

§ 423.501 Definitions

For purposes of this subpart, the following definitions apply:

Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Business transaction means any of the following kinds of transactions:

- (1) Sale, exchange, or lease of property.
- (2) Loan of money or extension of credit.
- (3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—
 - (i) Salaries paid to employees for services performed in the normal course of their employment; or
 - (ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Party in interest means the following:

- (1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.
- (2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity;

or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

- (i) Is an officer, director, or partner; or
- (ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

Prescription drug pricing standard means any methodology or formula for varying the pricing of a drug or drugs 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]

§ 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) 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) After evaluating all relevant information, CMS determines whether the application meets all the requirements described in this part.

(3) 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.

(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