

§ 423.800

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

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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 recoveries 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