# CMS Manual System

## Pub. 100-18 Medicare Prescription Drug Benefit Manual

**Department of Health & Human Services (DHHS)**
**Centers for Medicare & Medicaid Services (CMS)**

**Transmittal 5** **Date: September 26, 2008**

**SUBJECT: Chapter 1 of the Medicare Prescription Drug Benefit Manual**

**I. SUMMARY OF CHANGES:** Introduction of Chapter 1 of the Medicare Prescription Drug Benefit Manual into the CMS Manual System.

**NEW/REVISED MATERIAL - EFFECTIVE DATE*: September 26, 2008**
**IMPLEMENTATION DATE: September 26, 2008**

***Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously posted to http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage or http://www.cms.hhs.gov/manuals/ and disseminated via the Health Plan Management System (HPMS). However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.***

**NOTE: The Medicare Prescription Drug Benefit Manual can be accessed at** http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage **or** http://www.cms.hhs.gov/manuals/**. All revisions to Pub. 100-18 will be issued via HPMS.**

**II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)**
**(R = REVISED, N = NEW, D = DELETED)**

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|---|---|
| N† | 1/Entire Chapter/Introduction and General Provisions |

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.**

**IV. ATTACHMENTS:**

| | |
|---|---|
| | **Business Requirements** |
| X | **Manual Instruction** |
| | **Confidential Requirements** |
| | **One-Time Notification** |
| | **Recurring Update Notification** |

***Unless otherwise specified, the effective date is the date of service.**

†This Chapter is only designated as "NEW" for purposes of incorporation into this manual maintenance and numbering system.

# Prescription Drug Benefit Manual

# Chapter 1: Introduction and General Provisions

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***(Rev.5, 09-26-08)***

## 10 – Introduction

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

**This chapter provides an introduction to Pub. 100-18, Prescription Drug Benefit Manual, including:**

- Background regarding the establishment of the Voluntary Prescription Drug Benefit Program (Part D);
- Definitions of important concepts used throughout the manual; and
- Part D sponsor cost-sharing in beneficiary education and enrollment-related costs

Pub. 100-18 sets forth consolidated policy and operational guidance based on the current Part D program regulations. Except where specifically noted, the requirements in the manual apply to all Part D sponsors, including prescription drug plans (PDPs), Medicare Advantage prescription drug plans (MA-PD plans), and cost plans offering Part D coverage.

## 10.1 – Background

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended Title XVIII of the Social Security Act (the Act) by establishing the Voluntary Prescription Drug Benefit Program (Part D). Effective January 1, 2006, Part D is an optional prescription drug benefit for individuals who are entitled to Medicare benefits under Part A or enrolled in Medicare benefits under Part B. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit. The MMA also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

The regulations governing the Part D program are set forth in 42 CFR Part 423 – Voluntary Medicare Prescription Drug Benefit. There are a number of places in which Part D statutory provisions incorporate by reference specific sections of the Act that govern the Medicare Part C program (also known as the Medicare Advantage, or MA program, and formerly the Medicare+Choice, or M+C, program). The MA regulations are set forth at 42 CFR Part 422. Since the same organizations that offer MA coordinated care plans will also be required to offer MA-PD plans, Part 423 adopts the same organizational structure as Part 422. Wherever possible, CMS modeled the prescription drug regulations on the parallel provisions of the part 422 regulations.

Generally, Part D coverage is provided under PDPs, which offer only prescription drug coverage, or through MA-PD plans, which offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C. As described in chapter 5, section 20.4.3, PDPs must offer a basic prescription drug benefit (defined in chapter 5 section 20.4.2.1). As described in chapter 5, section 20.4.4, MA organizations must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is

offered, MA-PDs or PDPs (but not fallback PDPs), may also offer supplemental benefits (defined in chapter 5, section 20.4.2.1) under enhanced alternative coverage for a supplemental premium. Organizations offering drug plans have flexibility in the design of the prescription drug benefit packages, including the establishment of formularies. The MMA also provides for subsidy payments to sponsors of qualified retiree prescription drug plans (the retiree drug subsidy, or RDS) to encourage retention of non-Part D employer-sponsored benefits.

Since the MMA's enactment, several statutes have modified or amended the Part D program. These statutes include the QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005; the Tax Relief and Health Care Act (TRHCA) of 2006; and the Medicare Improvements for Patients and Providers Act of 2008.

## 10.2 – Process for Issuing Updates to Part D Guidance

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

Pub. 100-18 is the primary resource for consolidated policy guidance from the Centers for Medicare and Medicaid Services (CMS) regarding the Part D program. For detailed MA and cost plan program guidance, Medicare managed care organizations should also consult Pub. 100-16 (Medicare Managed Care Manual).

While Pub. 100-18 and Pub. 100-16 chapters are updated regularly to ensure that they contain detailed and current information, Part D sponsors should monitor and familiarize themselves with other sources of Part D policy and operational program guidance – particularly between Pub. 100-18. chapter updates and for chapters that have not yet been issued. Part D sponsors should monitor CMS regulations, including both preamble and regulation text; policy and operational guidance, including memoranda and other communications issued via the Health Plan Management System; and the annual call letter with instructions for the upcoming contract year.

The annual call letter is a key element of the guidance that CMS provides to help organizations bid and contract for the upcoming contract year. It is issued in the early spring of each year in advance of the bid submission deadline in June and contains important new information and operational requirements for Part C, Part D, and cost plan contractors.

## 20 – Definitions

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

The following definitions apply to terms that appear throughout the various chapters of the manual. Definitions with a more limited application are included in the specific chapters of the manual.

Actuarial equivalence: A state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.

Brand name drug: A drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan: A 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.

Eligible fallback entity or fallback entity: An entity defined at 42 CFR 423.855.

Fallback prescription drug plan: A plan defined at 42 CFR 423.855.

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

Full-benefit dual eligible individual: Has the meaning given the term at 42 CFR 423.772, except where otherwise provided.

Generic drug: A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Insurance risk: For a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA: Stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan: Has the meaning given the term in 42 CFR 422.2.

MA–PD plan: An MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account: The account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium: The amount calculated under 42 CFR 423.286 for Part D plans other than fallback prescription drug plans, and 42 CFR 423.867(a) for fallback prescription drug plans.

Program of All-Inclusive Care for the Elderly (PACE) Plan: A plan offered by a PACE organization.

PACE organization: Has the meaning given the term at 42 CFR 460.6.

Part D eligible individual: An individual who meets the requirements at 42 CFR 423.30(a).

Part D plan (or Medicare Part D plan): A PDP, an MA-PD plan, a PACE plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor: 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.

PDP region: A prescription drug plan region as determined by CMS under 42 CFR 423.112.

PDP sponsor: A nongovernmental entity that is certified under 42 CFR Part 423 as meeting the requirements and standards of 42 CFR Part 423 that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP: Prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of 42 CFR 423. This includes fallback prescription drug plans.

Service area: For: (1) a prescription drug plan, an area established in 42 CFR 423.112(a) within which access standards under 42 CFR 423.120(a) are met; (2) an MA-PD plan, an area that meets the definition of MA service area as described in 42 CFR 422.2, and within which access standards under 42 CFR 423.120(a) are met; (3) a fallback prescription drug plan, the service area described in 42 CFR 423.859(b); (4) a PACE plan offering qualified prescription drug coverage, the service area described in 42 CFR 460.22; and (5) a cost plan offering qualified prescription drug coverage, the service area defined in 42 CFR 417.1. Service area does not include facilities in which individuals are incarcerated.

Subsidy-eligible individual: A full subsidy eligible individual (as defined at 42 CFR 423.772) or other subsidy eligible individual (as defined at 42 CFR 423.772(d)).

Tiered cost-sharing: A process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

## 30 – Cost-Sharing in Beneficiary Education and Enrollment-Related Costs

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

As provided under 42 CFR 422.6 and 42 CFR 423.6, CMS charges and collects cost-sharing – or "user fees" – from MA organizations and PDP sponsors for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1-800-MEDICARE telephone line, community based outreach to support State health insurance assistance programs, other enrollment and information activities required under section 1851 of the Act, and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103-66). For more information about the procedures CMS follows to determine and assess annual user fees to MA organizations and PDP sponsors, refer to Pub. 100-16, chapter 1, section 40.

## 40 – Financial Relationships Between PDP Sponsors, Health Care Professionals, and Pharmaceutical Manufacturers

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

The financial relationships that exist between or among PDP sponsors, health care professionals (including physicians and pharmacists), or pharmaceutical manufacturers may be subject to the Federal anti-kickback statute and, if the relationship involves a physician, the physician self-referral statute. Nothing in 42 CFR Part 423 should be construed as implying that financial relationships described therein meet the requirements of the anti-kickback statute or physician self-referral statute or any other applicable Federal or State law or regulation. All such relationships must comply with applicable laws.

In addition to the provisions in 42 CFR Part 423, under section 6(a)(1) of the Inspector General Act of 1978, as amended, the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) has access to all records, reports, audits, reviews, documents, papers and other materials to which DHHS has access that relate to programs and operations for which the Inspector General has responsibilities under the Inspector General Act. The provisions in these regulations do not limit the OIG's authority to fulfill the Inspector General's responsibilities under Federal law.

## 50 – Employee Retirement Income Security Act of 1974 (ERISA) Application and Requirements

***(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)***

The rules contained in 42 CFR Part 423 apply for purposes of Title I of the MMA, and no inference should be drawn from anything in 42 CFR Part 423 regarding the applicability of Title I of ERISA. In addition, nothing in 42 CFR Part 423 should be construed as relieving a plan administrator or other fiduciary of obligations under Title I of ERISA.