

DRAFT Chapter 9 Prescription Drug Benefit Manual
DRAFT Chapter 21 Medicare Managed Care Manual
DRAFT Compliance Program Guidelines

For Medicare Advantage Organizations and Prescription Drug Plans

Table of Contents

- 10 – Introduction
- 20 – Definitions
- 30 – Overview of Mandatory Compliance Program
- 40 – Sponsor Accountability and Oversight of FDRs
- 50 – Components of an Effective Compliance Program
 - 50.1 – Element I: Written Policies, Procedures and Standards of Conduct
 - 50.1.1 – Commitment to Compliance with Federal and State Standards
 - 50.1.2 – Compliance Expectations Embodied in Standards of Conduct
 - 50.1.3 – Policies Implementing Compliance Program
 - 50.1.4 – Providing Guidance to Employees and FDRs on Dealing with Compliance Issues
 - 50.1.5 – Identifying How to Communicate Compliance Issues
 - 50.1.6 – Describing How Compliance Issues Are Investigated and Resolved
 - 50.1.7 – Policy of Non-Intimidation and Non-Retaliation
 - 50.1.8 – Governing Body Approval of Compliance Policies and Procedures and Standards of Conduct
 - 50.1.9 – Distribution of Compliance Policies and Procedures and Standards of Conduct
 - 50.2 – 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 – Effective Training and Education
 - 50.3.1 – General Compliance Training
 - 50.3.2 – Specialized Compliance Training
 - 50.3.3 – Fraud, Waste, and Abuse Training
 - 50.3.4 – Methods of Training
 - 50.3.5 – Measuring Effectiveness of Training
 - 50.4 – Effective Lines of Communication
 - 50.4.1 – Effective Lines of Communication among the Compliance Officer, Compliance Committee, Employees, Managers, Members of the Governing Body, and FDRs
 - 50.4.2 – Establishing a Mechanism to Field Compliance Questions and

- Concerns from Employees and FDRs
- 50.4.3 – Member Communications and Education
- 50.5 – 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 – Effective System for Routine Monitoring and Identification of Compliance Risks
 - 50.6.1 – Routine Monitoring and Auditing
 - 50.6.2 – Development of an Internal Risk Assessment
 - 50.6.3 – Development of the Monitoring and Auditing Work Plan
 - 50.6.4 – Audit Schedule and Methodology
 - 50.6.5 – Internal Audit
 - 50.6.6 – External Audit: Monitoring and Auditing FDRs
 - 50.6.7 – Use of Mechanisms to Measure Compliance and Compliance Program Effectiveness
 - 50.6.8 – OIG Exclusion / GSA Debarment
 - 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 – 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 Fraud or Misconduct
 - 50.7.4 – NBI MEDICs
 - 50.7.5 – Referrals to the NBI MEDICs
 - 50.7.6 – Identifying Providers with a History of Complaints
- 60 – Additional Vulnerabilities
 - 60.1 – Part B and Part D Coverage Issues

- Appendix A: Resources
- Government Resources
 - Other Resources

10 – Introduction

These Guidelines reflect the Centers for Medicare & 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”).

These Guidelines are published in both Chapter 9 of the Prescription Drug Benefit Manual and in Chapter 21 of the Medicare Managed Care Manual. Both Chapters are identical. They are published in both manuals to allow organizations offering both Medicare Advantage (MA) and Prescription Drug Plans (MA-PD) to reference one document for compliance program guidance.

The guidance in this Chapter outlines the minimum requirements necessary to qualify as having an effective Compliance Program. Sponsors may implement additional effectiveness measures at their discretion according to the specific needs of their organizations.

Chapter 9 of the Prescription Drug Benefit Manual previously addressed the prevention of fraud, waste and abuse (FWA) by Part D Sponsors. In contrast, this Chapter provides interpretive rules and guidance to help both Part C and Part D Sponsors to establish and maintain an effective Compliance Program to prevent, detect, and correct not only FWA, but also Medicare program noncompliance. This guidance is subject to change as policy, technology and Medicare business practices continue to evolve.

Each plan Sponsor is responsible for implementing an effective Compliance Program in its organization which meets the regulatory requirements set forth at 42 CFR §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi). Plan Sponsors should apply the principles outlined in these guidelines to all relevant decisions, situations, communications and development. 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. Plan Sponsors should consult their CMS Account Managers with specific questions about the guidance provided here or any future updates to this guidance.

These Compliance Program Guidelines do not apply to Program of All-Inclusive Care for the Elderly (PACE) plans or to sections 1833 and 1876 Cost Plans. However, given OIG guidance promoting compliance programs for all Medicare managed care organizations, CMS strongly encourages these plan Sponsors to voluntarily develop and implement effective compliance programs.

20 – Definitions

42 CFR §§ 417.1, 422.2, 423.100, 423.112, 423.120, 423.272, 423.30, 423.4, 423.501, 423.464, 423.859

The following definitions apply for purposes of these Guidelines only:

Abuse occurs when an individual or entity unintentionally provides information to Medicare which results in higher payments than the individual or entity is entitled to receive.

Act refers to the Social Security Act.

Appeal is a process whereby a Medicare beneficiary (or his/her representative) exercises the right to request a review of a Sponsor's first tier, downstream or related entity's claim determination to deny Medicare coverage or payment for a service in whole or in part.

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

Cost Plan is a drug benefit plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act (*See* 42 C.F.R. § 417.1, § 423.4).

Data Analysis is a tool for identifying potential payment errors and trends in utilization, referral patterns, formulary changes, and other indicators of potential fraud, waste or abuse. Data analysis is also used to investigate cases of potential fraud, waste or abuse once identified. Data analysis compares claim information and other related data (e.g., the provider registry) to identify potential errors and/or potential fraud by claim/prescription drug event characteristics (e.g., drugs provided, diagnoses, providers, or beneficiaries) individually or in the aggregate. Data analysis is an integrated, on-going component of fraud detection and prevention activity.

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.

Edit is computer logic within the Sponsor claims processing system that selects certain claims, evaluates or compares information on the selected claims or other accessible source, and depending on the evaluation, takes action on the claims, such as pay in full, pay in part, or suspend for manual review.

Fallback Prescription Drug Plan (Fallback, Fallback Plan) is a prescription drug plan offered by a fallback entity, as governed by 42 C.F.R. §§ 423.851-875, that:

- Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in 42 C.F.R. § 423.100;
- Provides access to negotiated prices, including discounts from manufacturers; and
- Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in regulation or in separate guidance.

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.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Fraud means an intentional deception or misrepresentation that the individual knows to be false or does not believe to be true, and that the individual makes knowing that the deception could result in some unauthorized benefit to himself/herself or to some other person.

HHS is the Department of Health and Human Services.

MAO stands for Medicare Advantage Organization. A Medicare Advantage Organization is any organization that holds either a Medicare Advantage contract or an MA-PD contract, or both, with CMS.

MA Prescription Drug Plan (MA-PD) is a CMS approved plan that provides qualified prescription drug coverage to Medicare beneficiaries. (*See* 42 C.F.R. § 423.4).

Medicare Drug Integrity Contractor (MEDIC) is an organization that CMS has contracted 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 FWA in Medicare Parts C and D. There is currently one National Benefit Integrity (NBI) MEDIC.

Medicaid is a medical assistance program provided to certain low income individuals under a state plan approved by CMS.

Medical Review involves a clinical assessment of the medical record documentation associated with a specific claim. Medical review can be conducted on a pre or post payment basis. A pre-payment review may be used as part of the pre-authorization process for specific drugs. Post-payment medical review, when used for medical necessity probe reviews, provides valuable information into the prescribing practices of providers and may identify overpayments.

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).

OIG is the Office of the Inspector General within the Department of Health and Human Services.

Part D Eligible Individual is an individual who meets the requirements of 42 C.F.R. § 423.30(a).

Part D Plan is a prescription drug plan (PDP), an MA-PD plan, or a PACE plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage under a policy, contract or plan that

- has been approved as specified in 42 C.F.R. § 423.272 and
- is offered by a PDP Sponsor that has a contract with CMS that meets the contract requirements under subpart K, including fallback prescription drug plans.

This includes employer and union-Sponsored plans.

Part D Plan Sponsor refers to a PDP Sponsor, MA organization offering a MA-PD plan, PACE organization offering qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. This includes employer and union Sponsored plans. PDP Sponsors are nongovernmental entities (including fallback entities) certified under Part D as meeting the requirements and standards of Part D.

Pharmacy Benefit Manager (PBM) is an entity that provides pharmacy benefit management services, including 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; maintaining patient Compliance Programs; performing drug utilization review; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies.

Pharmacy & Therapeutics (P&T) Committee is a committee, the majority of whose members consist of individuals who are practicing physicians or practicing pharmacists (or both), that is charged with developing and reviewing a formulary. Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict with respect to the Sponsor, the Part D Plan and pharmaceutical manufacturers and at least one practicing physician and at least one practicing pharmacist who have expertise in the care of elderly or disabled persons. (*See* 42 C.F.R. § 423.120(b)(1)).

Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit that features a comprehensive service delivery system and integrated Medicare and Medicaid financing.

Provider means any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services, if such licensing or certification is required by State law or regulation. When applicable to Part D, the term “provider” is generally used in

this Chapter to refer only to individuals or organizations that prescribe or supply prescription drugs that are reimbursable under Part D. If references apply to specific types of providers only (e.g. pharmacists), the specific provider type will be identified.

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.

Secretary means the Secretary of the Department of Health and Human Services.

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

Sponsor is a Medicare Advantage Organization (Part C), stand-alone Prescription Drug Plan (Part D), or Medicare Advantage Prescription Drug Plan (MA-PD).

TrOOP (True Out of Pocket) Cost is the amount a beneficiary must spend on Part D covered drugs to reach catastrophic coverage. Payments counting toward TrOOP include payments by beneficiary, family member or friend, SPAP, a charity, 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.

Waste is the inappropriate utilization and/or inefficient use of resources.

30 – Overview of Mandatory Compliance Program

42 CFR §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi), 42 U.S.C. § 1395w-104

All Part C and Part D Sponsors are required to adopt and implement an effective Compliance Program, which must include measures to prevent, detect and correct Part C or D programmatic noncompliance as well as fraud, waste and abuse.

The required seven elements of an effective Compliance Program include:

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 Medicare Compliance Program must include all of the regulatory requirements outlined above, must be tailored to each Sponsor's unique organization, operations and circumstances, must be fully implemented, and must be effective in preventing, detecting and correcting Medicare program noncompliance and FWA.

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) Assess the organization's risks;
- 2) Promote and enforce its Standards of Conduct;
- 3) Effectively train and educate its employees and first-tier, downstream and related entities (FDRs);
- 4) Effectively establish lines of communication within itself and between itself and its FDRs;
- 5) Oversee FDR compliance with Part C/D requirements;
- 6) Establish and implement an effective system for routine auditing and monitoring;
and
- 6) Identify and promptly respond to risks and findings.

CMS will consider an organization's size, structure, business model, activities, the extent of its delegation of responsibilities to other entities, the breadth of its operation, and the risks the organization faces in evaluating whether adequate resources have been devoted to the Compliance Program.

Sponsors must conduct routine auditing and monitoring of Medicare operational areas as well as of the Compliance Program itself. Compliance Program effectiveness is enhanced by the use of performance measurements that evaluate the effectiveness of the Compliance Program.

40 – Sponsor Accountability and Oversight of FDRs

42 CFR §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi)

Sponsors enter into contracts with FDRs to perform certain functions that would otherwise be the Sponsor's responsibility. For example, Sponsors may contract with entities such as management service organizations (MSO), provider groups, hospitals, skilled nursing facilities, pharmacy benefit managers (PBM), marketing firms, claims processing and adjustment companies, field marketing organizations, temporary employment agencies, and others. Sponsors may not delegate Compliance Program administrative functions (e.g. Compliance Officer, Compliance Committee, compliance reporting to senior management, etc.) to other entities; however, Sponsors may use

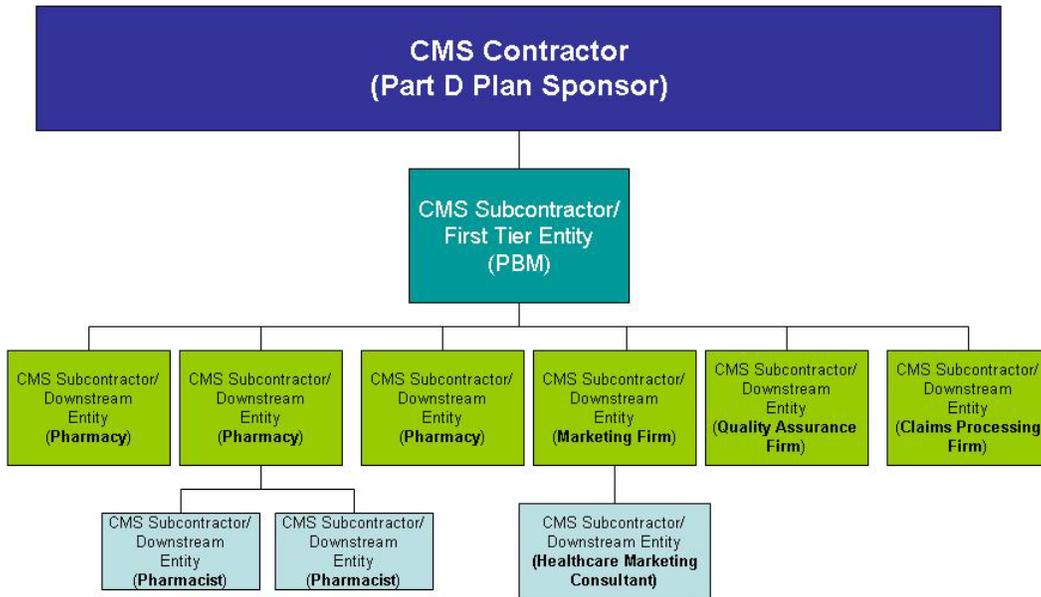
vendors for compliance activities such as monitoring and auditing, as long as the Sponsor's Compliance Department maintains oversight of those functions.

While a Sponsor may contract with FDRs to perform certain functions on its behalf, the Sponsor maintains **ultimate** responsibility for fulfilling the terms and conditions of its contract with CMS and for meeting the Medicare program requirements, including the Compliance Program requirements. CMS has the authority to hold the Sponsor accountable for any failure to meet the program requirements, even if the failure is due to its FDRs' conduct. Both Sponsors and their FDRs may be subject to liability under civil and/or criminal laws, such as the False Claims Act or the Anti-Kickback statute for fraud perpetrated in the administration or delivery of Parts C and D benefits.

These requirements apply to FDRs to whom the Sponsor has delegated responsibilities related to the Sponsor's core functions under its 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 core Medicare functions, for example, a contract between a Sponsor and a real estate broker in connection with the rental of office space.

The Sponsor's Compliance Officer, working with the organization's Compliance Committee, must develop procedures to promote and ensure that all FDRs to whom the Sponsor has delegated responsibilities related to its core functions under its Medicare contracts are in compliance with all applicable laws, rules and regulations with respect to Parts C and D delegated responsibilities. The Sponsor must have a risk assessment and FDR management program, effective training and education, effective internal controls, and effective monitoring and reporting mechanisms in place in order to exercise oversight, not only of its own internal operations, but also those of all delegated persons and entities. The use of metrics is strongly recommended to assist the Sponsor in observing compliance performance and operational trends.

Stakeholder Relationship Flow Chart



The regulations set forth several rules guiding Parts C and D Sponsors in the execution of contracts with FDRs. These contracts must contain specific provisions including, but not limited to, inspections, enrollee protection, Sponsor accountability, delegation, and record retention.

FDR contracts that enable the Sponsor to fully implement all aspects of the Parts C and D benefits are critical to protecting the Sponsor's interest. These contractual provisions must include requiring ongoing monitoring performed by, or on behalf of, the Sponsor which assess whether all FDRs are in compliance with Parts C and D provisions.

FDR Contract Revocation

Where a Sponsor delegates any of its activities or responsibilities to any FDR, the written arrangements must either provide for revocation of the delegation activities or specify other remedies in instances when CMS or the Sponsor determine that the parties have not performed satisfactorily. Therefore, contracts with FDRs that enable the Sponsor to implement any aspect of an effective Compliance Program are critical to protecting the Sponsor's interest.

Data Submission by FDR

Sponsors are responsible for all data submitted to CMS, including data generated and/or submitted by FDRs. CMS requires that FDR that generates claims data on behalf of a Sponsor certify to CMS the accuracy, completeness, and truthfulness of that data, and acknowledge that the data will be used for the purposes of obtaining Federal reimbursement. Sponsors are responsible for exercising oversight of Parts C and D data

generated or submitted by FDRs to ensure the accuracy of that data so that the Sponsor receives appropriate payments.

Preemption of State Laws

While Sponsors and FDRs are required to comply with applicable state laws, certain state laws and regulations, for example, some state marketing laws regarding false or deceptive advertising, may be superseded (“preempted”) by Parts C and D laws and regulations. CMS recommends that Sponsors contact CMS if there is a question as to whether a state law or regulation is preempted by Parts C or D laws and regulations.

50 – Components of an Effective Compliance Program

42 CFR §§ 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

42 CFR §§ 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 potential compliance issues;
5. Identify how to communicate compliance issues to appropriate compliance Personnel;
6. Describe how potential 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.

50.1.1 – Commitment to Compliance with Federal and State Standards

42 CFR §§ 422.503(b)(4)(vi)(A)(1), 423.504(b)(4)(vi)(A)(1)

A Sponsor must have written policies, procedures, and Standards of Conduct that clearly state its commitment to comply with all applicable statutory (Federal and State), regulatory and other requirements related to Parts C and D of the Medicare program. The Sponsor must be able to demonstrate, through written materials, a strong ethical culture and commitment to compliance with all applicable laws, regulations and requirements.

Effective Compliance Programs typically include a resolution of the full governing body stating the Sponsor’s commitment to compliant, lawful and ethical conduct. The resolution should be updated annually since governing body membership may change.

At a minimum, the Sponsor’s Standards of Conduct must clearly state a strong commitment by the organization, its employees and FDRs to comply with applicable statutory and regulatory requirements.

CMS expects the Sponsor’s Compliance Program to address compliance with all applicable laws, including but not limited to:

- Title XVIII of the Social Security Act.
- Medicare regulations governing Parts C and D found at 42 C.F.R. §§ 422 and 423 respectively.
- Federal and State False Claims Acts (31 U.S.C. §§ 3729-3733).
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)).
- The Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a(a)(5)).
- Physician Self-Referral (“Stark”) Statute (42 U.S.C. § 1395nn).
- Health Insurance Portability and Accountability Act.
- Fraud Enforcement and Recovery Act of 2009.
- Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal government.
- Other applicable criminal statutes.
- Applicable provisions of the Federal Food, Drug, and Cosmetic Act.
- All sub-regulatory guidance produced by CMS such as manuals, training materials, HPMS memos, and guides;
- Contractual commitments.

Sponsors are responsible for including Medicare-specific provisions of the Social Security Act and other laws in written policies and procedures and Standards of Conduct.

Written policies, procedures and Standards of Conduct will require updating to incorporate changes in applicable laws, regulations, and other program requirements.

50.1.2 – Compliance Expectations embodied in Standards of Conduct

42 CFR §§ 422.503(b)(4)(vi)(A)(2), 423.504(b)(4)(vi)(A)(2)

Standards of Conduct are a subset of a Sponsor's policies and procedures which include, among other things, the following:

The mission;
The commitment to compliance with law;
The commitment to conduct business with the highest ethical standards;
Procedures to avoid and address conflicts of interest; and
FWA prevention, detection and correction.

Standards of Conduct communicate to employees and FDRs that compliance is everyone's responsibility from the top to the bottom of the organization.

A Sponsor's written Standards of Conduct must:

- Clearly articulate the Sponsor's commitment to comply with all applicable Federal and State standards;
- Describe the Sponsor's compliance expectations of employees and FDRs;
- Implement the operation of the Compliance Program;
- Provide guidance to employees and others, including FDRs, on dealing with potential compliance issues;
- Identify how to communicate compliance issues to appropriate compliance personnel;
- Describe how potential compliance issues are investigated and resolved by the organization; and
- 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 authorities.

In addition, CMS expects the Standards of Conduct to state the requirement that employees, FDRs, management, and governing body members report violations of law, regulations, or CMS program requirements to the Sponsor.

The Standards of Conduct also specify the disciplinary actions that can be imposed for violation of law and ethics, Medicare program noncompliance and FWA, including oral or written warnings or reprimands, suspensions, terminations, financial penalties and potential reporting of the conduct to law enforcement.

The Standards of Conduct may be set forth in a separate Medicare-specific stand-alone document or as a supplement to a corporate Code of Conduct. In order to be effective, the Standards of Conduct should be written in a format that is easy to read and comprehend. Depending on where the Sponsor is located, consideration should be given to having Standards of Conduct and policies and procedures translated into the foreign language commonly spoken in the area.

50.1.3 – Policies Implementing Compliance Program

42 CFR §§ 422.503(b)(4)(vi)(A)(3), 423.504(b)(4)(vi)(A)(3)

Compliance policies and procedures are detailed and specific, and describe the operation of the Compliance Program. Compliance policies and procedures include compliance education and training requirements, reporting mechanisms such as a hotline, information on how the organization responds to complaints and concerns, auditing and monitoring requirements, disciplinary procedures, and investigation and remediation processes, among others. Policies and procedures may also describe compliance measurement efforts such as the use of a scorecard.

Policies and procedures specify the duties that employees must perform in their day-to-day work in order to achieve Medicare program compliance and to avoid FWA.

Sponsors must develop detailed policies and procedures to identify and address risks, such as violations of the False Claims Act, Stark Law, HIPAA, Anti-Kickback Statute, and Patient Protection and Affordable Care Act, and to remediate areas of weakness.

Sponsors are required to be knowledgeable about Medicare requirements for each operational and administrative area that may pose a risk of Medicare noncompliance and FWA.

Sponsors must have policies and procedures to implement each regulatory requirement of an effective Compliance Program. This Chapter refers to some, but not all, of the policies and procedures that are integral to an effective Compliance Program.

Among the policies and procedures crucial to the implementation of an effective Compliance Program are those relating to the avoidance of conflict of interests. For example, Sponsors are expected to implement in their Compliance Program:

- A process to ensure that members of the Sponsor's governing body, members of the P&T Committee and senior leadership are effectively screened for conflicts of interest through a certification, attestation, or other means. To be effective, screening for conflicts of interest should occur at the time of hire and annually thereafter. An effective screening for conflicts of interest would determine whether the individual has reviewed the organization's conflict of interest policy, whether the individual has disclosed any potential conflict of interests and

whether the individual has obtained management approval to work despite any conflicts, or has eliminated the conflict.

- The P & T Committee must include at least one member practicing physician and at least one practicing pharmacist, each of whom is independent and free of conflict of interest with respect to the Sponsor, the Part D plan and pharmaceutical manufacturers.
- A process to ensure that FDRs effectively screen their governing bodies, and senior leadership for conflicts of interest.

50.1.4 – Providing Guidance to Employees and FDRs on dealing with Compliance Issues

42 CFR §§ 422.503(b)(4)(vi)(A)(4), 423.504(b)(4)(vi)(A)(4)

Compliance policies and procedures and Standards of Conduct must include detailed and specific guidance to employees and FDRs regarding how to prevent, detect and respond to potential compliance issues. This includes instructions regarding lines of reporting authorities and how compliance issues are reported.

50.1.5 – Identifying How to Communicate Compliance Issues

42 CFR §§ 422.503(b)(4)(vi)(A)(5), 423.504(b)(4)(vi)(A)(5)

Compliance policies and procedures and Standards of Conduct must include detailed and specific guidance to employees and FDRs regarding how to report potential compliance issues. This includes instructions for using anonymous and confidential hotlines, assurances of non-retaliation for issues reported, and an explanation of how compliance reports are processed and investigated.

50.1.6 – Describing How Compliance Issues Are Investigated and Resolved

42 CFR §§ 422.503(b)(4)(vi)(A)(6), 423.504(b)(4)(vi)(A)(6)

Compliance policies and procedures and Standards of Conduct must include detailed and specific guidance to employees and FDRs describing how suspected, detected or reported compliance issues are investigated and resolved. Such policies must include a discussion regarding implementation of disciplinary procedures for noncompliant behavior.

50.1.7 – Policy of Non-Intimidation and Non-Retaliation

42 CFR §§ 422.503(b)(4)(vi)(A)(7), 423.504(b)(4)(vi)(A)(7)

Compliance policies and procedures and Standards of Conduct must include a policy of non-intimidation and non-retaliation in response to compliance or FWA reporting by any staff or FDR.

50.1.8 – Governing Body Approval of Compliance Policies and Procedures and Standards of Conduct

42 CFR §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Federal regulations emphasize the necessity of oversight by and involvement of the organization's governing body and senior leadership in the Compliance Program. Further, an effective Compliance Program establishes an organizational culture of compliance that emanates from the top of the corporate structure. Therefore, it is critical to an effective Compliance Program that the Sponsor's governing body and senior management be directly involved in the development and/or review of the compliance policies and procedures and the Standards of Conduct. If the organization's governing body has delegated a governing body committee, such as a board-level audit or compliance committee, to oversee the details of the Compliance Program, the governing body committee, rather than the full board, may undertake the development and review of the proposed policies, procedures and Standards of Conduct; however, the compliance policies and procedures and Standards of Conduct must be approved by the full governing body and by senior management, including the CEO and other senior officials.

CMS strongly recommends that the Sponsor establish a standardized process to require the governing body (or governing body committee), senior management, and the Compliance Committee to review and approve the Compliance policies and procedures and the Standards of Conduct at least annually.

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

42 CFR §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Compliance policies and procedures and Standard of Conduct cannot be effective if they are not distributed to and read and followed by employees. Therefore, CMS expects Sponsors and FDRs to distribute compliance policies and procedures and Standards of Conduct to all employees at the following times:

- Within 90 days of the time of hire of Sponsor and FDR employees (or initial contracting in the case of FDR organizations);
- Annually thereafter; and,
- Whenever policies and procedures/Standards of Conduct are revised or updated.

In addition, compliance policies and procedures and Standards of Conduct should be easily accessible to all employees of the Sponsor and of FDRs. This may include posting the policies, procedures and Standards on the employee intranet, on a Sponsor website for FDRs, in easily accessible department binders, etc.

Because distribution of compliance policies and procedures and Standards of Conduct is essential to effectiveness, CMS expects Sponsors to ensure that its employees and employees of FDRs, as a condition of employment, read and agree to comply with all written compliance policies and procedures and Standards of Conduct within 90 days of the date of hire and annually thereafter. The Sponsor must be able to demonstrate to CMS that all employees and employees of FDRs have done so. This may be accomplished by employee statements or certifications or otherwise. CMS strongly recommends that the Sponsor coordinate tracking efforts to ensure that employees and FDR employees meet these requirements.

The Sponsor's contracts with FDRs should include provisions that the FDR will implement and distribute to all FDR employees and board members either the Sponsor's Standards of Conduct and compliance policies and procedures, or comparable policies and procedures and Standards of Conduct of their own. The Sponsor need not review and approve the FDR's compliance policies and procedures and Standards of Conduct in advance to ensure consistency with CMS requirements. However, Sponsors will be held accountable for ensuring that their FDRs have compliance policies and procedures and Standards of Conduct that meet CMS requirements.

The Sponsor must periodically monitor and audit its own organization and those of its FDRs to ensure that there is documented proof that these requirements (distribution of Standards of Conduct and compliance policies and procedures within 90 days of hire / contracting and annually thereafter) are being followed.

50.2 – Compliance Officer, Compliance Committee and High Level Oversight

42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The Sponsor must designate a Compliance Officer and Compliance Committee who report directly to and are accountable to the organization'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 MAO or Part D Sponsor, or of its 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 governing body of the organization on the activities and status of the Compliance Program, including issues identified, investigated, and resolved by the Compliance Program.

(3) The governing body of the organization 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

42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

A Compliance Program cannot be effective in the absence of adequate resources. In most instances, the Medicare Compliance Officer position should be full-time and dedicated principally to the Medicare Compliance Program. The Medicare Compliance Officer may be the same individual as the corporate Compliance Officer; however, CMS strongly recommends that the two positions be staffed independently. 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 the corporate Compliance Officer can effectively implement the Medicare Compliance Program or whether the organization should assign a separate individual to serve as the Medicare Compliance Officer.

The organization must ensure that reports from the Medicare Compliance Officer reach the senior-most leader of the company, typically the CEO or President. Because federal regulations require a direct reporting relationship, the Medicare Compliance Officer's reports should not be routed to the CEO or President through operational management such as the COO, CFO, GC or other executives responsible for operational areas. However, the Medicare Compliance Officer's reports may be relayed to the CEO or President through divisional CEOs or Presidents who then report to the company's senior-most leader. For example, it would be acceptable for the Medicare Compliance Officer to report directly to the President of the division that houses the Medicare program, who then reports to the CEO of the company on the status and activities of the Medicare Compliance Program.

Similarly, because of the direct reporting requirement in the regulations, the Medicare Compliance Officer's reports to the governing body must be made through the compliance infrastructure. Thus, when an organization has both a Medicare Compliance Officer and a Corporate Compliance Officer, the Medicare Compliance Officer may

report compliance issues directly to the Corporate Compliance Officer, who then must ensure that compliance reports are provided to the governing body. Similarly, the Medicare Compliance Officer's reports may be made to the Medicare Compliance Committee and then routed through the Compliance Committee to the governing body. CMS strongly encourages Sponsors who have both a corporate Compliance Officer and a Medicare Compliance Officer to allow the Medicare Compliance Officer to attend meetings of the governing body and to make in-person reports to the governing body. However, even if the Medicare Compliance Officer does not make in-person reports, the regulatory requirement for a direct reporting relationship mandates that Medicare Compliance Officer of all Sponsors have express authority to report directly to the organization's senior-most leader and to the governing body at his/her discretion.

The Compliance Officer should not serve dual roles in both compliance and in operational areas. This leads to self-policing in the operational area in which he/she serves, which is a conflict of interest. Thus, there is a conflict of interest where the Compliance Officer is also the CFO, COO or GC.

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.

To be effective, the Compliance Officer must have training and/or experience working with MA, MA-PD or PDP programs and, preferably with regulatory authorities. Further, senior leadership's empowerment and support of the Compliance Officer is critical to his/her credibility and to his/her ability to establish and operate an effective Compliance Program. Therefore, CMS strongly recommends that the Compliance Officer be a member of senior management.

Duties of the Compliance Officer include but are not limited to:

- Ensuring that a Medicare Compliance report is provided at least on a quarterly basis, or more frequently as necessary, to the Sponsor's Corporate Compliance Officer, if any, board of directors, CEO, and Compliance Committee, on the status of the Sponsor's Medicare Compliance Program implementation, the identification and resolution of potential or actual instances of noncompliance, and the Sponsor's compliance oversight and audit activities.
- Interacting with the operational units of the company and being involved in and aware of the daily business activity Sponsor.
- Creating and coordinating, or appropriately delegating, educational training programs to ensure that the Sponsor's officers, directors, 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 suspected FWA and other misconduct without fear of retaliation.
- Maintaining the compliance reporting mechanism and closely coordinating with the internal audit department and the Special Investigations Unit (SIU), where applicable.
- Responding to reports of potential instances of FWA, including the coordination of internal investigations 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.
- Coordinating personnel issues with the Sponsor's Human Resources office (or its equivalent) to ensure that the HHS OIG exclusion lists and GSA debarment lists have been checked with respect to all employees, officers, directors, and FDRs monthly.
- Maintaining documentation for each report of potential noncompliance or FWA received from any source, including through any of the reporting methods (i.e. hotline, mail, in-person), which describes the initial report of noncompliance, the investigation, the results of the investigation, and all corrective and/or disciplinary action(s) taken as a result of the investigation as well as the respective dates when each of these events and/or actions occurred and the names and contact information for the person(s) who took and documented these actions.
- 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 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 an FWA issue is discovered that involves multiple parties.

The Medicare Compliance Officer should have the authority to:

- a. Interview or delegate the responsibility to interview the Sponsor's employees and other relevant individuals regarding compliance issues.

- b. Review and retain company contracts and other documents pertinent to the Medicare program.
- c. 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.
- d. Independently seek advice from legal counsel.
- e. Report misconduct to CMS, its designee or law enforcement.
- f. Conduct and direct internal audits and investigations of any FDRs.

50.2.2– Compliance Committee

42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

Sponsors must have a Compliance Committee in place that is dedicated to Medicare compliance. The governing body of the Sponsor shall establish a Compliance Committee, which typically is overseen by the Medicare Compliance Officer. The Compliance Committee advises the Medicare Compliance Officer, is accountable to the CEO or President, and assists in the implementation of the Compliance Program. The Medicare Compliance Committee may operate within the structure of an existing compliance committee, or may operate as a separate and distinct committee. In order to enable reasonable oversight of the Compliance Program by the governing body, the products of the Compliance Committee, including the status of the Compliance Program, must be reported to the governing body of the Sponsor or to a governing body committee responsible for Medicare program oversight, on at least a quarterly basis.

Examples of duties that the Compliance Committee is responsible for include, but are not limited to:

- Meeting at least on a quarterly basis, or more frequently as necessary to enable reasonable oversight by the governing body.
- Developing strategies to promote compliance and the detection of any potential violations.
- Ensuring that training and education are effective and appropriately completed.
- Assisting with the creation and implementation of the risk assessment and of the 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.

- Overseeing a system of internal controls designed to ensure compliance with Medicare regulations in daily operations.
- Supporting the Medicare 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 FWA confidentially or anonymously (if desired) without fear of retaliation.
- Reviewing and addressing reports of monitoring and auditing of areas in which the Sponsor is at risk for program noncompliance or FWA and ensuring that corrective action plans are implemented and monitored for effectiveness.
- Providing regular and ad hoc reports on the status of compliance with recommendations to the Sponsor's governing body.

An effective Compliance Committee includes individuals with a variety of backgrounds, and reflects the size and scope of the organization and the organization's resources. For example, Sponsors should consider including members of senior management (e.g., CFO, COO), auditors that perform medical reviews, pharmacists, registered nurses, and nationally certified pharmacy technicians on the Compliance Committee (to the extent that their organization is sufficiently staffed). Other staff 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

42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

Governing body engagement in the Compliance Program is critical to the meaningful and successful oversight of the Sponsor's Medicare operations. The governing body is ultimately accountable for compliance within the organization, and is obligated to oversee the Sponsor's Compliance Program. When compliance issues are presented to the governing body, it must make further inquiry and take appropriate action to address and satisfactorily resolve those issues.

The governing body must ensure that the Compliance Officer overseeing the Medicare Compliance Program has unfettered access to the governing body. The governing body

may delegate Compliance Program oversight to a specific committee of the governing body (e.g. Audit Committee, Compliance Committee, etc.), but the governing body as a whole remains accountable for ensuring the effectiveness of the Sponsor's Compliance Program. The governing body as a whole must review the status of the Compliance Program with sufficient frequency to ensure that it is conducting reasonable oversight of the Medicare Compliance Program. What constitutes sufficient frequency will depend on the circumstances, including considerations such as the size and structure of the organization, the scope of its Medicare program, its membership, the extent to which it delegates its responsibilities under its contract(s) with CMS, and its compliance challenges and risks, among other factors. The full board's reasonable oversight may be accomplished with thorough reports by a governing body committee delegated with Compliance Program oversight. 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.

Federal regulations require a governing body that is knowledgeable on the content and operations of the Compliance Program. Thus, the governing body must receive compliance training and education as to the structure and operation of the Compliance Program to enable it to be engaged, to ask questions and to exercise independent judgment over the compliance issues with which it is presented. The governing body must be knowledgeable about compliance risks and strategies, must understand the measurements of outcome, and must be able to gauge effectiveness of the Compliance Program.

Reasonable oversight requires the governing body (or a committee of the same) to participate in the development and implementation of the Compliance Program. Examples of areas of involvement of the governing body, or a designated committee of the same, include, but are not limited to:

- Approval of Standards of Conduct and policies and procedures;
- Approval of compliance and FWA training;
- Approval of the Compliance Program structure and operations;
- Development and approval of the risk assessment;
- Review of internal and external audit work plans;
- Review of outcomes from internal and external audits;
- Approval of corrective action plans resulting from audits;
- Regularly scheduled updates from the Compliance Officer overseeing the Medicare Compliance Program;
- Review and approval of performance goals for the Compliance Officer;
- Review and evaluation of the performance of the Compliance Program on at least an annual basis; and
- Evaluation of the senior management team's commitment to ethics and the Compliance Program.

The governing body must be assured that the Compliance Program is working. This may be best achieved by the collection and review of measurable evidence that the

Compliance Program is detecting and correcting Medicare program noncompliance on a timely basis. CMS strongly recommends that the Compliance Officer be required to produce data showing that the program has reduced the risks of program noncompliance and FWA.

The Sponsor must ensure that CMS is able to validate, through review of governing body meeting minutes, the appropriate level of the Sponsor's governing body engagement in oversight of the Medicare Compliance Program.

50.2.4 – Senior Management Involvement in Compliance Program

42 CFR §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

An effective Compliance Program cannot be achieved unless the CEO or President and other senior management as appropriate are engaged in the Compliance Program. It is critical that the CEO and senior management recognize the importance of the Compliance Program to the organization and that the Compliance Officer is crucial to protecting the organization and its governing body.

A critical role of the CEO or President and senior management is to ensure that the Compliance Officer is integrated into the organization and has the resources necessary to operate a robust and effective Compliance Program. The CEO should seek regular reporting 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 receive regular reporting of all governmental compliance enforcement activity, from Notices of Noncompliance to formal enforcement actions.

50.3 – Effective Training and Education

42 CFR §§ 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 and 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 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. However, even if deemed for FWA training, FDRs employees still must have compliance training

50.3.1 – General Compliance Training

42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

All Sponsor personnel, governing body members, and FDRs and their employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive general compliance training within 90 days of initial hiring (or contracting in the case of FDRs) and annually thereafter as a condition of employment. The compliance training must be made part of the orientation of new employees of both Sponsors and of FDRs, of newly contracted FDRs, and upon the appointment of a new Chief Executive, manager or governing body member. Sponsors are accountable for maintaining records of the time, attendance, topic and results of the training.

Sponsors must require that their FDRs either conduct their own compliance training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities. The Sponsor need not review and approve in advance any general Compliance Program training used by FDRs; however the Sponsor is accountable for ensuring that its FDRs' employees have training that meets CMS and regulatory requirements.

Sponsors must establish effective mechanisms to ensure that FDRs fulfill the compliance training requirements (e.g. incorporate the requirement into contracts with FDRs, collect attestations from FDRs, coupled with monitoring and auditing of a sample of FDRs to validate training requirements were fulfilled, etc.).

CMS expects Sponsors to review and update, if necessary, the general compliance training at least annually, and whenever changes in regulations, policy or guidance

require revision of the training materials. The governing body should review and approve the compliance training materials as part of its oversight responsibilities.

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 organization'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 potential noncompliance. Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of potential noncompliance or FWA.
- 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 formal 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 fraud and abuse or gifts and gratuities for Government employees.
- A review of potential conflicts of interest and the Sponsor's disclosure system.
- An overview of HIPAA, the CMS Data Use Agreement, and the importance of maintaining the confidentiality of Personal Health Information.
- An overview of the monitoring and auditing work plan of the organization.

50.3.2 – Specialized Compliance Training

42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

Training and education of employees, managers, directors and FDRs in Medicare program compliance includes specialized training on issues posing compliance risks based on the individual's job function (e.g., pharmacist, statistician, customer service, etc.). Specialized training is necessary upon initial hire or appointment to the job function, when requirements change, when an employee works in an area previously found to be non-compliant with program requirements or implicated in past misconduct,

and at least annually thereafter as a condition of employment. Specialized training content may be developed by the Sponsor, and/or employees may attend professional education courses that help meet this requirement.

Sponsors must require that FDRs administer specialized compliance training, or where there are sufficient organizational similarities, the Sponsor may choose to make its own specialized training programs available to these entities.

Examples of specialized training for Sponsor employees, directors and FDRs include, but are not limited to training for those involved in:

- Marketing the prescription drug benefit to Medicare beneficiaries;
- Managing or administering the exceptions and appeals process;
- Calculating TrOOP;
- Making negotiated prices available to beneficiaries;
- Submitting the payment bid to CMS;
- Payment reconciliation;
- Submitting Part C and D data to CMS;
- Negotiating rebate agreements with Pharmaceutical Manufacturers, wholesalers, and other suppliers of Part D drugs;
- Negotiating pharmacy network agreements;
- Administering the Compliance Program and operations, i.e., the Medicare Compliance Officer and his/her staff;
- Conducting administrative activities necessary for the operation of the Part C and D benefits;
- Managing employer group plans; and
- Security and authentication instructions involved in Health Information Technology.

Specialized compliance training must be reviewed and revised as needed but at least annually, especially as risk areas change and evolve over time. Sponsors must retain adequate records of their specialized training of employees, including attendance logs, materials distributed at training sessions and results of testing.

50.3.3 – Fraud, Waste, and Abuse Training

42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

August 21, 2009 HPMS Memo – *Fraud, Waste, and Abuse (FWA) Training Clarification*

Sponsors are responsible for ensuring that all of its employees, managers, CEO and other senior administrators and governing body members, as well as the employees of FDRs, receive FWA training. All persons who assist in the administration of the Sponsor's core

functions under its Medicare Parts C or D contracts or in the delivery of Medicare Parts C or D benefits, whether full-time, part-time, temporary, volunteer or otherwise, unless otherwise deemed to have met the FWA training through enrollment into the Medicare program, are required to take FWA training.

With the exception of pharmacies, training materials may be provided by the Sponsor to its FDRs or can be developed by the FDRs themselves. Pharmacies may not develop their own training materials. Training materials for pharmacies must be disseminated to them by the Sponsor or PBM. When the training materials are disseminated by the Sponsor or the PBM to the pharmacy, pharmacy staff may administer the training themselves.

FWA training must include, at a minimum, the following:

- Laws and regulations related to MA and Part D FWA (i.e. False Claims Act, Anti-Kickback statute, HIPAA, etc.).
- Obligations of FDRs to have appropriate policies and procedures to address FWA.
- A process for reporting to the Part C or D Sponsor suspected FWA.
- Protections for Sponsor employees and employees of FDRs who report suspected FWA.
- Types of FWA that can occur in the settings in which employees work.

In order to ensure consistency and reduce burden on Sponsors and FDRs, CMS has developed a web-based training module that can be used to satisfy the FWA training requirements. The FWA training is available on CMS' Medicare Learning Network® (MED Learn) website. Using CMS' training module is optional and a Sponsor may use another method. The benefits of using CMS' training module include the assurance that the training meets CMS' FWA training requirements, the ease of accessing the training on CMS' MED Learn website and the likely reduction in burden for FDRs that contract with Sponsors who adopt CMS' standardized training.

FDRs who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program or through accreditation as a supplier of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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.

Please note that, although deeming meets the requirements of FWA training for qualified individuals, deemed persons must still receive general Medicare Compliance Program training and specialized Medicare compliance training in connection with their job responsibilities.

50.3.4 – Methods of Training

42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

Sponsors are responsible for implementing compliance and FWA training through effective methods. Training can be conducted through interactive sessions led by expert facilitators, web-based tools, such as CMS' MED Learn site, Intranet sites, live or videotaped presentations, written materials, or any combination of these techniques, or any other methods, that are effective for the specific organization.

Effective training and education often includes engaging employees in substantive discussion to reinforce the organization's commitment to compliance with applicable laws, regulations, standards, and principles. Training should be designed to ensure that employees understand what is expected of them regarding compliance.

50.3.5 – Measuring Effectiveness of Training and Education

42 CFR §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

Sponsors must implement mechanisms to measure the effectiveness of the training. Such mechanisms may include the administering of tests or quizzes during training sessions, and the monitoring of compliance and FWA reporting logs, to determine whether reporting of compliance and FWA, as recorded in the logs, is indicative of enhanced understanding of compliance and FWA issues through effective training (i.e. number and quality of reports will increase if employees receive effective training).

It is highly recommended that the Compliance Officer obtain feedback from employees as to the effectiveness of training. Feedback can be obtained through evaluation forms, employee focus groups, one-to-one meetings between the compliance staff and small groups of employees and periodic attendance at departmental meetings.

Additionally, effectiveness is enhanced where the Compliance Officer establishes a dialogue with operational employees and their managers regarding compliance. Relevant inquiries would relate to what employees think is helpful about the program, where they could use assistance and additional training and what suggestions they have for improving the program.

A continuing problem in a particular operational area, despite the training provided, can be indicative of ineffective training (among other factors). The Sponsor must evaluate the training to determine whether the training is effective, must identify any deficiencies and must undertake remedial actions to correct any deficiencies.

50.4 – Effective Lines of Communication

42 CFR §§ 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 organization's employees, managers and governing body, and the organization's FDRs. Such lines of communication must be accessible to all, allow compliance issues to be reported when they arise and provide a means 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, Managers, Members of the Governing Body, and FDRs.

42 CFR §§ 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 includes information about the Compliance Officer, such as the Compliance Officer's name, office location and contact information, as well as information about the 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 in a timely manner and to all appropriate parties.

50.4.2 – Establishing a Mechanism to Field Compliance Questions and Concerns from Employees and FDRs

42 CFR §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

Sponsors must have a system in place to receive, record, respond to and track compliance questions or reports of potential or actual noncompliance or FWA from employees, members of the governing body, beneficiaries, and FDRs and their employees, while maintaining confidentiality (to the greatest extent possible), allowing anonymity if desired (e.g. through telephone hotlines or mail drops), and emphasizing and ensuring non-retaliation against reporters.

Sponsors must adopt, routinely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee or FDR who in good faith reports suspected misconduct. 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 Sponsor's written Standards of Conduct must require all employees, members of the governing body, and FDRs and their employees to report compliance concerns and suspected or actual misconduct and violations of law.

The methods of reporting and the non-retaliation policy must also be publicized around the company's offices. This information can be publicized, for example, through the use of posters, table tents, mouse pads, key cards and other prominent displays. The Sponsor must also document the education of employees and FDRs on the requirements of reporting noncompliance issues and the availability of the methods to report concerns. This training may be included in the annual general compliance training and documented by employee training logs. It should also be included in the new employee's orientation.

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

In order to encourage reporting, when a suspected compliance issue is reported, Sponsors should provide the complainant with information regarding expectations of a timely response, confidentiality, non-retaliation and progress reports.

50.4.3 – Member Communications and Education

42 CFR §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)

Sponsors must educate their members about identification and reporting of Medicare program noncompliance and FWA. Education methods may include flyers, letters, pamphlets that can be included in mailings to enrollees and members (such as enrollment packages, Explanation of Benefits ("EOB")), information published on Sponsor website (especially on Member links), etc.

50.5 – Well-Publicized Disciplinary Standards

42 CFR §§ 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

42 CFR §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must establish and publish disciplinary standards that reflect clear and specific disciplinary policies. The disciplinary standards and policies must describe the Sponsor's expectations for the reporting of compliance issues including noncompliant, unethical or illegal behavior and the expectations for assisting in the resolution of reported compliance issues. In addition, the disciplinary standards and policies must identify noncompliant, unethical or illegal behavior, such as through examples of violative conduct that employees might encounter in their jobs. Further, the standards / policies must provide for timely, consistent and effective enforcement of the standards when noncompliance or unethical behavior is found. Finally, the disciplinary measure must be appropriate to the seriousness of the violation.

50.5.2 – Methods to Publicize Disciplinary Standards

42 CFR §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

To encourage the reporting of incidents of unethical or non-compliant behavior, the Sponsor, under direction of the Medicare Compliance Officer, must prominently publicize compliance disciplinary standards to senior management and to employees and FDRs responsible for the administration or delivery of Parts C and D benefits, through mechanisms such as:

- Newsletters which explain compliance issues and methods.
- Guidelines as a regular topic at department staff meetings, in communications with FDRs, and in the annual general compliance training.
- Information about compliance issues and reporting methods posted to the organization's Intranet site.
- Posters prominently displayed throughout employee work and break areas, cafeteria table tents, or other such vehicles which emphasize the importance of compliance.

50.5.3 – Enforcing Disciplinary Standards

42 CFR §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

All employees and FDRs must be informed that violation of standards will result in appropriate disciplinary action, up to and including termination of employment. The Sponsor should have a provision in its contracts with FDRs that violations may result in termination of the contractual relationship with the Sponsor.

Sponsors must be able to demonstrate to CMS that disciplinary standards are enforced in a timely, consistent, effective and appropriate manner. Sponsors may accomplish this by maintaining and periodically reviewing records of discipline for compliance violations to promote consistency and fairness and to evaluate the appropriateness of the disciplinary action. Sponsors must also consistently undertake appropriate disciplinary action across the organization to ensure that the disciplinary policy has a deterrent effect.

To encourage compliance with Standards of Conduct, Sponsors should include compliance as a measure of an employee's job performance on the individual's annual performance review.

50.6 – Effective System for Routine Monitoring and Identification of Compliance Risks

42 CFR §§ 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 must include internal monitoring and audits and, as appropriate, external audits, to evaluate the organization's and FDRs' compliance with CMS requirements and the overall effectiveness of the Compliance Program.

50.6.1 – Routine Monitoring and Auditing

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Procedures for internal monitoring and auditing 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 reviews that are repeated regularly during the normal course of operations. Monitoring activities may occur to ensure corrective actions are undertaken or when no specific problems have been identified, to confirm ongoing compliance. An audit is a formal review of compliance with a particular set of internal standards (e.g.,

policies and procedures) or external standards (e.g., laws and regulations) used as base measures.

Sponsors must develop a monitoring and auditing work plan that addresses the risks associated with the Parts C and D benefits. The Medicare 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 Medicare Compliance Officer. The Medicare Compliance Officer may coordinate with the Audit Department, if any, in connection with these activities. To be effective, CMS expects the Medicare Compliance Officer to receive regular reports regarding performance, updates to systems, staffing, etc. It is the Medicare Compliance Officer's responsibility to provide updates on monitoring and auditing results to the Compliance Committee, the CEO, senior leadership and the governing body.

50.6.2 – Development of an Internal Risk Assessment

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

An effective monitoring and auditing program begins with an internal risk assessment. Sponsors must establish and implement policies and procedures to conduct a formal baseline assessment of the organization's major compliance and FWA risk areas. In order to establish an effective system for auditing and monitoring, the Sponsor must develop a risk assessment tool that takes 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 to 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
- Budget

Areas of particular concern for Parts C and D Sponsors include 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 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 organization, and the Sponsor must prioritize the

monitoring and auditing strategy accordingly. A comprehensive risk assessment must be completed at least once a year, or more often if necessary. 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. 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

42 CFR §§ 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 Medicare Compliance Officer and include actions such as reporting findings to CMS or to the MEDICs, if necessary.

50.6.4 – Audit Schedule and Methodology

42 CFR §§ 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 should plan a combination of desk and on-site audits, including unannounced internal audits or “spot checks” when developing the schedule. 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 produce a standard audit report that includes items such as:

- Audit Objectives
- Scope and Methodology
- Findings
 - Condition
 - Criteria
 - Cause
 - Effect
- Recommendations

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

- Determine which risk areas will most likely affect the organization, and prioritize the monitoring and audit strategy accordingly.
- Utilize statistical methods and/or risk assessment, when appropriate, 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 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.
- Conduct follow up review of areas previously found non-compliant to determine if the implemented corrective actions have fully addressed the underlying problem.

50.6.5 – Internal Audit

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

The Medicare Compliance Officer and Compliance Committee must ensure the implementation of an internal audit function appropriate to the organization's size, scope and structure. The internal audit function may be performed by a separate department dedicated specifically to internal audit (i.e. Internal Audit Department) or may be performed by members of other existing departments (e.g. Compliance Department). Staff dedicated to the internal audit function will be responsible for monitoring and auditing the Sponsor's operational areas to ensure compliance with Medicare regulations. The internal audit function should be allocated an annual budget based on the number of employees the Sponsor has dedicated to the administration of the Medicare Parts C and D benefits, taking into account the resources necessary to complete the goals set forth in the work plan each year.

Participants of the internal audit function are expected to include pharmacists, nurses, physicians, certified public accountants, fraud investigators, SIU staff and other highly skilled staff that have expertise in the areas under review. Sponsors must ensure that the internal auditors are independent, do not engage in self-policing (e.g. the Compliance Officer must not audit the effectiveness of the Compliance Program), and are knowledgeable of Medicare program requirements.

Sponsors must ensure that internal audit staff has access to the relevant personnel, information, records and areas of operation under review, including the operational areas at the plan and FDR level.

50.6.6 – External Audit: Monitoring and Auditing FDRs

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors remain 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 certain of those duties to other entities. The Sponsor must develop a strategy to monitor and audit its FDRs, to ensure that its FDRs are in compliance with all applicable laws and regulations.

Sponsors' contractual arrangements with first tier entities should provide for routine and random auditing. Sponsors must include in their work plan the number of FDRs that will be audited each year and how the entities will be identified for auditing. Sponsors should make it a priority to conduct a certain number of on-site audits. Additionally, Sponsors must ensure that their contracts with FDRs require record retention and provide rights of access to these records to CMS or its designee.

When a Sponsor has a large number of FDRs, making it impractical and/or cost prohibitive to obtain attestations of compliance from all of them or to monitor or audit all of them, the Sponsor must perform a risk assessment to identify its highest risk FDRs, then select a reasonable number of FDRs to audit from the highest risk groups.

Where FDRs perform their own audits, Sponsors should request a copy of the FDR's audit work plan and request the audit results. When corrective action is needed, Sponsors must ensure that corrective actions are taken by the entity. Although FDRs may perform their own internal auditing, the Sponsor remains obligated to perform its own auditing of FDRs.

Examples of reports that Sponsors should receive and review as part of their FDR monitoring and auditing efforts include, but are not limited to, the following:

Payment Reports that detail the amount paid by both the Sponsor and the beneficiary, the provider, the beneficiary 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 and the enrollee and their prescribing providers should be contacted and explanations for use should be received. 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 Durable Medical Equipment, such as scooters. These reports should be generated to identify possible prescriber and referral/provider, pharmacy fraud and DME fraud.

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 beneficiary resides (i.e., beneficiaries in rural areas would typically have longer trips to a doctor or pharmacy than beneficiaries living in urban areas).

50.6.7 – Use of Mechanisms to Measure Compliance and Compliance Program Effectiveness

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Measurement and tracking of compliance efforts are crucial to an effective Compliance Program. Sponsors are expected to use dashboards, scorecards, self-assessment tools or other mechanisms to measure Medicare program compliance within operational areas of their organizations and the program compliance of their FDRs. The mechanism used for measuring compliance may be tracked by the management of each operational area, and publicized to all employees. The results of the dashboard, scorecard, etc. must be shared with senior management and with the Board of Directors. It is highly recommended that compliance performance be linked to staff, management, executive and FDR compensation.

Sponsors must evaluate the effectiveness of the Compliance Program at least annually. The use of a self-assessment tool may be helpful in the evaluation. The results of the annual evaluation must be reported to senior management and to the Board. Compliance Program effectiveness is measured by evaluating the Sponsor’s implementation of and commitment to Compliance Program regulations and guidance as outlined in this Chapter and other relevant CMS regulations and guidance.

Sponsors must respond promptly to identified weaknesses in their Compliance Program, and must take appropriate corrective measures to ensure a fully effective Compliance Program.

50.6.8 – OIG Exclusion / GSA Debarment

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 42 CFR 1001.1901

Federal law prohibits the payment by Medicare, Medicaid or any other federal health care program for any item or service furnished by a person or entity excluded from participation in these federal programs. No Part C or D Sponsor or FDR may submit for payment any item or service provided by an excluded person or entity, or at the medical direction or on the prescription of a physician or other authorized person who is excluded.

Sponsors shall not pay for services, equipment or drugs prescribed or provided by a provider or supplier excluded by either the HHS OIG or GSA. Sponsors must review the

HHS OIG List of Excluded Individuals and Entities (LEIE list) exclusion list 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 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.

OIG's LEIE includes all health care providers that are excluded from participation in Federal health care programs, including those health care providers that might also be on the GSA list. It is CMS' guidance that Sponsors and FDRs must check the OIG and GSA lists monthly. In addition to health care providers (that, as noted, are also included on the OIG LEIE) the GSA list includes non-health care contractors with whom Sponsors may contract. Sponsors may not submit administrative costs in connection with excluded non-health care contractors. Therefore, it is important that Sponsors check the GSA list.

The OIG updates the LEIE monthly, and exclusions are generally posted 15 days prior to the exclusion effective date. Sponsors therefore have a reasonable amount of time to update their systems before the exclusion is effective, in order to reject claims beginning with the effective date of the exclusion. Any claims by an excluded entity not rejected at point-of-sale must be reversed upon identification, and the prescription drug event data (PDE) adjusted. Sponsors are expected to subscribe to the OIG LISTSERV via the OIG Website at <http://oig.hhs.gov/maillinglist.asp> to receive immediate notice of updates to the LEIE.

CMS made the Medicare Exclusion Database (MED) available to Sponsors beginning in July 2011, via the MED online system. The MED includes information from the LEIE and the National Provider Identifier (NPI). CMS adds the NPI information to the MED, as this information is not generally available on the LEIE. Sponsors who need access to MED online and/or need to download the files should obtain an "Individuals Authorized Access to the CMS Computer Services" (IACS) ID, through the IACS registration process at <http://www.eushelpdesk.com/IACS/med.html>.

Sponsors also must ensure that their FDRs develop and implement policies and procedures that require and document the review of the OIG LEIE for all prospective, potential, and actual employees of the FDRs using the same screening functions described above. Sponsors may include these requirements in their contracts with FDRs, and must perform appropriate monitoring and auditing of FDRs as outlined above, to confirm that FDRs comply with this requirement.

Sponsors must also implement a policy requiring all new and existing permanent and temporary employees, governing body members, FDRs and FDR employees to whom are delegated the Sponsor's core functions under its Parts C and D contracts to immediately disclose any exclusion, or other event that makes them ineligible to perform work related directly or indirectly to Federal health care programs.

Sponsors and their FDRs must have processes in place to identify and prevent payment for claims at point-of-sale for any drugs or services prescribed, dispensed or delivered by excluded providers. When Sponsors identify these claims at point-of-sale, the claims must be denied. The Sponsor must investigate and determine whether other claims were submitted by the excluded person or entity, or by any other excluded entity, and follow guidance as outlined in March 29th 2010 HPMS memo entitled *Excluded Provider Guidance*.

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

42 CFR §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors are expected to use data analysis as an effective tool for FWA prevention and detection at the Sponsor and FDR levels. Data analysis should include the comparison of claim information against other data (e.g., provider, drug 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.). Sponsors are also expected to use data analysis to monitor pharmacy billing and to detect unusual patterns. Sponsors may invest in data analysis software applications that give them the ability to analyze large amounts of data. 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, providers, suppliers) and at the prescriber level; and
- Use findings to determine where there is a need for a change in policy.

Sponsors are expected to 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.
- Percent increase in charges, number of visits/services from one period to another.

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

50.6.10 – Special Investigation Units (SIUs)

42 CFR §§ 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 investigative 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 separate from Compliance, or ensure that responsibilities generally conducted by an SIU are conducted by the Compliance Department. SIU responsibilities should include:

- Reducing or eliminating Parts C and D benefit costs due to FWA;
- Ensuring proper value of Parts C and D benefits, including correct pricing, quantity, and quality;
- Utilizing real-time systems that ensure accurate eligibility, benefits, services, refills, and pricing and that identify potential adverse drug interactions and quality of care issues;
- Reducing or eliminating fraudulent or abusive claims paid for with federal dollars;
- Preventing illegal activities;
- Identifying members with drug addiction problems and other overutilization issues;
- Identifying and recommending providers for exclusion, including those who have defrauded or abused the system;
- Referring potential 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;

- Assisting law enforcement by providing information needed to develop successful prosecutions; and
- Providing fraud awareness training to the employees of the Sponsor.

SIUs must be accessible 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

42 CFR §§ 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 to evaluate or inspect any books, contracts, medical records, patient care documentation, and other records of Sponsors, and 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 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 Parts C and D contracts and the Parts C and D regulations, such as copies of prescriptions, invoices, pharmacy licenses, claims records, signature logs, 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 to their facilities 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 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 MEDICs. This cooperation

includes providing CMS and/or the MEDICs or other contractors with access to all requested facilities and records associated in any manner with the Parts C or D program.

CMS has the discretionary authority to perform audits under 42 C.F.R. § 423.505(e)(2), which specifies 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 may deem necessary to enforce the contract.

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

50.7 – Procedures and System for Prompt Response to Compliance Issues

42 CFR §§ 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 organization 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 organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1).
3. The organization 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

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Parts C and D Sponsors must conduct timely and reasonable inquiries into any compliance incident or issue involving potential Medicare program noncompliance or potential FWA.

Program noncompliance and misconduct may occur at the level of the Sponsor or its FDRs. It may be discovered through a hotline, a website, a beneficiary complaint, during routine monitoring or self evaluation, an audit, or by regulatory authorities. Regardless of how the noncompliance or misconduct is identified, CMS expects Sponsors to initiate a reasonable inquiry as quickly as possible, but not later than two weeks after the date the potential noncompliance or misconduct or incident was identified.

A reasonable inquiry includes a preliminary investigation of the matter by the Medicare Compliance Officer and/or the Sponsor's Special Investigative Unit (SIU). If the issue appears to involve misconduct and the Sponsor does not have either the time or the resources to investigate the potential misconduct in a timely manner, it should refer the matter to the NBI MEDIC within two weeks of the date the potential misconduct is identified so the potentially noncompliant fraudulent or abusive activity does not continue.

Sponsors are responsible for monitoring for FWA and for potential Medicare program noncompliance within their organizations. When serious noncompliance or potential fraudulent or abusive activity is identified, CMS strongly encourages Sponsors to refer the activities to CMS or to the appropriate MEDIC.

50.7.2 – Corrective Actions

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

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

Corrective actions must be designed to correct the underlying problem that results in program violations and to prevent future noncompliance. The first step in developing a corrective action is to perform a root cause analysis to determine what caused or allowed the misconduct, problem or deficiency to occur. A corrective action must be tailored to address the particular misconduct, 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 misconduct or program noncompliance by an FDR, CMS recommends that the elements of the corrective action be detailed in a written agreement with the entity, which includes ramifications if the FDR fails to implement the corrective action satisfactorily.

In order to ensure that the FDR has implemented the corrective action, Sponsors can 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 misconduct committed by the Sponsor must be documented, and include ramifications should the Sponsor or its employee(s) fail to satisfactorily implement the corrective action. The Sponsor must enforce effective correction through disciplinary measures, including contract or employment termination, if warranted.

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

50.7.3 – Procedures for Self-Reporting Potential Fraud or Misconduct

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G), PPACA § 6402(d)(2), 63 Fed. Reg. 58,399 (1998)

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 fraud discovered at the plan level, and potential fraud by FDRs.

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

Sponsors with SIUs or other appropriate resources are required to investigate potentially fraudulent activity to make a determination whether potential fraud or misconduct has occurred. Where Sponsors do not have the time, resources, or experience to adequately investigate potentially fraudulent misconduct, then the matter should be referred to the NBI MEDIC within two weeks from when the potentially fraudulent activity is discovered.

Sponsors must conclude investigations of potential misconduct within a reasonable time period after the potentially fraudulent activity is discovered. If after conducting a reasonable inquiry, the Sponsor (e.g., the Medicare Compliance Officer or SIU) determines that potential fraud or misconduct related to the Parts C or D programs has occurred, the conduct must be referred to the NBI MEDIC promptly. Sponsors should also refer potential fraud 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 wrong doing and how the OIG will go about verifying irregularities.

Where a Sponsor discovers an incident of significant or serious Medicare program noncompliance, CMS expects the Sponsor to 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.

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

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Medicare Drug Integrity Contractor (MEDIC) is an organization that CMS has contracted 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 FWA in Medicare Part C and Part D. There is currently one National Benefit Integrity (NBI) MEDIC.

The NBI MEDIC responsibilities include: investigating potential fraud in Part C and Part D; receiving and resolving fraud complaints (from beneficiaries, plan sponsors, other interested parties); referring fraud cases to law enforcement; responding to law enforcement requests for information; providing support to law enforcement through investigations and case development; performing data analyses (proactive and reactive); identifying program vulnerabilities; and sharing information with stakeholders (beneficiaries, plan sponsors, state and local agencies).

50.7.5 – Referrals to the NBI MEDIC

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Cases meeting any of the following criteria should be referred to the NBI MEDIC:

- Potential criminal, civil, or administrative law violations
- Allegations extend beyond the PDP/MAPD, 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
- Scheme with large financial risk to the Medicare Program or beneficiaries

Every 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:

- Your name, organization, and contact information for follow up
- Summary of the Issue
 - Include the basic who, what, when, where, how, and why
 - Any potential legal violations
- Specific Statutes and Allegations
 - List civil, criminal, and administrative code or rule violations, state and federal
 - 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.
 - 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, beneficiary
- Data
 - Existing and potential data sources
 - Graphs and trending
 - Maps
 - Financial impact estimates
- 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

or

http://www.healthintegrity.org/html/contracts/medic/documents/HI_MEDIC_ComplaintForm_20111109.pdf

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.

MEDICs will investigate referrals from Sponsors, develop the investigations, and make referrals to appropriate law enforcement agencies or other outside entities when necessary. The 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.

50.7.6 – Identifying Providers with a History of Complaints

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

Sponsors are expected to maintain files on 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 are also expected to 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 are expected to 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.

60 – Additional Vulnerabilities

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G)

In this section, potential risks, schemes and vulnerabilities to the program are broadly discussed. This section is not an exhaustive discussion of all potential stakeholders and vulnerabilities that may be present. However, this section will help Sponsors to identify some potential risk areas present in the benefit.

60.1 – Part B and Part D Coverage Issues

42 CFR §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G), 423.100, 42 U.S.C. § 1395w-102

With the implementation of the prescription drug benefit, there is potential for inappropriate duplicate coverage between A, B, and D drugs. While the potential crossover between Parts A and D is unlikely, Medicare Parts B and D contain specific drugs covered under both programs, thus Sponsors are expected to have mechanisms in place to ensure drugs are adjudicated correctly to either Part B or D.

In almost all Part B settings, the question of whether coverage should be provided under Part D does not arise because the drugs are being provided in the context of a service or procedure, and thus the drugs are covered under Part B. For a limited number of categories, however, pharmacists and infusion providers have to determine whether to bill Part B or Part D, and Sponsors need to confirm whether Part D is being billed correctly.

The following are some of the potential schemes that could be perpetrated due to the crossover between Parts B and D.

- **Home Infusion**—Home infusion pharmacies are often paid delivery and dispensing fees for certain self-injectable medications (e.g., Epogen, Procrit), even if the beneficiary self-administers. As home infusion pharmacies are part of both Part B and Part D networks, these pharmacies may inappropriately submit the claim for coverage under an inappropriate benefit.
- **Duplicate Billing**—Claims may be inappropriately submitted by a provider under both Part B (medical) and Part D (pharmacy). Control mechanisms may include prior authorization processes that identify by diagnosis and other qualifying factors whether a drug is covered under Part B or Part D, and prevents the claim from being paid by the non-covered component. Additional control mechanisms and retrospective review for duplicate claims may vary between MA-PD and PDP, due to different levels of access to medical history and claims.
- **Crossover Drugs**—Some crossover drugs are traditionally purchased and administered by the physician’s office or clinic. These medications represent a potential revenue stream to the physician’s office. In some cases, the patient may be able to purchase the pharmaceutical under the Part D benefit at a community pharmacy and bring it to the physician’s office for administration. In these circumstances, the physician’s office may inappropriately bill for both the drug and the injection of the drug under Part B.
- **Differential Copays**—Beneficiaries may have different cost sharing obligations if a crossover drug is paid under Part B versus Part D, or vice versa. A beneficiary could

‘game the system’ to lower their cost sharing obligations by improperly submitting a claim to the inappropriate payer.

It is incumbent upon the Sponsor to institute a control, such as a prior authorization to ensure that the pharmacy is billing the correct program. Sponsors should have procedures in place to reverse claims in case a pharmacy is paid in error under Part D for what should have been a Part B covered product.

For additional detail related to coverage rules and/or Part B versus Part D crossover, please refer to <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/>.

Appendix A: Resources

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

Government Resources:

1. Office of the Inspector General, Compliance Program Guidance for the Healthcare Industry: <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>
2. Compliance Guidance for Medicare+Choice Organizations: <http://oig.hhs.gov/fraud/docs/complianceguidance/111599.pdf>
3. Compliance Guidance for Pharmaceutical Manufacturers: <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>
4. Compliance Guidance for Hospitals: <http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>
5. Federal Sentencing Guidelines: <http://www.ussc.gov/Guidelines>
6. Office of Inspector General’s (OIG) database of excluded individuals/entities: http://oig.hhs.gov/exclusions/exclusions_list.asp
7. General Services Administration (GSA) database of excluded individuals/ entities: <https://www.epls.gov/>
8. Fraud Alerts, Bulletins and Other Guidance from the OIG: <http://oig.hhs.gov/compliance/alerts/index.asp>
9. Medicare Modernization Act (MMA): <https://www.cms.gov/MMAUpdate/downloads/hr1.pdf>

10. False Claims Act:
http://www.justice.gov/jmd/ls/legislative_histories/pl199-562/pl199-562.html
11. Health Insurance Portability and Accountability Act (HIPAA):
<http://aspe.hhs.gov/admsimp/pl104191.htm>
12. Anti-Kickback Statute (see section 1128B(b)):
http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f
13. Stark Law (Physician Self-Referral):
<https://www.cms.gov/PhysicianSelfReferral/>
14. Department of Health and Human Services (DHHS), Office of Civil Rights – HIPAA website: <http://www.hhs.gov/ocr/hipaa/>
15. TRICARE Fraud & Abuse website:
<http://www.tricare.osd.mil/fraud/>
16. Freedom of Information Act (FOIA):
<http://www.foia.gov>; http://www.justice.gov/oip/04_1_1.html
17. The Patient Protection and Affordable Care Act:
<http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf>
18. National Benefit Integrity MEDIC
<http://www.healthintegrity.org/html/contracts/medic/index.html>
19. Medicare Parts C and D Fraud, Waste and Abuse Training:
http://cms.meridianksi.com/kc/ilc/course_info_enroll_lnkfrm_f1.asp?lgnfrm=wbt&table=crs&function=course_info_enroll&strBuildingID=5&strFunctionID=37&strFunctionPath=37&strFrom=Search&topic=All&keywords=

Other Resources:

1. Code of Ethics for Pharmacists:
<http://www.pharmacist.com/AM/Template.cfm?Section=Search1&template=/CM/HTMLDisplay.cfm&ContentID=2903>
2. Medicare Prescription Drug Benefit Model Guidelines: Drug Categories and Classes in Part D (Submitted by: United States Pharmacopeial Convention, Inc.):
<http://www.usp.org/hqi/mmg/>
3. Health Care Administrators Association (HCAA):
<http://www.hcaa.org/>

4. Heath Care Compliance Association (HCCA):
<http://www.hcca-info.org>
5. Society of Corporate Compliance and Ethics (SCCE):
<http://www.corporatecompliance.org>
6. American Health Lawyers Association (AHLA):
<http://www.healthlawyers.org>
7. New York State Office of Medicaid Inspector General (OMIG):
<http://omig.ny.gov>
8. Institute for Health Care Improvement (IHI):
<http://ihi.org>.
9. 2010 Federal Sentencing Guidelines Manual, Chapter 8, Sentencing of Organizations:
http://www.ussc.gov/Guidelines/2010_guidelines/Manual_HTML/Chapter_8.htm.
10. *“Leading Corporate Integrity: Defining the Role of the Chief Ethics & Compliance Officer (CECO)”*, Chief Ethics & Compliance Officer (CECO) Working Group, Ethics Resource Center:
<http://www.ethics.org/files/u5/RPceco.pdf>
11. Daniel Levinson, “Trustee Engagement and Hospital Success”, Trustees Magazine (July 2010):
http://www.trusteemag.com/trusteemag_app/jsp/articledisplay.jsp?dcrpath=TRUSTEEMAG/Article/data/07JUL2010/1007TRUviewpoint.
12. “Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors”, U.S. Dept. of Health and Human Services and The American Health Lawyers Assn. (2003):
<http://www.ucdmc.ucdavis.edu/compliance/pdf/respons.pdf>
13. Michael D. Greenberg, “Directors as Guardians of Compliance and Ethics Within the Corporate Citadel: What the Policy Community Should Know”, RAND Corporation (2010):
www.rand.org/pubs/conf_proceedings/2010/RAND_CF277.pdf.
14. 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>
15. Alan Yuspeh, Kathleen Whalen, Jerone Cecelic, Steven Clifton, Lisa Cobb,

Mark Eddy, Jill Fainter, Julie Packard, Susan Postal, Joe Steakley, and Paula Waddey, “Above Reproach: Developing a Comprehensive Ethics and Compliance Program,” (HCCA):

<http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/ComplianceBasics/DevelopComprehensiveComplianceProgram.pdf>

16. “Driving for Quality in Long-Term Care: A Governing Body of Directors Dashboard” Government-Industry Roundtable -- *A Report on the Office of Inspector General and Health Care Compliance Association Roundtable on Long-Term Care Governing body of Directors’ Oversight of Quality of Care*”:

<http://www.hcca-info.org/Content/NavigationMenu/ComplianceResources/ComplianceNews/FinalRoundtableReport013007.pdf>

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