

(1) *Exemption from negotiations.* These plans are exempt from the review and negotiation process in paragraph (a) of this section, and are not held to the revenue requirements standard in paragraph (b)(1) of this section.

(2) *Requirements regarding negotiated prices.* These plans are not required to provide access to negotiated prices. However, if they do, they must meet the applicable requirements of § 423.104(h).

(3) *Modification of pharmacy access standard and disclosure requirement.* If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost sharing and without regard to whether they are network pharmacies, § 423.120(a) and § 423.132 requiring certain network access standards and the disclosure of the availability of lower cost bioequivalent generic drugs does not apply to the plan.

(e) *Special rule for plans with standardized bids sufficiently below the national average monthly bid to result in a negative premium.* In the event of a negative premium, as described in § 423.286(d)(1), CMS negotiates the incorporation of the negative premium amount into the bid as either a reduction in the supplemental premium if the Part D plan already submitted a bid with an enhanced alternative benefit, or CMS requires the addition of new enhanced alternative benefit of no less value than the amount of the negative premium.

§ 423.279 National average monthly bid amount.

(a) Bids included. For each year (beginning with 2006) CMS computes a national average monthly bid amount from approved bids submitted under § 423.265 in order to calculate the base beneficiary premium, as provided in § 423.286(c). The national average monthly bid amount is equal to a weighted average of the standardized bid amounts for each prescription drug plan (not including fallbacks) and for each MA-PD plan described in section 1851(a)(2)(A)(i) of the Act. The calculation does not include bids submitted by MSA plans, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under

reasonable cost reimbursement contracts under section 1876(h) of the Act.

(b) Calculation of weighted average. (1) The national average monthly bid amount is a weighted average, with the weight for each plan equal to a percentage with the numerator equal to the number of Part D eligible individuals enrolled in the plan in the reference month (as defined in § 422.258(c)(1) of this chapter) and the denominator equal to the total number of Part D eligible individuals enrolled in a reference month in all Part D plans except MSA plans, fallbacks, MA private fee-for-service plans, specialized MA plans for special needs individuals, PACE programs under section 1894, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act.

(2) For purposes of calculating the monthly national average monthly bid amount for 2006, CMS assigns equal weighting to PDP sponsors (other than fallback entities) and assigns MA-PD plans included in the national average bid a weight based on prior enrollment (new MA-PD plans are assigned zero weight).

(c) Geographic adjustment. (1) Upon the development of an appropriate methodology, the national average monthly bid amount for Part D plans will be adjusted to take into account differences in prices for Part D drugs among PDP regions.

(2) CMS does not apply any geographic adjustments if CMS determines that price variations among PDP regions are negligible.

(3) CMS applies any geographic adjustment in a budget neutral manner so as to not result in a change in the aggregate payments that may have been made if CMS had not applied an adjustment.

(4) CMS does not apply any geographic adjustment until an appropriate methodology is developed.

§ 423.286 Rules regarding premiums.

(a) *General rule.* Except as provided in paragraphs (d)(3) and (e) of this section, and with regard to employer group waivers, the monthly beneficiary premium for a Part D plan in a PDP region is the same for all Part D eligible individuals enrolled in the plan. The

monthly beneficiary premium for a Part D plan is the base beneficiary premium, as determined in paragraph (c) of this section, adjusted as described in paragraph (d) of this section for the difference between the bid and the national average monthly bid amount, any supplemental benefits and for any late enrollment penalties.

(b) *Beneficiary premium percentage.* The beneficiary premium percentage for any year is a fraction, the—

(1) Numerator of which is 25.5 percent; and

(2) Denominator of which is as follows:

(i) 100 percent minus the percentage established in paragraph (b)(2)(ii) of this section.

(ii) The percentage established in this paragraph equals:

(A) The total reinsurance payments that CMS estimates will be paid under § 423.329(c) for the coverage year; divided by—

(B) The amount estimated under paragraph (b)(2)(i)(A) of this section for the year plus total payments that CMS estimates will be paid to Part D plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by both CMS and enrollees.

(c) *Base beneficiary premium.* The base beneficiary premium for a Part D plan for a month is equal to the product of the—

(1) Beneficiary premium percentage as specified in paragraph (b) of this section; and

(2) National average monthly bid amount (computed under § 423.279) for the month.

(d) *Adjustments to base beneficiary premium.* The base beneficiary premium may be adjusted to reflect any of the following scenarios, if applicable.

(1) *Adjustment to reflect difference between bid and national average bid.* If the amount of the standardized bid amount exceeds the adjusted national average monthly bid amount, the monthly base beneficiary premium is increased by the amount of the excess. If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount, the monthly base beneficiary premium is decreased by the amount of the excess.

If the amount of the adjusted national average monthly bid amount exceeds the standardized bid amount by an amount greater than the base beneficiary premium and results in a negative premium, then the beneficiary premium is zero, and the excess amount is applied to supplemental Part D benefits as described in § 423.272(e).

(2) *Increase for supplemental prescription drug benefits.* The portion of the Part D plan approved bid that is attributable to supplemental prescription drug benefits increases the beneficiary premium. This supplemental portion of the bid may be adjusted to reflect the average risk of enrollees in the plan as determined based on negotiations between CMS and the Part D sponsor offering the plan.

(3) *Increase for late enrollment penalty.* The base beneficiary premium for a Part D enrollee subject to the late enrollment penalty is increased by the amount of any late enrollment penalty.

(i) *Late enrollment penalty amount.* The penalty amount for a Part D eligible individual for a continuous period of eligibility (as provided in § 423.46(a)) is the greater of—

(A) An amount that CMS determines is actuarially sound for each uncovered month in the same continuous period of eligibility; or

(B) 1 percent of the base beneficiary premium (computed under paragraph (c) of this section) for each uncovered month in the period.

(ii) *Special rule for 2006 and 2007.* In 2006 and 2007 the penalty amount discussed in paragraph (d)(3) of this chapter equals the amount referenced in paragraph (d)(3)(i)(B) of this section unless another amount is specified in a separate issuance based on available analysis or other information as determined by the Secretary.

(e) *Decrease in monthly beneficiary premium for low-income assistance.* The monthly beneficiary premium may be eliminated or decreased in the case of a subsidy-eligible individual under § 423.780.

(f) *Special rules for fallback prescription drug plans.* The monthly beneficiary premium charged under a fallback prescription drug plan is calculated under § 423.867(a) and not under this section,

except that enrollees in fallback prescription drug plans are subject to late enrollment penalties under paragraph (d)(3) of this section and fallback prescription drug plan premiums are reduced or eliminated in the case of a subsidy-eligible individual, as described in paragraph (e) of this section.

§ 423.293 Collection of monthly beneficiary premium.

(a) *General rule.* Part D sponsors must charge enrollees a consolidated monthly Part D premium equal to the sum of the Part D monthly premium for basic prescription drug coverage (if any) and the premium for supplemental coverage (if any and if the beneficiary has enrolled in such supplemental coverage). Part D sponsors must also permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the sponsor using any of the methods listed in § 422.262(f) of this chapter.

(b) *Crediting of late enrollment penalty.* CMS estimates and specifies the portion of the late enrollment penalty imposed under § 423.286(d)(3) attributable to increased actuarial costs assumed by the Part D sponsor and not taken into account through risk adjustment provided under § 423.329(b)(1) or through reinsurance payments under § 423.329(c) as a result of the late enrollment.

(c) *Collection of late enrollment penalty—(1) Collection through withholding.* In the case of a late enrollment penalty that is collected by the government from a Part D eligible individual in the manner described in § 422.262(f)(1) of this chapter, CMS pays only the portion of the late enrollment penalty described in paragraph (b) of this section to the Part D sponsor offering the Part D plan in which the individual is enrolled.

(2) *Collection by plan.* In the case of a late enrollment penalty collected from a Part D eligible individual in a manner other than the manner described in § 422.262(f)(1) of this chapter, CMS reduces payments otherwise made to the Part D plan by an amount equal to the portion of the late enrollment penalty.

(d) *Special rule for fallback plans.* This section does not apply to fallback prescription drug plans. The fallback

plans follow the requirements set forth in § 423.867(b).

Subpart G—Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage

§ 423.301 Scope.

This subpart sets forth rules for the calculation and payment of CMS direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk-sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments. This subpart does not apply to fallback entities or fallback prescription drug plans.

§ 423.308 Definitions and terminology.

For the purposes of this subpart, the following definitions apply-

Actually paid means that the costs must be actually incurred by the Part D sponsor and must be net of any direct or indirect remuneration (including discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred by the Part D sponsor for the drug.

Allowable reinsurance costs means the subset of gross covered prescription drug costs actually paid that are attributable to basic prescription drug coverage for covered Part D drugs only and that are actually paid by the Part D sponsor or by (or on behalf of) an enrollee under the Part D plan. The costs for any Part D plan offering enhanced alternative coverage must be adjusted not only to exclude any costs attributable to benefits beyond basic prescription drug coverage, but also to exclude any costs determined to be attributable to increased utilization over the standard prescription drug coverage as the result of the insurance effect of enhanced alternative coverage in accordance with CMS guidelines on actuarial valuation.