

§ 423.782

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low income benchmark as defined in § 423.780(b)(2).

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 18182, Apr. 3, 2008; 73 FR 20508, Apr. 15, 2008; 73 FR 54253, Sept. 18, 2008; 76 FR 21576, Apr. 15, 2011; 88 FR 22340, Apr. 12, 2023]

§ 423.782 Cost-sharing subsidy.

(a) *Full subsidy eligible individuals.* Full subsidy eligible individuals are entitled to the following:

(1) Elimination of the annual deductible under § 423.104(d)(1).

(2) Reduction in cost-sharing for all covered Part D drugs covered under the PDP or MA-PD plan below the out-of-pocket limit (under § 423.104), including Part D drugs covered under the PDP or MA-PD plan obtained after the initial coverage limit (under § 423.104(d)(4)), as follows:

(i) Except as provided under paragraphs (a)(2)(ii) and (a)(2)(iii) of this section, copayment amounts not to exceed the copayment amounts specified in § 423.104(d)(5)(A). This applies to both:

(A) Those full-benefit dual eligible individuals who are not institutionalized and who have income above 100 percent of the Federal poverty line applicable to the individual's family size and

(B) Those individuals who have income under 135 percent of the Federal poverty line applicable to the individual's family size who meet the resources test described at § 423.773(b)(2).

(ii) Full-benefit dual-eligible individuals who are institutionalized or who are receiving home and community-based services have no cost-sharing for Part D drugs covered under their PDP or MA-PD plans.

(iii) Full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty line applicable to the individual's family size are subject to cost-sharing for covered Part D drugs equal to the lesser of:

(A) A copayment amount of not more than \$1 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or \$3 for

any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

(B) The copayment amount charged to other individuals under this paragraph (a)(2)(i) of this section.

(3) Elimination of all cost-sharing for covered Part D drugs covered under the PDP or MA-PD plan above the out-of-pocket limit (under § 423.104(d)(5)).

(b) *Other low-income subsidy eligible individuals.* Other low-income subsidy eligible individuals are entitled to the following:

(1) In 2006, reduction in the annual deductible to \$50. This amount is increased each year beginning in 2007 by the annual percentage increase in average per capita aggregate expenditures for Part D drugs, rounded to the nearest multiple of \$1.

(2) Fifteen percent coinsurance for all covered Part D drugs obtained after the annual deductible under the plan up to the out-of-pocket limit (under § 423.104(d)(5)(iii)).

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)) in 2006, copayments not to exceed \$2 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and \$5 for any other drug. For years beginning in 2007, the amounts specified in this paragraph (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

(c) When the out-of-pocket cost for a covered Part D drug under a Part D sponsor's plan benefit package is less than the maximum allowable copayment, coinsurance or deductible amounts under paragraphs (a) and (b) of this section, the Part D sponsor may only charge the lower benefit package amount.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 76 FR 21576, Apr. 15, 2011; 83 FR 16753, Apr. 16, 2018]

§ 423.800 Administration of subsidy program.

(a) *Notification of eligibility for low-income subsidy.* CMS notifies the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy.

(b) *Reduction of premium or cost-sharing by PDP sponsor or organization.* Based on information provided by CMS under paragraph (a) of this section, or obtained under paragraph (d) of this section, the Part D sponsor offering the Part D plan in which a subsidy eligible individual is enrolled must reduce the individual's premiums and cost-sharing as applicable, and provide information to CMS on the amount of those reductions, in a manner determined by CMS. The Part D sponsor must track the application of the subsidies under this subpart to be applied to the out-of-pocket threshold.

(c) *Reimbursement for cost-sharing paid before notification of eligibility for low-income subsidy.* The Part D sponsor offering the Part D plan must reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy under this subpart.

(d) *Use of the best available evidence process to establish cost-sharing.* Part D sponsors must—

(1) Accept best available evidence as defined in § 423.772 of this part received from beneficiaries or other individuals acting directly on their behalf; and

(2) Update the subsidy eligible individual's LIS status, and respond to requests for assistance in securing acceptable evidence of subsidy eligibility from beneficiaries or other individuals acting directly on their behalf in accordance with the process(es) established by CMS, and within the reasonable timeframe(s) as determined by CMS.

(e) *Timeframe for refunds and recoveries due to retroactive adjustments to cost sharing.* Sponsors must process retroactive adjustments to cost-sharing for low-income subsidy eligible individuals and any resulting refunds and recover-

ies in accordance with the timeframe specified in § 423.466(a) of this part.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1549, Jan. 12, 2009; 75 FR 19825, Apr. 15, 2010]

Subpart Q—Guaranteeing Access to a Choice of Coverage (Fallback Prescription Drug Plans)**§ 423.851 Scope.**

This subpart sets forth—the rights of beneficiaries to a choice of at least two sources of qualified prescription drug coverage; requirements and limitations on the bid submission, review and approval of fallback prescription drug 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.

(b) *Special rule for collection of premiums in fallback prescription drug plans.* In the case of a fallback prescription drug plan, the provisions of § 423.293 (b) concerning payments of the late enrollment penalty to the PDP sponsor do not apply and the monthly beneficiary premium is collected in the manner specified in § 422.262(f)(1) of this chapter, or paid directly to the fallback entity by the beneficiary if there are either no benefits, or insufficient benefits available to be collected in the manner specified under § 422.262(f)(1) of this chapter. The amount of any premiums collected by the fallback entity is deducted from management fees due from CMS.

§ 423.871 Contract terms and conditions.

(a) *General.* Except as may be appropriate to carry out the requirements of this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans are the same as the terms and conditions of contracts at §§ 423.504 and 423.505 for Part D plans.

(b) *Period of contract.* A contract with a fallback entity for fallback service areas for a PDP region is in effect for a period of 3 years. However, a fallback prescription drug plan may be offered for any year within the contract period for a particular area only if the area is a fallback service area for that year.

(c) *Entity not permitted to market or brand fallback prescription drug plans.*