

Review of Sponsors' Fraud Waste and Abuse Responsibilities Summary Document

Sponsor Responsibilities At The Time of Contract with CMS

Part D plan sponsors must be in compliance with all requirements as listed at 42CFR§ 423.504(b)(4)(vi) by the time that they sign a contract with CMS. CMS will provide final sub-regulatory guidance regarding the Part D plan sponsor's fraud, waste and abuse responsibilities in the Fall 2005.

Disclaimer

This document serves as a draft summary of the fraud, waste, and abuse responsibilities for Part D plan sponsors. This document is not to be considered final or complete guidance. CMS will publish future guidance and reserves the right to change, add to, or modify these guidelines.

Purpose

This document is presented to all potential Part D plan sponsors (sponsors) so that they are prepared for their compliance and program integrity (PI) obligations before they submit their bid to CMS on June 6, 2005. The fraud, waste, and abuse (FWA) responsibilities shall be considered *Direct Administration*. Plans shall consider these obligations when calculating *Section V - PMPM Non-Pharmacy Expenses Direct Administration* of the bid. CMS will be accepting comments on this document until June 24, 2005. Those interested in commenting may submit their comments via e-mail to CMSCompliance_Commen@ees.hhs.gov. (Please note that a _ is between "compliance" and "comment" in the e-mail address.) CMS will take all comments into consideration when completing final requirements and guidelines for sponsors related to CMS' FWA oversight of the Part D program.

Overview

All sponsors must have a comprehensive plan to detect, correct, and prevent FWA. These requirements are listed under the "compliance plan elements" in the *Medicare Prescription Drug Benefit* Regulations published on January 28, 2005.

Sponsors can implement FWA programs in one of two ways: 1) a separate and distinct FWA element of a compliance plan can be established or 2) the program to detect FWA can be integrated into the other seven elements of a compliance plan. How the sponsor opts to implement this comprehensive FWA plan is at the sponsor's discretion, but the sponsor should be prepared to demonstrate this plan upon CMS' request.

Role of CMS in Detecting FWA

CMS will be involved in detecting FWA in the Part D program via such methods as review and analysis of all data submitted to CMS by sponsors, investigation of fraud

complaints, and auditing of sponsor operations. CMS is establishing Medicare Drug Integrity Contractors (MEDICs) to assist with this analysis.

MEDICs will play an integral PI role for Part D. Their activities will include:

- Data analysis to identify potential Part D fraud;
- Investigation of potential Part D fraud;
- Development of potential Part D fraud cases for referral to law enforcement;
- Liaison to law enforcement for Part D issues; and,
- Audits of sponsor and subcontractor Part D operations.

Part D Sponsor Obligations to the MEDICs

At a minimum, in order to comply with CMS requirements related to the detection, correction, and prevention of FWA, sponsors shall cooperate and coordinate with MEDICs in the following ways:

- Access shall be provided to all requested facilities and records associated in *any* manner with the Part D program for 10 years from the end of the final contract period or completion of an audit, whichever is later, unless specific conditions apply. This includes allowing access to any government auditor acting on behalf of the Federal government or CMS to conduct an onsite audit at the facilities of the sponsor or any of the sponsor's subcontractors.
- All instances of potential or actual fraud identified within a sponsor's network and/or organization must be referred to the MEDIC for further investigation and/or potential referral to law enforcement.
- Complaints received by the sponsor or subcontractors alleging or demonstrating potential fraud must be referred to the MEDIC for further investigation.
- Referrals to the MEDIC shall be documented. (CMS will provide instructions for this documentation at a later date.)
- Sponsors shall be able to furnish all information requested by the MEDIC, including claims data, within 30 days from the date of the request unless otherwise specified. An example of when a sponsor will have to provide data within 30 days is for an audit of the sponsor and/or sponsor's subcontractor operations and facilities conducted by the MEDIC. In some rare instances, there may be a need to acquire information in less than 30 days (e.g., a case being prosecuted immediately).
- Once a sponsor has referred a case to the MEDIC, the sponsor should continue to track all aspects of the case, as specified by the MEDIC and provide updates to the MEDIC as needed.

FWA Obligations for Part D Sponsors

Sponsors maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of their contracts with CMS, including the compliance plan requirements found at 42CFR§ 423.504(b)(4)(vi). CMS understands that much of the

compliance activity may take place at the PBM, particularly activities such as the auditing of pharmacy claims and the FWA training and education programs. Nevertheless, the sponsor must maintain an overarching compliance structure. At a minimum, the sponsor's compliance program must monitor the activity of the PBM, and the sponsor must demonstrate a coordinated reporting structure between itself and its PBM (as well as other subcontractors). CMS must have assurances the sponsor can take appropriate corrective actions according to any circumstances or problems that may arise. Sponsors should understand that ultimately the sponsors are held accountable for their Part D subcontractor operations since sponsors enter into a contract with CMS and government payments are made to the sponsors.

CMS can revoke a subcontractor's right to provide services to Part D beneficiaries or programs if CMS determines that the subcontractor has not performed satisfactorily. Therefore, subcontractor contracts that enable the sponsor to fully implement all aspects of an effective compliance plan are critical to protecting the sponsor's interest. These contractual provisions must include requiring ongoing audits performed by, or on behalf of, the sponsor which assess whether the subcontractors are in compliance with all Part D provisions. In addition, sponsors must have contractual requirements regarding compliance programs established for both internal and external compliance procedures and cost containment recovery provisions in cases where there are infractions or errors made by a subcontractor in meeting contractual obligations.

Sponsors are ultimately responsible for data submitted to CMS by any of the sponsor's subcontractors. In the case that a subcontractor submits claims data on behalf of the sponsor, the subcontractor, in addition to the sponsor, must certify to CMS regarding the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data submitted on behalf of the sponsor will be used for the purposes of obtaining Federal reimbursement.

Required Components of a Part D FWA Program

Below are the required components of a comprehensive program to detect, correct, and prevent FWA. These requirements are reviewed in light of the mandatory elements of a Part D compliance plan.

Requirement #1: The sponsor must have written policies, procedures and standards of conduct that articulate the sponsor's commitment to detect, correct, and prevent FWA.

At a minimum, the sponsor must:

- Maintain a commitment to comply with Federal and state regulatory requirements related to the Medicare program, including but not limited to the Anti-Kickback Statute and False Claims Act. Sponsors will need to continually

monitor and update their compliance program to incorporate any modifications to applicable standards.

- Develop procedures that establish ramifications in instances where Federal or state statutes or regulatory requirements are breached.
- Distribute the sponsor's written standards of conduct related to FWA to all sponsor's employees at time of hire, to subcontractors at time of contract, when the standards are updated, and annually thereafter. As a condition of employment, sponsor's employees shall certify that they have received, read, and will comply with all written standards of conduct. In addition, these standards of conduct shall be shared with all subcontractors.
- Have employees and subcontractors sign a statement, attestation or certification related to conflict of interest at time of hire or contract and annually thereafter.
- Maintain policies that require the review of the Department of Health & Human Services Office of Inspector General (DHHS OIG) and General Services Administration (GSA) exclusion lists on a monthly basis to ensure that its employees and subcontractors are not included on such lists. If the sponsor's employees or subcontractors are on such lists, the sponsor's policies shall require the immediate removal of such employees or subcontractors from any work on all Federal health care programs.
- Describe the arrangements for identifying overpayments within its network and making repayments to CMS of any overpayments.
- Establish procedures for the identification of FWA in a sponsor's network.
- Maintain procedures for referring instances of potential FWA to the MEDIC for further investigation.
- Establish 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.
- Establish procedures for performing data requests for MEDICs, CMS, and law enforcement.
- Maintain policies and procedures to comply with the ten-year record retention requirement as listed in the Federal Regulation.
- Establish policies and procedures to ensure full disclosure of all sponsor pricing decisions including clear guidance on how all decisions were documented.
- Establish policies and procedures that maintain a commitment to legal and ethical Pharmacy & Therapeutic Committee decisions and formulary decisions.

Requirement #2: The sponsor's compliance officer and compliance committee will be accountable for the sponsor's FWA plan.

Compliance Officer

The sponsor shall dedicate a full-time employee to the role of compliance officer (CO) and shall not split the CO's role between two job functions. This individual will be responsible for developing, operating, and monitoring the FWA program with authority to report directly to the board of directors, the president, or the CEO. The sponsor should consider the CO's scope of responsibilities, the organization's size and resources, and the

complexity of the task in determining whether this CO needs to be a different individual than the one required in the overall compliance plan.

Compliance Committee

The governing body of the sponsor shall establish a compliance committee (CC) that is overseen by the CO, advises the CO and assists in implementation of the Part D compliance program.

Requirement #3: The sponsor must have effective training and education related to the detection, correction, and prevention of FWA. This training will extend to the CO, CC members, organization employees, subcontractors, agents, and directors.

Effective compliance training to prevent FWA should address:

- Pertinent laws related to FWA. (For example, Anti-Kickback Statute and False Claims Act provisions.)
- Training for sponsor staff and subcontracted entities on common fraudulent schemes in the pharmaceutical industry as identified by CMS, the DHHS OIG, or the Department of Justice.
- How Part D FWA may be identified.
- What to do when FWA is identified.
- The role of the MEDIC, CMS and law enforcement.
- How employees and subcontractors shall cooperate with the MEDIC, CMS, and law enforcement.

Sponsors should conduct effective training using web-based tools, live or videotaped presentations, written materials or a combination of these techniques.

Sponsors must retain written records of their FWA training of employees, including attendance logs and material distributed at training sessions. At a minimum, FWA training should be provided at the time of employee hire and annually thereafter.

Requirement #4: The sponsor must have effective lines of communication between the CO and the organization's employees, subcontractors, agents, directors, and members of the CC.

The sponsor shall establish a system to receive, record and respond to instances of potential FWA that are identified by beneficiaries, employees, subcontractors, agents, directors, and members of the CC. Confidentiality must be maintained, allowing anonymity if desired (e.g. through telephone hotlines or mail drops), and without retaliation. The sponsor must, at a minimum,

- Establish hotlines for employees, subcontractors, and beneficiaries to report FWA;

- Implement prompt follow-up investigation procedures in response to hotline inquiries within 30 days of the report;
- Implement and maintain a system that will track complaints of FWA; and,
- Maintain procedures to ensure honest, effective, and efficient working relationships with the MEDICs, CMS, and law enforcement.

Requirement #5: The sponsor must promote FWA plan standards through well-publicized disciplinary guidelines.

To encourage the reporting of incidents of potential or actual FWA, the sponsor, under direction of the CO, shall:

- Release newsletters which explain FWA.
- Include compliance guidelines as a regular topic at department staff meetings.
- Prominently display posters, cafeteria table tents, or other such vehicles which emphasize the importance of detecting, correcting, and preventing FWA.
- Post information about FWA and reporting methods on the organization's intranet site.

This information shall be provided to leadership, employees and subcontractors.

The sponsor shall disseminate, among its beneficiaries, employees and subcontractors, the procedures to ask compliance questions, or make reports of potential or actual noncompliance to the CO or to a designated subcontractor (e.g., Hotline). At a minimum, the published information (including outgoing greetings on "hotline" systems) must include:

- A description of the various methods available to report FWA.
- A statement that every attempt will be made to maintain confidentiality, but that confidentiality may not be guaranteed if law enforcement gets involved.
- 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 non retaliation or retribution for reports of FWA made in good faith.

Requirement #6: The sponsor must have procedures for effective internal monitoring and auditing of FWA.

Monitoring activities refer to reviews that are repeated on a regular basis during the normal course of operations. Monitoring may occur to ensure corrective actions are undertaken or when no specific problems have been identified to confirm ongoing compliance.

An audit refers to a more formal review of compliance with a particular set of internal (e.g. compliance plans) or external (e.g. laws and regulations) standards.

In order to have effective internal procedures, documented monitoring and auditing functions are needed. Procedures for internal monitoring and auditing should test and confirm compliance with the Part D benefit regulations and all applicable state and Federal laws as well as internal policies and procedures. This will enable sponsors to mitigate and identify possible FWA activities.

Risk Assessment

The sponsor shall have a risk assessment system that determines where the organization is at risk for FWA and prioritizes (ranks) the risks. The CO and CC shall participate in or contribute to the risk assessment process. The sponsor shall have a system of ongoing monitoring and auditing that is coordinated or executed by the CO to assess performance in, at a minimum, areas identified as being at risk. Sponsors shall document the processes used to implement their risk assessment system and provide the documentation, upon request, to CMS or MEDIC.

Internal Monitoring and Auditing

The sponsor shall have an internal monitoring and auditing system that identifies FWA within its organization. This monitoring and auditing should extend to all areas of the organization vulnerable to potential FWA including, at a minimum:

- Sponsor subcontracting operations;
- Claims processing (e.g. claims processing edits that will identify potential FWA at the point of sale, either prospective, retrospective or both);
- Marketing operations;
- Pricing;
- Rebates and other price concessions;
- Formulary development;
- Pharmacy & Therapeutics committee; and,
- CMS payment operations (e.g. "the bid," claims data submission for payment).

A key component of auditing and monitoring for FWA includes the use of data analysis. The sponsor or its designee will be expected to engage in data analysis to identify patterns of aberrant and potentially abusive utilization. When data analysis reveals the potential for FWA within a sponsor's network, the sponsor must refer these leads promptly to the MEDIC for further investigation. Documentation of how internal monitoring and auditing for FWA, including data analysis procedures, may be requested upon CMS audit.

Auditing and monitoring for FWA may be performed utilizing any of the following:

- Unannounced internal audits or "spot checks."
- Examination of the performance of the compliance program including review of training, the compliance issues log (e.g. hotline log), investigation files, certifications for receipt of standards of conduct, and conflict of interest disclosure/attestation.
- Review of areas previously found non-compliant to determine if the corrective actions taken have fully addressed the underlying problem.

- Use of objective, independent auditors that are knowledgeable of the Medicare program requirements and are not employed in the area under review.
- Access to existing audit resources, relevant personnel, and relevant areas of operation.

Requirement #7: The sponsor must have procedures for ensuring prompt responses to FWA and develop corrective action initiatives relating to such offenses.

Procedures for responding to and correcting potential FWA violations include:

- Referral of any abusive or potentially fraudulent conduct or inappropriate utilization activities, once identified via proactive data analysis or other processes, for further investigation to CMS or the MEDICs;
- Procedures to cooperate with law enforcement and the MEDICs;
- Immediate reporting of potential violations of Federal law to the DHHS OIG or, alternatively, to appropriate law enforcement authorities;
- Identification and repayment of any overpayments;
- Removal of any employees, subcontractors, beneficiaries, etc. who engage in fraudulent or abusive practices.

Reporting of Violations and Potential Violations

Self-reporting plays a critical role in reducing FWA and the maintenance of program integrity. While the regulations do not require sponsors to engage in mandatory self-reporting, self-reporting of FWA is a critical element to an effective compliance plan.

Conclusion

This document presented the required components of a compliance plan that sponsors must implement to detect, correct, and prevent FWA. It is hoped that each sponsor will build on these requirements, and develop the most effective FWA plan given its organization and operational structure.