

§ 423.1

42 CFR Ch. IV (10–1–06 Edition)

- 423.634 Reopening and revising determinations and decisions.
- 423.636 How a Part D plan sponsor must effectuate standard redeterminations or reconsiderations, or decisions.
- 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

Subpart N—Medicare Contract Determinations and Appeals

- 423.641 Contract determinations.
- 423.642 Notice of contract determination.
- 423.643 Effect of contract determination.
- 423.644 Reconsideration: Applicability.
- 423.645 Request for reconsideration.
- 423.646 Opportunity to submit evidence.
- 423.647 Reconsidered determination.
- 423.648 Notice of reconsidered determination.
- 423.649 Effect of reconsidered determination.
- 423.650 Right to a hearing.
- 423.651 Request for hearing.
- 423.652 Postponement of effective date of a contract determination when a request for a hearing for a contract determination is filed timely.
- 423.653 Designation of hearing officer.
- 423.654 Disqualification of hearing officer.
- 423.655 Time and place of hearing.
- 423.656 Appointment of representatives.
- 423.657 Authority of representatives.
- 423.658 Conduct of hearing.
- 423.659 Evidence.
- 423.660 Witnesses.
- 423.661 Discovery.
- 423.662 Prehearing.
- 423.663 Record of hearing.
- 423.664 Authority of hearing officer.
- 423.665 Notice and effect of hearing decision.
- 423.666 Review by the Administrator.
- 423.667 Effect of Administrator's decision.
- 423.668 Reopening of contract or reconsidered determination or decision of a hearing officer or the Administrator.
- 423.669 Effect of revised determination.

Subpart O—Intermediate Sanctions

- 423.750 Kinds of sanctions.
- 423.752 Basis for imposing sanctions.
- 423.756 Procedures for imposing sanctions.
- 423.758 Maximum amount of civil money penalties imposed by CMS.
- 423.760 Other applicable provisions.

Subpart P—Premium and Cost-Sharing Subsidies for Low-Income Individuals

- 423.771 Basis and Scope.
- 423.772 Definitions.
- 423.773 Requirements for eligibility.
- 423.774 Eligibility determinations, redeterminations, and applications.
- 423.780 Premium subsidy.

- 423.782 Cost-sharing subsidy.
- 423.800 Administration of subsidy program.

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback prescription drug plans)

- 423.851 Scope.
- 423.855 Definitions.
- 423.859 Assuring access to a choice of coverage.
- 423.863 Submission and approval of bids.
- 423.867 Rules regarding premiums.
- 423.871 Contract terms and conditions.
- 423.875 Payments to fallback prescription drug plans.

Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans

- 423.880 Basis and scope.
- 423.882 Definitions.
- 423.884 Requirements for qualified retiree prescription drug plans.
- 423.886 Retiree drug subsidy amounts.
- 423.888 Payment methods, including provision of necessary information.
- 423.890 Appeals.
- 423.892 Change of Ownership.
- 423.894 Construction.

Subpart S—Special Rules for States-Eligibility Determinations for Subsidies and General Payment Provisions

- 423.900 Basis and scope.
- 423.902 Definitions.
- 423.904 Eligibility determinations for low-income subsidies.
- 423.906 General payment provisions.
- 423.907 Treatment of territories.
- 423.908 Phased-down State contribution to drug benefit costs assumed by Medicare.
- 423.910 Requirements.

AUTHORITY: Secs 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

SOURCE: 70 FR 4525, Jan. 28, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 423.1 Basis and scope.

- (a) Basis. (1) This part is based on the indicated provisions of the following sections of the Social Security Act:
 - 1860D–1. Eligibility, enrollment, and information.
 - 1860D–2. Prescription drug benefits.
 - 1860D–3. Access to a choice of qualified prescription drug coverage.
 - 1860D–4. Beneficiary protections for qualified prescription drug coverage.

1860D-11. PDP regions; submission of bids; plan approval.

1860D-12. Requirements for and contracts with prescription drug plan (PDP) sponsors.

1860D-13. Premiums; late enrollment penalty.

1860D-14. Premium and cost-sharing subsidies for low-income individuals.

1860D-15. Subsidies for Part D eligible individuals for qualified prescription drug coverage.

1860D-16. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

1860D-21. Application to Medicare Advantage program and related managed care programs.

1860D-22. Special rules for Employer-Sponsored Programs

1860D-23. State pharmaceutical assistance programs.

1860D-24. Coordination requirements for plans providing prescription drug coverage.

1860D-31. Medicare prescription drug discount card and transitional assistance program.

1860D-41. Definitions; treatment of references to provisions in Part C.

1860D-42. Miscellaneous provisions.

(2) The following specific sections of the Medicare Modernization Act also address the prescription drug benefit program:

Sec. 102 Medicare Advantage conforming amendments.

Sec. 103 Medicaid amendments.

Sec. 104 Medigap.

Sec. 109 Expanding the work of Medicare Quality Improvement Organizations to include Parts C and D.

(b) *Scope.* This part establishes standards for beneficiary eligibility, access, benefits, protections, and low-income subsidies in Part D, as well as establishes standards and sets forth requirements, limitations, procedures and payments for organizations participating in the Voluntary Medicare Prescription Drug Program.

§ 423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means 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 means 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 means 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 is defined at § 423.855.

Fallback prescription drug plan is defined at § 423.855.

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at § 423.772, except where otherwise provided.

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

Group health plan is defined at § 423.882.

Insurance risk means, 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 § 422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

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

Monthly beneficiary premium means the amount calculated under § 423.286