

Prescription Drug Benefit Manual

Chapter 9 - Compliance Program Guidelines

and

Medicare Managed Care Manual

Chapter 21 – Compliance Program Guidelines

Table of Contents

(Chapter 9 - Rev. 15, 07-27-12)

(Chapter 21 - Rev. 109, 07-27-12)

10 – Introduction
20 – Definitions
30 – Overview of Mandatory Compliance Program
40 – Sponsor Accountability for and Oversight of FDRs
50 – Elements of an Effective Compliance Program
50.1 – Element I: Written Policies, Procedures and Standards of Conduct
50.1.1 – Standards of Conduct
50.1.2 – Policies and Procedures
50.1.3 – Distribution of Compliance Policies and Procedures and Standards of Conduct
50.2 – Element II: Compliance Officer, Compliance Committee and High Level Oversight
50.2.1 – Compliance Officer
50.2.2 – Compliance Committee
50.2.3 – Governing Body
50.2.4 – Senior Management Involvement in Compliance Program
50.3 – Element III: Effective Training and Education
50.3.1 – General Compliance Training
50.3.2 – Fraud, Waste, and Abuse Training
50.4 – Element IV: Effective Lines of Communication
50.4.1 – Effective Lines of Communication Among the Compliance Officer, Compliance Committee, Employees, Governing Body, and FDRs
50.4.2 – Communication and Reporting Mechanisms
50.4.3 – Enrollee Communications and Education
50.5 – Element V: Well-Publicized Disciplinary Standards
50.5.1 – Disciplinary Standards
50.5.2 – Methods to Publicize Disciplinary Standards

50.5.3 – Enforcing Disciplinary Standards

50.6 – Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks

50.6.1 – Routine Monitoring and Auditing

50.6.2 – Development of a System to Identify Compliance Risks

50.6.3 – Development of the Monitoring and Auditing Work Plan

50.6.4 – Audit Schedule and Methodology

50.6.5 – Audit of the Sponsor’s Operations and Compliance Program

50.6.6 – Monitoring and Auditing FDRs

50.6.7 – Tracking and Documenting Compliance and Compliance Program Effectiveness

50.6.8 – OIG/GSA Exclusion

50.6.9 – Use of Data Analysis for Fraud, Waste and Abuse Prevention and Detection

50.6.10 – Special Investigation Units (SIUs)

50.6.11 – Auditing by CMS or its Designee

50.7 – Element VII: Procedures and System for Prompt Response to Compliance Issues

50.7.1 – Conducting a Timely and Reasonable Inquiry of Detected Offenses

50.7.2 – Corrective Actions

50.7.3 – Procedures for Self-Reporting Potential FWA and Significant Non Compliance

50.7.4 – NBI MEDIC

50.7.5 – Referrals to the NBI MEDIC

50.7.6 – Responding to CMS-Issued Fraud Alerts

50.7.7 – Identifying Providers with a History of Complaints

Appendix A: Resources

Appendix B: Laws and Regulations to Consider in Standards of Conduct and/or Training

10 – Introduction

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

These compliance program guidelines reflect the Centers for Medicare and Medicaid Services (CMS) interpretation of the Compliance Program requirements and related provisions for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP) (Chapter 42 of the Code of Federal Regulations, Parts 422 and 423, hereinafter collectively referred to as “Parts C & D”). This chapter is designed to assist sponsors to establish and maintain an effective compliance program.

These compliance program guidelines apply fully to the prescription drug benefit programs of sections 1833 and 1876 Cost Plans. In addition, these compliance program guidelines apply to the prescription drug benefit programs of Program of All-Inclusive Care for the Elderly (PACE) plans only with respect to those portions of this chapter that pertain to Elements 6 and 7, which are embodied in 42 C.F.R. 423 §§504(b)(4)(vi)(F) and (G) respectively. These compliance program guidelines do not apply to the PACE plans or to sections 1833 and 1876 Cost Plans that do not have a prescription drug benefit program. However, given the Office of Inspector General (OIG) guidance promoting compliance programs for all sponsors, the CMS strongly encourages sponsors to voluntarily develop and implement effective compliance programs.

This guidance is subject to change as policy, technology and Medicare business practices continue to evolve.

Each sponsor must implement an effective compliance program that meets the regulatory requirements set forth at 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi). Sponsors should apply the principles outlined in these guidelines to all relevant decisions, situations, communications and developments. Any new rule-making or interpretive guidance (e.g., annual call letter or Health Plan Management System (HPMS) guidance memoranda) may update the guidance provided in this document. Sponsors may also wish to consult the resources listed in the Appendices, which provide additional information on some topics addressed in this chapter.

In this chapter, the word “must” is used to reflect requirements created by statute or regulation. The word “should” is used to indicate expectations created by this guidance. Recommendations are noted as “best practices.”

Chapter 9 previously addressed the prevention of fraud, waste and abuse (FWA) by only Part D sponsors. In contrast, this chapter provides interpretive rules and guidance to help all sponsors to establish and maintain an effective compliance program to prevent, detect, and correct FWA and Medicare program noncompliance

These guidelines, published in both Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 9 and in Pub. 100-16, Medicare Managed Care Manual, chapter 21, are

identical and allow organizations offering both Medicare Advantage (MA) and Prescription Drug Plans (PDP) to reference one document for guidance.

20 – Definitions

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

The following definitions apply for purposes of these guidelines only:

Abuse includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Act refers to the Social Security Act.

Appeal (Part C Plan): Any of the procedures that deal with the review of adverse organization determinations on the health care services an enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service as defined in 42 C.F.R. § 422.566(b). These procedures include reconsideration by the MA Plan and, if necessary, an independent review entity, hearings before Administrative Law Judges (ALJs), review by the Medicare Appeals Council (MAC), and judicial review.

Appeal (Part D Plan): Any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in 42 C.F.R. §423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Cost Plan is a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) with a cost-reimbursement contract under section 1876(h) of the Act (See 42

C.F.R. §417.1, §423.4). Cost Plan sponsors may contract to offer prescription drug benefits under the Part D program. (See, 42 C.F.R. §423.4.)

Data Analysis is a tool for identifying coverage and payment errors, and other indicators of potential FWA and noncompliance.

Deemed Provider or Supplier means a provider or supplier that has been accredited by a national accreditation program (approved by CMS) as demonstrating compliance with certain conditions.

DHHS is the Department of Health and Human Services. CMS is the agency within DHHS that administers the Medicare program.

DOJ is the Department of Justice.

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See, 42 C.F.R. §, 423.501).

Employee(s) refers to those persons employed by the sponsor or a First Tier, Downstream or Related Entity (FDR) who provide health or administrative services for an enrollee.

Enrollee means a Medicare beneficiary who is enrolled in a sponsor's Medicare Part C or Part D plan.

External Audit means an audit of the sponsor or its FDRs conducted by outside auditors, not employed by or affiliated with, and independent of, the sponsor.

FDR means First Tier, Downstream or Related Entity.

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. (See, 42 C.F.R. § 423.501).

Formulary means the entire list of Part D drugs covered by a Part D plan and all associated requirements outlined in Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 6.

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or

fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

FWA means fraud, waste and abuse.

Governing Body means that group of individuals at the highest level of governance of the sponsor, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control the sponsor in the best interest of the organization and its enrollees. As used in this chapter, governing body does not include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of the sponsor.

GSA means General Services Administration.

Internal Audit means an audit of the sponsor or its FDRs conducted by auditors who are employed by or affiliated with the sponsor.

Medicare is the health insurance program for the following:

- People 65 or older,
- People under 65 with certain disabilities, or
- People of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant).

Monitoring Activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

NBI MEDIC means National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC), an organization that CMS has contracted with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The NBI MEDIC's primary role is to identify potential FWA in Medicare Parts C and D.

OIG is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

Pharmacy Benefit Manager (PBM) is an entity that provides pharmacy benefit management services, which may include contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs. Some sponsors perform these functions in-house and do not use an outside entity as their PBM. Many PBMs also operate mail order pharmacies or have

arrangements to include prescription availability through mail order pharmacies. A PBM is often a first tier entity for the provision of Part D benefits.

PDP means Prescription Drug Plan.

Related Entity means any entity that is related to an MAO or Part D sponsor by common ownership or control and

- (1) Performs some of the MAO or Part D plan sponsor's management functions under contract or delegation;
- (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
- (3) Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than \$2,500 during a contract period. (See, 42 C.F.R. §423.501).

Special Investigations Unit (SIU) is an internal investigation unit responsible for conducting investigations of potential FWA.

Sponsor refers to the entities described in the Introduction to these guidelines.

TrOOP (True Out of Pocket) Costs are costs that an enrollee must incur on Part D covered drugs to reach catastrophic coverage. (These incurred costs are defined in regulation at §423.100 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 5, section 30). In general, payments counting toward TrOOP include payments by enrollee, family member or friend, Qualified State Pharmacy Assistance Program (SPAP), Medicare's Extra Help (low income subsidy), a charity, manufacturers participating in the Medicare coverage gap discount program, Indian Health Service, AIDS Drug Assistance Programs, or a personal health savings vehicle (flexible spending account, health savings account, medical savings account). Payments that do NOT count toward TrOOP include Part D premiums and coverage by other insurances, group health plans, government programs (non-SPAP), workers' compensation, Part D plans' supplemental or enhanced benefits, or other third parties, drugs purchased outside the United States, and over-the counter drugs and vitamins.

Waste is the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

30 – Overview of Mandatory Compliance Program

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

Section 1860D-4(c)(1)(D) of the Act, 42 C.F.R. §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi)

All sponsors are required to adopt and implement an effective compliance program, which must include measures to prevent, detect and correct Part C or D program noncompliance as well as FWA.

The compliance program must, at a minimum, include the following core requirements:

1. Written Policies, Procedures and Standards of Conduct;
2. Compliance Officer, Compliance Committee and High Level Oversight;
3. Effective Training and Education;
4. Effective Lines of Communication;
5. Well Publicized Disciplinary Standards;
6. Effective System for Routine Monitoring and Identification of Compliance Risks;
and
7. Procedures and System for Prompt Response to Compliance Issues.

In order to be effective, a sponsor's compliance program must be fully implemented, and should be tailored to each sponsor's unique organization, operations and circumstances.

A compliance program will not be effective unless sponsors devote adequate resources to the program. Adequate resources include those that are sufficient to do the following:

1. Promote and enforce its Standards of Conduct
2. Promote and enforce its compliance program;
3. Effectively train and educate its governing body members, employees and FDRs;
4. Effectively establish lines of communication within itself and between itself and its FDRs;
5. Oversee FDR compliance with Medicare Part C and D requirements;
6. Establish and implement an effective system for routine auditing and monitoring;
and
7. Identify and promptly respond to risks and findings.

CMS will consider a sponsor's size, structure, business model, activities, the extent of its delegation of responsibilities to other entities, the breadth of its operation, and the risks it faces in evaluating whether adequate resources have been devoted to the compliance program.

40 – Sponsor Accountability for and Oversight of FDRs

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi), 422.504(i), 423.504(b)(4)(vi), 423.505(i)

Sponsors may enter into contracts with FDRs to provide administrative or health care services for enrollees on behalf of the sponsor. Sponsors may not delegate compliance program administrative functions (e.g., compliance officer, compliance committee, compliance reporting to senior management, etc.) to entities other than its parent organization or corporate affiliate; however, sponsors may use FDRs for compliance activities such as monitoring, auditing, and training.

The sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Therefore, CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements.

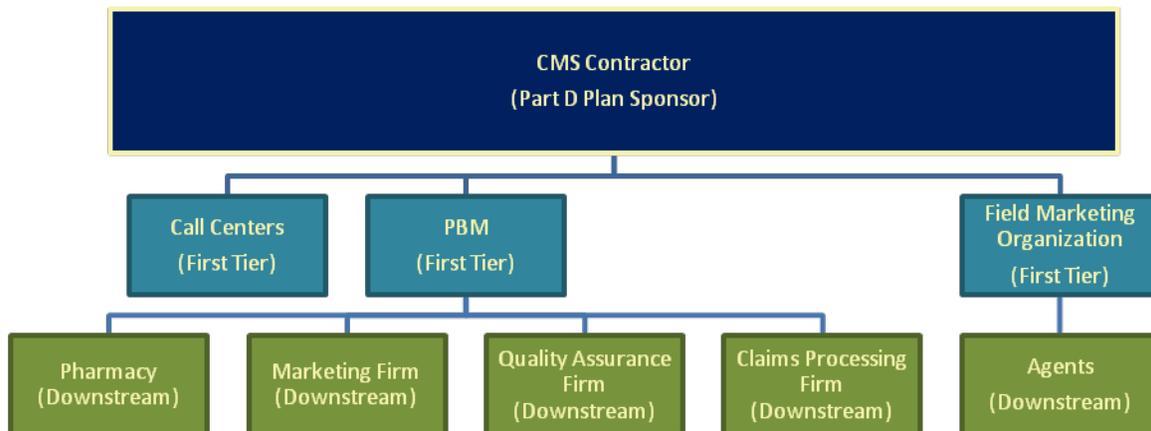
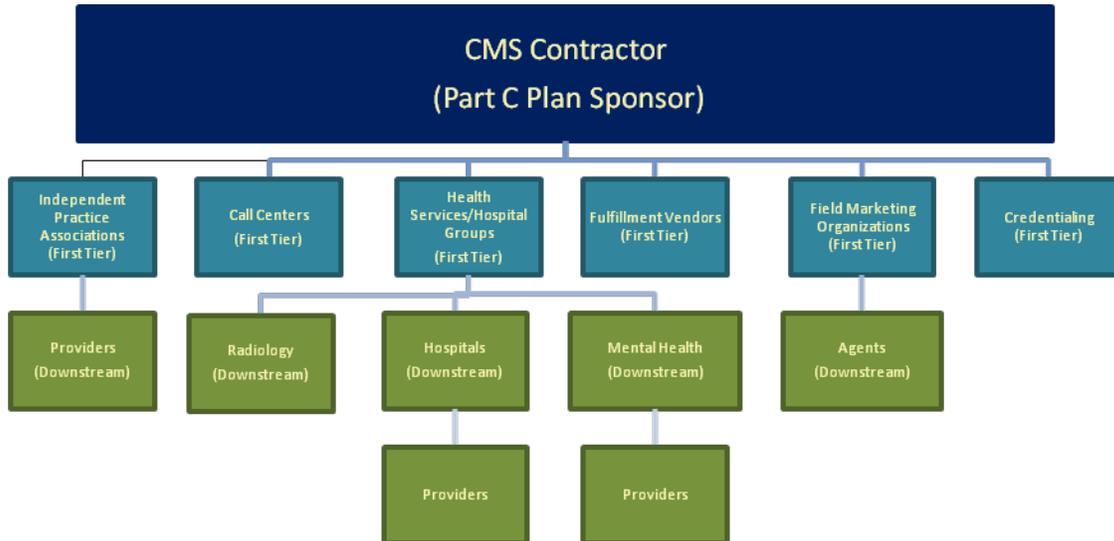
Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions relating to the sponsor's Medicare Parts C and D contracts. These requirements do not apply to persons and entities whose administrative contracts with the sponsor do not relate to the sponsor's Medicare functions, for example, a contract between a sponsor and a real estate broker in connection with the rental of office space.

Below are examples of functions that relate to the sponsor's Medicare Parts C and D contracts:

- Sales and marketing;
- Utilization management;
- Quality improvement;
- Applications processing;
- Enrollment, disenrollment, membership functions;
- Claims administration, processing and coverage adjudication;
- Appeals and grievances;
- Licensing and credentialing;
- Pharmacy benefit management;
- Hotline operations;
- Customer service;
- Bid preparation;
- Outbound enrollment verification;
- Provider network management;
- Processing of pharmacy claims at the point of sale;
- Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs;

- Administration and tracking of enrollees' drug benefits, including TrOOP balance processing;
- Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs;
- Entities that generate claims data; and
- Health care services.

Stakeholder Relationship Flow Charts



First tier and related entities may contract with downstream entities to fulfill their contractual obligations to the sponsors. A field marketing organization (first tier entity) may contract with a smaller brokerage firm (downstream entity) to sell the sponsors' Medicare Parts C and D products. That smaller brokerage firm may further contract with individual sales agents (downstream entities) to perform the day-to-day sales work. A related entity may also be either a first tier entity or a downstream entity.

It is critical that sponsors correctly identify those entities with which they contract that qualify as FDRs. Sponsors are required to comply with CMS requirements for FDRs. Unless it is very clear that an entity is or is not an FDR, the determination of FDR status requires an analysis of all of the circumstances. Sponsors should have clearly defined

processes and criteria to evaluate and categorize all vendors with which they contract. Below are some factors to consider in determining whether an entity is an FDR:

- The function to be performed by the delegated entity;
- Whether the function is something the sponsor is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance;
- To what extent the function directly impacts enrollees;
- To what extent the delegated entity has interaction with enrollees, either orally or in writing;
- Whether the delegated entity has access to beneficiary information or personal health information;
- Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from the sponsor;
- The extent to which the function places the delegated entity in a position to commit health care fraud, waste or abuse; and
- The risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA.

The method by which the analysis is performed is left to the discretion of the sponsor. Some sponsors use a multi-functional committee, consisting of members from the compliance and legal departments as well as the business owner of the FDR function, to make the determination.

The sponsor's compliance officer, working with the sponsor's compliance committee, must develop procedures to promote and ensure that all FDRs are in compliance with all applicable laws, rules and regulations with respect to Medicare Parts C and D delegated responsibilities. The sponsor must have a system in place to monitor FDRs. Sponsors are free to choose the method for monitoring their FDRs' compliance with Medicare program requirements. Sponsors must be able to demonstrate that their method of monitoring is effective. It is a best practice to use metrics to assist in observing compliance performance and operational trends.

For more information on requirements for contracts with FDRs, see Pub. 100-16, Medicare Managed Care Manual, chapter 11, §110.

50 – Elements of an Effective Compliance Program

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi)

This section discusses the seven elements of an effective compliance program, as set forth in the applicable Federal regulations governing Parts C and D.

50.1 – Element I: Written Policies, Procedures and Standards of Conduct

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Sponsors must have written policies, procedures and standards of conduct that –

1. Articulate the sponsor’s commitment to comply with all applicable Federal and State standards;
2. Describe compliance expectations as embodied in the Standards of Conduct;
3. Implement the operation of the compliance program;
4. Provide guidance to employees and others on dealing with suspected, detected or reported compliance issues;
5. Identify how to communicate compliance issues to appropriate compliance personnel;
6. Describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor; and
7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

The requirements that are discussed in this section must be included as part of the compliance program but may be stated either in policies and procedures or in Standards of Conduct. They may, but need not, appear in both documents.

50.1.1 – Standards of Conduct

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Standards of Conduct, also known in some organizations as the “Code of Conduct” or by other similar names, state the overarching principles and values by which the company operates, and define the underlying framework for the compliance policies and procedures. Standards of Conduct should describe the sponsor’s expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected.

The Standards of Conduct may be stated in a separate Medicare-specific stand-alone document or within the corporate Code of Conduct. Sponsors should update the Standards of Conduct to incorporate changes in applicable laws, regulations, and other program requirements, such as those listed in Appendix B.

Standards of Conduct communicate to employees and FDRs that compliance is everyone’s responsibility from the top to the bottom of the organization. For that reason, and because Standards of Conduct are the most fundamental statement of the sponsor’s governing principles, Standards of Conduct should be approved by the sponsor’s full governing body.

It is a best practice of some sponsors to include a resolution of the full governing body stating the sponsor’s commitment to compliant, lawful and ethical conduct. This communicates to employees and FDRs that compliance and ethics are valued and important to those at the highest levels of authority in the company.

50.1.2 – Policies and Procedures

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Compliance policies and/or procedures are detailed and specific, and describe the operation of the compliance program. Compliance policies may address issues such as sponsors’ compliance reporting structure, compliance and FWA training requirements, the operation of the hotline or other reporting mechanisms, and how suspected, detected or reported compliance and potential FWA issues are investigated and addressed and remediated. Sponsors should update the policies and procedures to incorporate changes in applicable laws, regulations, and other program requirements.

50.1.3 – Distribution of Compliance Policies and Procedures and Standards of Conduct

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

In order to be effective, compliance policies and procedures and Standards of Conduct must be distributed to employees who support the sponsor's Medicare business. Distribution must occur within 90 days of hire, when there are updates to the policies, and annually thereafter. Sponsors may choose their distribution method. Some examples are furnishing hard copies at the time of hire and electronic copies thereafter, emailing an electronic copy, or posting on the company intranet. The sponsors should have a method to demonstrate that the Standards of Conduct and policies and procedures were distributed to employees.

The Standards of Conduct should be written in a format that is easy to read and comprehend. Sponsors should consider translating Standards of Conduct and policies and procedures into other languages as necessary.

In order to communicate the sponsor's compliance expectations for FDRs, sponsors should ensure that Standards of Conduct and policies and procedures are distributed to FDRs' employees. Sponsors may make their Standards of Conduct and policies and procedures available to their FDRs. Alternatively, the sponsor may ensure that the FDR has comparable policies and procedures and Standards of Conduct of their own.

The sponsors should have a method to demonstrate that Standards of Conduct and policies and procedures were distributed to FDRs' employees. Sponsors or the FDR may make the policies available through methods such as a fax blast, placement on an FDR portal, in contract materials, etc. A best practice is to include appropriate contract provisions in the FDR contract, coupled with periodic monitoring of a sample of FDRs based on risk assessment, including a review of the FDRs' compliance policies and procedures and Standards of Conduct.

50.2 – Element II: Compliance Officer, Compliance Committee and High Level Oversight

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The sponsor must designate a compliance officer and a compliance committee who report directly and are accountable to the sponsor's chief executive or other senior management.

1. The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the sponsor, parent organization or corporate affiliate. The compliance officer may not be an employee of an FDR.
2. The compliance officer and the compliance committee must periodically report directly to the sponsor's governing body on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.
3. The sponsor's governing body must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance program.

50.2.1 – Compliance Officer

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The compliance officer position should be full-time. The sponsor is not required to have a separate compliance officer (“Medicare Compliance Officer”) dedicated only to its Medicare Parts C and D business, although CMS strongly recommends a dedicated Medicare compliance officer. Sponsors must assess the scope of the existing compliance officer's responsibilities, the size of the organization, and the organization's resources when determining whether a single compliance officer can effectively implement the Medicare compliance program and the sponsor's commercial or other governmental business.

The compliance officer must be an employee of the sponsor (preferred) or of its parent company or corporate affiliate. Sponsors may not delegate the compliance officer position or compliance program functions to first tier or downstream entities. When the compliance officer is not employed by the sponsor itself, but by the sponsor's parent company or corporate affiliate, the sponsor must ensure that the compliance officer has detailed involvement in and familiarity with the sponsor's operational and compliance activities.

The sponsor must ensure that reports from the compliance officer reach the sponsor's senior-most leader (typically the CEO or President). The direct reporting relationship between the compliance officer and the senior-most leadership refers to the direct reporting of information, not necessarily to a supervisory reporting relationship. This can be accomplished through a dotted line or matrix reporting.

The compliance officer must have express authority to provide unfiltered, in-person reports to the sponsor's senior-most leader. The compliance officer's reports should not be routed to the CEO or President through operational management such as the COO,

CFO, GC (General Counsel) or other executives responsible for operational areas. For example, the compliance officer's report to the CEO should not be filtered through the CFO. However, the compliance officer's reports may be relayed to the sponsor's senior-most leader through divisional Presidents. For example, the compliance officer may report directly to the President of the division that houses the Medicare program, who then reports to the CEO of the sponsor on the status and activities of the Medicare compliance program.

The compliance officer's reports to the sponsor's governing body must be made through the compliance infrastructure. The sponsor's governing body is responsible for Medicare compliance program oversight, not a parent company's governing body. The compliance officer must have express authority to provide unfiltered, in-person reports to the sponsor's governing body at his/her discretion.

The Medicare compliance officer may report compliance issues directly to the corporate compliance officer and/or the compliance committee, who then provide compliance reports directly to the sponsor's governing body. The compliance officer, in his/her discretion, need not await approval of the sponsor's governing body to implement needed compliance actions and activities, provided that those actions and activities, as appropriate, are reported to the governing body or governing body committee at its next scheduled meeting. It is a best practice for sponsors who have both a corporate compliance officer and a Medicare compliance officer to allow the Medicare compliance officer to regularly attend meetings of the sponsor's governing body and to make in-person reports to the sponsor's governing body. A related best practice is to allow the compliance officer to meet in Executive Session with the governing body.

The compliance officer should be independent. The compliance officer should not serve in both compliance and operational areas (e.g., where the compliance officer is also the CFO, COO or GC). This leads to self-policing in the operational area(s) in which he/she serves, which is a conflict of interest.

Because the compliance officer must be free to raise compliance issues without fear of retaliation, it is a best practice to require governing body approval before the compliance officer can be terminated from employment.

The compliance officer is responsible for the implementation of the compliance program. The compliance officer defines the program structure, educational requirements, reporting, and complaint mechanisms, response and correction procedures, and compliance expectations of all personnel and FDRs.

The compliance officer should have training and/or experience working with MA, MA-PD or PDP programs and, with regulatory authorities. It is a best practice for the compliance officer to be a member of senior management.

Duties of the compliance officer may include, but are not limited to:

- Ensuring that Medicare compliance reports are provided regularly to the sponsor's corporate compliance officer (if any), governing body, CEO, and compliance committee. Reports should include the status of the sponsor's Medicare compliance program implementation, the identification and resolution of suspected, detected or reported instances of noncompliance, and the sponsor's compliance oversight and audit activities;
- Being aware of daily business activity by interacting with the operational units of the sponsor;
- Creating and coordinating, by appropriate delegation, if desired, educational training programs to ensure that the sponsor's officers, governing body, managers, employees, FDRs, and other individuals working in the Medicare program are knowledgeable about the sponsor's compliance program, its written Standards of Conduct, compliance policies and procedures, and all applicable statutory and regulatory requirements;
- Developing and implementing methods and programs that encourage managers and employees to report Medicare program noncompliance and potential FWA without fear of retaliation;
- Maintaining the compliance reporting mechanism and closely coordinating with the internal audit department and the SIU, where applicable;
- Responding to reports of potential FWA, including the coordination of internal investigations with the SIU or internal audit department and the development of appropriate corrective or disciplinary actions, if necessary. To that end, the compliance officer should have the flexibility to design and coordinate internal investigations;
- Ensuring that the DHHS OIG and Government Services Administration ("GSA") exclusion lists have been checked with respect to all employees, governing body members, and FDRs monthly and coordinating any resulting personnel issues with the sponsor's Human Resources, Security, Legal or other departments as appropriate;
- Maintaining documentation for each report of potential noncompliance or potential FWA received from any source, through any reporting method (e.g., hotline, mail, or in-person);
- Overseeing the development and monitoring of the implementation of corrective action plans;
- Coordinating potential fraud investigations/referrals with the SIU, where applicable, and the appropriate NBI MEDIC. This includes facilitating any documentation or procedural requests that the NBI MEDIC makes of the sponsor.

Similarly, the compliance officer should collaborate with other sponsors, State Medicaid programs, Medicaid Fraud Control Units (MCFUs), commercial payers, and other organizations, where appropriate, when a potential FWA issue is discovered that involves multiple parties; and

- The compliance officer should have the authority to:
 - Interview or delegate the responsibility to interview the sponsor's employees and other relevant individuals regarding compliance issues;
 - Review company contracts and other documents pertinent to the Medicare program;
 - Review or delegate the responsibility to review the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements;
 - Independently seek advice from legal counsel;
 - Report potential FWA to CMS, its designee or law enforcement;
 - Conduct and/or direct audits and investigations of any FDRs;
 - Conduct and/or direct audits of any area or function involved with Medicare Parts C or D plans; and
 - Recommend policy, procedure, and process changes.

50.2.2– Compliance Committee

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

Sponsors must have a compliance committee in place that oversees the Medicare compliance program. The sponsor need not have a separate Medicare compliance committee, as long as the committee addresses Medicare compliance issues. In many organizations, the compliance committee is chaired by the compliance officer. The compliance committee serves to advise the compliance officer. The compliance committee is accountable to, and must provide regular compliance reports to, the sponsor's senior-most leader and governing body. Reports on the status of the compliance program are usually reported through the chairperson of the committee.

Duties of the compliance committee may include, but are not limited to:

- Meeting at least on a quarterly basis, or more frequently as necessary to enable reasonable oversight of the compliance program;
- Developing strategies to promote compliance and the detection of any potential violations;
- Reviewing and approving compliance and FWA training, and ensuring that training and education are effective and appropriately completed;
- Assisting with the creation and implementation of the compliance risk assessment and of the compliance monitoring and auditing work plan;
- Assisting in the creation, implementation and monitoring of effective corrective actions;
- Developing innovative ways to implement appropriate corrective and preventative action;
- Reviewing effectiveness of the system of internal controls designed to ensure compliance with Medicare regulations in daily operations;
- Supporting the compliance officer's needs for sufficient staff and resources to carry out his/her duties;
- Ensuring that the sponsor has appropriate, up-to-date compliance policies and procedures;
- Ensuring that the sponsor has a system for employees and FDRs to ask compliance questions and report potential instances of Medicare program noncompliance and potential FWA confidentially or anonymously (if desired) without fear of retaliation;
- Ensuring that the sponsor has a method for enrollees to report potential FWA
- Reviewing and addressing reports of monitoring and auditing of areas in which the sponsor is at risk for program noncompliance or potential FWA and ensuring that corrective action plans are implemented and monitored for effectiveness; and
- Providing regular and ad hoc reports on the status of compliance with recommendations to the sponsor's governing body.

The compliance committee should include individuals with a variety of backgrounds, and reflect the size and scope of the sponsor. Members of the compliance committee should have decision-making authority in their respective areas of expertise. Sponsors should include members of senior management (e.g., CFO, COO), as well as auditors, pharmacists, registered nurses, and nationally certified pharmacy technicians on the

compliance committee (to the extent that their organization has those positions on staff.). Other committee members might include personnel experienced in legal issues, statistical analysts, and staff/managers from various departments within the organization who understand the vulnerabilities within their respective areas of expertise.

50.2.3 – Governing Body

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The sponsor's governing body (e.g., Board of Directors or Board of Trustees) must exercise reasonable oversight with respect to the implementation and effectiveness of the sponsor's compliance program. The governing body of the organization that contracted with CMS or its parent company may oversee the Medicare compliance program. When compliance issues are presented to the sponsor's governing body, it should make further inquiry and take appropriate action to ensure the issues are resolved.

The sponsor's governing body may delegate compliance program oversight to a specific committee of the governing body (e.g., Board Audit Committee or Board compliance committee), but the governing body as a whole remains accountable for reviewing the status of the compliance program. The scope of the delegation from the full governing body to the governing body committee must be clear in the committee's charter and reporting.

The governing body must receive training and education as to the structure and operation of the compliance program. The governing body should be knowledgeable about compliance risks and strategies, should understand the measurements of outcome, and should be able to gauge effectiveness of the compliance program.

Reasonable oversight by the governing body (assisted by a committee, if desired) includes, but is not limited to:

- Approving the Standards of Conduct (this should be performed by the full governing body and not a committee);
- Understanding the compliance program structure;
- Remaining informed about the compliance program outcomes, including results of internal and external audits;
- Remaining informed about governmental compliance enforcement activity such as Notices of Non-Compliance, Warning Letters and/or more formal sanctions;

- Receiving regularly scheduled, periodic updates from the compliance officer and compliance committee; and
- Reviewing the results of performance and effectiveness assessments of the compliance program.

The following are examples of activities in which the governing body, or a governing body committee, may wish to have involvement. Alternatively, the governing body may delegate some or all of these activities to senior management or to the compliance committee:

- Development, implementation and annual review of compliance policies and procedures;
- Approval of compliance policies and procedures;
- Review and approval of compliance and FWA training;
- Review and approval of compliance risk assessment;
- Review of internal and external audit work plans and audit results;
- Review and approval of corrective action plans resulting from audits;
- Review and approval of appointment of the compliance officer;
- Review and approval of performance goals for the compliance officer;
- Evaluation of the senior management team's commitment to ethics and the compliance program; and
- Review of dashboards, scorecards, self-assessment tools, etc., that reveal compliance issues.

The governing body should collect and review measurable evidence that the compliance program is detecting and correcting Medicare program noncompliance on a timely basis. It is a best practice for the governing body to be provided with data showing that the program has reduced the risks of program noncompliance and FWA. Some indicators of an effective compliance program are:

- Use of quantitative measurement tools (e.g., scorecards, dashboard reports, key performance indicators) to report, and track and compare over time, compliance with key Medicare Parts C and D operations such as enrollment, appeals and grievances, prescription drug benefit administration;

- Use of monitoring to track and review open/closed corrective action plans, FDR compliance, Notices of Non-Compliance, warning letters, CMS sanctions, marketing material approval rates, training completion/pass rates, etc.;
- Implementation of new or updated Medicare requirements (e.g., tracking HPMS memo from receipt to implementation) including monitoring or auditing and quality control measures to confirm appropriate and timely implementation;
- Increase or decrease in number and/or severity of complaints from employees, FDRs, providers, beneficiaries through customer service calls or the Complaint Tracking Module (CTM), marketing misrepresentations, Parts A and B issues, etc.;
- Timely response to reported noncompliance and potential FWA, and effective resolution (i.e., non-recurring issues);
- Consistent, timely and appropriate disciplinary action; and
- Detection of noncompliance and FWA issues through monitoring and auditing:
 - Whether root cause was determined and corrective action appropriately and timely implemented and tested for effectiveness;
 - Detection of FWA trends and schemes via daily claims reviews, outlier reports, pharmacy audits, etc.; and
 - Actions taken in response to compliance reports submitted by FDRs.

The sponsor should ensure that CMS is able to validate, through review of governing body meeting minutes or other documentation, the active engagement of the governing body in the oversight of the Medicare compliance program. A governing body that is appropriately engaged asks questions, requires follow-up on issues and takes action when necessary.

50.2.4 – Senior Management Involvement in Compliance Program
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

An effective compliance program cannot be achieved unless the CEO (or senior-most leader) and other senior management, as appropriate, are engaged in the compliance program. The CEO and senior management must recognize the importance of the compliance program in the sponsor's success.

In situations where the contract holder engages in multiple lines of business (e.g., commercial, Medicare, etc.), with each line of business having its own CEO, the senior-most leader of the contract holder must be engaged in compliance program oversight.

The CEO and senior management should ensure that the compliance officer is integrated into the organization and is given the credibility, authority and resources necessary to operate a robust and effective compliance program. The CEO must receive periodic reports from the compliance officer of risk areas facing the organization, the strategies being implemented to address them and the results of those strategies. The CEO must also be advised of all governmental compliance enforcement activity, from Notices of Non-compliance to formal enforcement actions.

50.3 – Element III: Effective Training and Education

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The sponsor must establish, implement and provide effective training and education for its employees, including the CEO, senior administrators or managers, and for the governing body members, and FDRs.

The training and education must occur at least annually and be made a part of the orientation for new employees, including the chief executive and senior administrators or managers, governing body members, and FDRs.

FDRs who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.

Effectiveness of Training and Education

Effectiveness of training, education, compliance policies and procedures, and Standards of Conduct will be apparent through sponsor's compliance with all Medicare program requirements. Sponsors must ensure that employees are aware of the Medicare requirements related to their job function.

50.3.1 – General Compliance Training

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The sponsor's employees (including temporary workers and volunteers), and governing body members, must, at a minimum, receive general compliance training within 90 days of initial hiring, and annually thereafter. The following are examples of how sponsors may satisfy the general compliance training requirements:

- Classroom training;
- Online training modules; or
- Attestations that employees have read and received the sponsor's Standards of Conduct and/or compliance policies and procedures.

Sponsors must be able to demonstrate that their employees have fulfilled these training requirements. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.

Sponsors must ensure that general compliance information is communicated to their FDRs. The sponsor's compliance expectations can be communicated through distribution of the sponsor's Standards of Conduct and/or compliance policies and procedures to FDRs' employees. Distribution may be accomplished through Provider Guides, Business Associate Agreements or Participation Manuals, etc.

Sponsors should review and update, if necessary, the general compliance training whenever there are material changes in regulations, policy or guidance, and at least annually.

The following are examples of topics the general compliance training program should communicate:

- A description of the compliance program, including a review of compliance policies and procedures, the Standards of Conduct, and the sponsor's commitment to business ethics and compliance with all Medicare program requirements;
- An overview of how to ask compliance questions, request compliance clarification or report suspected or detected noncompliance. Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;
- The requirement to report to the sponsor actual or suspected Medicare program noncompliance or potential FWA;
- Examples of reportable noncompliance that an employee might observe;
- A review of the disciplinary guidelines for non-compliant or fraudulent behavior. The guidelines will communicate how such behavior can result in mandatory retraining and may result in disciplinary action, including possible termination

when such behavior is serious or repeated or when knowledge of a possible violation is not reported;

- Attendance and participation in compliance and FWA training programs as a condition of continued employment and a criterion to be included in employee evaluations;
- A review of policies related to contracting with the government, such as the laws addressing gifts and gratuities for Government employees;
- A review of potential conflicts of interest and the sponsor's system for disclosure of conflicts of interest;
- An overview of HIPAA/HITECH, the CMS Data Use Agreement (if applicable), and the importance of maintaining the confidentiality of personal health information;
- An overview of the monitoring and auditing process; and
- A review of the laws that govern employee conduct in the Medicare program.

See Appendix B for other examples of laws and regulations that may be discussed in training.

50.3.2 –Fraud, Waste, and Abuse Training

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The sponsor's employees (including temporary workers and volunteers), and governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter. Additional, specialized or refresher training may be provided on issues posing FWA risks based on the individual's job function (e.g., pharmacist, statistician, customer service, etc.). Training may be provided:

- upon appointment to a new job function;
- when requirements change;
- when employees are found to be noncompliant;
- as a corrective action to address a noncompliance issue; and
- when an employee works in an area implicated in past FWA.

Sponsors may choose to tailor the training in response to circumstances surrounding potential FWA and specific functions performed by FDRs.

Sponsors must be able to demonstrate that their employees and FDRs have fulfilled these training requirements as applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.

Sponsors must provide the FWA training directly to their FDRs or provide appropriate FWA training materials to their FDRs.

To reduce the potential burden on FDRs, CMS has developed and provided a standardized FWA training and education module. The module is available through the CMS Medicare Learning Network (MLN) at <http://www.cms.gov/MLNProducts>. Using CMS' training module is optional and a sponsor may use another method. However, this training meets CMS' FWA training requirements so sponsors should accept FDRs' use of this FWA training option. For details on accessing the FWA training and education on the MLN website, see the May 8, 2012, HPMS memo regarding Fraud, Waste and Abuse Training and Education Guidance.

Topics that should be addressed in FWA training include, but are not limited to the following:

- Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.);
- Obligations of FDRs to have appropriate policies and procedures to address FWA;
- Processes for sponsors and FDR employees to report suspected FWA to the sponsor (or, as to FDR employees, either to the sponsor directly or to their employers who then must report it to the sponsor);
- Protections for sponsor and FDR employees who report suspected FWA; and
- Types of FWA that can occur in the settings in which sponsor and FDR employees work.

Sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees, and must require FDRs to maintain records of the training of the FDRs' employees.

FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements. No additional

documentation beyond the documentation necessary for proper credentialing is required to establish that an employee or FDR or employee of an FDR is deemed. In the case of chains, such as chain pharmacies, each individual location must be enrolled into Medicare Part A or B to be deemed. See examples of such entities in Pub. 100-16, Medicare Managed Care Manual, chapter 6 §70.

50.4 – Element IV: Effective Lines of Communication

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

The sponsor must establish and implement effective lines of communication, ensuring confidentiality between the compliance officer, members of the compliance committee, the sponsor's employees, managers and governing body, and the sponsor's FDRs. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

50.4.1 – Effective Lines of Communication Among the Compliance Officer, Compliance Committee, Employees, Governing Body, and FDRs

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

Sponsors must have an effective way to communicate information from the compliance officer to others. Such information should include the compliance officer's name, office location and contact information; laws, regulations and guidance for sponsors and FDRs, such as statutory, regulatory, and sub-regulatory changes (e.g., HPMS memos); and changes to policies and procedures and Standards of Conduct.

Methods to communicate information may include physical postings of information, e-mail distributions, internal websites, and individual and group meetings with the compliance officer. The dissemination of information from the compliance officer must be made within a reasonable time and to all appropriate parties.

50.4.2 – Communication and Reporting Mechanisms

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

The sponsor's written Standards of Conduct and/or policies and procedures must require all employees, members of the governing body, and FDRs to report compliance concerns and suspected or actual violations related to the Medicare program to the sponsor.

Sponsors must have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, enrollees and FDRs and their employees. Reporting systems must maintain confidentiality (to the greatest extent possible), allow anonymity if desired (e.g., through telephone hotlines or mail drops), and emphasize the sponsor's / FDR's policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the compliance program. FDRs that partner with multiple sponsors may train their employees on the FDR's reporting processes including emphasis that reports must be made to the appropriate sponsor.

Sponsors must adopt, widely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee or FDR who in good faith reports suspected FWA. Employees and FDRs must be notified that they are protected from retaliation for False Claims Act complaints, as well as any other applicable anti-retaliation protections.

The methods available for reporting compliance or FWA concerns and the non-retaliation policy must be publicized throughout the sponsor's or FDR's facilities. This information can be publicized, for example, through the use of posters, table tents, mouse pads, key cards and other prominent displays. General compliance training should include the reporting requirements and the available methods for reporting.

Sponsors must make the reporting mechanisms user friendly, easy to access and navigate, and available 24 hours a day for employees, members of the governing body, and FDRs. It is a best practice for sponsors to establish more than one type of reporting mechanism to account for the different ways in which people prefer to communicate or feel comfortable communicating.

When a suspected compliance issue is reported, it is a best practice for sponsors to provide the complainant with information regarding expectations of a timely response, confidentiality, non-retaliation and progress reports.

50.4.3 – Enrollee Communications and Education

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

Sponsors must educate their enrollees about identification and reporting of potential FWA. Education methods may include flyers, letters, pamphlets that can be included in

mailings to enrollees (such as enrollment packages, Explanation of Benefits (“EOB”), and information published on sponsor websites (especially on enrollee links), etc.).

50.5 – Element V: Well-Publicized Disciplinary Standards

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must have well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that:

1. Articulate expectations for reporting compliance issues and assist in their resolution;
2. Identify noncompliance or unethical behavior; and
3. Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

50.5.1 – Disciplinary Standards

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must establish and implement disciplinary policies and procedures that reflect clear and specific disciplinary standards. The disciplinary policies must describe the sponsor’s expectations for the reporting of compliance issues including noncompliant, unethical or illegal behavior, that employees participate in required training, and the expectations for assisting in the resolution of reported compliance issues. In addition, the disciplinary policies must identify noncompliant, unethical or illegal behavior, through examples of violative conduct that employees might encounter in their jobs. Further, the policies must provide for timely, consistent and effective enforcement of the standards when noncompliant or unethical behavior is found. Finally, the disciplinary action must be appropriate to the seriousness of the violation.

50.5.2 – Methods to Publicize Disciplinary Standards

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

To encourage good faith participation in the compliance program, sponsors must publicize disciplinary standards for employees and FDRs. The standards should include the duty and expectation to report issues or concerns. The following are examples of the types of publication mechanisms that could be used:

- Newsletters;
- Regular presentations at department staff meetings;
- Communications with FDRs;
- General compliance training;
- Intranet site;
- Posters prominently displayed throughout employee work and break areas; and
- Cafeteria table tents.

50.5.3 – Enforcing Disciplinary Standards

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must be able to demonstrate to CMS that disciplinary standards are enforced in a timely, consistent and effective manner. Records must be maintained for a period of 10 years for all compliance violation disciplinary actions, capturing the date the violation was reported, a description of the violation, date of investigation, summary of findings, disciplinary action taken and the date it was taken. Sponsors should periodically review these records of discipline to ensure that disciplinary actions are appropriate to the seriousness of the violation, fairly and consistently administered and imposed within a reasonable timeframe. Sponsors may consider including compliance as a measure on an individual's annual performance review. In addition, a best practice followed by some sponsors is to publish de-identified disciplinary action in employee publications, such as a newsletter, in order to demonstrate to employees that disciplinary action is imposed for violations.

50.6 – Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and

audits and, as appropriate, external audits, to evaluate the sponsor's, including FDRs', compliance with CMS requirements and the overall effectiveness of the compliance program.

50.6.1 – Routine Monitoring and Auditing

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors must undertake monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare program noncompliance and potential FWA.

Monitoring activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective. An audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Sponsors must develop a monitoring and auditing work plan that addresses the risks associated with the Medicare Parts C and D benefits. The compliance officer and compliance committee are key participants in this process.

Sponsors must have a system of ongoing monitoring and auditing that is reflective of its size, organization, risks and resources to assess performance in, at a minimum, areas identified as being at risk. The monitoring and auditing work plan must be coordinated, overseen and/or executed by the compliance officer, assisted if desired by the compliance department staff and/or the compliance committee. The compliance officer may coordinate with the audit department, if any, in connection with these activities. The compliance officer must receive regular reports from the audit department or from those who are conducting the audits regarding the results of auditing and monitoring and the status and effectiveness of corrective actions taken. It is the responsibility of the compliance officer or his/her designee to provide updates on monitoring and auditing results to the compliance committee, the CEO, senior leadership and the sponsor's governing body. In addition, for specific work coordinated with the audit department, the compliance officer and Chief Audit Executive may share the responsibility to provide updates on monitoring and auditing results to the compliance committee, the CEO, senior leadership and the sponsor's governing body.

50.6.2 – Development of a System to Identify Compliance Risks

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors must establish and implement policies and procedures to conduct a formal baseline assessment of the sponsor's major compliance and FWA risk areas, such as through a risk assessment. The sponsor's assessment must take into account all Medicare business operational areas. Each operational area must be assessed for the types and levels of risks the area presents to the Medicare program and to the sponsor. Factors that sponsors may consider in determining the risks associated with each area include, but are not limited to:

- Size of department;
- Complexity of work;
- Amount of training that has taken place;
- Past compliance issues; and
- Budget.

Areas of particular concern for Medicare Parts C and D sponsors include, but are not limited to, marketing and enrollment violations, agent/broker misrepresentation, selective marketing, enrollment/disenrollment noncompliance, credentialing, quality assessment, appeals and grievance procedures, benefit/formulary administration, transition policy, protected classes policy, utilization management, accuracy of claims processing, detection of potentially fraudulent claims, and FDR oversight and monitoring.

Risks identified by the risk assessment must be ranked to determine which risk areas will have the greatest impact on the sponsor, and the sponsor must prioritize the monitoring and auditing strategy accordingly. Risks change and evolve with changes in the law, regulations, CMS requirements and operational matters. Therefore, there must be ongoing review of potential risks of noncompliance and FWA and a periodic re-evaluation of the accuracy of the sponsor's baseline assessments. Risk areas identified through CMS audits and oversight, as well as through the sponsor's own monitoring, audits and investigations are priority risks. The results of the risk assessment inform the development of the monitoring and audit work plan.

50.6.3 – Development of the Monitoring and Auditing Work Plan

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Once the risk assessment has been completed, a monitoring and auditing work plan must be developed. The compliance officer may coordinate with each department to develop a monitoring and auditing work plan based upon the results of the risk assessment. The work plan may include:

- The audits to be performed;

- Audit schedules, including start and end dates
- Announced or unannounced audits;
- Audit methodology;
- Necessary resources;
- Types of Audit: desk or onsite;
- Person(s) responsible;
- Final audit report due date to compliance officer; and
- Follow up activities from findings.

Sponsors must include in their work plans a process for responding to all monitoring and auditing results and for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems.

Corrective action and follow-up should be led or overseen by the compliance officer and assisted, if desired, by the compliance department staff, and include actions such as reporting findings to CMS or to the NBI MEDICs, if necessary.

50.6.4 – Audit Schedule and Methodology

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

The work plan must include a schedule that lists all of the monitoring and auditing activities for the calendar year. Sponsors may want to organize the schedule by month or quarter.

Sponsors must audit their operational areas and those of their first tier entities. It is a best practice for sponsors to use a combination of desk and on-site audits, including, as appropriate and as permitted by contractual agreements, unannounced audits or “spot checks” when developing the work plan. On-site audits provide the auditor an opportunity to assess the on-site operations, interview staff, and gain a better understanding of the performance of the area under review.

Sponsors should prepare a standard audit report that includes items such as:

- Audit Objectives;
- Scope and Methodology;
- Findings:
 - Condition;
 - Criteria;

- Cause;
- Effect; and
- Recommendations

In developing the types of audits to include in the work plan sponsors must:

- Determine which risk areas will most likely affect the sponsor, and prioritize the monitoring and audit strategy accordingly;
- Utilize appropriate methods in:
 - Selecting sponsor facilities, pharmacies, providers, claims, and other areas for audit;
 - Determining appropriate sample size;
 - Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe; and
 - Applying targeted or stratified sampling methods driven by data mining and complaint monitoring;
- Use special targeted techniques based on aberrant behavior;
- Assess compliance with internal processes and procedures;
- Examine the performance of the compliance program, including a review of training, reporting mechanisms (e.g., hotline log), investigation files, OIG/GSA exclusion list screenings, evidence of employee receipt of Standards of Conduct and conflict of interest disclosures/attestations, and sampling for evidence in support of attestations, if the sponsor uses attestations to monitor compliance; and
- Conduct follow up review by auditing, monitoring or otherwise of areas previously found non-compliant to determine if the implemented corrective actions have fully addressed the underlying problem.

50.6.5 – Audit of the Sponsor’s Operations and Compliance Program
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

The compliance officer and compliance committee must ensure the implementation of an audit function appropriate to the sponsor’s size, scope and structure. The audit function

may be performed by a separate audit department or may be performed by the compliance department. Staff dedicated to the audit function will be responsible for monitoring and auditing the sponsor's operational areas to ensure compliance with Medicare regulations. Adequate resources must be devoted to the audit function considering factors such as size and scope of the sponsor's Medicare Part C and D programs, its compliance history, current compliance risks, and the amount of resources necessary to meet the goals of its annual work plan.

Participants in the audit function must be knowledgeable about CMS operational requirements for the areas under review. Auditors may include, as needed, pharmacists, nurses, physicians, certified public accountants, fraud investigators, SIU staff, compliance staff with operational backgrounds and other highly skilled staff. These specific roles need not reside within the audit department or compliance department. Rather, they may reside in other departments provided their services are accessible to perform the necessary audit responsibilities.

Sponsors must ensure that auditors are independent and do not engage in self-policing. Operations staff may assist in audit activities provided the assistance is compatible with the independence of the audit function. For example, operations staff may gather data for samples requested by the auditor and may provide other types of information to auditors. Sponsors must ensure that audit staff have access to the relevant personnel, information, records and areas of operation under review, including the operational areas at the plan and FDR level.

Sponsors must audit the effectiveness of the compliance program and the results must be shared with the governing body. Audits of the compliance program should occur at least annually. In order to avoid self-policing, sponsors who exclusively use compliance department staff, including the compliance officer, for their auditing function should train employees who are not part of the compliance department to perform the audit, or outsource the audit to external auditors.

While the compliance department staff may not conduct the formal audit of the effectiveness of the compliance program, it may administer less formal measures of compliance program effectiveness, such as a self-assessment tool or dashboard or scorecard in support of the compliance program effectiveness audit.

50.6.6 – Monitoring and Auditing FDRs

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors are responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under their contracts with CMS, regardless of whether the sponsor has delegated some of that responsibility to FDRs. The sponsor must develop a strategy

to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first tier entities are monitoring the compliance of the entities with which they contract (the sponsors' "downstream" entities). Sponsors must also monitor any related entities to ensure those entities are compliant with all applicable laws and regulations.

Sponsors must include in their work plan the number of first tier entities that will be audited each year and how the entities will be identified for auditing. It is a best practice for sponsors to conduct a number of on-site audits.

Sponsors must conduct specific monitoring of first tier entities to ensure they fulfill the compliance program requirements. When a sponsor has a large number of first tier entities, making it impractical and/or cost prohibitive to monitor or audit all first tier entities for all compliance program requirements, the sponsor may perform a risk assessment to identify its highest risk first tier entities, then select a reasonable number of first tier entities to audit from the highest risk groups. Monitoring of first tier entities for compliance program requirements must include an evaluation to confirm that the first tier entities are applying appropriate compliance program requirements to downstream entities with which the first tier contracts.

When FDRs perform their own audits, it is a best practice for sponsors to obtain a summary of the audit work plan and audit results that relate to the services the FDR performs. Examples of reports that sponsors should receive and review as part of their FDR monitoring and auditing efforts include, but are not limited to:

- **Payment Reports** that detail the amount paid by both the sponsor and the enrollee; in addition, payment reports identifying the provider, the enrollee and a description of the drug (including dosage and amount) or service provided. These reports should be used to identify over and under payments, duplicate payments, timely payments, and pricing aberrances, and to help verify correct pricing;
- **Drug Utilization Reports** that identify the number of prescriptions filled by a particular enrollee and in particular, numbers of prescriptions filled for suspect classes of drugs, such as narcotics, to identify possible therapeutic abuse or illegal activity by an enrollee. Enrollees with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports. Likewise, Drug Utilization Management reports from FDRs may be a useful tool in identifying FWA;
- **Provider Utilization Reports** that identify the number and types of visits and services submitted for payment to identify possible spikes and/or irregularities such as a provider submitting claims for services that would not normally be performed by the provider's specialty;
- **Prescribing and Referral Patterns by Physician Reports** that identify the number of prescriptions and referrals written by a particular provider and typically focus on a

class or particular type of drug, such as narcotics, or a specific type of DME, such as scooters. These reports should be generated to identify possible prescriber and referral/provider, pharmacy fraud and DME fraud; and

- **Geographic ZIP Reports** that identify possible doctor shopping schemes or script mills by comparing the geographic location (ZIP code) of the patient to the location of the provider that wrote the prescription and should include the location of the dispensing pharmacy. These reports should generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (for example, 30 miles). “Normal distance” should take into account where the enrollee resides (i.e., enrollees in rural areas would typically have longer trips to a doctor or pharmacy than enrollees living in urban areas).

When corrective action is needed, sponsors must ensure that corrective actions are taken by the entity. Although first tier entities may perform their own internal auditing, the sponsor remains obligated to perform its own auditing of first tier entities.

50.6.7 – Tracking and Documenting Compliance and Compliance Program Effectiveness

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors should track and document compliance efforts. In addition to formal audits and monitoring, it is a best practice for sponsors to regularly track and document compliance using dashboards, scorecards, self-assessment tools that the sponsor creates or purchases, and other mechanisms that show the extent to which operational areas and FDRs are meeting compliance goals. Compliance of operational areas should be tracked by management and publicized to employees. Issues of noncompliance identified in dashboards, scorecards and self-assessment tools, etc., should be shared with senior management. Sponsors should consider including compliance performance as a measure for staff, management, and FDR evaluations.

50.6.8 – OIG/GSA Exclusion

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

The Act §1862(e)(1)(B), 42 C.F.R. §§ 422.503(b)(4)(vi)(F), 422.752(a)(8), 423.504(b)(4)(vi)(F), 423.752(a)(6), 1001.1901

This section provides guidance regarding sponsors’ implementation of FWA safeguards to identify excluded providers and entities. Medicare payment may not be made for items or services furnished or prescribed by an excluded provider or entity. Sponsors

shall not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the DHHS OIG or GSA.

Sponsors must review the DHHS OIG List of Excluded Individuals and Entities (LEIE list) and the GSA Excluded Parties Lists System (EPLS) prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter, to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs. Monthly screening is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to exclusions lists since the last time the list was checked. After entities are initially screened against the entire LEIE and EPLS at the time of hire or contracting, sponsors need only review the LEIE supplement file provided each month, which lists the entities added to the list that month, and review the EPLS updates provided during the specified monthly time frame.

OIG's LEIE includes all health care providers and suppliers that are excluded from participation in federal health care programs, including those health care providers and suppliers that might also be on the EPLS. In addition to health care providers (that are also included on the OIG LEIE) the EPLS includes non-health care contractors.

Links to instructions for accessing this information are available in Appendix A: Resources.

50.6.9 – Use of Data Analysis for Fraud, Waste and Abuse Prevention and Detection

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors must perform effective monitoring in order to prevent and detect FWA. Sponsors may accomplish this through the use of data analysis. Data analysis should include the comparison of claim information against other data (e.g., provider, drug or medical service provided, diagnoses or beneficiaries) to identify unusual patterns suggesting potential errors and/or potential fraud and abuse. Data analysis should factor in the particular prescribing and dispensing practices of providers who serve a particular population (e.g., long term care providers, assisted living facilities, etc.). Use of data analysis may include monitoring pharmacy and medical billing to detect unusual patterns. Sponsors may invest in data analysis software applications that give them the ability to analyze large amounts of data to detect FWA both internally and externally. Data analysis should:

- Establish baseline data to enable the sponsor to recognize unusual trends, changes in drug utilization over time, physician referral or prescription patterns, and plan formulary composition over time;

- Analyze claims data to identify potential errors, inaccurate TrOOP accounting, and provider billing practices and services that pose the greatest risk for potential FWA to the Medicare program;
- Identify items or services that are being over utilized;
- Identify problem areas within the plan such as enrollment, finance, or data submission;
- Identify problem areas at the FDR (e.g., PBM, pharmacies, pharmacists, physicians, other health care providers and suppliers); and
- Use findings to determine where there is a need for a change in policy.

Sponsors should develop indicators that will be used to identify norms, abnormalities, and individual variables that describe statistically significant time-series trends. Examples include:

- Standard deviations from the mean;
- Percent above the mean or median; and
- Percent increase in charges, number of visits/services from one period to another.

Sponsors should routinely generate and review reports on pharmacy billing, medical claims, etc., based upon the data analysis performed to identify pharmacies and other FDRs that require further review.

50.6.10 – Special Investigation Units (SIUs)

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

An effective program to control FWA includes policies and procedures to identify and address FWA at both the sponsor and FDR levels in the delivery of Parts C and D benefits. An SIU is an internal investigation unit, often separate from the compliance department, responsible for conducting surveillance, interviews, and other methods of investigation relating to potential FWA. Depending upon the size of and resources available within the organization, sponsors must either establish a specific SIU or ensure that responsibilities generally conducted by an SIU are conducted by the compliance department. Sponsors are not expected to perform law enforcement activities and may refer all matters indicative of FWA to the NBI MEDIC or law enforcement.

SIU responsibilities should include:

- Reducing or eliminating Medicare Parts C and D benefit costs due to FWA;
- Reducing or eliminating fraudulent or abusive claims paid for with federal dollars;
- Preventing illegal activities;
- Identifying enrollees with overutilization issues;
- Identifying and recommending providers for exclusion, including those who have defrauded or abused the system to the NBI MEDIC and/or law enforcement;
- Referring suspected, detected or reported cases of illegal drug activity, including drug diversion, to the NBI MEDIC and/or law enforcement and conducting case development and support activities for NBI MEDIC and law enforcement investigations; and
- Assisting law enforcement by providing information needed to develop successful prosecutions.

SIUs must be accessible through multiple channels such as via phone, email, Internet message submission, and mail. Sponsors must ensure that suspicions of FWA can be reported anonymously to the SIU.

Sponsors must ensure that the SIU and compliance department communicate and coordinate closely to ensure that the Medicare Parts C and D benefits are protected from fraudulent, abusive and wasteful schemes throughout the administration and delivery of benefits, both at the sponsor and FDR levels.

50.6.11 – Auditing by CMS or its Designee

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 422.504(e)(2), 423.505(e)(2)

CMS has the discretionary authority to perform audits under 42 C.F.R. 44 422.504(e)(2) and 423.505(e)(2), which specify the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of sponsors or FDRs that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract.

Sponsors must allow access to any auditor acting on behalf of the federal government or CMS to conduct an on-site audit. On-site audits require a thorough review of required documentation. Such reviews include any information needed to determine compliance with the Medicare Parts C and D regulations and contracts, such as copies of

prescriptions, invoices, provider and pharmacy licenses, claims records, signature logs, records documenting delivery status by postal carrier, long-term care delivery notice to nursing staff, other forms of documentation of medication delivery, purchase records, contracts, rebate and discount agreements, as well as interviews of the staff. The interviews gauge whether control activities are practiced as dictated by the company's policy and applicable Parts C and D requirements are being followed. On-site audits are based on sampling or results of desk audits. In most cases, CMS or its designee will provide reasonable notice to the sponsor of the time and content of the audit.

The OIG has independent authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement.

Sponsors and FDRs must provide records to CMS or its designee. Sponsors should cooperate in allowing access as requested. Failure to do so may result in a referral of the sponsor and/or FDR to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning in line with 42 C.F.R. Subpart O. MEDICs and other contractors tasked to conduct audits by CMS, as well as contractors trained by CMS and engaged by sponsors to conduct CMS data validation audits, are acting on behalf of the federal government and are not required to sign the sponsor's confidentiality statement prior to the start of an on-site audit. Sponsors and FDRs are required to cooperate with CMS and CMS' contractors, such as the NBI MEDICs. This cooperation includes providing CMS and/or the NBI MEDICs or other contractors access to all requested records associated in any manner with the Parts C or D program.

When CMS or its designee (e.g., the NBI MEDIC) requests information that will be used for an audit, CMS or its designee will notify the sponsor of an appropriate time period within which to provide the requested information.

50.7 – Element VII: Procedures and System for Prompt Response to Compliance Issues

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Sponsors must establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

1. If the sponsor discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

2. The sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible individuals) in response to the potential violation referenced above.
3. The sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Medicare program to CMS or its designee (such as the NBI MEDIC).

50.7.1 – Conducting a Timely and Reasonable Inquiry of Detected Offenses

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Sponsors must conduct a timely and well-documented reasonable inquiry into any compliance incident or issue involving potential Medicare program noncompliance or potential FWA.

Program noncompliance and FWA may occur at the level of the sponsor or its FDRs. It may be discovered through a hotline, a website, an enrollee complaint, during routine monitoring or self evaluation, an audit, or by regulatory authorities. Regardless of how the noncompliance or FWA is identified, sponsors must initiate a reasonable inquiry as quickly as possible, but not later than 2 weeks after the date the potential noncompliance or potential FWA incident was identified.

A reasonable inquiry includes a preliminary investigation of the matter by the compliance officer or a delegated member of his/her staff and/or the sponsor's SIU. If the issue appears to involve potential fraud or abuse and the sponsor does not have either the time or the resources to investigate the potential fraud or abuse in a timely manner, it should refer the matter to the NBI MEDIC within 30 days of the date the potential fraud or abuse is identified so that the potentially fraudulent or abusive activity does not continue.

Sponsors are responsible for monitoring for FWA and Medicare program noncompliance within their organizations. When serious noncompliance or waste occurs, CMS strongly encourages sponsors to refer the matter to CMS. When potential fraudulent or abusive activity is identified, CMS strongly encourages sponsors to refer the matter to the appropriate MEDIC (currently, the NBI MEDIC).

50.7.2 – Corrective Actions

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Sponsors must undertake appropriate corrective actions in response to potential noncompliance or potential FWA.

Corrective actions must be designed to correct the underlying problem that results in program violations and to prevent future noncompliance. A root cause analysis determines what caused or allowed the FWA, problem or deficiency to occur. A corrective action must be tailored to address the particular FWA, problem or deficiency identified, and must include timeframes for specific achievements.

The sponsor must ensure that FDRs have corrected their deficiencies. When developing corrective actions for FWA or program noncompliance by an FDR, the elements of the corrective action should be detailed in writing and include ramifications if the FDR fails to implement the corrective action satisfactorily. Also, the sponsor / FDR contract should include language that details the ramifications of failing to maintain compliance or engaging in FWA, such as contract termination.

In order to ensure that the FDR has implemented the corrective action, sponsors should conduct independent audits or review the FDR's monitoring or audit reports. Sponsors must continue to monitor corrective actions after their implementation to ensure that they are effective.

The elements of the corrective action that address noncompliance or FWA committed by the sponsor's employee(s) or FDRs must be documented, and include ramifications should the sponsor's employee(s) or its FDRs fail to satisfactorily implement the corrective action. The sponsor must enforce effective correction through disciplinary measures, including employment or contract termination, if warranted.

Thorough documentation must be maintained of all deficiencies identified and corrective actions taken.

50.7.3 – Procedures for Self-Reporting Potential FWA and Significant Non Compliance

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Self-reporting of FWA and Medicare program noncompliance is voluntary. CMS nonetheless strongly encourages self-reporting as an important practice in maintaining an effective compliance program. Sponsors should self-report potential FWA discovered at the plan level, and potential fraud and abuse by FDRs, as well as significant waste and significant incidents of Medicare program noncompliance.

Where sponsors notify the MEDICs of potential FWA in accordance with the guidelines described below, the MEDICs will refer potential FWA to law enforcement when appropriate. Issues that are referred to the NBI MEDIC and are determined not to be potential FWA will be returned to the sponsor to be addressed.

Sponsors are required to investigate potential FWA activity to make a determination whether potential FWA has occurred. Sponsors must conclude investigations of potential FWA within a reasonable time period after the activity is discovered. If after conducting a reasonable inquiry, the sponsor (e.g., the compliance officer or SIU) determines that potential FWA related to the Medicare Parts C or D programs has occurred, the matter should be referred to the NBI MEDIC promptly. Sponsors should also refer potential FWA at the FDR levels to the NBI MEDIC so that the NBI MEDIC can help identify and address any scams or schemes.

Sponsors should also consider reporting potentially fraudulent conduct to government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol) or the Department of Justice. All health care providers doing business with Medicare that want to disclose violations of law are eligible to disclose fraudulent conduct under the Provider Self-Disclosure Protocol. The Protocol offers a detailed step-by-step explanation of how a provider should proceed in reporting and assessing the extent of potential fraud and how the OIG will go about verifying irregularities.

Where a sponsor discovers an incident of significant Medicare program noncompliance, the sponsor should report the incident to CMS as soon as possible after its discovery. This will enable CMS to provide guidance to the sponsor on mitigation of the harm caused by the incident of noncompliance. While no bright line definition exists as to what is a "significant" or "serious" incident that should be reported, sponsors should err on the side of over-reporting rather than under-reporting.

Self-reporting offers sponsors the opportunity to minimize the potential cost and disruption of a full scale audit and investigation, to negotiate a fair monetary settlement, and to potentially avoid an OIG permissive exclusion preventing the entity from doing business with Federal health care programs.

50.7.4 – NBI MEDIC

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Medicare Drug Integrity Contractors (MEDIC) are organizations that CMS contracts with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The MEDIC's primary role is to identify potential fraud and abuse in

Medicare Part C and Part D. There is currently one National Benefit Integrity (NBI) MEDIC.

NBI MEDICs will investigate referrals from sponsors, develop the investigations, and make referrals to appropriate law enforcement agencies or other outside entities when necessary. The NBI MEDIC will keep the sponsor apprised of the development and status of the investigation. If the NBI MEDIC determines a referral to be a matter related to noncompliance or mere error rather than fraud or abuse, the matter will be returned to CMS and/or the sponsor for appropriate follow-up.

Sponsors should refer cases involving potential fraud or abuse that meet any of the following criteria to the NBI MEDIC:

- Suspected, detected or reported criminal, civil, or administrative law violations;
- Allegations that extend beyond the Parts C and D plans, involving multiple health plans, multiple states, or widespread schemes;
- Allegations involving known patterns of fraud;
- Pattern of fraud or abuse threatening the life or well being of beneficiaries; and
- Scheme with large financial risk to the Medicare Program or beneficiaries.

50.7.5 – Referrals to the NBI MEDIC

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Each sponsor referral to the NBI MEDIC should contain specifics that will allow an investigator to follow-up on a case including basic identifying information and contacts as well as a description of the allegations.

If available, a referral should include:

- Name of:
 - compliance officer or SIU investigator, and
 - Organization;
- Contact information for follow up;
- Summary of the Issue:
 - Include the basic who, what, when, where, how, and why; and

- Any potential legal violations;
- Specific Statutes and Allegations:
 - List civil, criminal, and administrative code or rule violations, state and federal; and
 - Provide detailed description of the allegations or pattern of fraud, waste, or abuse;
- Incidents and Issues:
 - List incidents and issues related to the allegations;
- Background information:
 - Contact information for the complainant, the perpetrator or subject of the investigation, and beneficiaries, pharmacies, providers, or other entities involved; and
 - Additional background information that may assist investigators, such as names and contact information of informants, relators, witnesses, websites, geographic locations, corporate relationships, networks;
- Perspectives of Interested Parties:
 - Perspective of Plan, CMS, enrollee;
- Data:
 - Existing and potential data sources;
 - Graphs and trending;
 - Maps; and
 - Financial impact estimates; and
- Recommendations in Pursuing the Case:
 - Next steps, special considerations, cautions.

Call the NBI MEDIC at 1-877-7SafeRX (1-877-772-3379).

For referral forms, go to:

http://www.healthintegrity.org/html/contracts/medic/case_referral.html

The NBI MEDIC may request additional information in order to fully investigate and resolve the matter. The sponsor shall furnish additionally requested information within 30 days, unless the NBI MEDIC specifies otherwise. In instances where the MEDIC requires information in less than 30 days, all parties involved will be notified as soon as

possible. Sponsors should provide updates to the NBI MEDIC when new information regarding the matter is identified.

50.7.6 – Responding to CMS-Issued Fraud Alerts

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

CMS issues alerts to Part D sponsors concerning fraud schemes indentified by law enforcement officials. Typically, these alerts describe alleged activities involving pharmacies practicing drug diversion or prescribers participating in illegal remuneration schemes. Sponsors may take action (including denying or reversing claims) in instances where the sponsor’s own analysis of its claims activity indicates that fraud may be occurring. A sponsor’s decision to deny or reverse claims should be made on a claim-specific basis.

When a Fraud Alert is received, the sponsor should review its contractual agreements with the identified parties. It would be appropriate for the sponsor to consider terminating the contract(s) with the identified parties if law enforcement has issued indictments against particular parties and the terms of the sponsor’s contract(s) authorizes contract termination in those circumstances.

Sponsors are also obligated to review their past paid claims from entities identified in a fraud alert. With the issuance of a fraud alert, CMS has placed sponsors on notice (see 42 CFR 423.505(k)(3)) that they should review claims involving identified providers. To meet the “best knowledge, information, and belief” standard of certification, sponsors should make their best efforts to, identify claims that may be or may have been part of an alleged fraud scheme and remove them from their sets of prescription drug event data submissions.

50.7.7 – Identifying Providers with a History of Complaints

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G), 422.504(d)-(e)

Sponsors should maintain files for a period of 10 years on both in-network and out-of-network providers who have been the subject of complaints, investigations, violations, and prosecutions. This includes enrollee complaints, NBI MEDIC investigations, OIG and/or DOJ investigations, US Attorney prosecution, and any other civil, criminal, or administrative action for violations of Federal health care program requirements. Sponsors should also maintain files that contain documented warnings (i.e., fraud alerts) and educational contacts, the results of previous investigations, and copies of complaints resulting in investigations. Sponsors must comply with requests by law enforcement,

CMS and CMS' designee regarding monitoring of providers within the sponsor's network that CMS has identified as potentially abusive or fraudulent.

Appendix A: Resources

*(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)*

For more information on topics discussed in this chapter, including developing and implementing effective compliance and fraud and abuse plans, see:

Government Resources:

1. National Benefit Integrity MEDIC:
<http://www.healthintegrity.org/html/contracts/medic/index.html>
2. Stop Medicare Fraud:
<http://www.stopmedicarefraud.gov>
3. The Patient Protection and Affordable Care Act:
<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>
4. Compliance Guidance for Medicare+Choice Organizations:
<http://oig.hhs.gov/fraud/docs/complianceguidance/111599.pdf>
5. Office of the Inspector General, Compliance Program Guidance for the Healthcare Industry:
<http://oig.hhs.gov/compliance/compliance-guidance/index.asp>
6. Federal Sentencing Guidelines:
<http://www.ussc.gov/Guidelines>
7. Fraud Alerts, Bulletins and Other Guidance from the OIG:
<http://oig.hhs.gov/compliance/alerts/index.asp>
8. False Claims Act:
http://www.justice.gov/jmd/ls/legislative_histories/pl99-562/pl99-562.html
9. Health Insurance Portability and Accountability Act (HIPAA):
<http://aspe.hhs.gov/admnsimp/pl104191.htm>
10. Anti-Kickback Statute (see section 1128B(b)):
http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f
11. Stark Law (Physician Self-Referral):
<https://www.cms.gov/PhysicianSelfReferral/>
12. TRICARE Fraud & Abuse:
<http://www.tricare.osd.mil/fraud>

Other Resources:

1. Health Care Administrators Association (HCAA):
<http://www.hcaa.org/>
2. Health Care Compliance Association (HCCA):
<http://www.hcca-info.org>
3. Society of Corporate Compliance and Ethics (SCCE):
<http://www.corporatecompliance.org>
4. American Health Lawyers Association (AHLA):
<http://www.healthlawyers.org>
5. National Health Care Anti-Fraud Association (NHCAA):
<http://www.nhcaa.org>
6. Institute for Health Care Improvement (IHI):
<http://ihi.org>
7. Corporate Responsibility and Health Care Quality – A Resource for Health Care Boards of Directors, U.S. Dept. of Health and Human Services Office of the Inspector General and The American Health Lawyers Assn.:
<http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>

Links to OIG and GSA Exclusions Databases

- OIG LISTSERV via the OIG Website: <http://exclusions.oig.hhs.gov/>
- General Services Administration (GSA) database of excluded individuals/entities: <https://www.epls.gov/>

Appendix B: Laws and Regulations to Consider in Standards of Conduct and/or Training

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

- Title XVIII of the Social Security Act
- Medicare regulations governing Parts C and D found at 42 C.F.R. §§ 422 and 423 respectively
- Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)
- Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)
- False Claims Acts (31 U.S.C. §§ 3729-3733)
- Federal Criminal False Claims Statutes (18 U.S.C. §§ 287,1001)
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
- The Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))
- Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))
- Physician Self-Referral (“Stark”) Statute (42 U.S.C. § 1395nn)
- Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act
- Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal Government (42 U.S.C. §1395w-27(g)(1)(G))
- Fraud Enforcement and Recovery Act of 2009
- All sub-regulatory guidance produced by CMS and HHS such as manuals, training materials, HPMS memos, and guides