Centers for Medicare and Medicaid Services

Prescription Drug Benefit Manual
Chapter 9 – Part D Program to Control Fraud, Waste and Abuse

CMS is pleased to release the final chapter for the Prescription Drug Benefit Manual regarding a program to control fraud, waste and abuse. CMS thoughtfully considered each of the comments we received to the draft chapter released on February 8, 2006. This chapter provides both interpretive rules and guidelines for Part D plan sponsors on how to implement the regulatory requirements under 42 C.F.R. § 423.504(b)(4)(vi)(H) to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse as an element of their compliance plan. While CMS regulations require Sponsors to implement a comprehensive fraud and abuse program, the adoption of the methods suggested within this chapter on how to implement a comprehensive fraud and abuse program are left to the discretion of each Sponsor. Additionally, this chapter outlines CMS' guidelines for operational issues such as handling complaints, and coordinating with CMS and law enforcement.

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Prescription Drug Benefit Manual

Chapter 9 – Part D Program to Control Fraud, Waste and Abuse

Last Updated – Rev.2, 04-25-2006

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10 – Part D Program to Control Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

This chapter provides both interpretive rules and guidelines Part D plan sponsors (hereinafter "Sponsors") on how to implement the regulatory requirements under 42 C.F.R. § 423.504(b)(4)(vi)(H) to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse as an element of their compliance plan. While CMS regulations require Sponsors to implement a comprehensive fraud and abuse program, the adoption of the methods suggested within this chapter on how to implement a comprehensive fraud and abuse program are left to the discretion of each Sponsor.

Additional information related to Part D Program Integrity and fraud, waste and abuse may be found at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/.

Please note that this manual chapter does not address or provide guidance for Medicare Advantage (MA) issues that do not relate to the Medicare Part D prescription drug benefit. MA organizations should consult the Medicare Managed Care Manual for issues related to the Part C benefit.[1]

10.1 – Definition of Terms Used in this Chapter

(Rev.2, 04-25-2006)

For the illustrative purposes of this manual only, the following terms are generally defined as follows. For the legally operative definitions of some of these terms, please see applicable statutes, regulations, and published HHS-OIG Compliance Guidance, if any. Unless otherwise stated in this Chapter, the following definitions apply:

Act: The Social Security Act and titles referred to as titles of any other Act.

Administrator: The Administrator of the Centers for Medicare & Medicaid Services.

Appeal: A process whereby a person with Medicare (or such person's representative) exercises the right to request a review of a contractor claim determination to deny Medicare coverage or payment for a service in full or in part.

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

Brand Name Drug: A drug for which an application is approved under Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(c)), including an application

[1] *See* www.cms.hhs.gov/manuals.

referred to in Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)). (*See* 42 C.F.R. § 423.4).

Centers for Medicare and Medicaid Services (CMS): CMS means the Centers for Medicare and Medicaid Services, an Agency within the Department of Health and Human Services.

Contractor: Any person or entity that directly contracts with CMS to provide items or services or perform tasks related to the Medicare Program. Contractor includes all PDPs, MA-PDs, Fallbacks, Cost Plans, MEDICs, Program Safeguard Contractors (PSCs), Durable Medical Equipment Regional Carriers (DMERCs), fiscal intermediaries, carriers, Medicare Administrative Contractors (MACs) and Regional Home Health Intermediaries (RHHIs).

Cost Plan: 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: 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, as well as in investigating cases of potential fraud, waste or abuse once identificed. 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.

The Department (DHHS): DHHS means the Department of Health and Human Services.

Department of Justice (DOJ): DOJ means the Department of Justice.

Edit: 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.

E-Prescribing: The transmission in electronic form of a prescription(s), information on a beneficiary's eligibility for drug benefits, medication history, and related health information between prescriber, dispenser, PBM, health plan, or other related entity either directly or through an e-prescribing network.

Employer Plans: PDP or MA-PD plans, sponsored by employers/unions, which have contracted directly with CMS to become prescription drug plans or Medicare Advantage plans for their own members, pursuant to a CMS waiver. Also includes plans being

offered and sold to employer/union groups by PDPs, MA Organizations, and Cost Plan Sponsors, pursuant to CMS waivers.

Fallback Prescription Drug Plan (Fallback, Fallback Plan): 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.

Federal Bureau of Investigation (FBI): FBI means the Federal Bureau of Investigation.

Formulary: The entire list of Part D drugs covered by a Part D plan.

Low Income Subsidy: A program to provide low-income Medicare beneficiaries with extra assistance with premium and cost sharing under Part D. Low-income subsidy applicants who are not deemed eligible for the subsidy will have to meet an income and asset test, and eligibility will be determined by either the State Medicaid Agency or the Social Security Administration. Beneficiaries may fall into two groups: those who quality for full subsidy with no coverage gap and nominal cost sharing, and those beneficiaries who qualify for other low-income benefits with reduced deductibles and coinsurance and sliding scale premium subsidies (note these individuals have incomes/assets valued higher than those receiving the full subsidy). (*See* 42 C.F.R. § 423 Subpart P).

Medicare Advantage (MA): A public or private entity organized and licensed by a state as a risk-bearing entity (with the exception of provider sponsored organization receiving waivers) that is certified by CMS as meeting the Medicare Advantage contract requirements. (*See* 42 C.F.R. § 422.2).

Medicare Advantage Prescription Drug Plan (MA-PD): An MA plan that provides qualified prescription drug coverage. (*See* 42 C.F.R. § 423.4).

Medicare Drug Integrity Contractor (MEDIC): An organization that the CMS has contracted with to perform specific program integrity functions for Part D under the Medicare Integrity Program. The MEDIC is CMS' designee to manage CMS' audit, oversight, and anti-fraud and abuse efforts in the Part D benefit.

Medicaid: Medical assistance provided under a state plan approved under Title XIX of the Act.

Medical Review: Involves a thorough 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: The health insurance program for the aged and disabled under Title XVIII of the Act.

Monitoring Activities: 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.

Office of the Inspector General (OIG): OIG means the Office of the Inspector General for the Department of Health and Human Services.

Part D Eligible Individual: An individual who is entitled to Medicare benefits under Part A or enrolled in Part B and lives in the Part D plan's service area pursuant to 42 C.F.R. § 423.30(a). (*See* 42 C.F.R. § 423.4).

Part D Plan: 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. This includes employer- and union-sponsored plans. (*See* 42 C.F.R. § 423.4).

Part D Plan Sponsor: Refers to a PDP Sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage. This includes employer- and union-sponsored plans. (*See* 42 C.F.R. § 423.4).

Pharmacy Benefit Manager (PBM): 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: A committee, the majority of whose members shall 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 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): A capitated benefit authorized by the Balanced Budget Act of 1997 (BBA) that features a comprehensive medical and social service delivery system and integrated Medicare and Medicaid financing.

Prescription Drug Plan (PDP): Prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 C.F.R. § 423.272 to offer qualified prescription drug coverage. (*See* 42 C.F.R. § 423.4).

Provider: Any Medicare provider or supplier (for example, hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, renal dialysis facility, hospice, physician, non-physician practitioner, laboratory, supplier, pharmacy, pharmacist). (*See* www.cms.hhs.gov/apps/glossary/default.asp.) 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.

Recoupment: The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Reinsurance: The reinsurance payment amount for a Part D eligible individual enrolled in a Part D plan for a coverage year is equal to 80 percent of the allowable reinsurance costs attributable to that portion of gross prescription drug costs incurred in the coverage year after the individual has incurred true out-of-pocket costs that exceed the annual out-of-pocket threshold specified in 42 C.F.R. § 423.104(d)(5)(iii). (*See* 42 C.F.R. § 423.329(c)).

Risk Corridors: Specified risk percentages above and below the target amount. For each year, CMS establishes a risk corridor for each Part D plan. Risk corridors will serve to decrease the exposure of plans where allowed costs exceed plan payments for the basic Part D benefit. (*See* 42 C.F.R, § 423.336(a)(2)).

Symmetrical risk corridors means that the same size corridors exist below the target amount as above it. The actual upper or lower limits of each corridor equal the target amount plus or minus the product of the risk percentage times the target amount. Plans would always be at full financial risk for all spending on supplemental drug coverage.

State Pharmaceutical Assistance Program (SPAP): A State program that provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals. (*See* Section 1860-D23 of the Act; 42 C.F.R. § 423.464(e)).

Secretary: The Secretary of the Department of Health and Human Services.

Service Area: For a prescription drug plan an area established in 42 C.F.R. § 423.112(a) within which access standards under § 423.120(a) are met. For an MA-PD plan, an area that meets the definition of MA service area as described in § 422.2, and within which access standards under § 423.120(a) are met. For a fallback prescription drug plan, the

service area described in § 423.859(b). Service area does not include facilities in which individuals are incarcerated. (*See* 42 C.F.R. § 423.4).

TrOOP (True Out of Pocket Costs): The amount a beneficiary must spend on Part D covered drugs to reach catastrophic coverage. It is based on the standard benefit design $250 deductible + $500 beneficiary coinsurance during initial coverage + $2850 coverage gap = $3600 (these numbers are for 2006 and will increase by law in subsequent years). 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.

20 – Overview of Fraud, Waste and Abuse Chapter

(Rev.2, 04-25-2006)

All Sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse.[2] This requirement is listed as one of the compliance plan elements in the *Medicare Prescription Drug Benefit* regulations published on January 28, 2005.[3] The regulations list the core elements of a compliance plan, including the requirement to have in place a comprehensive fraud, waste and abuse program.[4] The specific requirements of the compliance program for the Part D benefit include:

1. Written Policies and Procedures and Standards of Conduct
2. Compliance Officer and Compliance Committee
3. Training and Education
4. Effective Lines of Communication
5. Enforcement of Standards through well publicized disciplinary guidelines
6. Monitoring and Auditing
7. Corrective Action Procedures
8. Comprehensive Fraud and Abuse Plans – Procedures to voluntarily self-report potential fraud or misconduct

The purpose of this chapter is to assist Sponsors in implementing a comprehensive program to prevent and detect fraud, waste and abuse in the prescription drug program pursuant to both statutory and regulatory authorities.[5] Specifically, this chapter provides recommendations for Sponsors to implement a program to control fraud, waste and abuse

[2] 42 C.F.R. § 423.504(b)(4)(vi)(H).
[3] 70 Fed. Reg. 4194 (2005).
[4] 42 C.F.R. § 423.504(b)(4)(vi).
[5] 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.505(b)(4)(vi)(H).

as part of an effective Part D compliance program. Additionally, this chapter outlines CMS' guidelines for operational issues such as handling complaints, and coordinating with CMS and law enforcement. While CMS regulations require Sponsors to implement a comprehensive fraud and abuse plan, the adoption of the approaches suggested within this chapter on how to implement a comprehensive fraud and abuse plan is left to the discretion of each Sponsor based on the size, scope and resources of its organization.

It is worth noting that for many Sponsors, traditional fraud, waste and abuse programs have been aimed at the conduct of third parties submitting claims to the Sponsor and are often implemented by Special Investigation Units (SIUs), whereas their compliance programs typically encompass the organization's efforts to monitor itself and its subcontractors with respect to contract regulations and compliance with applicable laws and regulations. However, CMS does not interpret the requirement to have in place a program to control fraud, waste and abuse to be limited to the conduct of third parties submitting claims to the Sponsor.[6] CMS believes that, under this requirement, Sponsors must to have policies and procedures in place to identify and address fraud, waste and abuse at both the Sponsor and the third party levels in the delivery of prescription drugs through the Medicare benefit.

Furthermore, not all Sponsors have SIUs in place, nor does this chapter intend to imply that Sponsors that do not have SIUs should develop them. Instead, since the regulations placed the requirement for Sponsors to have a comprehensive fraud and abuse program within the compliance plan requirements, this Chapter provides guidance to Sponsors on how to incorporate a comprehensive fraud, waste and abuse program within their compliance plans. To the extent that a Sponsor has an existing fraud, waste and abuse program that is operated through its SIU, the Sponsor should make certain that the SIU and compliance department work closely together to ensure that the Medicare Prescription Drug benefit is reasonably protected from fraudulent, abusive and wasteful schemes throughout the administration and delivery of prescription drugs.

Additionally, the guidance provided in this chapter should not be misconstrued to mean that Sponsors should undertake law enforcement activities. Rather, Sponsors should implement effective fraud, waste and abuse programs, consistent with industry standards, to detect problems, make referrals to CMS or the appropriate CMS contractor for further investigation and follow-up, and undertake corrective action. The reporting of potential fraud to CMS and/or its designee is an important mechanism for protecting Medicare beneficiaries from harm and the Medicare Trust Fund from fraud, waste and abuse. While self-reporting of potential fraud is voluntary,[7] CMS believes that self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse.

Finally, it should be noted that recommendations made in this chapter are reflected by the use of the term "should," whereas statutory or regulatory program requirements are reflected by the use of the term "shall" or "must."

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[6] 42 U.S.C. § 1395w-104.

[7] 42 C.F.R. § 423.504(b)(4)(vi)(H).

30 – CMS' Use of MEDICs to Detect Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

CMS has contracted with private organizations, called Medicare Drug Integrity Contractors (MEDICs), to assist in the management of CMS' audit, oversight, and anti-fraud and abuse efforts in the Part D benefit.[8] Some of the main functions of the MEDIC include identifying and investigating potential Part D fraud and abuse, developing potential Part D fraud or abuse cases for referral to law enforcement agencies, acting as a liaison to law enforcement, and serving as an auditor of Sponsor and subcontractor Part D operations.[9] CMS will release future information regarding Sponsors' expectations and responsibilities regarding interactions with the MEDICs when task orders are awarded.

The following table describes the various activities MEDICs may perform as detailed in the Umbrella Statement of Work[10] to prevent, detect, and audit fraud and abuse of the Part D benefit. This table is not exhaustive.

[8] CMS RFP CMS-2006-0017, Medicare Prescription Drug Benefit (Part D), Medicare Drug Integrity Contractor. May 25, 2005.

[9] The www.fbo.gov

[10] Id.

Exhibit 1: MEDIC Responsibility and Activity Summary

Responsibility	MEDIC Activity
Prevent	• Review bids for participation in the prescription drug program. • Review the fraud and abuse components of compliance plans. • Assist CMS in developing a list of entities that may require future monitoring based upon past history. • Use established or self-developed data systems to efficiently and proactively evaluate inappropriate activity that may be present in the Part D benefit. • Educate entities about potential prescription drug fraud, waste and abuse. • Facilitate intermediate sanctions as appropriate.
Detect	• Conduct thorough reviews and audits of participating entities as necessary (announced and/or unannounced/targeted). (See below for specific types of audits that may be conducted.) • Conduct complaint investigations. • Conduct preliminary investigations into entities that may be conducting fraudulent prescription drug benefit enrollment, eligibility determination, and benefit distribution. • Investigate aberrant behavior identified, and develop and refer such cases to the appropriate law enforcement agency and/or, take administrative action as necessary, when appropriate. • Perform data analysis to detect outliers that may indicate potential fraud, waste and abuse. • Identify potential overpayments. • Provide support to law enforcement agencies for investigations of potential fraud and abuse, including investigations for which an initial referral to law enforcement did not originate from the MEDIC or another CMS contractor.
Audit	• Perform one-third audits of the following information: o Bids as the data relates to Medicare utilization and costs. o Enhanced alternative cost sharing as the data relates to Medicare utilization and costs. o Reinsurance costs. o Risk corridor costs. o Low-income subsidy payments. o Direct subsidy payments. o Federal reinsurance subsidies. o Risk corridor payments. o Subsidized coverage for qualifying low-income individuals. o Administrative cost and its allocation. o Rebates. o Formulary. o Claims data. o TrOOP data. o Allocation of costs betweens PDPs and MA. o Established co-pays correctly given and calculated. • Perform other type of audits including: o Fraud and abuse compliance plan audit. o Beneficiary protection audit. o Pharmacy and Therapeutic Committee audit. o Medicare Advantage audit. o Audit of Employer Part D Plans. o Audit of Sponsor oversight of its contractors. o Audit of actuarial equivalence attestation. o Audit of creditable coverage disclosures.

40 – Part D Sponsor Accountability and Oversight

(Rev.2, 04-25-2006)

The regulations governing the Part D benefit explicitly define the major entities with which a Sponsor may contract. While it may be common practice for Sponsors to enter into contracts with third parties to perform certain functions that would otherwise be the responsibility of the Sponsor, the Sponsor maintains **ultimate responsibility** for fulfilling the terms and conditions as set out in the contract with CMS. To that end, Sponsors will be held liable for the failure to meet contractual requisites performed by first tier entities, downstream entities, and related entities working on their behalf to meet those contractual requisites.[11] Additionally, where a Sponsor delegates any of its activities or responsibilities to any related entity, contractor, subcontractor or pharmacy, 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.[12] First tier entities, downstream entities, and related entities may also be subject to any applicable civil and criminal laws for fraud perpetrated in the delivery of the Part D benefit, such as the False Claims Act or the Anti-Kickback statute.

The Part D regulations establish several definitions relating to entities that may contract with the Sponsor.[13] Terms that are used throughout the Subpart K of the final Medicare prescription drug regulations include: (1) first tier entity; (2) downstream entity; (3) related entity; and (4) contractor.[14]

First Tier Entity

The term first tier entity means any party that enters into a written arrangement acceptable to CMS with a Sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.[15] In most cases, this will be pharmacy benefit managers (PBMs).

Downstream Entity

The term downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Sponsor and a first tier entity. These written arrangements continue down to the level of ultimate provider of both health and administrative services.[16]

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[11] 42 C.F.R. § 423.505(i).
[12] 42 C.F.R. § 423.505(i)(4)(ii).
[13] 42 C.F.R. § 423.501.
[14] 42 C.F.R. § 423 Subpart K.
[15] 42 C.F.R. § 423.501.
[16] 42 C.F.R. § 423.501.

An example of these relationships would be if a Sponsor enters into a contract with a pharmacy benefit manager (PBM). In this scenario, the PBM would be the first tier entity. The PBM then enters into a contract with various pharmacies. Those pharmacies would then be considered downstream entities. If pharmacies enter into a contract with several pharmacists to staff its pharmacy, those pharmacists would also be considered downstream entities.

Related Entity

The term related entity means any entity that is related to the Sponsor by common ownership or control and:

1. Performs some of the 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 Sponsor at a cost of more than $2,500 during a contract period.[17]

An example of a related entity would be one where a Sponsor is the parent company of its own in-house PBM.[18]

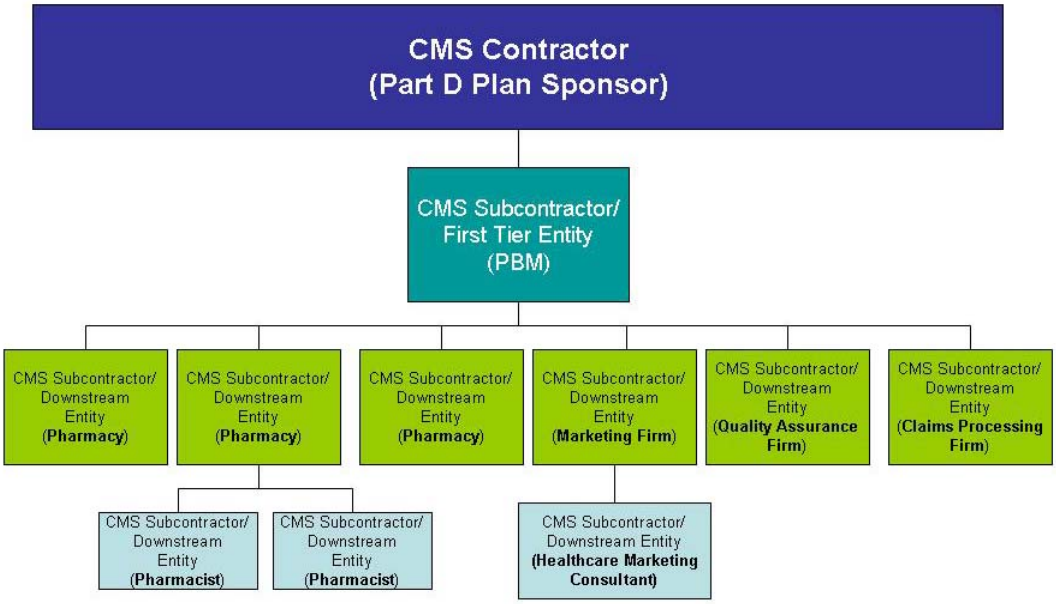
Contractor

In this Chapter, a contractor is any entity or individual that directly contracts with CMS to provide items or services, or perform tasks related to the Part D Program. Therefore, types of contractors include Part D Sponsors and Medicare Prescription Drug Integrity Contactors (MEDICs).

The following exhibit illustrates the various stakeholders involved in the prescription drug benefit and potential existing relationships.

[17] 42 C.F.R. § 423.501.
[18] Under this scenario, the PBM would also be considered a first tier entity.

Exhibit 2: Stakeholder Relationship Flow Chart



Related Entities that perform Part D functions on behalf of the Sponsor (PBM, marketing, claims processing, etc.) would be either first tier entities or downstream entities under this configuration.

The regulations set forth several rules guiding Part D Sponsors in the execution of contracts with third parties (such as related entities, first tier entities, and downstream entities) for the purpose of distributing some of its Part D benefit responsibilities arising out of the Sponsor's contract with CMS. Contracts of this nature must contain specific provisions including, but not limited to, inspections, enrollee protection, Sponsor accountability, delegation, and record retention.[19]

Preemption of State Laws

While Sponsors, first tier entities, downstream entities, an related entities are required to comply with applicable state laws, we note that certain state laws and regulations, for example, some state marketing laws regarding false or deceptive advertising, may be superseded ("preempted") by Part D laws and regulations. We recommend that Sponsors contact CMS if there is a question as to whether a state law or regulation is preempted by Part D laws and regulations.

[19] 42 C.F.R. § 423.505(e)(2); §505(i); §505(j).

40.1 – Delegating Compliance Functions to First Tier Entities, Downstream Entities, and Related Entities

(Rev.2, 04-25-2006)

CMS realizes each Sponsor has a unique business model and structure and some Sponsors will subcontract certain functions that other Sponsors may choose to perform themselves. CMS further realizes that some Sponsors will rely on the expertise and operations that first tier entities, downstream entities, and related entities offer. Sponsors have the flexibility to determine how and to what extent they will delegate their program to control fraud, waste and abuse to these entities, just as Sponsors have the flexibility to determine how and to what extent they will delegate other aspects of their contractual requirements.

To the extent that any compliance functions are delegated to first tier entities, downstream entities, and related entities, Sponsors are ultimately responsible for complying with all statutory, regulatory and other requirements. To ensure proper oversight of the Sponsor's compliance program and efforts, however, the Part D Compliance Officer and compliance committee functions may not be delegated or subcontracted.[20] The Part D Compliance Officer, in working with the compliance committee, should develop processes and procedures to promote and ensure that any first tier entities, downstream entities, or related entities are in compliance with all applicable laws, rules and regulations with respect to any Part D delegated responsibilities.

40.2 – Contracts Executed Between Sponsors and First Tier Entities, Downstream Entities, and Related Entities

(Rev.2, 04-25-2006)

First tier entity, downstream entity, and related entity contracts that enable the Sponsor to fully implement all aspects of the Part D benefit 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 first tier entities, downstream entities, and related entities are in compliance with Part D provisions.[21]

First Tier Entity, Downstream Entity, and Related Entity Contract Revocation

Where a Sponsor delegates any of its activities or responsibilities to any first tier entity, or downstream entity, 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.[22] Therefore, contracts with first tier entities, downstream entities, and related entities that enable the Sponsor to

[20] *See* 2007 MA and PDP Call Letters, (http://www.cms.hhs.gov/PrescriptionDrugCovContra/).
[21] 42 C.F.R. § 423.505(i)(4)(iii).
[22] 42 C.F.R. § 423.505(i)(4)(ii).

implement any aspect of an effective compliance plan are critical to protecting the Sponsor's interest.

Data Submission by First Tier Entities, Downstream Entities, and Related Entities

Sponsors are responsible for all data submitted to CMS, including data generated and/or submitted by related entities, first tier entities, and downstream entities.[23] CMS requires that any related entity, contractor, or subcontractor 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.[24] Sponsors are responsible for exercising oversight of Part D data generated or submitted by first tier entities, downstream entities, and related entities to ensure the accuracy of that data so that the Sponsor receives appropriate payments.

50 –The Basics of a Program to Control Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

This section details the elements of a comprehensive program to detect, correct and prevent fraud, waste and abuse in the Part D benefit.

50.1 – Benefits of an Effective Program to Detect, Prevent and Control Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

Section 1860D-4(c)(1)(D) of the Act requires Part D Plans to have in place a program to control fraud, waste and abuse.[25] In an effort to consolidate the various compliance requirements in the Part D Voluntary Prescription Drug Delivery Program and its implementing regulations,[26] CMS included the requirement pertaining to fraud, waste and abuse as a component of a Part D Plan Sponsor's overall compliance plan.

Having a fraud, waste and abuse program in place will benefit CMS, Sponsors, and Medicare beneficiaries because it will re-target Medicare dollars to appropriate uses of Part D monies. Sponsors must comply with the compliance plan requirements set forth in the regulation in order to develop an efficient and effective program that detects and prevents fraud, waste and abuse in their Part D Plans.[27] This chapter provides additional guidance to assist Sponsors in fulfilling the statutory and regulatory requirement to develop a comprehensive Part D fraud, waste and abuse program.[28] We believe the suggestions in this chapter will help Sponsors develop the fraud, waste and abuse

[23] 42 C.F.R § 423.505(k).
[24] 42 C.F.R. § 423.505(k)(3).
[25] 42 U.S.C. § 1395w-104.
[26] 70 Fed. Reg. 4194, 4338 (Jan. 28, 2005).
[27] 42 C.F.R. § 423.504(b)(4)(vi).
[28] 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.504(b)(4)(vi)(H).

component of the compliance plan based on the unique structure of the prescription drug benefit. These recommendations provide a road map to assist Sponsors in developing and implementing an effective fraud, waste and abuse program to protect their plans and the Medicare Trust Fund from fraud, waste and abuse.

Sponsors maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.[29] To that end, Sponsors are charged with oversight and management of the Part D benefit to ensure that beneficiaries receive the highest quality of care they are entitled to under the benefit, while at the same time protecting the integrity of Medicare funds. Therefore, it is beneficial for Sponsors to prepare, implement, and monitor all the compliance plan requirements to promote and ensure compliance with the regulations and to protect their contractual standing with CMS. Such actions should assist Sponsors in their efforts to comply with applicable laws, thus reducing their potential for enforcement action.

Sponsors may implement a program to detect, prevent and control fraud, waste and abuse in one of two ways:

1. A fraud, waste and abuse program that considers the methods described in this chapter and incorporates them into the appropriate components of a Sponsor's existing structure; or

2. Fraud, waste or abuse provisions can be integrated into each of the elements of the Sponsor's existing compliance plan. (This chapter provides guidance on how to add a fraud, waste and abuse element to each component of a general compliance plan.)

While CMS regulations require Sponsors to implement a comprehensive fraud and abuse program, the adoption of the methods suggested within this chapter on how to implement a comprehensive fraud and abuse program are left to the discretion of each Sponsor. If a Sponsor chooses the first approach, the fraud, waste and abuse program should specifically address detecting, preventing and correcting fraud, waste and abuse in its Part D program taking into account the recommendations made in this chapter. Sponsors have the flexibility to determine how and to what extent they will assign or delegate the management of their program to control fraud, waste and abuse.

If a Sponsor chooses the second approach, it should apply the methods for detection, correction, and prevention of fraud, waste and abuse detailed in this chapter into the existing compliance policies, procedures, and standards of conduct written for its organization.

Each Sponsor must determine which method is best based on the size, structure, and resources of its organization. Irrespective of the method a Sponsor chooses to implement its fraud, waste and abuse program, the Part D Compliance Officer should be the chief overseer of the Sponsor's Part D compliance program and efforts. Additionally, the

[29] 42 C.F.R. § 423.505(i)(1).

Sponsor should be prepared to demonstrate its program upon request by CMS or its designee, e.g., the MEDIC.

We note that the Medicare Advantage (MA) regulations found at 42 C.F.R. § 422.503(b)(4)(vi) require that MA organizations have in place a compliance plan that mirrors the compliance plan requirements for Part D plan sponsors found at 42 C.F.R. § 423.504(b)(4)(vi), with the exception of the requirement to have a comprehensive program to control fraud and abuse as an element of the organizations compliance plan. Because this chapter provides guidance specifically to Sponsors on how to implement a comprehensive program to control fraud and abuse as required under the Part D regulations,[30] and because this chapter addresses both Sponsors that offer MA products as well as Sponsors that offer only stand alone prescription drug plans, we do not address the similarities to the MA compliance plan regulations. The absence of these references does not mean to imply that MA organizations that offer prescription drug coverage cannot enhance their existing compliance plans that apply to their MA organizations to include provisions to detect, correct and prevent fraud, waste and abuse, as required for the Part D aspect of their business. Sponsors must consider their own organizational structures, as well as their size, scope and resources when determining the most appropriate methods for implementing a program to control fraud, waste and abuse.

It should be noted that recommendations made in this chapter are reflected by the use of the term "should," whereas statutory or regulatory program requirements are reflected by the use of the term "shall" or "must."

50.2 –Components of a Comprehensive Program to Detect, Prevent and Control Part D Fraud, Waste and Abuse as Part of the General Compliance Plan Requirements

The following represents the specific regulatory requirements of a compliance plan, as well as recommendations we believe will help Sponsors in developing the fraud, waste and abuse component of the compliance program based on the unique structure of the prescription drug benefit.

50.2.1 – Written Policies and Procedures

(Rev.2, 04-25-2006)

The Part D Sponsor must have written policies, procedures and standards of conduct that articulate the Sponsor's commitment to comply with all applicable Federal and State standards.[31]

Written policies, procedures, and standards of conduct clearly stating a Sponsor's commitment to comply with all applicable Federal and state statutory, regulatory and

[30] 42 C.F.R. § 423.504(b)(4)(vi)(H).
[31] 42 C.F.R. § 423.504(b)(4)(vi)(A).

other requirements related to the Medicare program are a critical component of a comprehensive program to detect, prevent and control fraud, waste and abuse. To help foster a culture of compliance within an organization, Sponsor's senior management should communicate a strong and explicit organizational commitment to compliance standards and ethical corporate behavior. Having written standards in place with a strong commitment by senior management can help mitigate the risks associated with the Part D program.

Written policies, procedures and standards of conduct should be updated as necessary to incorporate any changes in applicable laws, regulations, and other requirements.

Written standards should include a code of conduct and policies and procedures as described below.

50.2.1.1 – Code of Conduct/Ethics

(Rev.2, 04-25-2006)

An effective compliance program will have a code of conduct that articulates an organization's commitment to ethical behavior. The Sponsor's written code of conduct for its Part D business should: (1) clearly articulate the Sponsor's commitment to comply with all applicable statutory, regulatory, and other Part D program requirements; (2) delineate the Sponsor's expectations of employees and first tier entities, downstream entities, and related entities involved with the Part D business to act in an ethical and compliant manner and (3) include the ramifications of failure to comply with them. The code of conduct should encourage employees, management, and board members or other governing body members to report violations of law and policy to the Sponsor, CMS, its responsible designee (such as the MEDICs) and/or to law enforcement. The written code of conduct should specify the disciplinary actions that can be imposed for non-compliance, including oral or written warnings or reprimands, suspensions, terminations, and financial penalties.

The code of conduct should be written in a format that is easy to read and comprehend, and should be approved by the Sponsor's governing body (such as the board of directors) or a committee of the governing body. The code of conduct should be reviewed periodically and validated by senior management and by the governing body. When developing the code of conduct Sponsors should review existing codes of conduct used in the industry.

50.2.1.2 – Policies and Procedures

(Rev.2, 04-25-2006)

The Sponsor's policies and procedures should represent the organization's response to day-to-day risks to help reduce the prospect of fraudulent, wasteful and abusive activity by identifying and responding to risk areas. Because risk areas evolve and change over time, it is important for the Sponsor's policies and procedures to be reviewed and revised

periodically. Examples of policies and procedures Sponsors should have in place to implement a comprehensive program to detect, prevent and control fraud, waste and abuse include but are not limited to:

- A commitment to comply with applicable statutory, regulatory and other requirements, subregulatory guidance, and contractual commitments related to the delivery of the Medicare Part D benefit, including but not limited to:
  - Federal and state False Claims Acts[32]
  - Anti-Kickback Statute[33]
  - Prohibition on inducements to beneficiaries[34]
  - Health Insurance Portability and Accountability Act[35]
  - Other applicable criminal statutes[36]
  - Code of Federal Regulations – specifically, 42 C.F.R. § 400, 403, 411, 417, 422, 423, 1001, and 1003
  - All sub-regulatory guidance produced by CMS for Part D such as manuals, training materials, and guides
  - Applicable Civil Monetary Penalties and Exclusions
  - Applicable provisions of the Federal Food, Drug and Cosmetic Act
  - Applicable State laws
  - Contractual commitments

- Procedures for the identification of potential fraud, waste and abuse in a Sponsor's network.

- A process to conduct a timely, reasonable inquiry into potential violations of Federal and state criminal, civil, administrative laws, rules and regulations in a timely basis.

- A process to refer potential violations of applicable Federal and state criminal, civil and administrative laws, rules and regulations to the MEDIC and/or law enforcement for further investigation within a reasonable period (but not more than 60 days after a determination that a violation may have occurred).

- A process to ensure the Sponsor, its subcontractors, agents and brokers are marketing in accordance with applicable federal and state laws, including state licensing laws, and CMS policy.[37]

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[32] 31 U.S.C. §§ 3729-3733.
[33] 42 U.S.C. § 1320-7b(b).
[34] 42 U.S.C. § 1320a-7a(a)(5).
[35] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (codified as amended in scattered sections of 18 U.S.C. and 42 U.S.C.)
[36] Examples of Title 18 U.S.C. violations include: §201, bribery; §287, false claims; §371, conspiracy to commit fraud; §669, theft of embezzlement in connection with health care; §1001, false statements; §1035, false statements relating to health care; §1341, mail fraud; §1343, wire fraud; §1347, health care fraud; §1518, obstruction of a federal health care fraud investigation; § 1956-57, money laundering. Examples of Title 21 U.S.C. offenses include violations of §331, Food Drug & Cosmetic Act; and §801-971, Controlled Substances Act.

- Procedures for responding timely to data requests by CMS, MEDICs, and law enforcement, or their designees.

- A process to identify overpayments and underpayments at any level within the Sponsor's network and properly report and repay, where applicable, such overpayments in accordance with CMS policy.

- A process to identify improper coverage determinations, services or enrollment at any level within its network and properly report and repay, where applicable, any overpayments resulting from inaccurate enrollment numbers in accordance with CMS policy.

- A process to identify any claims that were submitted for drugs that were prescribed by an excluded or deceased provider, and a process to report and properly repay any overpayments resulting from inaccurate payments in accordance with CMS policy.

- A process to ensure full disclosure to CMS upon request of all Sponsor pricing decisions for Part D items or services, related data and pricing records.[38] This policy should ensure transparency in the pricing structure to include all rebate and negotiated price discounts applicable to Part D drugs and services and hold the Sponsors and first tier entities, downstream entities, and related entities accountable for accurately reporting pricing information.[39]

- Policies and procedures for coordinating and cooperating with MEDICs, CMS, and law enforcement, including policies that fully cooperate with any audits conducted by the above-mentioned entities, or their designees and information requests from law enforcement agencies to support health oversight matters.

- Policies that emphasize confidentiality, anonymity, and non-retaliation for compliance related questions, or reports of potential non-compliance.

- Procedures for corrective actions designed to correct any underlying problems that result in Medicare Part D program violations and prevent future misconduct.

- Procedures to retain all records documenting any and all corrective actions imposed for conduct related to the administration or delivery of Part D benefits and follow-up compliance reviews for future health oversight purposes and/or referral to law enforcement, if necessary.

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[37] *See* e.g., CMS Marketing Guidelines For Part D Plan Sponsors, http://www.cms.hhs.gov/pdps/PrtDPlnMrktngGdlns.asp.
[38] 42 C.F.R. §§ 423.308, 423.505(d)(2)(xii).
[39] Any information disclosed or obtained by CMS or its designee for program integrity activities will be kept confidential in accordance with 42 C.F.R. § 423.322(b).

- Policies that ensure and document the review of the DHHS OIG and General Services Administration (GSA) exclusion lists for all new employees and at least once a year thereafter to ensure that its employees, board members, officers, and first tier entities, downstream entities, or related entities that assist in the administration or delivery or Part D benefits are not included on such lists.[40] If the Sponsor's employees, board members, officers, managers or first tier entities, downstream entities, or related entities are on such lists, the Sponsor's policies shall require the immediate removal of such employees, board members, or first tier entities, downstream entities, or related entities from any work related directly or indirectly on all Federal health care programs and take appropriate corrective actions.[41]

    - Implement a policy requiring all new and existing employees responsible for administering or delivering Part D benefits to immediately disclose any debarment, exclusion, or other event that makes them ineligible to perform work related directly or indirectly to Federal health care programs.

    - Implement a policy that will require Sponsors to determine whether any future prospective or potential employee responsible for any aspect of administering or delivering Part D benefits is listed on an OIG or GSA exclusion, debarment, licensure or sanctions registry prior to hiring such prospective employee.

    - The Sponsor should obtain certifications from first tier entities, downstream entities, and related entities that these entities will review the OIG and GSA exclusions lists upon initially hiring and annually thereafter to ensure that any employee or manager responsible for administering or delivering Part D benefits is not excluded from Federal health care programs. The Sponsor should likewise obtain certifications that if an employee of the first tier entity, downstream entity, or related entity responsible for the administration of delivery of any Part D benefits is on such lists, that employee will immediately be removed from any work related directly or indirectly to all Federal health care programs and the entity will take appropriate corrective actions.

- A process to comply with the ten-year record retention requirement as listed in the Federal Regulation and all clarifying instructions subsequently issued by CMS.[42]

- A commitment to Pharmacy & Therapeutic (P&T) Committee decisions that are made in accordance with CMS regulations and guidance.[43] In addition, the determination of clinical efficacy and the appropriateness of formulary drugs should precede and be paramount to cost considerations.

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[40] http://exclusions.oig.hhs.gov/search.aspx, http://epls.arnet.gov/.
[41] 42 U.S.C. § 1320a-7.
[42] 42 C.F.R. § 423.505(d).
[43] *See* 42 C.F.R. § 423.120(b).

- P&T committee members should sign and continually update conflict of interest statements that divulge their relationships to Sponsors or pharmaceutical manufacturers.[44]
- The P&T committee should demonstrate a clear and transparent decision-making process when making formulary decisions.
- The P&T committee should establish a process for reviewing exceptions and other utilization management processes. The policy should include provisions for drug utilization review (DUR) and Prior Authorizations (PA).

- Establish a process to ensure Sponsor's officers, directors and managers sign a statement, attestation or certification related to conflict of interest at time of hire and annually thereafter. This certification should state (1) that the individual has reviewed the organization's conflict of interest policy; (2) that the individual has disclosed any potential conflict of interests; and (3) that the individual has obtained management approval to work despite any conflicts or has eliminated the conflict.

  - The Sponsor should have policies, procedures and a disclosure protocol for:
    a. Ensuring that officers, directors and managers do not have a conflict that provides a potential unfair competitive or monetary advantage as a result of the Sponsor performing the Medicare contract (e.g., ownership, control or contractual arrangement with a drug manufacturer creates an incentive to include a certain drug on a pharmacy; ownership, control or contractual arrangement with a first tier entity or downstream entity that would create an incentive to use that entity, etc.).
    b. Ensuring that the Sponsor's judgment is not biased or in some way compromised (e.g., Sponsor's formulary decisions and/or choice of contractors are not determined by ownership, control or inappropriate contractual agreement).
    c. Ensuring that ownership, control, or contractual arrangements between third-parties and the Sponsor or the Sponsor's directors, officers, managers or employees do not create a conflict;
    d. Designating a system for employees, officers, directors and managers who are seeking employment from health care providers, health plans or other Sponsors to determine if this outside employment would create a conflict;
    e. Designating a system for employees and others to bring potential conflicts to the attention of an appropriate individual;
    f. Ensuring that conflicts do not arise because of a Sponsor's access to proprietary data as a result of its Medicare responsibilities;
    g. Ensuring that a Sponsor's relationships with its vendors, suppliers, first tier entities, downstream entities, or related entities do not violate the Anti-Kickback Act and/or other applicable federal and state laws or regulations; and
    h. Ensuring that all CMS reporting requirements for potential conflicts and appropriate lobbying disclosure requirements are satisfied.

[44] 42 C.F.R. § 423.120(b)(ii).

- The Sponsor should obtain certifications from first tier entities, downstream entities, and related entities that these entities will require its managers, officers and directors responsible for the administration or delivery of Part D benefits to sign a conflict of interest statement, attestation, or certification at the time of hire and annually thereafter certifying that the manager, officer or director is free from any conflict of interest in administering or delivering Part D benefits.

50.2.1.3 – Distribution of Code of Conduct and Policies and Procedures

(Rev.2, 04-25-2006)

The Code of Conduct and the applicable policies and procedures should be made available to Sponsor's employees at time of hire, when the standards are updated, and annually thereafter. As a condition of employment, Sponsor's employees should certify that they have received, read, and will comply with all written standards of conduct.

Sponsors should also encourage first tier entities, downstream entities, and related entities to adopt and follow a code of conduct particular to their own organization that reflects a commitment to detecting, preventing and correcting fraud, waste and abuse in the administration or delivery of Part D benefits. Furthermore, Sponsors are encouraged to share their code of conduct with first tier entities, downstream entities, and related entities upon request in order to relay the Sponsor's own commitment and policies and procedures aimed at preventing, detecting and preventing fraud, waste and abuse in Medicare Part D.

50.2.2 – Compliance Officer and Committee

(Rev.2, 04-25-2006)

The Part D Sponsor must designate a compliance officer and compliance committee that is accountable to senior management.[45]

This section contains guidelines that Sponsors should follow with regard to the structure, roles, and functions of their compliance officer and compliance committee.

Irrespective of the method in which a Sponsor chooses to prevent, detect, and reduce fraud, waste and abuse, Sponsors must have a compliance officer and compliance committee in place and this function may not be subcontracted.[46]

[45] 42 C.F.R. § 423.504(b)(4)(vi)(B).
[46] *See* Medicare Advantage and Prescription Drug Plan 2007 Call Letters.

50.2.2.1 – Compliance Officer

(Rev.2, 04-25-2006)

Sponsors must have a Compliance Officer in place.[47] CMS recommends that Sponsors dedicate a full-time employee to oversee the compliance program and operations for the Medicare prescription drug benefit (hereinafter referred to as the "the Part D Compliance Officer"). The Part D Compliance Officer may be the same individual as the corporate Compliance Officer, however CMS strongly recommends that the two positions be staffed independently. Sponsors should 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 Part D compliance program or whether the organization should assign a separate individual to serve as the Part D Compliance Officer.

The Part D Compliance Officer will be responsible for developing, operating, and monitoring the fraud, waste and abuse program and should have the authority to report directly to the corporate Compliance Officer (if separate from the Part D Compliance Officer), the board of directors, and the president and/or the CEO. Sponsors must ensure the Part D Compliance Officer does not hold other responsibilities that could lead to self-policing of his/her activities (e.g., the Part D Compliance Officer should not also be or be subordinate to the chief financial officer (CFO)).

Sponsors should state in the Part D Compliance Officer's position description duties that the Compliance Officer is responsible for ensuring compliance with the Medicare Part D Program requirements. To the extent that any of the duties of the Part D Compliance Officer are delegated, it is important the Part D Compliance Officer maintain appropriate oversight of those duties he or she delegated. Examples of duties that the Part D Compliance Officer should be responsible for include but are not limited to:

- Developing and monitoring the implementation and compliance with Part D related polices and procedures through the creation and implementation of a workplan as discussed in Section 50.2.6.

- Developing an organizational chart that depicts the reporting relationship between the Part D Compliance Officer and compliance committee.

- Reporting, at least on a quarterly basis, or more frequently as necessary, to the Sponsor's Corporate Compliance Officer, board of directors, president and/or CEO, and compliance committee, on the status of the Sponsor's compliance program implementation, the identification and resolution of potential or actual instances of noncompliance, and the Sponsor's oversight and audit activities.

[47] 42 CFR § 423.504(b)(4)(vi)(B).

- Creating and coordinating, or appropriately delegating, educational training programs to ensure that the Sponsor's officers, directors, managers, employees, and other individuals working on the Part D program are knowledgeable of the Sponsor's compliance program; its written standards of conduct, policies, and procedures; and the applicable statutory, regulatory, and other requirements.

- Ensuring that first tier entities, downstream entities, and related entities, particularly those involved in sales and marketing activities, are aware of and follow the requirements for Medicare Part D sales and marketing activities.[48]

- Briefing the compliance committee and governing body on the status of compliance training.

- Developing and implementing methods and programs that encourage managers and employees to report suspected fraud and other misconduct without fear of retaliation.

- Maintaining the compliance reporting mechanism and closely coordinating with the internal audit department and the SIU, where applicable.

- Responding to reports of potential instances of Part D fraud, waste or abuse, including the coordination of internal investigations and the development of appropriate corrective or disciplinary actions, if necessary. To that end, the Part D Compliance Officer should have the flexibility to design and coordinate internal investigations (e.g., responding to reports of problems or suspected violations) and execute any resulting corrective action (e.g., making necessary improvements to policies and practices and taking appropriate disciplinary action).

- Coordinating personnel issues with the Sponsor's Human Resources office (or its equivalent) to ensure that the DHHS OIG and GSA exclusion lists[49] have been checked with respect to all employees, officers, directors and managers as well as first tier entities, downstream entities, and related entities are not included on such lists.

- Reporting any potential fraud or misconduct related to the Part D program to CMS, its designee and/or law enforcement in accordance with Section 50.2.8.2 of this Chapter.

- Maintaining documentation, for each report of potential fraud, waste or abuse received through any of the reporting methods (i.e. hotline, mail, in-person), which describes the initial report of non-compliance, the investigation, the results of the investigation, and all corrective and/or disciplinary action(s) taken as a

[48] *See* Part D Plan Marketing Guidelines, http://www.cms.hhs.gov/pdps/PrtDPlnMrktngGdlns.asp
[49] http://oig.hhs.gov/fraud/exclusions.html; http://epls.arnet.gov/.

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 the implementation of corrective action plans.

- Coordinating potential fraud investigations/referrals with the SIU, where applicable, and the appropriate MEDIC and facilitate any documentation or procedural requests that the MEDIC makes of the Part D plan. Similarly, the Part D Compliance Officer should collaborate with other Sponsors, state Medicaid programs, Medicaid Fraud Control Units (MCFUs), commercial payers, and other organizations when a fraud, waste or abuse issue is discovered to involve multiple parties.

- The Part D compliance officer should have the authority to:
    a. Report directly to the Board of Directors.
    b. Interview or delegate the responsibility to interview the Sponsor's employees and other relevant individuals.
    c. Review and retain company contracts and other documents pertinent to the Part D program.
    d. 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.
    e. Seek advice from legal counsel.
    f. Report misconduct to CMS, its designee and/or law enforcement.
    g. Conduct and direct internal audits and investigations of any first tier entities, downstream entities, or related entities.

50.2.2.2 – Compliance Committee

(Rev.2, 04-25-2006)

Sponsors must have a compliance committee in place.[50] The governing body of the Sponsor shall establish a compliance committee that is overseen by the Part D Compliance Officer, advises the Part D Compliance Officer and assists in implementation of the Part D compliance program. This compliance committee may operate within the structure of the existing compliance committee, or may operate as a separate and distinct committee. Examples of duties that the compliance committee should be responsible for include but are not limited to:

- Meet at least on a quarterly basis, or more frequently as necessary.

[50] 42 CFR § 423.504(b)(4)(vi)(B).

- Develop strategies to promote compliance and the detection of any potential violations.

- Ensuring that training and education are appropriately completed.

- Assist with the creation and implementation of the monitoring and auditing workplan.

- Assist in the creation of effective corrective action plans and ensure that they are implemented and monitored.

- Develop innovative ways to implement appropriate corrective and preventive action.

- Oversee a system of internal controls to carry out the organization's standards as part of its daily operations.

- Support the Part D Compliance Officer's needs for sufficient staff and resources to carry out his or her duties.

- Ensure the Sponsor has appropriate, up-to-date compliance policies and procedures.

- Ensure the Sponsor has a system for employees, first tier entities, downstream entities, and related entities to ask compliance questions, and report potential instances of fraud, waste or abuse confidentially or anonymously (if desired) without fear of retaliation.

- Review and address reports of monitoring and auditing of areas in which the Sponsor is at risk of fraud, waste or abuse and ensuring that corrective action plans are implemented and monitored.

- Provide regular and ad hoc reports on the status of compliance with recommendations to the Sponsor's Board of Directors.

Members of the compliance committee should include individuals with a variety of backgrounds, and reflect the size of the organization and the organization's resources. For example, Sponsors should consider including members of senior management (e.g., Chief Financial Officer, Chief Operating Officer), pharmacists, registered nurses, nationally certified pharmacy technicians, and auditors that perform medical review on the compliance committee to the extent that their organization is sufficiently staffed and where a large compliance committee would reflect the size and scope of the organization. Other staff members might include personnel experienced in legal issues, staff/ manager from various departments within the organization who are in the best position to understand vulnerabilities within their respective areas of expertise, and statistical analysts.

50.2.3 – Training and Education

(Rev.2, 04-25-2006)

The Part D Sponsor must provide effective training and education between the Part D Compliance Officer and organization employees, subcontractors, agents, and directors who are involved in the Part D benefit.[51]

This section provides recommendations on how Sponsors can develop training and education programs that will help them comply with the regulations as well as assist them in fraud, waste and abuse prevention efforts. Compliance training should address pertinent laws related to fraud and abuse (e.g., Anti-Kickback Statute, False Claims Act, etc.,) and include a discussion of Part D vulnerabilities as identified by the Sponsor, CMS, the OIG, the Department of Justice,[52] and other organizations.

All persons involved with the Sponsor's administration or delivery of the Part D benefit should receive general compliance training. To the extent that it is feasible and reasonable, first tier entity, downstream entity, and related entity staff should be permitted to attend the Sponsor's training or agree to conduct their own Part D compliance training in accordance with the guidance provided below.

50.2.3.1 – General Compliance Training

(Rev.2, 04-25-2006)

All Sponsor personnel responsible for the administration or delivery of Part D benefits should receive general compliance training upon initial hiring, upon the initial adoption of a compliance program, and annually thereafter as a condition of employment. Sponsors should maintain records of the time, attendance, topic and results of training. Sponsors should also consider requiring that any first tier entities, downstream entities, and related entities with any Part D responsibilities on behalf of the Sponsor to have their own training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities.

The governing body, compliance committee members, officers and senior management should receive training on the structure and operation of the compliance program on an annual basis. Supervisors should be trained to respond appropriately to compliance inquiries and reports of potential non-compliance. Training should include: treating each question/ report confidentially; non-retaliation against any employee asking a question or making a report; and knowing when to refer the incident to the compliance officer.

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

[51] 42 C.F.R. § 423.504(b)(4)(vi)(C).
[52] 70 Fed. Reg. 4194, 4338 (Jan. 28, 2005).

- A description of the compliance program, including a review of compliance policies and procedures, the code of conduct, and the organization's commitment to business ethics and compliance with all statutory, regulatory, and Medicare program requirements.

- Overview of system or process to ask compliance questions, request compliance clarification or report potential non-compliance. Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions, or reports of potential non-compliance.

- Review of the disciplinary guidelines for non-compliant or fraudulent behavior which results 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.

- Review of policies related to contracting with the government, such as the laws addressing fraud and abuse or gifts and gratuities for Government employees.

- Review of potential conflicts of interest and the Sponsor's disclosure/attestation system.

- Overview of HIPAA, the CMS Data Use Agreement, and the importance of maintaining the confidentiality of Personal Health Information.

- Overview of the monitoring and auditing workplan of the organization.

50.2.3.2 – Specialized Compliance Training

(Rev.2, 04-25-2006)

Employees that have specific responsibilities in Medicare Part D business areas should receive specialized training on issues posing compliance risks based on their job function (e.g., pharmacist, statistician, etc.) upon initial hire, when requirements change, or 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, or employees may attend professional education courses that help meet this objective.

Sponsors should require that any first tier entities, downstream entities, and related entities with any Part D responsibilities on behalf of the Sponsor to have their own

specialized compliance training, or where there are sufficient organizational similarities, the Sponsor may choose to make its training programs available to these entities.

Examples of specialized training for Sponsor employees, directors and agents 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 D data to CMS.
- Negotiating rebate agreements with Pharmaceutical Manufacturers, wholesalers, and other suppliers of Part D drugs.[53]
- Negotiating pharmacy network agreements.
- Administering the compliance program and operations, i.e., the Part D Compliance Officer and his/her staff.
- Conducting administrative activities necessary for the operation of the Part D benefit.
- Managing employer group plans.
- Security and authentication instructions involved in Health Information Technology.

Because Sponsors maintain ultimate responsibility over the administration of the Part D benefit, where resources are available, Sponsors should consider offering training and education to their first tier entities, downstream entities, and related entities. In the case of chain pharmacies and large PBMs, Sponsor-held training and education may supplement existing training programs. This may include web-based tools, intranet sites and videotaped presentations. Independent pharmacies, which in general have fewer resources, may appreciate the access that a training program affords to critical Part D information.

Some first tier entities, downstream entities and related entities may be providing services to multiple Sponsors, and it may become cumbersome for them to attend training at the various Sponsor locations. Rather, first tier entities and downstream entities that provide services to multiple Sponsors may prefer to host their own Part D training that meets CMS training recommendations.

[53] This recommendation is provided to suggest that those individuals responsible for negotiating rebate agreements or price concessions on behalf of the Sponsor are aware of the particular responsibilities and vulnerabilities associated with such negotiations. CMS in no way is attempting to interfere with the competitive model that underlies Part D, in violation of Section 1860D-11(i) of the Act. Rather, CMS is attempting to protect the processes by which the competitive model operates.

Because risk areas evolve and change over time, general and specialized compliance training should be reviewed and revised as needed but at least annually. Additionally, Sponsors should retain adequate records of their training of employees, including attendance logs and material distributed at training sessions. Sponsor employees should certify at least annually that they have received general and specialized compliance training. These materials should be made available to CMS upon request.

50.2.3.3 – Methods of Training

(Rev.2, 04-25-2006)

The Sponsor should have in place a mechanism for the Part D Compliance Officer to continually disseminate the compliance message in new and innovative ways. This is not to suggest that Sponsors who have developed effective methods for communicating the organization's compliance message abandon those successful methods. A variety of teaching methods may suit the needs of different organizations, depending on the size of the workforce and scale of training. Training can be conducted interactively led by expert facilitators, via web-based tools and Intranet sites, live or videotaped presentations, written materials, or a combination of these techniques.

Other methods include lecturing or "talking head" videos. Such methods of training are best reserved for introductory training that explains the organization's commitment to compliance. The best training and education approach is to engage employees in substantive discussion to reinforce the organization's compliance with applicable laws, regulations, standards, and principles. In addition, training should be designed to ensure that employees understand what is expected of them. Sponsors should consider administering tests or quizzes during training sessions to ensure that employees understand the compliance goals of the organization. In addition, training could be incorporated into the organization's orientation of new employees.

50.2.4 – Effective Lines of Communication

(Rev.2, 04-25-2006)

The Part D Sponsor must have effective lines of communication between the Compliance Officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.[54]

[54] 42 C.F.R. § 423.504(b)(4)(vi)(D).

50.2.4.1 – Effective Lines of Communication Between the Compliance Officer, Employees, Contractors, Agents, Directors, and Compliance Committee

(Rev.2, 04-25-2006)

Sponsors should have a system in place to receive, record, and respond to compliance questions, or reports of potential or actual non-compliance from employees, contractors, agents and directors while maintaining confidentiality, allowing anonymity if desired (e.g. through telephone hotlines or mail drops), and ensuring non-retaliation against callers.

Sponsors must establish a system that fosters effective lines of communication between the Compliance Officer and the organization's employees, subcontractors, agents, directors, and members of the compliance committee regarding how to report compliance concerns and suspected or actual misconduct.[55] The Sponsor should also establish effective lines of communication with its enrollees. An organization that fosters open communication can be highly effective at identifying, reporting and mitigating misconduct under the Part D benefit.

It is crucial that a confidential or anonymous reporting mechanism be in place for those who may be uncomfortable reporting concerns directly to a supervisor or to the Part D Compliance Officer. Sponsors should adopt, routinely publicize, and enforce a zero-tolerance policy for retaliation or retribution against any employee or subcontractor who reports suspected misconduct. Employees and subcontractors should be notified that they are protected from retaliation under 31 U.S.C. § 3730(h) for False Claims Act complaints, as well as any other applicable anti-retaliation protections.

The Sponsor's written standards should require all employees, contractors, agents and directors to report compliance concerns and suspected or actual misconduct. These concerns and risks should be captured via independent mechanisms, which may include hotlines, suggestion boxes, employee exit interviews, e-mails, and other forums that promote information exchange. Such a mechanism shall be made available and easily accessible to the Sponsor's employees, contractors, agents and directors.

50.2.4.2 – Establishing a Mechanism to Field Compliance Questions and Concerns from Employees First Tier Entities, Downstream Entities and Related Entities

(Rev.2, 04-25-2006)

Although Sponsors can develop any mechanism to field compliance questions and concerns, one of the most common methods is through the establishment of a hotline. Hotlines may be developed and maintained internally or the Sponsor may employ an

[55] 42 C.F.R. § 423.504(b)(4)(vi)(D).

independent contractor to operate the hotline. Regardless of the method used to field such reports, i.e., hotline or other mechanism, Sponsors should make it easily available for employees, contractors, agents and directors to access. For example, Sponsors could develop hotline posters with an easy to remember hotline phone number that is accessible 24 hours a day. Routine reminders would also be helpful so employees and subcontractors remember that this reporting mechanism exists. Hotline numbers should be prominently posted and available to all employees and contractors throughout the organization.

After employees, contractors, agents or directors report a suspected compliance issue, Sponsors should provide the complainant with information about a timely response, confidentiality, and provision of progress reports. Sponsors should establish procedures for responding to reports of a suspected compliance issues in a timely manner, assuring the complainant that the reports will be handled in a confidential manner. Any information provided to the complainant regarding the progress of the investigation can be expected to differ depending upon the particular facts and circumstances of the issue.

Sponsors should implement prompt follow-up investigation procedures in response to hotline inquiries and other complaints.

The effectiveness of hotlines relies on several criteria, namely confidentiality, accessibility, intake, and follow-up. Follow-up investigations stemming from hotline inquiries and other complaints should be initiated within 2 weeks of receiving the complaint. Reporting potential fraud, waste or abuse can be highly sensitive. Sponsors should establish a process to document and track reported concerns and issues, including the status of related investigations and corrective actions. Such a process will help improve the Sponsor's efficacy in resolving reports and preventing or correcting ongoing non-compliance. Sponsors may want to analyze the reports to identify patterns of possible misconduct by certain departments within the plan, or by pharmacy, PBMs, providers, and beneficiaries.

Screening Enrollee Complaints[56]

Sponsors must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Sponsor or any other entity or individual through whom the Sponsor provides covered benefits under any Part D plan it offers.[57] The regulations define grievance as any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities or behavior of a Part D plan Sponsor, regardless of whether remedial action is requested.[58]

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[56] Sponsors must follow the grievance procedures outlined in 42 C.F.R. Subpart M, and the procedures outlined in the Medicare Part D Reporting Requirements, http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_01.25.06.pdf. *See also* "Part D Enrollee Grievances, Coverage Determinations and Appeals," http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDManualAppeals_11.30.05.pdf

[57] 42 C.F.R. § 423.564(a).

[58] 42 C.F.R. § 423.560.

In order to adequately receive such complaints, address the concerns, and track records on these complaints,[59] Sponsors should have a complaint tracking system including, at a minimum, a call center with an explicit process for handling customer complaints for beneficiaries, and should make this log available to CMS or its designee, e.g. the MEDIC, upon request. Such complaints may come through the customer service phone number, which should not be the same as the employee hotline number described above. CMS expects that potential fraud complaints will be referred to the MEDIC in accordance with the procedures set forth in 50.2.8.2 of this Chapter.

Enrollee Communications and Education

Sponsors should consider various methods to educate enrollees on prescription drug fraud, waste and abuse. Such methods may include flyers, letters or pamphlets that can be included in mailings to enrollees (such as enrollment package, Explanation of Medicare Benefits ("EOB"), etc.). These communications should be available to CMS or its designee, e.g. the MEDIC, upon request.

50.2.5 – Enforcement of Standards

(Rev.2, 04-25-2006)

The Part D Sponsor must enforce standards through well-publicized disciplinary guidelines.[60]

Enforcement of standards is an essential element of a compliance plan. Additionally, the enforcement of standards is essential to Sponsors' efforts to prevent, detect, and reduce fraud, waste and abuse. This section discusses guidelines that Sponsors should follow when enforcing standards through well-publicized disciplinary guidelines. The following topic areas are addressed in this section: (1) involvement of CEO and other senior management; (2) methods to publicize disciplinary guidelines; and (3) enforcing standards of conduct.

50.2.5.1 – Involvement of Chief Executive Officer (CEO) and other Senior Management

(Rev.2, 04-25-2006)

To help communicate a strong and explicit organizational commitment to compliance goals and standards, the Sponsor's governing body, CEO, chief operating officer (COO), general counsel, chief financial officer (CFO), and other senior officials should be directly involved in the development and/or review of standards for conduct. Management involvement in this process helps communicate the need for all employees to comply with the organization's standards of conduct.

[59] 42 C.F.R. § 423.564(g).
[60] 42 C.F.R. § 423.504(b)(4)(vi)(E).

50.2.5.2 – Methods to Publicize Disciplinary Guidelines

(Rev.2, 04-25-2006)

To encourage the reporting of incidents of unethical or noncompliant behavior, the Sponsor, under direction of the Part D Compliance Officer, may consider using any of the following methods to publicize disciplinary guidelines:

- Newsletters which explain compliance issues and methods.

- Include compliance guidelines as a regular topic at department staff meetings, in communications with subcontractors, and in the annual general compliance training.

- Post information about compliance issues and reporting methods to the organization's Intranet site.

- Prominently display posters, cafeteria table tents, or other such vehicles which emphasize the importance of compliance.

This information should be made available to senior management, employees, first tier entities, downstream entities, and related entities as appropriate.

The Sponsor should disseminate among its senior management and employees responsible for the administration or delivery of Part D benefits, as well as among first tier entities, downstream entities, and related entities, when appropriate, the procedures to ask compliance questions, and make reports of potential fraud, waste or abuse to the Part D Compliance Officer or to the MEDIC. The reporting procedures should include:

- A description of the various methods available to make reports or ask compliance questions.

- A description of how anonymous reports may be made and how the anonymous system will allow the reporter to provide additional information (if needed) and receive status updates on the investigation.

- A description of the Sponsor's policy on no retaliation or retribution for reports made in good faith.

- A description of how to report potential fraud to the appropriate MEDIC, and/or to law enforcement, e.g. by displaying its toll-free number.

50.2.5.3 – Enforcing Standards of Conduct

(Rev.2, 04-25-2006)

Sponsor's guidelines should reflect clear and specific disciplinary policies, and provide the consequences of violating the organization's standards of conduct. All employees should be informed that violation of standards may result in appropriate disciplinary action, up to and including termination of employment. The Sponsor should have a provision its contract with first tier entities, downstream entities, and related entities that violations may result in termination of the contractual relationship with the Sponsor.

Sponsors should also enforce standards of conduct through other practices. It is good business practice to maintain and periodically review records of discipline for compliance violations to promote consistency and fairness. Sponsors should also consistently undertake appropriate disciplinary action across the organization so that the disciplinary policy has a deterrent effect.

50.2.6 – Monitoring and Auditing

(Rev.2, 04-25-2006)

The Part D Sponsor must have procedures for effective internal monitoring and auditing.[61]

An internal monitoring and auditing program will help protect the Medicare program and beneficiaries from Part D fraud, waste and abuse and may help mitigate the Sponsor's, first tier entities, downstream entities, and related entities' liability resulting from potentially fraudulent, abusive or wasteful activities. Procedures for internal monitoring and auditing should test and confirm compliance with the Part D benefit regulations, subregulatory guidance, contractual agreements, and all applicable state and federal laws, as well as internal policies and procedures to protect against potential fraud, waste or abuse.

Sponsors should develop a monitoring and auditing workplan ("workplan") that addresses the risks associated with the Part D benefit. The Part D Compliance Officer and compliance committee are key participants in this process.

Sponsors should have a system of ongoing monitoring that is reflective of its size, organization and resources and is coordinated, overseen or executed by the Part D Compliance Officer to assess performance in, at a minimum, areas identified as being at risk. The monitoring system includes the Part D Compliance Officer receiving regular reports of performance, documentation review, and updates on peripheral issues such as systems, staffing, etc. The Part D Compliance Officer should provide updates on the monitoring results to the compliance committee and senior leadership.

[61] 42 C.F.R. § 423.504(b)(4)(vi)(F).

An audit refers to a formal review of compliance with a particular set of internal (e.g., policies and procedures) or external (e.g., laws and regulations) standards used as base measures. Monitoring activities refer to 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.

50.2.6.1 – Development of the Monitoring and Auditing Workplan

(Rev.2, 04-25-2006)

The workplan should include information regarding all the components and activities needed to perform monitoring and auditing, such as:

(1) Internal Audit Department Requirements,
(2) Audit Schedule and Methodology, and
(3) Types of Auditing.

50.2.6.1.1 – Internal Audit Department

(Rev.2, 04-25-2006)

In developing the Part D workplan the Part D Compliance Officer and compliance committee should consider, to the extent one does not already exist, the creation of an internal audit department appropriate to the organization's size, scope and structure. The internal audit department should be allocated an annual budget based on the number of employees the Sponsor has dedicated to the administration of the Medicare Part D benefit, taking into account the resources necessary to complete the goals set forth in the workplan each year. Sponsors should ensure that the internal audit department staff has the appropriate skills and expertise to perform the work. For example, to the extent that resources are available, the internal audit department should include pharmacists, nurses, physicians, certified public accountants, and other highly skilled staff that have expertise in the areas under review. Additionally, Sponsors should ensure the internal audit department staff are knowledgeable of Medicare program requirements, and should provide specialized training to internal audit department staff annually. To the extent that the creation of an internal audit department is unreasonable given the Sponsor's size, scope and resources, the Sponsor should consider delegating this responsibility to a third party.

Sponsors should ensure that the internal audit department staff is independent and objective. For example, staff performing internal audits should not audit their own work. Sponsors should ensure internal audit staff has access to the relevant personnel, information, records and areas of operation under review so they can adequately perform the audits. Such access would include the operational areas at the plan level as well as the subcontractor level.

50.2.6.1.2 – Audit Schedule and Methodology

(Rev.2, 04-25-2006)

The workplan should include a schedule that includes a list of all the monitoring and auditing activities for the calendar year. Sponsors may want to organize the schedule by month or quarter. Examples of what the schedule should contain include but are not limited to:

- Responsible Internal Audit Staff Member
- Start and Completion Date
- Whether or not it will be announced or unannounced
- Whether or not it will be a desk audit or an on-site audit
- When the results will be presented to the Part D Compliance Officer and compliance committee

Sponsors should consider a combination of desk and on-site audits, including unannounced internal audits or "spot checks," when developing the schedule. While desk audits are more cost efficient and can be effective in the review of a large amount of high level data, 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 workplan Sponsors should:

- Conduct a risk assessment of all program areas and rank the results according to risk.

- Determine which risk areas will most likely affect their organization and prioritize the monitoring and audit strategy accordingly. In addition to the review of risk areas present in a Part D plan, Sponsors should review risk areas associated with beneficiaries, providers, pharmacies, PBMs, wholesalers, and manufactures, as well as the Sponsors themselves.
    - Sponsors should consult resources such as this chapter**,** including Section 70, *Potential Risks for Fraud, Waste and Abuse*, the annual OIG

workplan, and resources developed by the industry that identify high risk areas in the prescription drug benefit.
    - Among other things, Sponsors should perform regular audits of bids, pricing data, changes in drug prices, and data for determining risk adjustments and TrOOP.
    - Sponsors should separately assess the risks of their pharmacy network to assure compliance with all areas of pharmacy dispensing.

- Utilize statistical methods, when appropriate, in:
    - Randomly selecting Sponsor facilities, pharmacies, providers, claims, and other areas for review;
    - Determining appropriate sample size; and
    - Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe.

- Utilize statistical methods, when appropriate, in applying targeted or stratified sampling methods driven by data mining and complaint monitoring.

- Utilize special target techniques based on aberrant behavior.

- Assess compliance with internal processes and procedures.

- Examine the performance of the compliance program including review of training, the reporting mechanism (e.g. hotline log), investigation files, sanction screenings, certifications for receipt of standards of conduct, and conflict of interest disclosure/attestation.

- Conduct follow up review of areas previously found non-compliant to determine if the corrective actions taken have fully addressed the underlying problem.

Sponsors should also include in their workplan a process for responding to all monitoring and audit results. Corrective action and follow-up should be led or overseen by the Part D Compliance Officer and include actions such as the repayment of identified overpayments and making reports to MEDICs, if necessary. The Part D Compliance Officer should maintain a records system to track all compliance actions taken and outcomes of any follow-up reviews to evaluate the success of implementation efforts that may be provided, and provide updates on the monitoring and auditing results and corrective action to the compliance committee and senior leadership on at least a quarterly basis. When appropriate, the Sponsor should inform CMS, the MEDIC or law enforcement of aberrant findings

50.2.6.1.3 – Monitoring and Auditing First Tier Entities, Downstream Entities, and Related Entities

(Rev.2, 04-25-2006)

As stated in the preamble to the Title I regulations, we recognize that Sponsors are not law enforcement entities, and we do not expect Sponsors to pursue fraudulent activities in the same manner that law enforcement would. However, just as other contractors who administer Medicare benefits are responsible for monitoring for wasteful, abusive, and fraudulent activities in their organizations, we have the same expectations for Part D plan sponsors.[62]

Therefore, Sponsors should develop as part of their workplan a strategy to monitor and audit first tier entities, downstream entities, and related entities involved in the administration or delivery of the drug benefit. Because Sponsors and first tier entities, downstream entities, and related entities must follow applicable state and federal laws and regulations, Sponsors must have a plan in place to monitor and audit first tier entity, downstream entity, and related entity responsibilities and activities with respect to the administration and delivery of the drug benefit. Specific data should be analyzed from first tier entities, downstream entities, and related entities as applicable and appropriate, and reviewed regularly as routine reports are collected and monitored.

Sponsors should include routine and random auditing as part of their contractual agreement with first tier entities, downstream entities, and related entities. Sponsors should include in their workplan the number of first tier entities, downstream entities, and related entities that will be audited each year, how the entities will be identified for auditing, and should make it a priority to conduct a certain number of on-site audits. Sponsors must ensure their contracts with first tier entities, downstream entities, and related entities require record retention and provide rights of access to these records to CMS or its designee.[63]

Audits should include a review of documentation such as prescriptions, invoices, pharmacy licenses, claim transaction records, signature logs, purchase records, and negotiated prices, as well as verification that network providers are in compliance with the minimum standards pharmacy practice as established by the States,[64] and verification that network pharmacies post or distribute notices instructing enrollees to contact their plains to obtain a coverage determination or request and exception if they disagree with information provided by a pharmacist.[65] Audits should also include a review of first tier entity, downstream entity, and related entity contracts, as well as rebate, discount, and all other relevant agreements (and supporting data). Additionally, Sponsors should conduct interviews with first tier entity, downstream entity and related entity staff to gauge whether applicable Part D requirements are being followed.

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[62] 70 Fed. Reg. 4194, 4339 (January 28, 2005).
[63] 42 C.F.R. §423.505(i)(2).
[64] 42 C.F.R. § 423.153(c)(1).
[65] 42 C.F.R. § 423.562(a)(3).

To aid in their monitoring and oversight efforts of first tier entities, downstream entities, and related entities in addition to other monitoring and auditing activities, Sponsors should generate or receive and review reports such as the following:

Payment Reports which detail the amount paid by both the Sponsor and the beneficiary, the pharmacy provider, the beneficiary and a description of the drug provided, including dosage and amount. These reports should be used to identify over and under payments, duplicate payments, timely payments, pricing aberrances, and to help verify correct pricing.

Drug Utilization Reports which identify the number of prescriptions filled by a particular enrollee and in particular numbers 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 subcontractors may be a useful tool in identifying fraud, waste and abuse.

Prescribing Patterns by Physician Reports which identify the number of prescriptions written by a particular provider and typically focus on a class or particular type of drug such as narcotics. These reports should be generated to identify possible prescriber/provider or pharmacy fraud.

Geographic Zip Reports which 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).

In the event that first tier entities, downstream entities, and related entities perform their own audits related to the prescription drug benefit, Sponsors should seek written assurances from these entities that they have an adequate audit workplan in place. Sponsors should regularly receive these audit results with respect to their enrollees, and likewise seek assurances that corrective actions are taken by the entity when appropriate.

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

(Rev.2, 04-25-2006)

The use of data analysis by a Sponsor is another effective tool for fraud, waste and abuse prevention and detection at the Sponsor and first tier entity, downstream entity, and related entity levels. Data analysis should include the comparison of claim information against other data (e.g., provider, drug provided, diagnoses, or beneficiaries) to identify potential errors and/or potential fraud. Data analysis typically provides an overarching view of what is happening and can help Sponsors identify trends and assist in the development of more focused audits. 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.) Plans should 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 fraud, waste and abuse to the Medicare program;
- Identify items or services that are being overutilized;
- Identify problem areas within the plan such as enrollment, finance, or data submission;
- Identify problem areas at the first tier entity, downstream entity, and related entity level (e.g., PBM, pharmacies, and pharmacists) and at the prescriber level; and
- Use findings to determine where there is a need for a change in policy.

Sponsors should develop indicators that will be used to identify norms, abnormalities, and individual variables that describe statistically significant time-series trends. Examples of such statistically significant time series trends over time and in comparison to relative time periods:

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

50.2.6.3 – Other Monitoring and Oversight Efforts

(Rev.2, 04-25-2006)

Sponsors should consider adopting other monitoring and oversight efforts to assist in mitigating risks of fraud, waste and abuse in the delivery of the Part D benefit.

50.2.6.3.1 – Claims Processing System Recommendations

(Rev.2, 04-25-2006)

Claims processing systems can be an effective tool for plans to monitor the delivery of the prescription drug benefit. Sponsors should use claims processing systems that can be programmed to recognize various claims components and respond to each recognized component.[66] Sponsors should have systems capability to establish an edit on a given provider and use that edit to automatically deny a claim or suspend payment on a claim when appropriate.

Examples of edits include but need not be limited to:

- Controls on early refills outside of long-term care settings.[67]
- Limits on the number of days before a refill is permitted outside of long-term care settings.
- Edits to prevent payment for statutorily excluded drugs.
- Limits on the number of times a prescription can be refilled.
- Brand name versus generic drugs.
- Number of prior authorizations.
- Real time contraindication (e.g. drug- drug interactions).
- Sex and age edits compared to the drug prescribed.
- Therapeutic edits.
- Excessive claims for controlled substances.
- Insufficient or excessive dosage edits.
- Step therapy edits.
- Identifying drugs provided outside of the Part D benefit by Patient Assistance Programs.

System edits may be used to trend billing practices in a certain region by reviewing providers, beneficiaries, etc. within that zip code. Also, editing should be used to review how a provider is prescribing the same drug or very similar drugs by utilizing name brand versus generic and to review utilization patterns to trend the types of prescriptions being used by beneficiaries.

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[66] Plans must follow instructions regarding prescriptions drug claims processing as dictated by CMS. *See* http://www.cms.hhs.gov/pdps/PDClaimProc.asp for additional information regarding requirements.

[67] *See* CMS Frequently Asked Question ID # 6986, "May Part D plans reject claims as "too soon" when an enrollee no longer has access to their previously filled prescription medication because they have been admitted or discharged from a long term care facility?"

50.2.6.3.2 –Identifying Providers with a History of Complaints

(Rev.2, 04-25-2006)

Sponsors should maintain files on providers who have been the subject of complaints, investigations, violations, and prosecutions. This includes enrollee complaints, 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. Also, Sponsors should 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. Plans are expected to comply with law enforcement, CMS and CMS' designee requests to monitor providers within their network that CMS has viewed as potentially abusive or fraudulent.

50.2.6.3.3 – Sponsors Shall Deny Claims for Drugs that are Prescribed by an Excluded Provider

(Rev.1, 02-08-06)

Sponsors shall not pay for drugs prescribed or provided by a provider excluded by either the HHS OIG or GSA.[68] Sponsors should review the HHS OIG and GSA exclusion lists at least once a year, and have processes in place to prevent the payment of claims for services provided by excluded providers. If a Sponsor discovers any claims that were submitted for drugs that were prescribed by an excluded provider, the Sponsor should investigate to determine whether other claims have been submitted for items prescribed by the excluded provider and report the claims to the MEDIC.

50.2.6.4 –Auditing by CMS or its Designee

(Rev.2, 04-25-2006)

CMS is required to annually audit the financial records of "at least one-third" of the Part D Sponsors offering Part D drug plans.[69] Therefore when requested, Sponsors must be prepared to allow CMS to audit its financial records, including data relating to Medicare utilization and costs.[70] The one-third audit authority applies to all Sponsors.

Examples of an organization's financial records include but are not limited to:

- Data relating to Medicare utilization and costs.
- Reinsurance costs.
- Low-income subsidy payments.
- Risk corridor cost.

[68] *See* 42 C.F.R. § 1001.1901; http://oig.hhs.gov/fraud/exclusions.html; http://epls.arnet.gov/.
[69] 42 U.S.C. § 1395w-112; 42 C.F.R. § 423.504(d).
[70] 42 C.F.R. § 423.504(d).

- Bid calculation.
- Rebate information.

Sponsors must allow access to any auditor acting on behalf of the federal government or CMS to conduct an on-site audit.[71] On-site audits may also be conducted, at the discretion of CMS, of any subcontracted entity of the Sponsor. Independent of the aforementioned authority for conducting the one-third audits described above, CMS may inspect and audit any pertinent contracts, books, documents, papers, and records of a Sponsor or its subcontractor involving transactions related to CMS' contract with the Sponsor.[72]

On-site audits require a thorough review of required documentation. Such reviews include any information needed to determine compliance with the Part D contract and the Part D regulation, 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 Part D requirements are being followed. On-site audits are based on random sampling or results of desk audits. In most cases, CMS or its designee will provide reasonable notice to the Sponsor, first tier entity, downstream entity, or related entity 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, first tier entities, downstream entities and related entities must provide records to CMS or its designee and should cooperate in allowing them access to their facilities as requested. Failure to do so may result in a referral of the Sponsor and/or subcontractor to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning in line with 42. C.F.R. Subpart O. MEDICs tasked to conduct audits by CMS are acting on the 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.[73] Sponsors, first tier entities, downstream entities, and related entities are required to cooperate with CMS and CMS' contractors, such as the MEDICs. This cooperation includes providing CMS and/or the MEDICs with access to all requested facilities and records associated in any manner with the Part D program for 10 years (6 years for RDS Sponsors) from the end of the final contract period or completion of an audit, which ever is later. In cases when there is a termination, dispute, or allegation of fraud or similar fault by the Part D plan Sponsor, the record retention requirements may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault.[74]

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[71] 42 C.F.R. § 423.505(e)(3).
[72] 42 C.F.R. §§ 423.505(e)(2); 423.505(i)(2).
[73] Pursuant to 42 C.F.R. § 423.322(b), employees and contractors of DHHS, such as the MEDICs, may use the information disclosed or obtained in accordance with the regulation only for the purposes of, and to the extent necessary in, carrying out the regulation including, but not limited to, determination of payments and payment-related oversight and program integrity activities.
[74] 42 C.F.R. § 423.505(e)(4)(ii).

In addition, random desk audits are necessary for CMS and its designees to cover all oversight within the 3-year audit cycle.[75] Each random yearly audit should also include at least one area to be audited that overlaps with an area audited in a previous year within the 3-year audit cycle. Randomizing the oversight areas to be audited will prevent complacency in any oversight areas audited and ensure readiness for an audit of any oversight area.

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, related entity(s), contractor(s), subcontractor(s), or their transferees 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. This notification will be routed through the Sponsor's account manager.[76]

50.2.7 Prompt Responses to Detected Offenses and Corrective Action Plans

Developing Prompt Responses to Detected Offenses and Corrective Action Plans

This section discusses recommendations for implementing the regulation requiring that the Part D Sponsor have procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D Sponsor.[77]

(Rev.2, 04-25-2006)

50.2.7.1 Conducting a Timely and Reasonable Inquiry of Detected Offenses

Part D Sponsors must conduct a timely, reasonable inquiry into any conduct where evidence suggests there has been misconduct related to payment or delivery of prescription drug items or services under the Part D contract.[78] Such misconduct may occur at the level of the Sponsor or its first tier entities, downstream entities, or related

[75] See "Part D Oversight Strategy for Contractors/Industry" for additional information. http://www.cms.hhs.gov/pdps/ovesightpaperforindustry102405.pdf.
[76] CMS central office and regional office account managers will manage each Sponsor's Part D program operations. Account managers will work with Sponsors to resolve day-to-day compliance issues.
[77] 42 C.F.R. § 423.504(b)(4)(vi)(G).
[78] 42 C.F.R. § 423.504(b)(4)(vi)(G)(1).

entities. However, regardless of where the misconduct is identified, Sponsors are responsible for initiating a timely and reasonable inquiry.

Potential instances of fraud, waste and abuse may come to the attention of the Part D Compliance Officer or other members of senior management through a number of sources (e.g., employee or beneficiary complaints, audits). Sponsors should initiate a reasonable inquiry immediately, but no later than two weeks from the date the potential misconduct is identified.

A reasonable inquiry includes a preliminary investigation of the matter by the Part D Compliance Officer and/or Special Investigative Unit (SIU) for the Sponsor (see section 50.2.7.2 for information SIUs). In the event the Sponsor does not have either the time or the resources to investigate the potential misconduct it should refer the matter to the MEDIC within two weeks of the date the potential misconduct is identified so the potentially fraudulent or abusive activity does not continue.

As stated previously, we recognize that Sponsors are not law enforcement entities, and we do not expect Sponsors to pursue fraudulent activities in the same manner that law enforcement would. However, just as other contractors who administer Medicare benefits are responsible for monitoring for wasteful, abusive, and fraudulent activities in their organizations, we have the same expectations for Part D plan sponsors. Once identified, Sponsors should refer the activities to CMS or the appropriate MEDIC. MCS and its contractors will investigate all cases referred as potentially fraudulent and refer them to the appropriate law enforcement agency as warranted.[79]

50.2.7.2– Special Investigation Units (SIUs)

(Rev.2, 04-25-2006)

For those Sponsors who have established SIUs, the following section summarizes CMS' expectations of the roles and responsibilities of SIUs in assisting with Part D fraud, waste and abuse investigations.

CMS views the work of the SIUs as crucial to identifying potential fraud, waste and abuse committed by subcontractors involved in the delivery of the prescription drug benefit. A SIU is an internal investigative unit, often separate from the Compliance Office and often staffed by former law enforcement personnel responsible for conducting surveillance, interviews, and other methods of investigation.[80,81] Goals of SIUs typically include but are not limited to:

- Reducing or eliminating prescription drug costs due to fraud, waste and abuse.

[79] 70 Fed. Reg. 4194, 4339 (January 28, 2005).
[80] *Filter Out the Frauds*. Insurance & Technology, September 2004. www.insurancetech.com.
[81] Some Plans may have units that serve the same function, but do not call them SIU. This section refers to those units as well.

- Ensuring proper value of prescription drugs, including correct pricing, quantity, and quality.

- Utilizing real-time systems that ensure accurate eligibility, benefits, refills, and pricing at the point of sale and that identify potential adverse drug interactions.

- Reducing or eliminating fraudulent or abusive claims paid for with federal dollars.

- Preventing illegal activities.

- Identifying members with drug addiction problems.

- Identifying and recommending providers for exclusion, including physicians, pharmacists, and PBMs who have defrauded or abused the system.

- Referring potential cases of illegal drug activity, including drug diversion, to the MEDIC and/or law enforcement and conducting case development and support activities for MEDIC and/or law enforcement investigations.

- Assisting law enforcement by providing information needed to develop successful prosecutions.

SIUs are typically accessible via phone, email, Internet message submission, and mail. Suspicions of fraud, waste or abuse typically can be reported to SIUs anonymously.

Traditionally, SIUs objectives have been aimed at the conduct of third parties submitting claims to the Sponsor. However, CMS does not interpret the requirement to have in place a program to control fraud, waste and abuse to be limited to the conduct of third parties submitting claims to the Sponsor.[82] CMS believes in order to have an effective program to control fraud, waste and abuse, Sponsors should have policies and procedures in place to identify and address fraud, waste and abuse at both the Sponsor and the third party levels in the delivery of prescription drugs through the Medicare benefit.

Furthermore, not all Sponsors have SIUs in place, nor does this chapter intend to imply that Sponsors that do not have SIUs should develop them. Instead, since the regulations placed the requirement for Sponsors to have a comprehensive fraud and abuse program within the compliance plan requirements, this chapter provides guidance to Sponsors on how to incorporate a comprehensive fraud, waste and abuse program within their compliance programs. To the extent that a Sponsor has an existing fraud, waste and abuse program that is operated through its SIU, the Sponsor should make certain that the SIU and compliance department work closely together to ensure that the Medicare Prescription Drug benefit is reasonably protected from fraudulent, abusive and wasteful

[82] 42 U.S.C. § 1395w-104.

schemes throughout the administration and delivery of prescription drugs, both at the Sponsor level and at the first tier entity, downstream entity, and related entity levels.

50.2.8 - Corrective Actions

(Rev.2, 04-25-2006)

Part D Sponsors must conduct appropriate corrective actions (for example, repayment of overpayments and disciplinary actions against responsible individuals) in response to potential violations.[83]

50.2.8.1 – Conducting Appropriate Corrective Actions

(Rev.2, 04-25-2006)

Corrective actions should be designed to correct the underlying problem that results in program violations and prevent future misconduct.

A corrective action plan should be tailored to address the particular misconduct identified. The corrective action plan should provide structure with timeframes so as not to allow continued misconduct. When developing corrective actions for misconduct committed by a Sponsor's first tier entity, downstream entity, or related entity the elements of the corrective action should be detailed in a written agreement with the entity that includes ramifications should the subcontractor fail to satisfactorily implement the corrective action. Likewise, the elements of the corrective action plan that addresses misconduct committed by the Sponsor should be documented, and should include ramifications should the Sponsor or its employee(s) fail to satisfactorily implement the corrective actions. Corrective action plans should continue to be monitored after the implementation to ensure that they are effective.

50.2.8.2 – Recommended Procedures for Reporting by Sponsors

(Rev.2, 04-25-2006)

The reporting of potential fraud to CMS and/or its designee is an important mechanism for protecting Medicare beneficiaries from harm and the Medicare Trust Fund from fraud, waste and abuse. While the regulations make it clear that self-reporting of potential fraud is voluntary,[84] CMS believes that self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse. CMS believes that Sponsors should self-report potential fraud discovered at the plan level, and also report potential fraud that is discovered at the first tier entity, downstream entity, or related entity levels. This is especially encouraged when potential fraud is discovered at the first tier entity, downstream entity, or related entity level because the conduct

[83] 42 C.F.R. § 423.504(b)(4)(vi)(G)(2).
[84] 42 C.F.R. § 423.504(b)(4)(vi)(H).

discovered may very well be systemic and the MEDIC will have information across Sponsors to compare.

Sponsors should notify the MEDICs of potential fraud, waste or abuse 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 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 encouraged to investigate potentially fraudulent activity so they can 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, CMS recommends the matter be referred to the MEDIC within two weeks from when the potentially fraudulent activity is discovered. In other words, where the Sponsor cannot determine whether or not the conduct has risen to the level of potential fraud due to limited resources, the Sponsor should refer the activity to the MEDIC for investigation.

If after conducting a reasonable inquiry by the Sponsor (e.g. the Part D Compliance Officer, the SIU) it is determined that potential fraud or misconduct related to the Part D program has occurred, the conduct should be referred to the MEDIC promptly, but no later than 60 days after the determination that a violation may have occurred. To the extent that potential fraud is discovered at the first tier entity, downstream entity, or related entity levels, the Sponsor should refer the conduct to the MEDIC sooner so that the MEDIC can help identify and address any scams or schemes. If this timeframe cannot be met, Sponsors should contact the MEDIC for further guidance.

Sponsors are also encouraged to consider reporting the 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.[85] There are no pre-disclosure requirements or preliminary qualifying characteristics that must be met. 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.

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 the Federal health care programs.

[85] 63 Fed. Reg. 58,399 (1998); http://www.oig.hhs.gov/fraud/docs/complianceguidance/dispress.pdf.

50.2.8.3 – Referrals to the MEDICs

(Rev.2, 04-25-2006)

Once it is determined that a referral should be made to the MEDIC, Sponsors should develop a referral package that includes, to the extent available, the following:

- Provider name, all known billing and tax identification numbers, and addresses.
- Type of provider involved in the allegation and the perpetrator, if an employee of the provider.
- Type of item or service involved in the allegation.
- Place of service.
- Nature of the allegation(s).
- Timeframe of the allegation(s).
- Narration of the steps taken and information uncovered during the Sponsor's screening process.
- Date of Part D service, drug code(s).
- Beneficiary name, beneficiary Health Insurance Claim (HIC) number, address and telephone number.
- Name and telephone number of the Sponsor employee who received the complaint.
- Contact information of the complainant, if not the beneficiary.
- All documents pertaining to prior sanctions and/or compliance history and corrective actions taken, if any.

Because this is not an all-inclusive list, the MEDIC has the right to request additional information so the matter can be resolved. If the MEDIC requests additional information the Sponsor shall furnish the requested information within 30 days, unless the MEDIC otherwise specifies. In some rare instances, there may be a need to acquire information in less than 30 days, e.g., in case of risk to patient health. In those instances, all parties involved will be notified as soon as possible. Additionally, Sponsors should provide updates to the MEDIC when new information regarding the matter is identified.

MEDICs will further investigate referrals from Sponsors, develop the investigations, and make referrals to appropriate law enforcement agencies or other outside entities when necessary. To the extent it is feasible, the MEDIC will keep the Sponsor apprised of the development and status of the investigation. If a MEDIC determines a referral to be a matter related to non-compliance or mere error rather than fraud or abuse, it will be returned to CMS and/or the Sponsor for appropriate follow-up.

As mentioned in Section 30 of this Chapter, CMS will release future information regarding Sponsors' expectations and responsibilities regarding interactions with the MEDICs when task orders are awarded.

60 – Implementing a Comprehensive Program to Detect, Correct and Prevent Fraud, Waste and Abuse and Procedures to Voluntarily Self-Report Potential Fraud or Misconduct

(Rev.2, 04-25-2006)

Sponsors must have a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authority.[86]

As stated in section 50.1, Part D Sponsors may implement a program to control fraud, waste and abuse in one of two ways:

1. A fraud, waste and abuse program that considers the methods described in this chapter and incorporates them into the appropriate components of a Sponsor's existing structure; or

2. Fraud, waste or abuse provisions can be integrated into each of the elements of the Sponsor's existing compliance plan. (This chapter provides guidance on how to add a fraud, waste and abuse element to each component of a general compliance plan.)

In an effort to consolidate the various compliance requirements in the Part D statutes and regulations,[87] CMS included the requirement to have a program that controls fraud, waste and abuse as a component of a Part D Plan Sponsor's overall compliance plan. Section 50 of this chapter details the seven core elements of a compliance plan as required by regulation**,** and expands upon the regulatory requirements to provide guidance to Sponsors on how to develop a comprehensive Part D fraud, waste and abuse program by integrating a fraud, waste and abuse program inside of the Sponsor's compliance plan.

Self-reporting of potential fraud was addressed as an available corrective action in section 50.2.8.2. Self-reporting of fraud, waste and abuse is a critical element to an effective program to control fraud, waste and abuse. If after conducting a reasonable inquiry by the Sponsor (e.g. the Part D Compliance Officer, the SIU) it is determined that potential fraud or misconduct has occurred, the conduct should be referred to the MEDIC promptly, but no later than 60 days after the determination that a violation may have occurred. To the extent that potential fraud is discovered at the first tier entity, downstream entity, or related entity levels, the Sponsor should refer the conduct to the MEDIC sooner so that the MEDIC can help identify and address any scams or schemes. If this timeframe cannot be met, Sponsors should contact the MEDIC for further guidance.

[86] 42 C.F.R.§ 423.504(b)(4)(vi)(H).
[87] 70 Fed. Reg. 4194 (2005).

Sponsors are also encouraged to consider reporting the conduct to other government authorities such as the Office of Inspector General (through the OIG's Provider Self-Disclosure Protocol), or the Department of Justice as discussed in section 50.2.8.2.

70 – Examples of Risks for Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

In this section, potential schemes, risks, and vulnerabilities to the Part D benefit are broadly discussed. This section does not detail the complexity of analysis required to adequately determine if fraud, waste or abuse have occurred. However, we feel that this section will be helpful for Sponsors in identifying potential risk areas present in the Part D benefit.

In this section, we also identify the various key stakeholders that we believe are instrumental in the delivery of the Part D benefit, and some of the risks associated with those stakeholders. The schemes, risks and vulnerabilities can be perpetrated by multiple stakeholders and their impact may vary by degree of severity. Given that Sponsors maintain ultimate responsibility for delivery of the benefit, Sponsors should review these risks and develop their program to control fraud, waste and abuse accordingly.

This list is not an exhaustive discussion of all the potential stakeholders or vulnerabilities that may be present in the Part D benefit. Further, the schemes identified with each stakeholder are not necessarily unique to that stakeholder, and may be a scheme, risk or vulnerability associated with other stakeholders. These examples of fraud, waste and abuse are not intended to modify any substantive requirements or impose new requirements on Sponsors.

70.1 – Examples of Risks for Part D Plan Sponsors, PBMs, Pharmacies, Prescribers, Wholesalers, Pharmaceutical Manufacturers, and Medicare Beneficiaries

(Rev.2, 04-25-2006)

70.1.1 – Part D Plan Sponsor Fraud, Waste and Abuse (PDP, MA-PD, Cost Plans, Employer- or Union-Sponsored Plans)

(Rev.2, 04-25-2006)

The following section describes examples of Sponsor fraud, waste and abuse. Because some Sponsors operate their own PBMs or have in-house PBM functions, some of the examples cited in the PBM section are applicable here. Examples of potential fraud, waste and abuse include but are not limited to:

- *Failure to provide medically necessary services*: Fails to provide, to a Part D plan enrollee, medically necessary items or services that the organization is required to provide (under law or under the contract) to a Part D plan enrollee, and that failure adversely affects (or is substantially likely to affect) the enrollee.

- *Marketing Schemes*: When a Sponsor, or its subcontractor, violates the Medicare marketing guidelines, or other federal or state laws, rules, and regulations to improperly enroll beneficiaries in a Part D Plan. Examples of such violations include, but are not limited to:
    - Offering beneficiaries a cash payment as an inducement to enroll in Part D;
    - Unsolicited door-to-door marketing;
    - Use of unlicensed agents;
    - Enrollment of beneficiary without their knowledge or consent;
    - Stating that a marketing agent/broker works for or is contracted with the Social Security Administration or CMS;
    - Misrepresents the product being marketed as an approved Part D Plan when it actually is a Medigap policy or non-Medicare drug plan;
    - Misrepresents the Medicare Advantage or Prescription Drug Plan being marketed (i.e., enrolling Medicare beneficiaries in a MA-PD when they wanted a PDP);
    - Requests financial beneficiary information or check numbers (i.e., potential identity theft by a Part D Plan's marketing agents).
    - Requires beneficiaries to pay up front premiums.

- *Improper bid submissions*: The Sponsor inappropriately overestimates or underestimates the bid to manipulate risk corridors and/or payments, including miscalculations of administrative ratio costs within the bids (wrong service lines).

- *Payments for excluded drugs*: Sponsors must ensure that they only provide coverage for "covered Part D drugs,"[88] as listed in their approved formularies, and in accordance with section 1860D-2(e)(2).

- *Multiple billing*: Several payers billed for the same prescription, except as required for coordination of benefit transactions, such as the same prescription being covered and paid for under Medicare Part A or Part B, and then a second time under Part D, and/or possibly Medicaid.

- *Non-Compendium Payments*: Payments for Part D drugs that are not for a "medically accepted indication."[89]

[88] 42 C.F.R. § 423.100.
[89] *See* 42 U.S.C. § 1395w-102.

- *Inappropriate formulary decisions*: Where Sponsors or PBMs engage in formulary decision processes in which costs take priority over criteria such as clinical efficacy and appropriateness.

- *Inappropriate Enrollment/Disenrollment:* Improperly reporting enrollment and disenrollment data to CMS to inflate prospective payments. For example, Sponsor fails to effect timely disenrollment of beneficiary from CMS systems upon beneficiary's request.

- *Appeals process handled incorrectly*: Medicare beneficiary denied their right to appeal or denied a timely appeal.

- *Adverse selection*: Selecting or denying beneficiaries based on their illness profile or other discriminating factors. The Sponsor may anticipate costs being too high with certain beneficiaries with many or severe comorbid diseases, and improperly acts to expel or refuses to enroll a beneficiary in violation of the regulations or the contract.

- *False information*: Plan misrepresents or falsifies information it furnishes to CMS or to an individual under the Part D drug benefit program.

- *Delinquent reimbursements*: Beneficiary is not reimbursed by the plan following retroactive low income subsidy determination.

- *Duplicative premiums*: Receiving duplicative co-pays or premiums from beneficiaries.

- *Excessive premiums*: Imposes on Part D plan enrollees premiums in excess of the monthly basic and supplemental beneficiary premiums permitted under the regulation.

- *Inaccuracies in eligibility or coordination of benefits*: Inaccurate or incomplete information on eligibility or benefits can lead to wasteful expenditure on drugs. Part D Plan Sponsors and/or PBMs can mitigate waste associated with inaccurate information through the use of real-time systems to verify eligibility, available benefits and payer status.

- *Incorrect calculation of TrOOP*: Miscalculation of a beneficiary's TrOOP to manipulate beneficiary status in coverage (e.g., falsifying TrOOP calculations to keep beneficiaries in the coverage gap, or falsifying TrOOP calculations to push beneficiaries through the coverage gap into catastrophic coverage), or other incorrect calculation of TrOOP that may result in improper payments by CMS or beneficiaries.

- *Inaccurate data submission*: Sponsor submits inaccurate or incomplete prescription drug event (PDE) data or Part D plan quarterly data.

- *Catastrophic coverage manipulation*: Sponsors manipulate catastrophic coverage to increase payment by CMS.

- *Failure to disclose or misrepresentation of rebates, discounts or price concessions*: Sponsor fails to disclose or misrepresents rebates, discounts, price concessions, or other value added gifts, including concessions offered by pharmaceutical manufacturers.

- *Bait and switch pricing*: When a beneficiary is led to believe that a drug will cost one price, but at the point of sale the beneficiary is charged a higher amount. This includes frequent formulary changes to induce beneficiaries to sign up for specific drugs that are later removed.

- *Manipulation of low-income subsidy enrollees:* Sponsor provides false or misleading information regarding the number of its members who have applied for and qualify for the low income subsidy in order to receive unwarranted low income subsidy payments.

70.1.2 – PBM Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

The following section describes examples of PBM fraud, waste and abuse. Because many Sponsors operate their own PBMs or perform the PBM function themselves, some of the examples cited in the Part D Plan section are applicable here. Examples of potential fraud, waste and abuse include but are not limited to:

- *Prescription drug switching*: The PBM receives a payment to switch a beneficiary from one drug to another or influence the prescriber to switch the patient to a different drug.

- *Unlawful remuneration*: PBM receives unlawful remuneration in order to steer a beneficiary toward a certain plan or drug, or for formulary placement. Includes unlawful remuneration from vendors beyond switching fees.

- *Inappropriate formulary decisions*: PBMs or their P&T committees make formulary decisions where cost takes precedence over clinical efficacy and appropriateness of formulary drugs.

- *Prescription drug splitting or shorting*: PBM mail order pharmacy intentionally provides less than the prescribed quantity and does not inform the patient or make arrangements to provide the balance but bills for the fully-prescribed amount. Splits prescription to receive additional dispensing fees.

- *Failure to offer negotiated prices:* Occurs when a PBM does not offer a beneficiary the negotiated price of a Part D drug.

70.1.3 – Pharmacy Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

The following section describes examples of pharmacy fraud, waste and abuse. Examples of potential fraud, waste and abuse include but are not limited to:

- *Inappropriate billing practices*: Inappropriate billing practices at the pharmacy level occur when pharmacies engage in the following types of billing practices:
  - Incorrectly billing for secondary payers to receive increased reimbursement.
  - Billing for non-existent prescriptions.
  - Billing multiple payers for the same prescriptions, except as required for coordination of benefit transactions.
  - Billing for brand when generics are dispensed.
  - Billing for non-covered prescriptions as covered items.
  - Billing for prescriptions that are never picked up (i.e., not reversing claims that are processed when prescriptions are filled but never picked up).
  - Billing based on "gang visits," e.g., a pharmacist visits a nursing home and bills for numerous pharmaceutical prescriptions without furnishing any specific service to individual patients.
  - Inappropriate use of dispense as written ("DAW") codes.
  - Prescription splitting to receive additional dispensing fees.
  - Drug diversion.

- *Prescription drug shorting*: Pharmacist provides less than the prescribed quantity and intentionally does not inform the patient or make arrangements to provide the balance but bills for the fully-prescribed amount.

- *Bait and switch pricing*: Bait and switch pricing occurs when a beneficiary is led to believe that a drug will cost one price, but at the point of sale the beneficiary is charged a higher amount.

- *Prescription forging or altering*: Where existing prescriptions are altered, by an individual without the prescriber's permission to increase quantity or number of refills.

- *Dispensing expired or adulterated prescription drugs*: Pharmacies dispense drugs that are expired, or have not been stored or handled in accordance with manufacturer and FDA requirements.

- *Prescription refill errors*: A pharmacist provides the incorrect number of refills prescribed by the provider.

- *Illegal remuneration schemes:* Pharmacy is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs, or steer patients to plans.

- *TrOOP manipulation:* When a pharmacy manipulates TrOOP to either push a beneficiary through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible, or manipulates TrOOP to keep a beneficiary in the coverage gap so that catastrophic coverage is never realized.

- *Failure to offer negotiated prices:* Occurs when a pharmacy does not offer a beneficiary the negotiated price of a Part D drug.

70.1.4 – Prescriber Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

The following section describes examples of prescriber fraud, waste and abuse. Examples of potential fraud, waste and abuse include but are not limited to:

- *Illegal remuneration schemes:* Prescriber is offered, or paid, or solicits, or receives unlawful remuneration to induce or reward the prescriber to write prescriptions for drugs or products.

- *Prescription drug switching*: Drug switching involves offers of cash payments or other benefits to a prescriber to induce the prescriber to prescribe certain medications rather than others.

- *Script mills*: Provider writes prescriptions for drugs that are not medically necessary, often in mass quantities, and often for patients that are not theirs. These scripts are usually written, but not always, for controlled drugs for sale on the black market, and might include improper payments to the provider.

- *Provision of false information*: Prescriber falsifies information (not consistent with medical record) submitted through a prior authorization or other formulary oversight mechanism in order to justify coverage. Prescriber misrepresents the dates, descriptions of prescriptions or other services furnished, or the identity of the individual who furnished the services.

- *Theft of prescriber's DEA number or prescription pad*: Prescription pads and/or DEA numbers can be stolen from prescribers. This information could illegally be used to write prescriptions for controlled substances or other medications often sold on the black market. In the context of e-prescribing, includes the theft of the provider's authentication (log in) information.

70.1.5 – Wholesaler Fraud, Waste and Abuse

The following section describes examples of wholesaler fraud, waste and abuse. Examples of potential fraud, waste and abuse include but are not limited to:

- *Counterfeit and adulterated drugs through black and grey market purchases:* This includes but is not limited to fake, diluted, expired, and illegally imported drugs.

- *Diverters:* Brokers who illegally gain control of discounted medicines intended for places such as nursing homes, hospices and AIDS clinics. Diverters take the discounted drugs, mark up the prices, and rapidly move them to small wholesalers. In some case the pharmaceuticals may be marked up six times before being sold to the consumer.

- *Inappropriate documentation of pricing information:* Submitting false or inaccurate pricing or rebate information to or that may be used by any Federal health care program.

70.1.6 -- Pharmaceutical Manufacturer Fraud, Waste and Abuse

(Rev.2, 04-25-2006)

The following section describes examples of potential or suspect Pharmaceutical Manufacturer fraud, waste and abuse. These areas, and others are discussed in the "OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, Notice" 68 Fed. Reg. 23733-23739 (2003). Please refer to this guidance for further risk details and compliance implementation and development. Examples of potential fraud, waste and abuse include but are not limited to:

- *Lack of integrity of data to establish payment and/or determine reimbursement*: Pharmaceutical manufacturers may be liable under the False Claims Act, civil monetary penalties and/or the Federal Anti-Kickback statute if government reimbursement for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, including rebates, directly or indirectly, and the manufacturer has knowingly failed to generate or report such information completely and accurately.
    - *Inappropriate documentation of pricing information*: Manufacturers must maintain accurate and complete documentation of their pricing information.

- *Kickbacks, inducements, and other illegal remuneration*: The Anti-Kickback statute may be implicated by the following types of activities:

- Inappropriate marketing and/or promotion of products (sales, marketing, discounting, etc.) reimbursable by federal health care programs.
- Inducements offered if the purchased products are reimbursable by any of the federal health care programs. Examples of potentially improper inducements, including inappropriate discounts, inappropriate product support services, inappropriate educational grants, inappropriate research funding, or other inappropriate remuneration.

- *Formulary and formulary support activities*: Examples of potential fraud and abuse include inappropriate relationships with formulary committee members, payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a Plan's formulary.

- *Inappropriate relationships with physicians*: Potentially inappropriate relationships between pharmaceutical manufacturers and physicians include:
  - "Switching" arrangements, when manufacturers offer physicians cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product.
  - Incentives offered to physicians to prescribe medically unnecessary drugs.
  - Consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research funding.
  - Improper entertainment or incentives offered by sales agents.

- *Illegal off-label promotion*: Illegal promotion of off-label drug usage through marketing, financial incentives, or other promotion campaigns.

- *Illegal usage of free samples*: Providing free samples to physicians knowing and expecting those physicians to bill the federal health care programs for the samples.

70.1.7 – Medicare Beneficiary Fraud, Waste and Abuse Risks

(Rev.2, 04-25-2006)

Typically, Medicare beneficiaries tend to be victims, not perpetrators, of fraudulent, wasteful or abusive schemes. However, there are some schemes committed by beneficiaries that may impact payers. The following section describes examples of the types of fraud, waste or abuse that could be perpetrated by beneficiaries in Part D, as well as examples where beneficiaries might be victimized. Examples of potential fraud, waste and abuse include but are not limited to:

- *Misrepresentation of status*: A Medicare beneficiary misrepresents personal information, such as identity, eligibility, or medical condition in order to illegally receive the drug benefit. Enrollees who are no longer covered under a drug benefit plan may still attempt to use their identity card to obtain prescriptions.

- *Identity theft*: Perpetrator uses another person's Medicare card to obtain prescriptions.

- *TrOOP manipulation:* A beneficiary manipulates TrOOP to push through the coverage gap, so the beneficiary can reach catastrophic coverage before they are eligible.

- *Prescription forging or altering*: Where prescriptions are altered, by someone other than the prescriber or pharmacist with prescriber approval, to increase quantity or number of refills.

- *Prescription diversion and inappropriate use*: Beneficiaries obtain prescription drugs from a provider, possibly for a condition from which they do not suffer, and gives or sells this medication to someone else. Also can include the inappropriate consumption or distribution of a beneficiary's medications by a caregiver or anyone else.

- *Resale of drugs on black market*: Beneficiary falsely reports loss or theft of drugs or feign illness to obtain drugs for resale on the black market.

- *Prescription stockpiling*: Beneficiary attempts to "game" their drug coverage by obtaining and storing large quantities of drugs to avoid out-of-pocket costs, to protect against periods of non-coverage (i.e., by purchasing a large amount of prescription drugs and then disenrolling), or for purposes of resale on the black market.

- *Doctor shopping*: Beneficiary or other individual consults a number of doctors for the purpose of inappropriately obtaining multiple prescriptions for narcotic painkillers or other drugs. Doctor shopping might be indicative of an underlying scheme, such as stockpiling or resale on the black market.

- *Improper Coordination of Benefits*: Improper coordination of benefits where beneficiary fails to disclose multiple coverage policies, or leverages various coverage policies to "game" the system.

- *Marketing Schemes*: A beneficiary may be victimized by a marketing scheme where a Sponsor, or its agents or brokers, violates the Medicare Marketing Guidelines, or other applicable Federal or state laws, rules, and regulations to improperly enroll the beneficiary in a Part D Plan.

70.2 – Additional Vulnerabilities

(Rev.2, 04-25-2006)

In addition to the above mentioned potential schemes, risks, and vulnerabilities, listed below are four other major areas of concern.

70.2.1 – Coordination with State Pharmacy Assistance Programs

(Rev.2, 04-25-2006)

42 C.F.R. § 423.464 requires coordination of benefits with other providers of prescription drug coverage, including State Pharmacy Assistance Programs (SPAPs). SPAPs under Part D will be providing wrap-around benefits in the form of financial assistance by supplementing Part D premiums prior to and for the "coverage gap" portion of the benefit. Oversight of this coordination is essential to:

- Prevent double billing.
- Ensure that the Part D Plans remain the primary payer.
- Ensure that benefits are coordinated so that TrOOP tracking of SPAPs is taken into account.

Additionally, an oversight and monitoring program will also ensure that expenditures by other plans are excluded for the purposes of reaching the beneficiaries true out-of–pocket (TrOOP) expenditures in the TrOOP calculation.

70.2.2 – NABP and NADDI's Lists of Susceptible Pharmaceuticals

(Rev.2, 04-25-2006)

In February 2004, the National Association of Boards of Pharmacy (NABP) released the updated Model Rules for the Licensure of Wholesale Distributors. The formulation of the updated Model Rules was a collaborative effort among NABP, pharmacy representatives, the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), state regulatory authorities, and the wholesale distributor industry to protect the public from the use of counterfeit drugs and devices. The drugs most vulnerable to counterfeiting are usually single source injectable drugs, are commonly prescribed, have substantial wholesale cost with revenue-generating power, or are in limited supply.

Additionally, the National Association of Drug Diversion Investigators, Inc., (NADDI),[90] publishes a list of abused pharmaceutical substances. These are narcotics that are most frequently abused or illegally sold/counterfeited.

70.2.3 –Drugs Excluded From Part D Coverage

(Rev.2, 04-25-2006)

Pursuant to section 1927 of the Social Security Act and the final Part D regulations at 42 C.F.R. § 423.100, a Part D drug is:

- Defined as a drug that may be dispensed only upon a prescription;
- Approved by FDA for safety and efficacy;
- A biological product;
- Insulin and medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; or
- A vaccine.

A drug is considered to be a Part D drug only if prescribed for a "medically accepted indication." Drugs may not be covered under Part D if they are not prescribed for a medically accepted indication. Coverage for other than a medically accepted indication is not permitted under the statute because such drugs would not be considered Part D drugs.

In accordance with section 1860D–2(e)(2) of the Act, covered Part D drugs shall specifically exclude drugs or classes of drugs, or their medical uses, which may be excluded or restricted from coverage under the Medicaid program,[91] with the exception of smoking cessation agents. Thus, it is the responsibility of the Part D plans to prohibit the inappropriate payment for these excluded drugs or indications, i.e. edits or prior authorization.

70.2.4 – Part B and Part D Coverage Issues[92]

(Rev.2, 04-25-2006)

Prior to the implementation of the Medicare Modernization Act (MMA), Medicare beneficiaries received coverage for a limited number of drugs provided under Parts A and B. 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

[90] www.naddi.org.
[91] 42 U.S.C. § 1396r-8.
[92] *See* CMS' draft document *Medicare Part B versus Part D Coverage Issues* for additional information, http://new.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/BvsDCoverage_07.27.05.pdf.

drugs covered under both programs. As a consequence, there is a greater likelihood of crossover between Part B and D drugs; and it will be incumbent on Sponsors to have mechanisms in place to ensure drugs are adjudicated correctly to either Part B or D.

The statutory definition of "covered Part D drug" states that Sponsors must exclude any drug that would otherwise be considered a Part D drug for which, as so prescribed and dispensed or administered to that individual, payment would be available under Parts A or B.[93]

The implementation of the Part D benefit does not alter coverage or associated rules for drugs currently covered under Part B. Part B covers drugs in a variety of settings. In almost all of these settings the question of whether coverage should be provided under Part D will 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 will have to determine whether to bill Part B or Part D; and Sponsors will 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 will be part of both Part B and Part D networks, these pharmacies might inappropriately submit the claim for coverage under inappropriate benefit.

- **Duplicate Billing**—Claims could be submitted by a provider under both medical for Part B and pharmacy for Part D. Control mechanisms may include prior authorization processes that identify by diagnosis and other qualifying factors if 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 of the medications that will be 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. If a PDP or MA-PD carves out purchase of the medications for Part D coverage to a specialty or mail service pharmacy that will deliver patient-specific medication to a physician's office, this could represent a loss of revenue. 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

[93] 42 U.S.C. § 1395w-102; 42 C.F.R. § 423.100.

these circumstances, the physicians may inappropriately bill for both the drug and the injection of the drug under Part B.

- **Differential Copays**—Beneficiary 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/.

80 – Other Part D Sponsor Federal Compliance Considerations

(Rev.2, 04-25-2006)

The effective implementation of the Part D Drug Benefit relies on Sponsors' compliance with all applicable federal and state regulatory requirements related to the Medicare program. Sponsors, first tier entities, downstream entities, and related entities must also ensure that legal/ethical standards are met. Sponsors will need to continually monitor and update their compliance program to incorporate any modifications to applicable regulations and contractual requirements.

CMS strongly encourages Sponsors to alert MEDICs/CMS of any potential fraud or misconduct relating to the Part D program and the delivery of prescription drugs. Sponsors that self-report violations may receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. When MEDICs discover Sponsor violations of criminal, civil or administrative law, they will report them to the appropriate law enforcement entity. Both the DOJ and the OIG have longstanding policies favoring self-disclosure.

The following section outlines some of the key federal compliance considerations (in addition to the MMA) that Sponsors may need to comply with as they fulfill their program integrity functions.

80.1 – The False Claims Act[94]

(Rev.2, 04-25-2006)

Sponsors should devise their compliance programs so that their policies and procedures are consistent with the Federal Civil False Claims Act. The False Claims Act prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor, or state Medicaid program.[95]

When submitting claims data to CMS for payment, Sponsors and their subcontractors must certify that the claims data is true and accurate to the best of their knowledge and belief.[96] The False Claims Act is enforced against any individual/entity that knowingly submits (or causes another individual/entity to submit) a false claim for payment to the Federal government. In addition, parties have a continuing obligation to disclose to the government any new information indicating the falsity of the original statement. Since Sponsors maintain ultimate responsibility for adhering to all terms and conditions of its contract with CMS, they must monitor their subcontractors for compliance with all applicable regulations.[97]

80.2 – The Anti-Kickback Statute[98]

(Rev.2, 04-25-2006)

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward business payable (or reimbursable) under the Medicare or other Federal health care programs. In addition to applicable criminal sanctions, an individual or entity may be excluded from participation in the Medicare and other Federal health care programs and subject to civil monetary penalties.[99] For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Sponsors shall have policies and procedures employed to ensure that illegal remuneration is not permitted and shall specify follow-up procedures if they uncover unlawful remuneration schemes.[100]

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[94] 31 U.S.C. §§ 3729-3733.
[95] 31 U.S.C. § 3729(a)(1)-(7).
[96] 42 C.F.R. § 423.505(k)(3).
[97] 42 C.F.R. § 423.504(i).
[98] 42 U.S.C. § 1320-7b(b).
[99] 42 U.S.C. § 1320a-7b (a)(i).
[100] 42 C.F.R. § 423.504(b)(4)(vi)(A) & (G).

80.3 – The Health Insurance Portability and Accountability Act[101]

(Rev.2, 04-25-2006)

Among other things, the Health Insurance Portability and Accountability Act (HIPAA), was enacted for the purpose of improving the efficiency and effectiveness of health information systems through the establishment of standards and requirements for the electronic transmission of certain health information. This purpose has been effectuated through the promulgation of various regulations including those establishing standards for certain electronic transactions, minimum security requirements, and minimum privacy protections for individually identifiable health information that is held by covered entities (i.e., protected health information). Additional rules have or will establish national identifiers under HIPAA for providers, plans and employers. Covered entities include health plans, health care clearing houses and certain health care providers (namely those that conduct covered transactions).

The Office for Civil Rights (OCR) is the Departmental component responsible for implementing and enforcing the privacy regulations.[102] The Centers for Medicare and Medicaid Services (CMS) is the Departmental component responsible for implementing and enforcing the other HIPAA regulations.

Implementing these standards will improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in health care.

80.4 – The Freedom of Information Act (FOIA)

(Rev.2, 04-25-2006)

The Freedom of Information Act (FOIA) is codified at 5 U.S.C. §552. Its basic purpose is to promote the continued existence of an informed citizenry. More generally, FOIA makes information collected by government agencies available to the public. Consistent with our approach under the Part C program, CMS will not release information under the Part D program that would be considered proprietary in nature or that would tend to stifle the availability of discounts or rebates from pharmaceutical manufacturers negotiated by Part D plans or their first tier entities, downstream entities, or related entities. Most FOIA provisions affect how and when CMS is required (or restricted) from releasing information submitted by Sponsors and should not affect how or when Sponsors release information to CMS.

[101] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (codified as amended in scattered sections of 18 U.S.C. and 42 U.S.C.).
[102] *See* The Office for Civil Rights for additional information, http://www.hhs.gov/ocr/hipaa.

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, Fraud Prevention and Detection Compliance Guidance: http://www.oig.hhs.gov/fraud/complianceguidance.html

2. Compliance Guidance for Medicare+Choice Organizations: http://oig.hhs.gov/authorities/docs/cpgm_c.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/authorities/docs/cpghosp.pdf

5. Effective Compliance and Ethics Program- Federal Sentencing Guidelines: http://www.ussc.gov/2004guid/8b2_1.htm

6. Office of Inspector General's (OIG) database of excluded individuals/entities: http://exclusions.oig.hhs.gov/search.html

7. General Services Administration (GSA) database of excluded individuals/ entities: http://epls.arnet.gov/

8. Fraud Alerts, Bulletins and Other Guidance from the OIG: http://oig.hhs.gov/fraud/fraudalerts.html

9. Title I of the Medicare Modernization Act (MMA): http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-1321.pdf

10. Title II of the Medicare Modernization Act (MMA): http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-1322.pdf

11. False Claims Act: http://www.usdoj.gov/usao/vaw/civil_div/title31_3729.html

12. Health Insurance Portability and Accountability Act (HIPAA): http://aspe.hhs.gov/admnsimp/pl104191.htm

13. Anti-Kickback Statute (see section 1128B(b)): http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f

14. Department of Health and Human Services (DHHS), Office of Civil Rights – HIPAA website:
http://www.hhs.gov/ocr/hipaa/

15. Medicare Part D Reporting Requirements:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_01.25.06.pdf

16. Medicare Part B versus Part D Coverage Issues (Draft for Discussion Purposes Only):
http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf

17. Part D Plan Marketing Guidelines:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MarketingGuidelines_11.01.05.pdf

18. TRICARE Fraud & Abuse website:
http://www.tricare.osd.mil/fraud/

19. Freedom of Information Act (FOIA):
http://www.usdoj.gov/04foia/foiastat.htm

Other Resources:

1. Code of Ethics for Pharmacists:
http://www.aphanet.org/pharmcare/ethics.html

2. The Code of Ethics of the American Pharmaceutical Association:
http://www.aphanet.org/AM/Template.cfm?Section=Search&template=/CM/HTMLDisplay.cfm&ContentID=2809

3. Medicare Prescription Drug Benefit Model Guidelines: Drug Categories and Classes in Part D (Submitted by: United States Pharmacopeial Convention, Inc.):
http://www.usp.org/

4. Health Care Administrators Association (HCAA):
http://www.hcaa.org/