PART D OVERSIGHT STRATEGY
FOR CONTRACTORS/INDUSTRY
(October 24, 2005)

Purpose

This paper describes The Centers for Medicare & Medicaid Services (CMS's) Part D oversight program for Prescription Drug Plans (PDPs), and Medicare Advantage Prescription Drug Plans (MA-PDs).

Introduction

The Part D Oversight Program is modeled after the existing program utilized for Medicare Advantage Organizations (MAOs). The Part D oversight program will be data-driven to the extent possible, fueled by data provided by contractors and beneficiaries. It will be jointly administered by the following CMS organizational components: The Center for Beneficiary Choices (CBC), The Office of Financial Management (OFM), and the CMS regional offices.

- CBC and the 10 CMS regional offices lead on operational oversight issues including contractor management and compliance/enforcement; and,
- OFM leads on preventing, identifying, and addressing fraud, waste and abuse

The goals of CMS' oversight strategy are to identify Part D program vulnerabilities, assure strict adherence to Part D regulatory and program requirements, and detect and prevent fraud, waste, and abuse. CMS will accomplish these objectives without impeding the ability of Part D contactors to deliver industry standard performance.

As a result of this high level of participation in Part D, the oversight program will be built upon a centralized data-driven oversight program, fueled by data provided by contractors and beneficiaries. While receipt and analysis of data is central to this oversight strategy, regularly scheduled and focused/targeted program compliance and program integrity audits will be necessary to ensure program compliance and document the Agency's program oversight responsibilities.

CMS has already released two documents related to its proposed oversight strategy. These documents, described below, are located on CMS' webpage titled, "Plan reporting and Oversight" (located at http://www.cms.hhs.gov/pdps/PlnRpt_Ovrsit.asp):

1. *Part D Sponsors' Fraud Waste and Abuse Responsibilities* - This document summarizes Part D plan sponsor responsibilities regarding the prevention and detection of potential fraud, waste, and abuse in the Prescription Drug Program. [Note: A draft version of this document for industry comment dated June 15, 2005 is currently posted]

2. *Reporting Requirements* – This document provides an overview of CMS' periodic reporting requirements and represents CMS' expectations of data elements to be reported by Part D Sponsors at the distinct Plan level (i.e., data will be reported for each Plan offered under each Part D Contract) unless otherwise specified. [Note: The final version of this document dated April 18, 2005 is posted]

Later this year CBC will release a draft Part D Program Audit Guide for industry comment.

Oversight Strategy

The process flow chart, provided as Attachment 1 of this report, describes the oversight strategy for the Part D program. Each section of the chart is described in detail below:

Contractor Management Activities

Contractor management activities will be the first line compliance intervention point in identifying and correcting Part D program non-compliance. Much of what comprises contractor management activity will be based upon analysis of self-reported, unaudited plan data that flows into CMS from Part D contractors. For example, all complaint data captured by CMS will flow to the Medicare Drug Benefit Group (MDBG) where reports will be generated and findings evaluated. Additionally, CMS will be evaluating Prescription Drug Event (PDE) data, formulary, enrollment and other data sources to ensure compliance with program requirements.

CMS will also receive feedback from beneficiaries regarding their experience with Medicare Part D contractors via consumer satisfaction surveys, and through a nationwide complaints tracking system. The complaints tracking system will track complaints entered by CMS staff in the central and regional offices; and by staff from contractors hired by CMS to help oversee the Medicare Part D program.

These data and the reports produced from them will be an integral part of the Agency's contractor management activities. A summary of the Part D data systems and reports that CMS will utilize to facilitate contractor management activities is provided in Attachment 2.

CMS staff are developing systems to identify acceptable thresholds and ranges of data and subsequently observe trends for Medicare Part D organization reported data from which "report cards" can be developed. Aberrant findings would trigger the need for a more detailed investigation to identify potential problems.

CMS has contracted with program integrity contractors, known as Medicare Drug Integrity Contractors (MEDICs), to assist the Agency in overseeing the Medicare Part D program. These MEDIC contractors will also perform data analysis for fraud, waste and abuse identification purposes. CMS is aware of the confidential nature of this data and will ensure that its MEDIC contractors protect the confidentiality of all data including actual rebate dollars.

Account Managers:
CMS central office and regional office account managers will be the central hub for managing each contractor's Part D program operations. They will coordinate, integrate, and manage reports and information provided by various data owners throughout the Agency. Account managers will work with Part D contractors to resolve day to day compliance issues. They will coordinate and manage all Part D plan audits, including regularly scheduled and focused/targeted audits (by CMS and its contractors) to avoid duplication and minimize burden on the Medicare Part D organizations. They will also refer large, repeat and/or egregious Part D program violations to CBC Medicare Plan Accountability Group (MPAG) and suspected fraud, abuse and waste cases to OFM and/or the appropriate MEDIC contractor.

Compliance and Enforcement

Large, repeat and/or egregious Part D program violations are routed to MPAG in CMS central office to determine an appropriate level of compliance intervention. Central office staff and CMS regional offices will evaluate referral cases for potential enforcement actions such as intermediate sanctions, Civil Money Penalties, or referral to law enforcement.

Auditing

Audits are necessary for several reasons. First, data will not be submitted to CMS for certain aspects of the Part D program. Second, CMS must verify that the unaudited, plan-reported, data submitted by sponsors are credible and accurate. Third, CMS will need to audit plans when irregularities or outliers are identified in self-reported, unaudited data. Finally, CMS must audit plans on a periodic basis to provide external audit agencies (Office of the Inspector General (OIG), Government Accountability Office (GAO) and Chief Financial Office (CFO) auditors with evidence that the Agency has adequate internal controls in place to carry out its program oversight responsibilities and manage its programs effectively.

Audits will be conducted by a cross-functional team that will likely be comprised of an Account Manager, a Caseworker, a Managed Care Operations Specialist, at least one Pharmacist, and other audit staff with relevant expertise in the Medicare Part D program. CMS may also bolster its audit teams with contractor support staff on an as needed basis. Each member of the team will perform specific functions. For example the Managed Care Specialist would perform audits on enrollment and eligibility and marketing while the Pharmacist(s) review(s) formularies and quality. This team will ensure the right mix of expertise, and provide for independence and unbiased objectivity in carrying out the audit.

Regularly scheduled and focused/targeted program audits will serve as one of the primary mechanisms that CMS uses for ensuring and documenting compliance with Part D program requirements.

Regularly Scheduled Audits:

1. Program Audit:
   CMS will follow a 3-year comprehensive regularly scheduled audit cycle for Part D plans where CMS will audit all aspects of the Part D plan over the course of a 3-year audit cycle. This comprehensive 3-year audit cycle will consist of yearly randomized desk audits. The program audit will also include one on-site audit within the 3-year audit cycle.

2. 1/3 Payment Audit:
   The MMA requires an audit of at least one-third of all Part D organizations' financial records including bids, data relating to Medicare utilization and allowable costs under section 1858(c).

Focused/Targeted Audits:

CMS will also conduct focused/targeted audits when questionable findings are identified through contractor management activities, such as data analysis or analysis of appeals, grievance and complaint data. In instances of allegations of fraud, waste or abuse, OFM and the appropriate MEDIC will conduct audits.

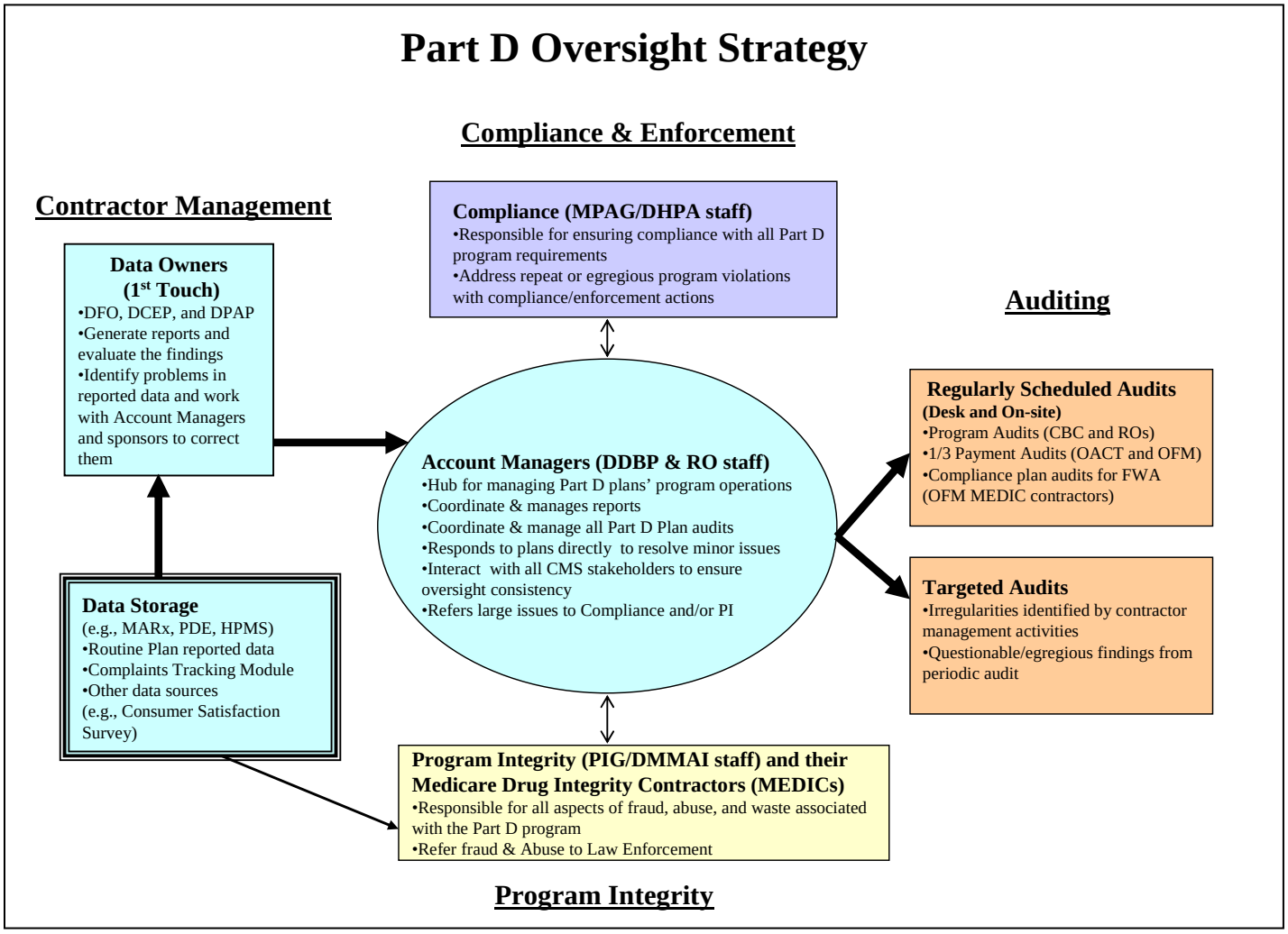
In situations where focused/targeted audits are conducted, these audit activities will substitute for regularly scheduled audit activity. This will minimize the burden on Part D organizations.

Program Integrity

In addition to monitoring and evaluating data to identify potential fraud, waste, and abuse, MEDICs shall perform the following functions (this list is not exhaustive):

- Conduct investigations of potential fraud and abuse;
- Monitor drug utilization patterns for potential fraud and abuse through data analysis (including those prescriptions that are e-prescribed);
- Conduct data analysis of pricing data to detect outliers and inappropriate changes in formularies;
- Investigate aberrant behavior identified by the Part D organizations, beneficiaries, CMS, Medicare Part D Integrity Contractors and other key stakeholders as potentially fraudulent, and develop and refer such cases to the appropriate law enforcement (LE) agency or to CMS for administrative action as necessary;
- Conduct on-site program integrity audits of PDP and MA-PD plans as necessary;
- Report to CMS regularly on fraud and abuse related to enrollment, disenrollment, and/or complaint indicators;
- Conduct preliminary investigations into non-approved PDPs conducting fraudulent enrollment, eligibility determination and benefit distribution;
- Conduct program integrity audits of fallback plans; and
- Review PDP and MA-PD fraud and abuse plans.

Attachment 1. Process flow diagram for Part D Oversight



List of Acronyms:

- ✓ DFO – Division of Finance & Operations
- ✓ DCEP – Division of Clinical & Economic Performance
- ✓ DPAP – Division of Program Analysis & Performance
- ✓ MARx –Medicare Advantage Prescription Drug
- ✓ PDE – Prescription Drug Event
- ✓ HPMS – Health Plan Management System
- ✓ MPAG – Medicare Plan Accountability Group
- ✓ DHPA – Division of Health Plan Accountability
- ✓ DDBP – Division of Drug Benefit Purchasing
- ✓ RO – Regional Office(s)
- ✓ PIG – Program Integrity Group
- ✓ DMMAI –Division of MMA Integrity
- ✓ MEDICs – Medicare Drug Integrity Contractors
- ✓ CBC – Centers for Beneficiary Choices
- ✓ OACT – Office of the Actuary
- ✓ OFM – Office of Financial Management
- ✓ FWA – Fraud, Waste & Abuse

Attachment 2 – Part D Data Systems and Reports for Facilitating Contractor Management Activity

Part D data review, monitoring and reporting processes will allow validation for accurate claims payment and program oversight. The minimum data required for successful delivery of the payment and oversight programs are all elements of the prescription drug events and related professional tables, the beneficiary information contained in the enrollment database, the Plan reported elements within HPMS, the files generated from the complaint tracking module, and supportive factors obtained directly from Plans, providers, and other government sources. We will develop reports and related intervention metrics to serve as the triggers to adhoc data mining and reporting for thorough quality, safety, regulatory and payment deliverables. The overall impact of these systems and analysis will result in improved healthcare delivery, medication therapy management and optimal value for the dollars spent.

Utilization Management: Assess cost-effective and appropriate use of medications, carryout drug trend analysis and utilization cost trends to determine cost-effectiveness of part D program. The generation of these reports will require cross linking of prescription drug event (PDE) data and beneficiary eligibility data with formulary data and Medispan data.

Medication Adherence and Persistence: Medication adherence is the extent to which a patient acts in accordance with the prescribed dosing regimen. Medication persistence is the accumulation of time from initiation to discontinuation of therapy. Assess medication adherence and persistence for the specified drug list. Monitor beneficiary adherence and persistence with medications; determine if there is an adherence benefit by using mail order pharmacies. Calculate adherence for members that have two or more prescriptions filled for drugs in the supplied list. To calculate medication persistence, check that beneficiaries continue to get their prescriptions filled for a particular drug specified on the drug list. The medication adherence and persistence calculations will be carried out on six months basis.

Quality Assurance: Analyze PDE and enrollment data to identify patient safety issues including drug-drug interactions and drug safety issues.

Performance Measures: Generate reports based on plans reported data to HPMS for Appeals, Enrollment/Disenrollment, Generic dispensing rate, Medication Therapy Management, Rebates And Prior Authorization/Step Edits/Non-Formulary Exceptions.

Coverage Determination: Analyze OIS PDE and enrollment data and HPMS step edits and prior authorization data to ensure that the plans are compliant with reported formulary; verify that the plans are not discriminatory in their determinations and check that there is enough coverage determination on appropriate medications.

Complaint Tracking: HPMS complaints tracking data will be analyzed to provide oversight and feedback on the nature of complaints, call abandonment rates, effectiveness of complaint resolution process, for example, time to answer and to assess customer satisfaction.

Long Term Care (LTC) - Pharmacy Access: Analyze data to verify LTC facilities' contracted pharmacies provide adequate access to LTC residents with Part D coverage. To run these standard reports, MDS data, PDE and enrollment and eligibility data from OIS will have to be integrated.