8th ANNUAL PHARMACEUTICAL REGULATORY COMPLIANCE CONGRESS

Pre-Conference Symposium

"Fraud and Abuse Issues in Part D Pricing and Contracting"

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Presentation Outline

I. Current Part D Enforcement Climate
II. Overview of Part D Plan Compliance Requirements
III. CMS's Part D Sub-Regulatory Guidance Relevant to Manufacturers
IV. Part D Risk Areas for Manufacturers
V. Recent Developments
VI. Manufacturer Effectiveness Review
VII. Conclusion

Current Part D Enforcement Climate

"A fraud on you [a PDP] is a fraud on the government…"

James G. Sheehan, Associate U.S. Attorney for the Eastern District of Pennsylvania, as quoted in BNA's Health Care Daily Report September 29, 2005.

Current Part D Enforcement Climate

"Pricing arrangements found in contracts between drug manufacturers and Part D plans will likely come under increased OIG scrutiny in 2007 and 2008."

Briefings on Part D Compliance September 2006.

Current Part D Enforcement Climate

"Secret payments to pharmacy benefit managers and misleading pricing are two of the biggest [Part D] fraud concerns to watch for . . ."

Jim Sheehan as quoted in BNA's Health Care Daily Report December 14, 2005.

Current Part D Enforcement Climate

"Medication therapy management programs carry compliance risks . . . "

Briefings on Part D Compliance September 2006.

Current Part D Enforcement Climate

"[P]lans that incorrectly state their actual costs to [CMS] . . . or fail to disclose payments from drugmakers also may be in violation of false claims laws."

Jim Sheehan as quoted in BNA's Health Care Daily January 24, 2006.

Current Part D Enforcement Climate

"Drug companies should be cautious of compliance pitfalls when doctors or patients ask for Part D help . . ."

Briefings on Part D Compliance September 2006.

Part D Sponsor Fraud, Waste and Abuse Program Obligations

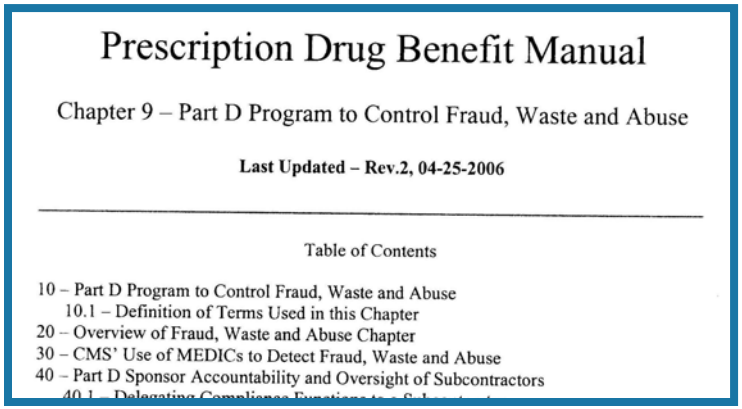
- Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State standards.
- The designation of a compliance officer and compliance committee accountable to senior management.
- Effective training and education between the compliance officer and organization employees, contractors, agents, and directors.

Part D Sponsor Fraud, Waste and Abuse Program Obligations

- Effective lines of communication between the compliance officer and the organization's employees, contractors, agents, directors, and members of the compliance committee.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Procedures for effective internal monitoring and auditing.
- Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor.

Part D Sponsor Fraud, Waste and Abuse Program Obligations

- Each Part D plan sponsor also must implement a “comprehensive fraud and abuse plan” to detect, correct, and prevent fraud, waste, and abuse.



Prescription Drug Benefit Manual

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

Last Updated – Rev.2, 04-25-2006

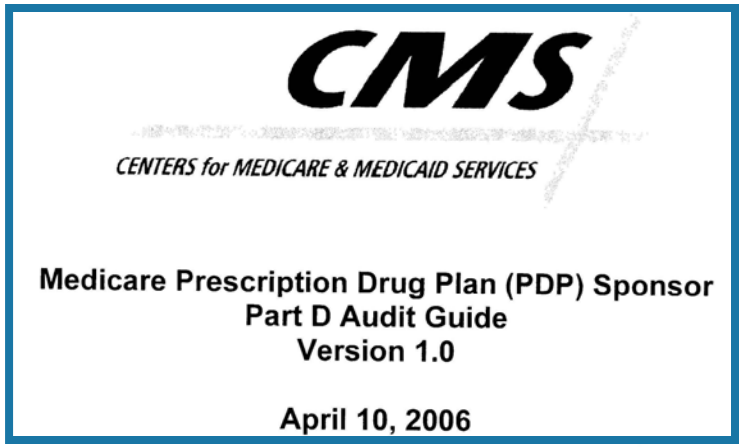
Table of Contents

General Compliance with Laws

- PDPs also must comply with federal laws and regulations designed to prevent fraud, waste and abuse, including, but not limited to:
  - applicable provisions of Federal criminal law
  - False Claims Act
  - Anti-Kickback statute

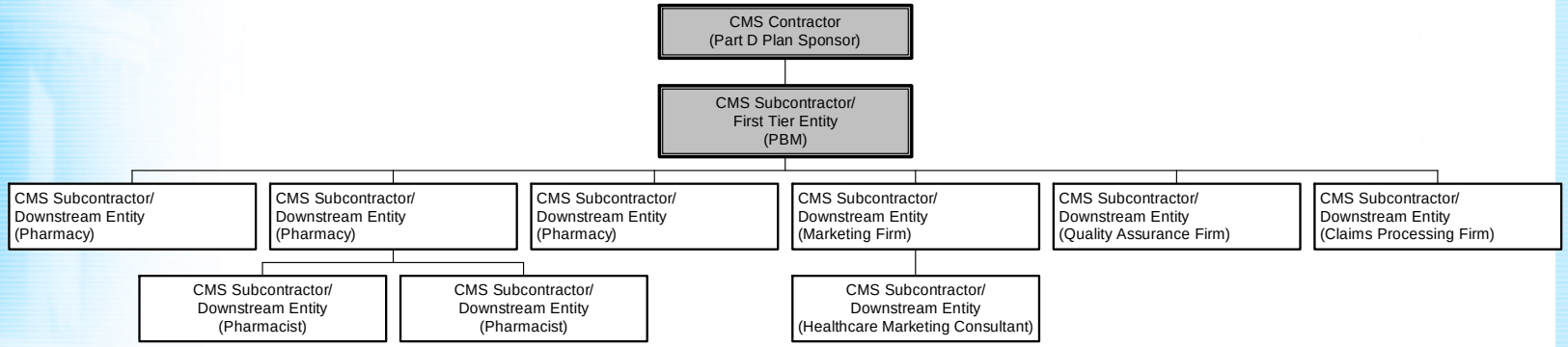
“Downstream Entity” Contract Provision Requirements

- PDP contracts include provisions that any services or other activity performed by a related entity, contractor or subcontractor or first-tier or downstream entity be performed in accordance with a contract or written agreement.
- Downstream services also must be furnished consistent with, and in compliance with, the PDP’s contractual obligations.



Part D Stakeholder Relationship Oversight

- Are manufacturers “downstream entities” to PDPs?
- Rebate agreements versus service agreements.



Source: Draft Chapter 9 of Prescription Drug Manual

Prescription Drug Manual Chapter 9 Fraud, Waste and Abuse Guidance

- CMS's examples of pharmaceutical manufacturer fraud, waste and abuse
  - Lack of integrity of data to establish payment and/or determine reimbursement/inappropriate documentation of pricing information

Prescription Drug Manual Chapter 9
Fraud, Waste and Abuse Guidance

- Pharmaceutical manufacturers may be liable under the False Claims Act, civil monetary penalties and/or the Federal Anti-Kickback statute if manufacturer knowingly fails to generate or report information completely and accurately.

- Manufacturers must maintain accurate and complete documentation of pricing information

Highlights from 2007 Call Letter

- CMS states:
  - If PBM retains portion of manufacturer rebates negotiated “on behalf of” PDP, such “price concession” must be deducted from sponsor’s incurred costs.
  - PDPs expected to take “necessary steps” to comply, such as negotiating PBM contracts that “ensure reporting of 100%” of manufacturer rebates for Part D plan drugs.
  - “Best practices” suggest combined use of a 100% reporting requirement plus an “auditing clause.”

Medicare Part D HPMS Reporting Requirements for Contract Year 2007

Section X. Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions

Part D Sponsors will be responsible for reporting multiple data elements related to rebates. These data will be monitored as components of a Part D Sponsor's operational costs. CMS recognizes the importance of maintaining confidentiality of these records. CMS will do everything within its authority to limit access to those who have appropriate use or oversight role and will track those who have accessed these records.

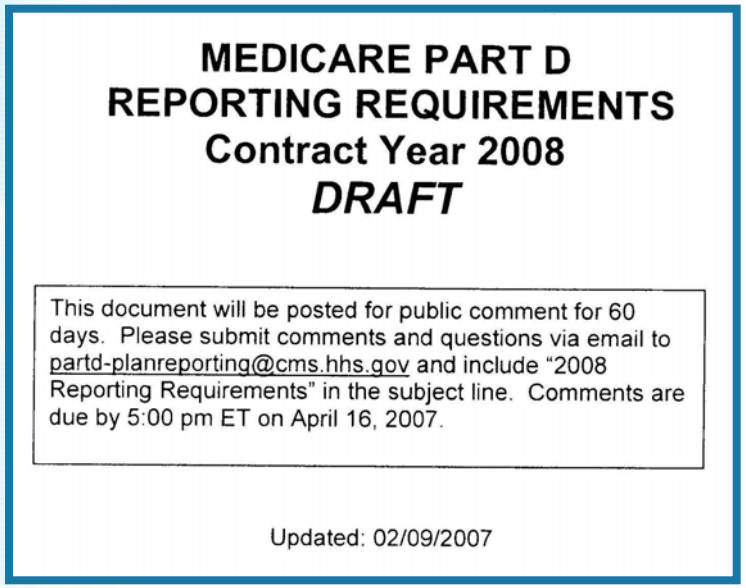
Rebates, discounts, and other price concessions will be reported at the CMS Part D Sponsor level. Reporting will not be combined by the subcontractor PBM to include multiple Part D Sponsor data. For example: (1) national Part D sponsors with multiple regional plans contracting independently or through a PBM will report rebates from the level of the national Part D sponsor; (2) regional or local Part D sponsor whether utilizing subcontractor PBM or not report at the Part D sponsor specific level; (3) PBM providing Part D coverage outside of a subcontractor role will report rebates at the PBM level. Rebate information should be summarized for each drug, rolled up to include multiple strengths, package sizes, dosage formulations, or combinations.

Reporting timeline:

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Reporting Period	January 1 – March 31	April 1 – June 30	July 1 – September 30	October 1 – December 31
Data due to CMS/HPMS	September 30	December 31	March 31	June 30

Data files to be uploaded through the HPMS at the CMS Part D Sponsor level as specified above.

Part D Price Reporting



MEDICARE PART D
REPORTING REQUIREMENTS
Contract Year 2008
DRAFT

This document will be posted for public comment for 60 days. Please submit comments and questions via email to partd-planreporting@cms.hhs.gov and include "2008 Reporting Requirements" in the subject line. Comments are due by 5:00 pm ET on April 16, 2007.

Updated: 02/09/2007

Reportable data includes any direct or indirect remuneration that would serve to decrease the costs incurred by the Part D sponsor for the drug, including:

- Discounts
- chargebacks or rebates
- cash discounts
- free goods contingent on a purchase agreement
- up-front payments
- coupons
- goods in kind
- free or reduced price services
- grants
- other price concessions
- similar benefits

Part D Price Reporting

Discounts and Other Price Concessions File Record Layout			
Field Name	**Field Type**	**Field Length**	**Field Description**
Manufacturer/ Company Name	CHAR REQUIRED	100	List the name of each manufacturer for whom there is an associated discount, price concession, or other value add.
Description	CHAR REQUIRED	250	Describe the discount, price concession, or other value adds.
Value	NUM (CUR) REQUIRED	12	Provide the value of the discount, price concession, or other value adds. •0 is not an allowable value
Justification	CHAR OPTIONAL	4000	For each discount, price concession, or value add, provide a justification for receipt.

Certification Compliance Issues

- United States v. Sulzbach (Sept. 18, 2007)
  - DOJ false claims lawsuit against former chief compliance officer of Tenet Healthcare Corp.
  - At issue is her signing CIA certifications attesting to compliance with all legal requirements
  - But questions over whether compensation paid to certain physicians under employment agreements was FMV; potential Stark Law issues

Certification Compliance Issues (Continued)

  - Outside counsel report finding FMV problems was issued prior to CIA certifications being made
  - Lawsuit alleges personal FCA liability for the defendant
- What are implications for Part D Plan certification of reportable data?
- What are implications for pharmaceutical manufacturers that supply data to Plans?

Kickbacks, Inducements, and Other Illegal Remuneration

- Inappropriate marketing and/or promotion of products (sales, marketing, discounting, etc.) reimbursable by federal health care programs.

Kickbacks, Inducements, and Other Illegal Remuneration

- Inducements offered if the purchased products are reimbursable by any of the federal health care programs:
  - improper inducements
  - inappropriate discounts
  - inappropriate product support services
  - inappropriate educational grants
  - inappropriate research funding
  - other inappropriate remuneration.

Formulary and Formulary Support Activities

- Inappropriate relationships with formulary committee members
- Payments to PBMs
- Formulary placement payments in order to have manufacturer's products included on a Plan's formulary.

Inappropriate Relationships with Physicians

- “Switching” arrangements
- Incentives to physicians to prescribe medically unnecessary drugs
- Consulting and advisory payments
  - payments for detailing
  - business courtesies
  - gratuities
  - educational and research funding
- Improper entertainment or incentives offered by sales agents.

Illegal Off-Label Promotion

- Illegal promotion of off-label drug usage
  - marketing
  - financial incentives
  - 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

Other Part D Risk Areas for Pharmaceutical Manufacturers

- "Swapping" of governmental and non-governmental business
- Government reporting practices
- Patient Assistance Programs

Other Part D Enforcers

- MEDICS
- OIG
- DOJ
- FBI
- Other federal agencies

Additional Part D Compliance Resources and Issuances

- CMS's Instructions for 2007 Contract year to PDP Sponsors dated April 3, 2006 ("**2007 Call Letter**") and 2008 Draft Call Letter
- Medicare Part D Reporting Requirements Contract Year 2007 (updated 01/18/2006)
  - Draft Reporting Requirements for Contract Year 2008 (updated 2/09/2007)
- Final PDP and MA-PD Part D Audit Guides for Part D Program Audits (11/13/2006)

Additional Part D Compliance Resources and Issuances

- **Medicare Part D Formulary Guidance -**

  http://www.cms.hhs.gov/PrescriptionDrugCovContra/03_RxContracting_FormularyGuidance.asp#TopOfPage

- **Medication Therapy Management Guidance -**

  http://www.cms.hhs.gov/PrescriptionDrugCovContra/08.asp#TopOfPage

- **Part D Transition Guidance –**

  http://www.cms.hhs.gov/PrescriptionDrugCovContra/09_Transition.asp#TopOfPage

- **Part D Special Guidance –**

  http://www.cms.hhs.gov/PrescriptionDrugCovContra/10_RxContracting_SpecialGuidance.asp#TopOfPage

- **Interested Third Party Guidance –**

  http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_RxContracting_ThirdParty.asp#TopOfPage

- **Prescription Drug Benefit Manual –**

  http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

Additional Part D Compliance Resources and Issuances

- HHS OIG Report "General Prescription Drug Plan Sponsors' Compliance Plans" OEI-03-06-00100 (Dec. 2006)
- GAO Report to Congressional Committees "Medicare Advantage Required Audits of Limited Value" GAO-07-945 (July 2007)
- HHS OIG Report "CMS's Implementation of Safeguards During Fiscal Year 2006 to Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans" OEI-06-06-00280 (Oct. 2007)
- OIG Advisory Opinions relating to Part D

Recent Audit Reports of CMS Oversight of Part D

- OIG found many PDP compliance plans did not address all 8 require elements (Dec. 2006)
  - CMS agreed with OIG findings
  - Routine audits in 2007 to review compliance plans
  - CMS to hold sponsors accountable

Recent Audit Reports of CMS Oversight of Part D

- GAO found that CMS had not met "1/3 audit" requirement (July 2007)
  - Also found that CMS did not act to recover funds
  - CMS agreed; will finalize and implement approach to meeting requirement
  - CMS also promised to seek legislative authority to pursue financial recoveries

Recent Audit Reports of CMS Oversight of Part D

- OIG identified 6 CMS "safeguard" activities:
  - complaint process
  - data monitoring
  - financial audits
  - monitoring contract compliance
  - oversight of PDP efforts to reduce FWA
  - education and guidance to stakeholders

Recent Audit Reports of CMS Oversight of Part D

- OIG's cited deficiencies:
  - further development of safeguard activities needed
  - complaints not investigated timely
  - limited CMS ability to monitor enrollees switching plans
  - neither CMS or MEDIC had conducted significant data analysis

Recent Audit Reports of CMS Oversight of Part D

- OIG recommendations:
  - Develop comprehensive safeguard strategy
  - Ensure that all fraud complaints receive proper attention
  - Address legal concerns that impede program integrity

Part D Compliance Effectiveness Review – Structure

- Who “owns” the compliance responsibilities for the company’s Part D business?
- What is the reporting chain between the person responsible for overseeing Part D compliance and the company’s Board?
- Has the company developed a list of the key Part D risk areas relevant to its business?

Part D Compliance Effectiveness Review – Structure

- What was the process used to develop such list, taking into account both internal and external expertise? Was the process adequate?

- What resources are necessary to address Part D compliance in a meaningful way? How was the level of required resources determined and by whom?

Part D Compliance Effectiveness Review – Structure

- Is the compliance officer trained and equipped to oversee Part D compliance?
- What systems ensure that employees with Part D compliance responsibilities are held accountable for such activities?
- Has the company identified its Part D business partners, including Part D plans, sponsors, PBMs, pharmacies, long-term care pharmacies, specialty pharmacies, pharmacists, prescribers, P & T Committee members?

Part D Compliance Effectiveness Review – Structure

- Has the company reviewed its written agreements with Part D plans to determine the nature and extent of compliance obligations imposed on the company by contract?
- Who is (are) the company's liaison(s) with plans on issues relating to compliance? What is the anticipated mechanism for coordinating with plans on any compliance issues?
- How is the company's list of Part D compliance risk areas updated? By whom? How often?
- Who is responsible for monitoring and reviewing Part D sub-regulatory guidance as it is issued to identify implications for pharma?

Written Standards

- Does the company's code of conduct reflect commitment to Part D compliance?
- Are there written policies and procedures that address the Part D risk areas and describe the company's internal controls for each area?
- Are existing policies and procedures adequate? What modifications are necessary? What new policies and procedures need to be developed?

Written Standards

- Who will make any appropriate modifications to existing written standards? Who is drafting the new policies and procedures? Who is responsible for making sure these activities get done?

- Does the company have policies and procedures that enable identification of Part D business partners and auditing of those relationships?

Written Standards

- Does the company have policies and procedures for identifying the relationships with PDPs that are specifically identified in the regulations as relevant to disclosure of pricing, which are:
  - Discounts
  - Chargebacks
  - Rebates
  - Cash discounts
  - Free goods contingent on a purchase agreement
  - Up-front payments
  - Coupons
  - Goods in kind
  - Free or reduced price services
  - Grants
  - Price concessions or similar benefits offered to some or all purchasers

Written Standards

- What policies and procedures are in place to ensure that such arrangements will be and have been properly disclosed to PDPs for reporting purposes?

- What policies and procedures are in place to ensure that arrangements with PDPs reflect fair market value? How well is the company documenting the steps that it is taking to support fair market value of arrangements with PDPs? What additional steps need to be taken?

Written Standards

- What protocols are the company following regarding negotiations with PDPs with which the company also does non-Part D business?

- What written standards does the company have that address the non-pricing arrangements with PDPs identified in the FWA Guidance such as product support services, educational grants, research funding, other remuneration?

Written Standards

- What written standards does the company follow that address interactions with P&T committees? Interactions with prescribers? With pharmacies and pharmacists? Do current standards adequately address Part D? If not, what needs to be done, who will do it and when?

- What written standards does the company follow that address off-label promotion? Do current standards adequately address Part D? If not, what needs to be done, who will do it and when?

Training and Education

- What training and education on Part D compliance has been developed and implemented?
- Who is getting Part D training? Who else should be getting Part D training?
- What remains outstanding in the development and implementation of Part D compliance training?
- Are modification to policies and procedures for Part D reflected in training materials? Who will draft the required updates to training?

Training and Education

- Who is preparing new training materials for new Part D policies and procedures?
- Who is responsible for making sure the training updates get done?
- How often is training conducted?
- Is the training designed in a manner that effectively conveys the key information to those who need it? How do you know?

Reporting Of and Responding to Detected Offenses

- What mechanisms are in place for employees to ask Part D compliance questions or matters?
- Is there a mechanism for anonymous reporting?
- Does the company have a policy for protecting persons who raise questions or make compliance inquires involving Part D?

Reporting Of and Responding to Detected Offenses

- Has the non-retaliation policy been working effectively in the past? How do you know?
- Who is responsible for investigating Part D compliance complaints? What resources does/should this person have and what additional resources are needed?
- Who responds to Part D inquiries?

Voluntary Reporting

- Who has the responsibility for assessing whether the company has an obligation to disclose potential non-compliance to third persons?

- What internal and external resources are available to support this analysis should it arise? What additional resources need to be approved and/or retained for this scenario?

Auditing and Oversight

- Who is responsible for Part D compliance auditing?
- How is that person held accountable for the auditing function?
- What is the process for developing and updating the company's Part D audit workplan?
- What is the process for responding to items identified through the internal audit activities?

Auditing and Oversight

- What resources are needed to support the audit function?
- What is the mechanism for reporting of audit findings?
- Who is responsible for ensuring internal corrective action in response to audit findings?

Follow-up Reviews

- When should the first follow-up Part D compliance effectiveness review be performed?
- How often should subsequent follow-up reviews be done?
- Who should do them?
- Who receives copies of the follow-up audit results reports?

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