

§ 423.506

Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(1) Employees.

(2) First tier, downstream, and related entities.

(3) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary or both.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraph (p)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (p)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every Part D sponsor must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential functions that the Part D sponsor identifies under paragraph (p)(1)(ii) of this section, for purposes of this paragraph (p)(2) of this section essential functions include at a minimum, the following:

(i) Benefit authorization (if not waived), adjudication, and processing

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of prescription drug claims at the point of sale.

(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.

(iii) Provision of pharmacy technical assistance.

(iv) Operation of an enrollee exceptions and appeals process including coverage determinations.

(v) Operation of call center customer services.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 73 FR 30683, May 28, 2008; 73 FR 54251, Sept. 18, 2008; 73 FR 70599, Nov. 21, 2008; 74 FR 1545, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011; 76 FR 54634, Sept. 1, 2011; 77 FR 22170, Apr. 12, 2012; 79 FR 29964, May 23, 2014; 80 FR 7964, Feb. 12, 2015; 81 FR 80557, Nov. 15, 2016; 83 FR 16750, Apr. 16, 2018; 86 FR 6119, Jan. 19, 2021; 87 FR 27900, May 9, 2022; 88 FR 22340, Apr. 12, 2023; 89 FR 30838, Apr. 23, 2024]

§ 423.506 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the Part D plan sponsor and CMS.

(b) *Term of contract.* Each contract is for a period of 12 months.

(c) *Qualification to renew a contract.* In accordance with 423.507, an entity is determined qualified to renew its contract annually only if the Part D plan sponsor has not provided CMS with a notice of intention not to renew and CMS has not provided the Part D organization with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although a Part D plan sponsor may be determined qualified to renew its contract under this section, if the sponsor and CMS cannot reach agreement on the bid under subpart F, no renewal takes place, and the failure to reach agreement is not subject to the appeals provisions in subpart N of this part.

(e) The provisions of this section do not apply to fallback entities.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68732, Dec. 5, 2007]

§ 423.507 Nonrenewal of contract.

(a) *Nonrenewal by a Part D plan sponsor.* (1) Except for fallback entities, a

Part D plan sponsor may elect not to renew its contract with CMS, effective at the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If a Part D plan sponsor does not intend to renew its contract, it must notify—

(i) CMS in writing by the first Monday of June in the year in which the contract ends;

(ii) Each Medicare enrollee by mail at least 90 calendar days before the date on which the nonrenewal is effective. The sponsor must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan and PDP options available for obtaining qualified prescription drug coverage within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3)(i) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years in the PDP region or regions served by the contract unless there are circumstances that warrant special consideration, as determined by CMS.

(ii) If a PDP sponsor does not renew any of its PBPs in a PDP region, CMS does not approve plan bids submitted by the organization in that PDP region for 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(iii) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.

(4) During the same 2-year period specified under paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who

have an ownership interest of less than 5 percent.

(ii) An owner of a whole or part interest in a mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or by 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.

(5) If a Part D plan sponsor does not renew a contract under this paragraph (a), it must ensure the timely transfer of any data or files.

(b) [Reserved]

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 74 FR 1546, Jan. 12, 2009; 75 FR 19821, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011; 83 FR 16750, Apr. 16, 2018; 89 FR 30838, Apr. 23, 2024]

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent. If the PDP sponsor submits a request to end the term of its contract after the deadline provided in § 423.507(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (b) through (f) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare Part D program.

(b) *Notification of termination.* If the contract is terminated by mutual consent, the Part D plan sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

(c) *Notification of modification.* If the contract is modified by mutual consent, the Part D plan sponsor must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(d) *Timely transfer of data and files.* If a contract is terminated under paragraph (a) of this section, the Part D plan sponsor must ensure the timely transfer of any data or files.