

during the term of a pharmacy reimbursement contract that is based on the cost of a drug, which includes, but is not limited to, drug pricing references and amounts based on any of the following:

- (1) Average wholesale price.
- (2) Wholesale acquisition cost.
- (3) Average manufacturer price.
- (4) Average sales price.
- (5) Maximum allowable cost.
- (6) Other cost, whether publicly available or not.

Related entity means any entity that is related to the PDP sponsor by common ownership or control and—

- (1) Performs some of the Part D plan sponsor's management functions under contract or delegation;
- (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
- (3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds \$25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 22170, Apr. 12, 2012; 80 FR 29963, Nov. 6, 2015; 89 FR 30837, Apr. 23, 2024; 89 FR 63828, Aug. 6, 2024]

§ 423.502 Application requirements.

(a) *Scope.* This section sets forth application requirements for an entity that seeks a determination from CMS that it is qualified to contract as a sponsor of a Part D plan.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting an Notice of Intent to Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the all requirements described in this part.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity is qualified to contract as a Part D plan sponsor and meets the requirements of this part.

(2) A CMS determination that an entity is qualified to act as a Part D plan sponsor is distinct from the bid negotiations that occur under subpart F of part 423 and such negotiations are not subject to the appeals provisions included in subpart N of this part.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 USC 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exemptions to disclosure), must label the material "privileged" and include an explanation of the applicability of an exemption specified in 45 CFR part 5.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19819, Apr. 15, 2010]

§ 423.503 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) *Information used to evaluate applications.* With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits and any essential operations test.

(2) *Issuing application determination.* After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(3) *Limitation on PDP contracts under a single parent organization.* CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor.

(4) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 423.503(c) when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 423.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in paragraphs (b)(2) through (4) of this section, if a Part D plan sponsor fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act

CMS may deny an application based on the applicant's failure to comply with the requirements of the Part D program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant:

(A) Was under an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(C) Filed for or is currently in federal or state bankruptcy proceedings.

(D) Received any combination of Part C or Part D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 423.186.

(E) Met or exceeded 13 points for compliance actions on any one contract.

(I) CMS determines the number of points each Part D plan sponsor accumulated during the performance period for compliance actions based on the following point values:

(i) Each corrective action plan issued during the performance period under § 423.505(n) counts for 6 points.

(ii) Each warning letter issued during the performance period under § 423.505(n) counts for 3 points.

(iii) Each notice of noncompliance issued during the performance period under § 423.505(n) counts for 1 point.

(2) CMS adds all the point values for each Part D plan sponsor to determine if any organization meets CMS' identified threshold.

(ii) CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent completed the acquisition of the

subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

(2) In the absence of 12 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part D program.

(3) If CMS has terminated, under § 423.509, or non-renewed, under § 423.507(b), a Part D plan sponsor's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's substantial failure to comply with the requirements of the Part D program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A "covered person" as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Except for fallback entities, which are governed under subpart Q of this part, CMS notifies each applicant that applies to be determined qualified to contract as a Part D plan sponsor, under this part, of its determination on the application and the basis for the determination. The determination may be one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that

it qualifies to contract as Part D plan sponsor.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear qualified to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the notice, the applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the applicant indicating—

(i) That the applicant is not qualified to contract as a Part D sponsor under Part D of title XVIII of the Act;

(ii) The reasons why the applicant does is not so qualified; and

(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

(4) *Nullification of approval of application.* If CMS discovers through any means that an applicant is not qualified to contract based on information gained subsequent to application approval (for example, failure of an essential operations test, absence of required employees, etc.), CMS gives the applicant written notice indicating that the approval issued under paragraph (c)(1) of this section is nullified and the applicant no longer qualifies to contract as a Part D plan sponsor.

(i) This determination is not subject to the appeals provisions in subpart N of this part.

(ii) This provision only applies to applicants that have not previously entered into a Part D contract with CMS and neither it, nor another subsidiary of the applicant's parent organization,