

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.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 30683, May 28, 2008]

#### § 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.

*Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

*Eligible fallback entity or fallback entity* is defined at § 423.855.

*Fallback prescription drug plan* is defined at § 423.855.

*First tier entity* means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

*Fiscally sound operation* means an operation which at least maintains a

positive net worth (total assets exceed total liabilities).

*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 for Part D plans other than fallback prescription drug plans, and § 423.867(a) for fallback prescription drug plans.

*PACE Plan* means a plan offered by a PACE organization.

*PACE organization* is defined in § 460.6 of this chapter.

*Part D eligible individual* means an individual who meets the requirements at § 423.30(a).

*Part D plan (or Medicare Part D plan)* means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

## § 423.6

*Part D plan sponsor or Part D sponsor* refers to 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* means a prescription drug plan region as determined by CMS under § 423.112.

*PDP sponsor* means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

*Pharmacist* means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

*Prescription drug plan or PDP* means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 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 this part. This includes fallback prescription drug plans.

*Related entity* means any entity that is related to the Part D sponsor by common ownership or control and

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

*Service area (Service area does not include facilities in which individuals are incarcerated.)* means for—

(1) A prescription drug plan, an area established in § 423.112(a) within which access standards under § 423.120(a) are met;

(2) An MA-PD plan, an area that meets the definition of MA service area as described in § 422.2 of this chapter, and within which access standards under § 423.120(a) are met;

(3) A fallback prescription drug plan, the service area described in § 423.859(b);

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(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.22 of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in § 417.1 of this chapter.

*Subsidy-eligible individual* means a full subsidy eligible individual (as defined at § 423.772) or other subsidy eligible individual (as defined at § 423.772).

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

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### § 423.6 Cost-sharing in beneficiary education and enrollment-related costs.

The requirements of section 1857(e)(2) of the Act and § 422.6 of this chapter with regard to the payment of fees established by CMS for cost sharing of enrollment related costs apply to PDP sponsors under Part D.

## Subpart B—Eligibility and Enrollment

### § 423.30 Eligibility and enrollment.

(a) *General rule.* (1) An individual is eligible for Part D if he or she:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B; and

(ii) Lives in the service area of a Part D plan, as defined under § 423.4.

(2) Except as provided in paragraphs (b), (c), and (d) of this section, an individual is eligible to enroll in a PDP if:

(i) The individual is eligible for Part D in accordance with paragraph (a)(1) of this section;

(ii) The individual resides in the PDP's service area; and

(iii) The individual is not enrolled in another Part D plan.

(3) Retroactive Part A or Part B determinations. Individuals who become entitled to Medicare Part A or enrolled in Medicare Part B for a retroactive effective date are Part D eligible as of the month in which a notice of entitlement Part A or enrollment in Part B is provided.