits organizations involved in Federal health care programs from engaging in some practices that are common in other business sectors, such as offering or receiving gifts to reward past or future referrals. The intention of the statute prohibits remuneration, whether monetary, in-kind, or other forms, in exchange for referrals of Federal health care program business.

The statute also prohibits remuneration to induce, or in return for, the purchasing, leasing, ordering, arranging, or recommending any goods, services or other reimbursable items by another Federal health care program. An example of a violation of the anti-kickback statute would be a hospice company taking management staff on a vacation and in turn the nursing home refers residents specifically to that hospice company.

## Exclusion Statute

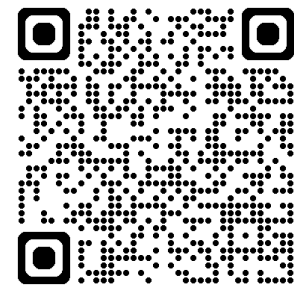
OIG is required to exclude individuals and entities convicted of certain criminal offenses from participating in Federal health care programs. The criminal offenses include:

- Medicare or Medicaid fraud or other offenses related to the delivery of items or services under Medicare or Medicaid.
- Abuse or neglect.
- Felony convictions for other health care related fraud, theft, or other financial misconduct.
- Felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances.
- Discretionary exclusion on additional offenses as determined by the OIG such as misdemeanor convictions related to health care fraud, professional performance, financial integrity, provision of unnecessary or substandard services, submission of false claims among others.

Individuals or entities excluded from participation in the Federal health care programs will not be eligible to receive payment from any Federally funded health care program such as Medicare, Medicaid, TRICARE, and the Veteran's Health Administration. If an excluded provider treats a patient, any orders or prescriptions from that provider will also not be covered under a federal health care program.

Providers must ensure that any staff (as defined above) are not excluded from participating in Federal health care programs by visiting the [OIG's Exclusion](#) website. The exclusion list is updated monthly, which indicates that providers should establish a process for routinely reviewing individuals included in the definition of staff to ensure

**You can find more information on fraud, waste and abuse laws here:**



they are not excluded during the course of their employment or contractual work with the organization.

LeadingAge Illinois/Iowa also developed a resource for members to use on the OIG Exclusion List, which can be found [here](#).

## **False Claims Act**

The civil False Claims Act provides a way for the Government to recover money when an individual or an organization knowingly submits or causes false or fraudulent claims to be submitted for payment. Among other things, the False Claims Act prohibits:

- Knowingly presenting or causing to be presented a false or fraudulent claim for payment or approval to the Federal Government.
- Knowingly making, using, or causing to be made or used a false record or statement to have a false or fraudulent claim paid or approved by the Government, and
- Knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

The False Claims Act also includes when a person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information which means that individuals or entities cannot avoid liability by ignoring inaccuracies in their claims. Examples of false claims include billing for services that were not actually rendered, services that were provided under a previously submitted claim, upcoding, or when information is not supported by the medical record. In addition, the False Claims Act includes a whistleblower provision that allows an individual to file a lawsuit on behalf of the United States and if appropriate, entitles them to a percentage of any recoveries.

## **Criminal Health Care Fraud Statute**

The Criminal Health Care Fraud Statute makes it a criminal offense to defraud a health care benefits program. The Statute includes prohibition of knowingly and willfully executing or attempting to execute a scheme to either defraud any health care benefit program or obtain any money or property from any health care benefit program by means of false or fraudulent pretenses.

## **HIPAA Privacy and Security Rules**

The Standards in the HIPAA Privacy, Security, and Breach Notification rules include the use and disclosure of individuals identifiable health information by covered entities outlined in the rule including health care providers, health plans, and clearinghouses. The Privacy Rule places limits and conditions on the use and disclosure of protected health information without first obtaining an individual's consent and allows individuals certain rights over their protected health information.

The Security Rule is a series of administrative, physical, and technical safeguards that covered entities must take to ensure the confidentiality, integrity, and security of electronic protected health information. In addition, the Breach Notification Rule requires entities to provide notification following a breach of unsecured protected health information. More information on HIPAA Rules can be found [here](#).

## Antitrust Statutes

The U.S. Antitrust Laws represent the nation's commitment to competition and the competitive process. This Statute allows for prosecution of individuals and entities for collusion, monopolization, and other crimes that undermine the free market. In addition, it promotes competition and innovation while protecting consumers, workers, and taxpayers.

This may have an impact on your organization if you share any information on rates for goods and services or conditions of employment such as wage rates or benefits.

You can find more information on the Antitrust Statutes [here](#).

**See Antitrust Red  
Flags for  
Employment  
Practices [Here](#):**



## References:

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