

that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information.

(3) All amounts paid under the Part D plan by or on behalf of an enrollee (such as the deductible, coinsurance, cost sharing, or amounts between the initial coverage limit and the out-of-pocket threshold) in order to obtain Part D drugs that are covered under the Part D plan. If an enrollee who is paying 100 percent cost sharing (as a result of paying a deductible or because the enrollee is between the initial coverage limit and the out-of-pocket threshold) obtains a covered Part D drug at a lower cost than is available under the Part D plan, such cost-sharing will be considered an amount paid under the plan by or on behalf of an enrollee under the previous sentence of this definition, if the enrollee's costs are incurred costs as defined under § 423.100 of this part and documentation of the incurred costs has been submitted to the Part D plan consistent with plan processes and instructions for the submission of such information. These costs are determined regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

*Reopening*—(1) *Global reopening* means a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

(2) *Targeted reopening* means a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

*Target amount* means the total amount of payments (from both CMS and by or on behalf of enrollees) to a Part D plan for the coverage year for all standardized bid amounts as risk adjusted under § 423.329(b)(1) of this part, less the administrative expenses (including return on investment) assumed in the standardized bids.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1544, Jan. 12, 2009; 75 FR 19819, Apr. 15, 2010; 88 FR 22340, Apr. 12, 2023; 89 FR 30837, Apr. 23, 2024]

**§ 423.315 General payment provisions.**

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Monthly payments.* CMS provides a direct subsidy in the form of advance monthly payments equal to the Part D plan's standardized bid, risk adjusted for health status as provided in § 423.329(b), minus the monthly beneficiary premium as determined in § 423.286.

(c) *Reinsurance subsidies.* CMS provides reinsurance subsidy payments described in § 423.329(c) on a monthly basis during a year based on either estimated or incurred allowable reinsurance costs as provided under § 423.329(c)(2)(i), and final reconciliation to actual allowable reinsurance costs as provided in § 423.343(c).

(d) *Low-income subsidies.* CMS makes payments for premium and cost sharing subsidies, including additional coverage above the initial coverage limit, on behalf of certain subsidy-eligible individuals as provided in §§ 423.780 and 423.782. CMS provides low-income cost-sharing subsidy payments described in § 423.782 through interim payments of amounts as provided under § 423.329(d)(2)(i) and reconciliation to actual allowable reinsurance costs as provided in § 423.343(d).

(e) *Risk-sharing arrangements.* CMS may issue lump-sum payments or adjust monthly payments in the following payment year based on the relationship of the Part D plan's adjusted allowable risk corridor costs to predetermined risk corridor thresholds in the coverage year as provided in § 423.336.

(f) *Retroactive adjustments and reconciliations.* CMS reconciles payment year disbursements with updated enrollment and health status data, actual low-income cost-sharing costs and actual allowable reinsurance costs as provided in § 423.343.

(g) *Special rules for private fee-for-service plans*—(1) *Application of reinsurance.* For private fee-for-service plans (as defined by § 422.4(a)(3) of this chapter) offering qualified prescription drug coverage, CMS determines the amount of reinsurance payments as provided under § 423.329(c)(3).

(2) *Exemption from risk corridor provisions.* The provisions of § 423.336 regarding risk sharing do not apply.

**§ 423.322 Requirement for disclosure of information.**

(a) *Payment conditional upon provision of information.* Payments to a Part D sponsor are conditioned upon provision of information to CMS that is necessary to carry out this subpart, or as required by law.

(b) *Restrictions on use of information.*  
(1) Officers, employees, and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this subpart for the purposes of, and to the extent necessary—

(i) In carrying out this subpart, including, but not limited to, determination of payments, and payment-related oversight and program integrity activities.

(ii) In conducting oversight, evaluation, and enforcement under Title XVIII of the Act.

(2) The United States Attorney General and the Comptroller General of the United States may use the information disclosed or obtained in accordance with the provisions of this subpart for purposes of, and to the extent necessary in, carrying out health oversight activities.

(3) The restrictions described in paragraphs (b)(1) and (2) of this section do not limit either of the following:

(i) OIG's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(ii) CMS' ability to use data regarding drug claims in accordance with section 1848(m) of the Act.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 54251, Sept. 18, 2008; 80 FR 7963, Feb. 12, 2015]

**§ 423.329 Determination of payments.**

(a) *Subsidy payments—(1) Direct subsidy.* CMS makes a direct subsidy payment for each Part D eligible beneficiary enrolled in a Part D plan for a month equal to the amount of the plan's approved standardized bid, adjusted for health status (as determined under § 423.329(b)(1)), and reduced by the base beneficiary premium for the

plan (as determined under § 423.286(c) and adjusted in § 423.286(d)(1)). The direct subsidy payment may be increased by the excess amount of a negative premium as described in § 423.286(d)(1), if applicable.

(2) *Subsidy through reinsurance.* CMS makes reinsurance subsidy payments as provided under paragraph (c) of this section.

(3) *Low-income cost-sharing subsidy.* CMS makes low-income cost-sharing subsidy payments as provided under paragraph (d) of this section.

(b) *Health status risk adjustment—(1) Establishment of risk factors.* CMS establishes an appropriate methodology for adjusting the standardized bid amount to take into account variation in costs for basic prescription drug coverage among Part D plans based on the differences in actuarial risk of different enrollees being served. Any risk adjustment is designed in a manner so as to be budget neutral in the aggregate to the risk of the Part D eligible individuals who enroll in Part D plans.

(2) *Considerations.* In establishing the methodology under paragraph (b)(1) of this section, CMS takes into account the similar methodologies used under § 422.308(c) of this chapter to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(3) *Data collection.* In order to carry out this paragraph, CMS requires—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 of this chapter and other information as CMS determines necessary.

(4) *Publication.* CMS publishes the risk adjustment factors established under paragraph (b)(1) of this section for the upcoming calendar year in the