



PBM Compliance with Medicare Part D

Executive Summary

This white paper lays out the role and reporting requirements of the PBMs participating in Medicare Part D plans. It also discusses regulatory mandates and audits, while presenting an action plan to ensure full compliance and survive federal scrutiny.

Medicare prescription drug coverage is insurance that is provided by an insurance company or other private company approved by Medicare. The Medicare Part D prescription drug program is overseen by the Centers for Medicare and Medicaid Services (CMS). Part D was enacted as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and went into effect on January 1, 2006.

Individuals are eligible for prescription drug coverage under a Part D plan if they are entitled to benefits under Medicare Part A and/or enrolled in Part B. Beneficiaries can obtain the Part D drug benefit through two types of private plans: They can join a Prescription Drug Plan (PDP) for drug coverage only, or they can join a Medicare Advantage plan (MA) that covers both medical services and prescription drugs (MA-PD).

Part D plans must offer a standard benefit, which is defined in terms of the benefit structure. Part D plans may establish their own formularies, within statutory guidelines. Part D drug coverage excludes drugs not approved by the Food and Drug Administration, those prescribed for off-label use, drugs not available by prescription

for purchase in the United States and drugs for which payments would be available under Parts A or B of Medicare.

In 2011, the standard benefit requires payment of a \$310 deductible, then 25% coinsurance drug costs up to an initial coverage limit of \$2,830. Once this initial coverage limit is reached, the beneficiary is given a 50% discount on the total cost of brand-name drugs while in the “coverage gap,” until the total out-of-pocket cost reaches \$4,550. Medicare will phase in additional discounts on the cost of both brand-name and generic drugs. By 2020, these changes will effectively close the coverage gap and the beneficiary’s responsibility will be 25% of the costs. Once the beneficiary reaches catastrophic coverage in a given year, he or she pays the greater of 5% coinsurance or \$2.50 for generic drugs and \$6.30 for brand-name drugs.

The average (weighted) monthly premium for PDPs was \$37.25 in 2010. Beneficiaries with income below 150% poverty are eligible for the low-income subsidy, which helps pay for all or part of the monthly premium, annual deductible and drug co-payments.

CMS reports that there are over 1,400 different prescription drug plans in 2011. However, this includes every different benefit structure and every state or service area as a separate plan. The actual number of plan sponsors is 70. Moreover, some of these sponsors are affiliates or subsidiaries of others, so the true number of independent participating companies is about 50.

Medicare Prescription Drug Benefits Overview

Catastrophic Coverage: over \$6,440 in total drug costs	Beneficiary pays 5%	Plan Pays 15%	Medicare pays 80%
Coverage Gap ("Donut Hole"): up to \$6,440 total drug costs (\$4,550 out of pocket)	Employee pays 100%, but receives 50% discount on brand name drug (discounts increase to 2020, when gap is eliminated)		
Rebate: when beneficiary reaches \$2,830 total drug costs	Medicare pays beneficiary a \$250 rebate		
Standard Coverage: up to \$2,830 in total drug costs (\$940 out of pocket)	Beneficiary pays 25%	Plan pays 75%	
Deductible: < \$310 total costs	Beneficiary pays 100%		

Figure 1

The PBM's Role in Part D

PBMs may serve as Prescription Drug Plans themselves, or they may contract with health insurers to provide PBM services. If a PBM serves as a PDP, it must comply with Medicare regulations regarding enrollment, benefits and premiums, and it must implement a mandatory compliance plan. If a PBM only contracts with health insurers, the insurers are required to bear those compliance responsibilities. However, insurers are required to exercise "proper monitoring, oversight and auditing to ensure Medicare program compliance."¹

Part D clients typically rely on their PBM to submit prescription drug event (PDE) files to CMS. These files are the basis for all federal Part D subsidies. Substantial discrepancies may exist between these files and the claim expenses charged by the PBM to the Part D plan.

Part D Reporting Requirements

CMS requires Part D Plans to report to CMS a large volume of data on access to care, benefits and payments. The table on page 3 summarizes these requirements.

In addition, Part D Plans must report to each other electronically on the beneficiary's true out-of-pocket (TrOOP) expenditures, which determine the level of benefits and thus the beneficiary's co-payments. The TrOOP facilitator, a federal contractor, reports the patient's TrOOP expenditures to the Part D Plan. The Part D Plan is responsible for updating the patient aggregate tables, which support the calculation of patient responsibility at the point of service.

Common compliance problems for Part D plans include:

- Timely TrOOP reporting.
- Mid-year plan changes by patients.
- Post-adjudication adjustments to the financial responsibilities.
- Billed claims adjustments.

Financial Information Reporting (FIR) is a process in which point-in-time financial information is moved from one PBM to another PBM when a beneficiary switches plans during a plan year. This information is necessary for the new PBM to accurately process claims and attribute plan balances and status for reporting to the plan sponsor. Some plans have encountered problems in the timely processing of FIR data and have therefore charged incorrect co-pays. Similarly, adjustments to financial responsibilities and billed claims may change a beneficiary's TrOOP expenditures and thus move the beneficiary from one benefit tier to another.

High-level Compliance Overview

The risks of noncompliance with Medicare regulations are great, because fraudulent claims can be prosecuted under the False Claims Act. This law rewards whistleblowers and can result in treble damages plus huge fines.

CMS requires each participating Part D Plan to implement and conduct a compliance plan according to standards described in the Prescription Drug Benefit Manual. CMS conducted compliance plan audits of 33 plan sponsors in

Part D Plan Compliance

Report Type	Types of Data Required	Frequency of Reporting
Enrollment	Numbers enrolled, denied and incomplete applications	Quarterly
Retail, Home Infusion and Long-Term Care Pharmacy Access	Percent of beneficiaries by distance from retail pharmacies, number of contracted retail pharmacies and number of prescriptions filled at retail pharmacies owned or contracted by the plan.	Annual
Access to Extended Day Supplies at Retail Pharmacies	For plans with mail order pharmacy benefits, number of retail pharmacies in the state or service area that are contracted to provide comparable 90-day supplies.	Annual
Medication Therapy Management Programs	Number of beneficiaries eligible for MTMP, number who opted out or dis-enrolled, prescription cost on a per MTMP beneficiary per month basis, number of prescriptions for these beneficiaries, including patient-level identification data.	Annual
Prompt Payment by Part D Sponsors	Number of paper and electronic claims paid timely and not paid timely.	Twice per year
Pharmacy Support of Electronic Prescribing	Number of pharmacies (retail, long-term care and infusion) that are enabled to receive electronic prescriptions according to Medicare requirements.	Annual
Grievances	Number of beneficiary grievances, sorted by type of beneficiary (low-income or other) and type of grievance, along with percentage of grievances handled timely.	Quarterly
Pharmacy & Therapeutics (P&T) Committees' Provision of Part D Functions	Changes in P&T committee membership and organization and changes in other organizations that perform certain Part D functions.	Annual
Coverage Determinations and Exceptions	Total number of pharmacy transactions, number rejected due to formulary requirements or other utilization management requirements, number of prior authorizations received, number of prior authorizations approved, number of exceptions requested, number of exceptions approved.	Quarterly
Appeals	Number of re-determinations following an adverse coverage determination by the plan, including full and partial reversals of the original determination.	Quarterly
Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions	Rebates and discounts received from each manufacturer for each rebated drug, including non-cash gifts such as disease management programs.	Annual
Long-Term Care (LTC) Utilization	For each LTC pharmacy in the service area, the number of formulary prescriptions and non-formulary prescriptions, with costs of formulary and non-formulary prescriptions.	Annual
Licensure and Solvency, Business Transactions and Financial Requirements	Detailed data on licensing, revenue and expenses, assets and liabilities and cash flow.	Quarterly
Fraud, Waste and Abuse Compliance Programs	Number of potential fraud and abuse incidents reported, broken down by type of incident, source of report (internal vs. external) and follow-up actions including inquiries and reports to CMS and other authorities.	Annual
Employer/Union-Sponsored Group Health Plan Sponsors	Enrollment data for any participating employers, unions and other groups.	Annual
Plan Oversight of Agents	Number of agents who recruit members, number of agents investigated based on complaints, follow-up actions including reports to authorities and number of agent-assisted enrollments.	Annual

Figure 2

2010 and is conducting additional audits in 2011. Compliance plan requirements include:

- Implementing written policies and procedures.
- Designating a compliance officer and compliance committee.
- Conducting effective training and education.
- Developing effective lines of communication.
- Conducting internal monitoring and auditing.
- Enforcing standards through well-publicized disciplinary guidelines.
- Responding promptly to detected problems and undertaking corrective action.

The Office of the Inspector General (OIG) states that “a good faith effort by the company to comply with applicable statutes and regulations as well as federal healthcare program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior.” Under federal sentencing guidelines, companies with effective compliance plans may receive reduced sentences in case of a conviction.

CMS Targeted Compliance Issues

CMS is now targeting several areas related to PBM compliance:

- Pharmaceutical manufacturer grants to PBMs, particularly if tied to purchases.
- Any remuneration from a manufacturer or its agents directly or indirectly to a person in a position to influence formulary decisions related to the manufacturer’s products.
- Payments and rebates from manufacturers to PBMs, unless authorized in advance by the PBM’s customer and the actual amounts are disclosed in writing at least annually to the customer.
- Lump-sum payments for inclusion in a formulary or for exclusive or restricted formulary status.
- Arrangements with PBMs that assume risk.
- Manufacturer funding for purchasers’ or PBMs’ formulary support activities, especially communications with physicians and patients.

In 2010, CMS expanded its audit program for Medicare Part D plans, adding 33 on-site audits. CMS targeted five areas for attention:

- Formulary administration (e.g., transition, utilization management, protected class drugs).

- Prescription drug coverage determinations, appeals, grievances.
- Premium billing.
- Enrollment/disenrollment.
- Compliance plan (always audited along with other programmatic areas).

These audits resulted in five sanctions and one plan being terminated from Medicare. Several plans were required to stop marketing and enrolling new members, resulting in an unknown loss of revenue. Financial penalties have been as high as \$586,800, though most have been in the range of \$10,000 to \$50,000. The most frequent issue was “Failure to Issue Accurate Annual Notices of Change and Evidence of Coverage.” One plan was terminated and cited for:

- Denial of access to drugs in six classes of clinical concern.
- Imminent and serious risk to health and safety.
- Transition fill failures.
- Improper prior authorization and step therapy.
- No compliance plan or structure.
- No internal monitoring and auditing.

CMS describes its approach as not just a “paper exercise,” but a real validation of compliance activities including data, personnel and documentation. In particular, CMS emphasizes that the compliance officer should report to the Board or CEO, and that senior management must be directly involved in the compliance program. CMS published the following list of “Indicators that you do NOT have an effective program”:

- Compliance officer does not report to the Board/chief executive.
- No compliance committee.
- No confidential and anonymous reporting.
- Employees afraid to report up.
- Ignores monitoring; no or infrequent audits.
- Responds to incident but no systemic fix.
- No or negative recognition for compliance reports and complaints.
- Discipline inadequate or inconsistent.
- Allegations not effectively investigated.
- No systematic efforts to build a strong ethical culture.

How to Protect Your PBM from CMS Audit

CMS plans to audit every Part D Plan sponsor. Every PBM should conduct its own internal compliance audit in advance of CMS's audit, focusing on the areas that CMS is targeting. Your PBM must implement a compliance program that meets CMS requirements, but a compliance plan "on the shelf" is not enough.

Your likelihood of passing the audit without penalty is enhanced if you can show CMS that you have made good-faith efforts to strengthen your compliance performance and not just tried to meet the minimum requirements. Your CEO and other top executives should meet regularly to discuss compliance improvement initiatives and should document their actions. Minutes and other documents should demonstrate your

Board's active involvement in approving the compliance plan, monitoring ongoing performance and taking action when necessary. Internal Web sites and other employee information should discuss compliance as an important component of organizational success. Incentive systems should include rewards for improving compliance, not just penalties for failure.

In our experience, CMS handles good-faith compliance efforts reasonably. For example, we served as an intermediary between a company that had discovered a compliance problem and CMS. We assisted the company in negotiating anonymously with CMS and in developing a voluntary disclosure letter that described the company's proposed remedy. CMS responded favorably and the company was able to resolve the issue without penalty.

Footnotes

¹ "Mandatory Compliance Plans," presentation by Brenda Tranchida, Director, Program Compliance and Oversight Group, Center For Medicare, February 7, 2011.

About the Author

David Ricks is a Manager with Cognizant Business Consulting. He has over 20 years of experience in healthcare management and consulting, focused primarily on pharmacy benefit managers, healthcare payers, and government-sponsored healthcare programs. David earned his MBA at Harvard Business School and his BA at Columbia University. He can be reached at David.Ricks@cognizant.com.

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