

§ 423.6

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);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in § 460.12(c) 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).

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

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

Unbranded biological product means a product licensed under a biologics li-

42 CFR Ch. IV (10–1–24 Edition)

cense application (BLA) under section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. 262(a) or 262(k)) and marketed without a brand name. It is licensed under the same BLA as the corresponding brand name biological product.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68731, Dec. 5, 2007; 76 FR 21570, Apr. 15, 2011; 84 FR 25671, June 3, 2019; 86 FR 6114, Jan. 19, 2021; 88 FR 22337, Apr. 12, 2023; 89 FR 30829, Apr. 23, 2024]

§ 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 does all of the following:

(i) Is entitled to Medicare benefits under Part A or enrolled in Medicare Part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under § 407.1(a)(6)) of this subchapter.

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

(iii) Is a United States citizen or is lawfully present in the United States as determined in 8 CFR 1.3.

(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.

(b) *Coordination with MA plans.* A Part D eligible individual enrolled in a MA-PD plan must obtain qualified prescription drug coverage through that plan. MA enrollees are not eligible to enroll in a PDP, except as follows:

(1) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MA private fee-for-service plan (as defined in section 1859(b)(2) of the Act) that does not provide qualified prescription drug coverage; and

(2) A Part D eligible individual is eligible to enroll in a PDP if the individual is enrolled in a MSA plan (as defined in section 1859(b)(3) of the Act).

(c) *Enrollment in a PACE plan.* A Part D eligible individual enrolled in a PACE plan that offers qualified prescription drug coverage under this Part must obtain such coverage through that plan.

(d) *Enrollment in a cost-based HMO or CMP.* A Part D eligible individual enrolled in a cost-based HMO or CMP (as defined under part 417 of this chapter) that elects to receive qualified prescription drug coverage under such plan is ineligible to enroll in another Part D plan. A Part D eligible individual enrolled in a cost-based HMO or CMP offering qualified prescription drug coverage is eligible to enroll in a PDP if the individual does not elect to receive qualified prescription drug coverage under the cost-based HMO or CMP and otherwise meets the requirements of paragraph (a)(2) of this section.

[70 FR 4525, Jan. 28, 2005, as amended at 80 FR 7962, Feb. 12, 2015; 87 FR 66510, Nov. 3, 2022]

§ 423.32 Enrollment process.

(a) *General rule.* A Part D eligible individual who wishes to enroll in a PDP may enroll during the enrollment periods specified in § 423.38, by filing the appropriate enrollment form with the PDP or through other mechanisms CMS determines are appropriate.

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.2262.

(1) The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the PDP sponsor. Individuals who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

(2) Part D eligible individuals enrolling or enrolled in a Part D plan must provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, and consent to the release of the information provided by the individual on other insurance, group health plan or other third-party payment arrangements, as well as any other information on reimbursement of Part D costs collected or obtained from other sources, in a form and manner approved by CMS.

(c) *Timely process an individual's enrollment request.* A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines and enroll Part D eligible individuals who are eligible to enroll in its plan under § 423.30(a) and who elect to enroll or are enrolled in the plan during the periods specified in § 423.38.

(d) *Notice requirement.* The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

(e) *Maintenance of enrollment.* An individual who is enrolled in a PDP remains enrolled in that PDP until one of the following occurs:

(i) The individual successfully enrolls in another PDP or MA-PD plan;

(ii) The individual voluntarily disenrolls from the PDP;

(iii) The individual is involuntary disenrolled from the PDP in accordance with § 423.44(b)(2);

(iv) The PDP is discontinued within the area in which the individual resides; or