

effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the prospective monthly payments made to the Part D sponsor covering the period of the month following the contract termination.

(ii) CMS notifies the Part D plan sponsor's Medicare enrollees in writing of CMS's decision to terminate the Part D plan sponsor's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the Part D plan sponsor's contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining qualified prescription drug coverage, including alternative PDP sponsors and MA-PDs in a similar geographic area.

(iii) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the Part D plan sponsor's contract. This notice is published in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(c) *Corrective action plan*—(1) *General rule*. Before terminating a contract for reasons other than the grounds specified in paragraph (a)(4) or (a)(5) of this section, CMS provides the Part D plan sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(2) *Exception*. If a contract is terminated under paragraph (a)(4) or (a)(5) of this section, the Part D plan sponsor does not have the opportunity to submit a corrective action plan.

(d) *Appeal rights*. If CMS decides to terminate a contract, it sends written notice to the Part D plan sponsor informing it of its termination appeal rights in accordance with § 423.642.

§ 423.510 Termination of contract by the Part D sponsor.

(a) *Cause for termination*. The Part D plan sponsor may terminate its contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice of termination*. The Part D plan sponsor must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the Part D sponsor is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining qualified prescription drug coverage within the services area, including alternative PDPs, MA-PDPs, and original Medicare and must receive CMS approval.

(3) To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's geographic area.

(c) *Effective date of termination*. The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the Part D plan sponsor's notice of intent to terminate.

(d) *CMS's liability*. CMS's liability for payment to the Part D plan sponsor ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization*. CMS does not enter into an agreement with an organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS.

(f) *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.

§ 423.512 Minimum enrollment requirements.

(a) *Basic rule*. Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement:

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(1) At least 5,000 individuals are enrolled for the purpose of receiving prescription drug benefits from the organization; or

(2) At least 1,500 individuals are enrolled for purposes of receiving prescription drug benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) of this chapter;

(3) Except as provided for in paragraph (b) of this section, a Part D plan sponsor must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* CMS waives the requirement of paragraphs (a)(1) and (a)(2) of this section during the first contract year for a sponsor in a region.

§ 423.514 Reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following—

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) Information demonstrating that the Part D plan sponsor has a fiscally sound operation.

(5) Other matters that CMS may require.

(b) *Significant business transactions.* Each Part D plan sponsor must report to CMS annually, within 120 days of the end of its fiscal year (unless, for good cause shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions, as defined in § 423.501, between the Part D plan sponsor and a party in interest, including the following:

(i) Indication that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(2) A combined financial statement for the Part D plan sponsor and a party in interest if either of the following conditions is met:

(i) Thirty five percent or more of the costs of operation of the Part D sponsor go to a party in interest.

(ii) Thirty five percent or more of the revenue of a party in interest is from the Part D plan sponsor.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(2) of this section must display in separate columns the financial information for the Part D plan sponsor and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must be examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from a Part D plan sponsor showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) of this section for a particular entity.

(d) *Reporting and disclosure under Employee Retirement Income Security Act of 1974 (ERISA).* (1) For any employees' health benefits plan that includes a Part D plan sponsor in its offerings, the PDP sponsor must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (for the particular PDP sponsor) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The PDP sponsor must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each Part D plan sponsor must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

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