

plans, and the determination of enrollee premium and plan payments for these plans.

§ 423.855 Definitions.

As used in this subpart, unless specified otherwise—

Actual costs means the subset of prescription drug costs (not including administrative costs or return on investment, but including costs directly related to the dispensing of covered Part D drugs during the year) that are attributable to standard benefits only and that are incurred and actually paid by the sponsor or organization under the plan.

Actually paid has the same meaning described in § 423.308.

Eligible fallback entity or fallback entity means an entity that, for a particular contract period—

(1) Is a PDP sponsor that does not have to be a risk-bearing entity (or, if applying to become a fallback entity, an entity that meets all the requirements to become a Part D plan sponsor except that it does not have to be a risk-bearing entity); and

(2) Does not submit a risk bid under § 423.265 for offering a prescription drug plan for any PDP region for the first year of that contract period. An entity is treated as submitting a risk bid if the entity is acting as a subcontractor for an integral part of the drug benefit management activities of an entity that is or applies to become a non-fallback PDP sponsor. An entity is not treated as submitting a bid if it is a subcontractor of an MA organization, unless that organization is acting as or applies to become a non-fallback PDP sponsor for a prescription drug plan.

Fallback prescription drug plan means a prescription drug plan (PDP) offered by a fallback entity that—

(1) Offers only defined standard or actuarially equivalent standard prescription drug coverage as defined in § 423.100;

(2) Provides access to negotiated prices, including discounts from manufacturers; and

(3) Meets all other requirements established for prescription drug plans, except as otherwise specified by CMS in this subpart or in separate guidance.

Qualifying plan means a full-risk or limited-risk prescription drug plan, as defined in § 423.258, or an MA-PD plan described in section 1851(a)(2)(A)(i) of the Act, that provides required prescription drug coverage, as defined in § 423.100. An MA-PD plan must be open for enrollment and not operating under a capacity waiver to be counted as a qualifying plan. A PDP must not be operating under a restricted enrollment waiver, such as those that may be granted to special needs plans or employer group plans, in order to be counted as a qualifying plan in an area.

§ 423.859 Assuring access to a choice of coverage.

(a) *Choice of at least 2 qualifying plans in each area.* Each Part D eligible individual must have available a choice of enrollment in at least 2 qualifying plans (as defined in § 423.855) in the area in which the individual resides. This requirement is not satisfied if only one entity offers all the qualifying plans in the area. At least 1 of the 2 qualifying plans must be a prescription drug plan.

(b) *Fallback service area—*(1) *For coverage year.* Before the start of each coverage year CMS determines if Part D eligible individuals residing in a PDP region have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, do not have available a choice of enrollment in a minimum of two qualified plans, CMS designates the region or portion of a region as a fallback service area. Each Part D eligible individual in a fallback service area is given the opportunity to enroll in a fallback prescription drug plan.

(2) *For mid-year changes.* If a contract with a qualifying plan is terminated in the middle of a contract year (as provided for in § 423.508, § 423.509, or § 423.510), CMS determines if Part D eligible individuals residing in the affected PDP region still have access to a choice of enrollment in a minimum of 2 qualifying plans, as described in paragraph (a) of this section. If CMS determines that Part D eligible individuals in a PDP region, or some portion of the region, no longer have available a

choice of enrollment in a minimum of two qualifying plans, CMS designates the region or portion of a region as a fallback service area.

(c) *Access to coverage in the territories.* CMS may waive or modify the requirements of this part if—

(1) CMS determines that waiver or modification is necessary to secure access to qualified prescription drug coverage for Part D eligible individuals residing in a State other than the 50 States or the District of Columbia; or

(2) An entity seeking to become a prescription drug plan in an area such as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D requirement in order to provide qualified prescription drug coverage.

§ 423.863 Submission and approval of bids.

(a) *Submission of bids*—(1) *Solicitation of bids.* Separate from the risk bidding process under § 423.265, CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more PDP regions of a fallback prescription drug plan during the contract period specified in § 423.871(b).

(2) *Timing of bids.* CMS determines when to solicit bids for 2006 so that potential fallback prescription drug plans have enough time to prepare a bid. After that, bids are solicited on 3 year cycles, or annually thereafter as needed to replace contractors between contracting cycles.

(3) *Format of bid.* CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

(b) *Negotiation and acceptance of bids*—(1) *General rule.* Except as provided in this section, the provisions of § 423.272 apply for the approval or disapproval of fallback prescription drug plans. CMS enters into contracts under this paragraph with eligible fallback entities for the offering of approved fallback prescription drug plans in potential fallback service areas.

(2) *Flexibility in risk assumed and application of fallback prescription drug plan.* In order to ensure access in an area in accordance with § 423.859(a), CMS may approve limited risk plans

under § 423.272(c) for that area. If the access requirement is still not met after applying § 423.272(c), CMS provides for the offering of a fallback prescription drug plan in that area.

(3) *Limitation of 1 Plan for all fallback service areas in a PDP region.* All fallback service areas in any PDP region for a contract period must be served by the same fallback prescription drug plan.

(4) *Competitive procedures.* CMS uses competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5)) to enter into a contract under this paragraph. The provisions of section 1874A(d) of the Act apply to a contract under this section in the same manner as they apply to a contract under that section.

(5) *Timing of contracts.* CMS approves a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans are otherwise offered. In the event of mid-year changes and as required by § 423.859(b)(2), CMS approves a fallback prescription drug plan for a PDP region in a manner so that the fallback prescription drug plan is offered within 90 days of notice.

(6) *No national fallback prescription drug plan.* CMS may not enter into a contract with a single fallback entity for the offering of fallback prescription drug plans throughout the United States.

§ 423.867 Rules regarding premiums.

(a) *Monthly beneficiary premium.* Except as provided in § 423.286(d)(3) (relating to late enrollment penalty) and subject to subpart P (relating to low-income assistance), the monthly beneficiary premium under a fallback prescription drug plan must be uniform for all fallback service areas in a PDP region. It must equal 25.5 percent of CMS's estimate of the average monthly per capita actuarial cost, including administrative expenses, of providing coverage in the PDP region based on similar expenses of prescription drug plans that are not fallback prescription drug plans.