

## § 423.251

excluded from both the count of measures and the applicable improvement measures for the current and next year's Star Ratings for the affected contract. Contracts affected by extreme and uncontrollable circumstances do not have the option of reverting to the prior year's improvement rating.

(6) *Missing data.* For an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described in paragraph (i)(2)(ii) of this section applies. Missing data includes data where there is a data integrity issue as defined at § 423.184(g)(1).

(7) *Cut points for non-CAHPS measures.*

(i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms described in paragraph (a)(2) of this section.

(ii) The cut points calculated as described in paragraph (i)(7)(i) of this section are used to assess all affected contracts' measure Star Ratings.

(8) *Reward factor.* (i) Through the 2025 Star Ratings, CMS excludes the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the determination of the performance summary and variance thresholds for the reward factor described in paragraph (f)(1) of this section.

(ii) All affected contracts are eligible for the Reward Factor based on the calculations described in paragraph (i)(8)(i) of this section.

(9) *Special rules for the 2022 Star Ratings only.* For the 2022 Star Ratings only, CMS will not apply the provisions in paragraph (i)(7) or (8) of this section and CMS will not exclude the numeric values for affected contracts with 60 percent or more of their enrollees in the FEMA-designated Individual Assistance area at the time of the extreme and uncontrollable circumstance from the clustering algorithms or from the determination of the performance

## 42 CFR Ch. IV (10–1–24 Edition)

summary and variance thresholds for the Reward Factor.

(j) *Special rules for 2021 Star Ratings only.* (1) For the 2021 Star Ratings:

(i) The measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

(ii) The measure-level change score calculation described at § 423.184(f)(4)(i) is not applied for CAHPS measures and the measure-level change score used for the 2020 Star Ratings is applied in its place for all CAHPS-based measures.

(iii) The provisions of § 423.184(g)(2) are not applied for failure to submit CAHPS-based measures.

(iv) [Reserved]

(2) [Reserved]

[83 FR 16743, Apr. 16, 2018, as amended at 84 FR 15842, Apr. 16, 2019; 85 FR 19291, Apr. 6, 2020; 85 FR 33911, June 2, 2020; 85 FR 54872, Sept. 2, 2020; 86 FR 6118, Jan. 19, 2021; 87 FR 27899, May 9, 2022; 88 FR 22338, Apr. 12, 2023; 89 FR 30835, Apr. 23, 2024]

### Subpart E [Reserved]

### Subpart F—Submission of Bids and Monthly Beneficiary Premiums; Plan Approval

#### § 423.251 Scope.

This section sets forth the requirements and limitations on submission, review, negotiation and approval of competitive bids for prescription drug plans and MA-PD plans; the calculation of the national average bid amount; and the determination of enrollee premiums.

#### § 423.258 Definitions.

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

*Full risk plan* means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

*Limited risk plan* means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in § 423.265(d) in its bid submitted for the plan. This term does not include a fallback prescription drug plan.

*Standardized bid amount* means, for a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid; for a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage; for a MA-PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

**§ 423.265 Submission of bids and related information.**

(a) *Eligibility for bidding.* An applicant may submit a bid to become a Part D plan sponsor.

(b) *Bid submission*—(1) *General.* Not later than the first Monday in June, each potential Part D sponsor must submit bids and supplemental information described in this section for each Part D plan it intends to offer in the subsequent calendar year.

(2) *Substantial differences between bids*—(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception.* A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

(3) *Limit on number of plan offerings.* Potential Part D sponsors' bid submissions may include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering.

(4) *Bid acceptance.* CMS may decline to accept any or every bid submitted by a Part D sponsor or potential Part D sponsor.

(5) *Limitations on changes.* After a Part D sponsor is permitted to begin marketing prospective plan year offer-

ings for the following contract year (consistent with § 423.2263(a)), the Part D sponsor must not change, and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law.

(c) *Basic rule for bid.* Each potential Part D sponsor must submit a bid and supplemental information in a format to be specified by CMS for each Part D plan it offers. Each bid must reflect a uniform benefit package, including premium (except as provided for the late enrollment penalty described in § 423.286(d)(3)) and all applicable cost sharing, for all individuals enrolled in the plan. Each bid must reflect the applicant's estimate of its average monthly revenue requirements to provide qualified prescription drug coverage (including any supplemental coverage) for a Part D eligible individual with a national average risk profile for the factors described in § 423.329(b)(1).

(1) *Included costs.* The bid includes costs (including administrative costs and return on investment/profit) for which the plan is responsible in providing basic and supplemental benefits.

(2) *Excluded costs.* The bid does not include costs associated with payments by the enrollee for deductible, co-payments, coinsurance, and liability above the plan allowance in the case of out-of-network claims, payments projected to be made by CMS for reinsurance, or any other costs for which the sponsor is not responsible.

(3) *Actuarial valuation.* The bid must be prepared in accordance with CMS actuarial guidelines based on generally accepted actuarial principles. A qualified actuary must certify the plan's actuarial valuation (which may be prepared by others under his or her direction or review), and must be a member of the American Academy of Actuaries to be deemed qualified. Applicants may use qualified outside actuaries to prepare their bids.

(d) *Specific requirements for bids.* The bid and supplemental information submission must include the following information: