

(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.

(e) *Agreement to limit new Part D applications.* As a condition of the consent to a mutual termination, CMS will require, as a provision of the termination agreement language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions for a period up to 2 years, absent circumstances warranting special consideration.

(f) *Prohibition against Part D program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the 2-year period specified in paragraph (e) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A “covered person” as used in this paragraph means one of the following:

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

(2) 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 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.

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

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19821, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011]

§ 423.509 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the Part D plan sponsor meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) Based on credible evidence, has committed or participated in false, fraudulent, or abusive activities affecting the Medicare, Medicaid, or other State or Federal health care programs, including submission of false or fraudulent data.

(5) Substantially fails to comply with the requirements in subpart M of this part relating to grievances and appeals.

(6) Fails to provide CMS with valid risk adjustment, reinsurance and risk corridor related data as required under § 423.322 and § 423.329 (or, for fallback entities, fails to provide the information in § 423.871(f)).

(7) Substantially fails to comply with the service access requirements in § 423.120.

(8) Substantially fails to comply with either of the following:

(i) Marketing requirements in subpart V of this part.

(ii) Information dissemination requirements of § 423.128 of this part.

(9) Substantially fails to comply with the coordination with plans and programs that provide prescription drug coverage as described in subpart J of this part.

(10) Substantially fails to comply with the cost and utilization management, quality improvement, medication therapy management and fraud, abuse and waste program requirements as specified in subparts D and K of this part.

(11) Fails to comply with the regulatory requirements contained in this part.

(12) Fails to meet CMS performance requirements in carrying out the regulatory requirements contained in this part.

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.* (i) CMS notifies the Part D plan in writing 90 days before the intended date of the termination.

(ii) The Part D plan sponsor notifies its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

(iii) The Part D plan sponsor notifies the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D plan sponsor's service area.

(iv) If a Part D plan sponsor's contract is terminated under paragraph (a) of this section, it must ensure the timely transfer of any data or files.

(2) *Immediate termination of contract by CMS.* (i) The procedures specified in (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(B) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the violation specified in paragraph (a)(4) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the Part D plan sponsor covering the period of the month following the contract termination.

(iii) 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.

(iv) 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) *Opportunity to develop and implement a corrective action plan*—(1) *General.* (i) Before providing a notice of intent to terminate the contract, CMS will provide the Part D plan sponsor with notice specifying the Part D plan sponsor's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The Part D plan sponsor is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions.* The Part D plan sponsor will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the Part D plan sponsor;

(ii) The Part D plan sponsor experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4) of this section.

(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

(e) *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.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 73 FR 20507, Apr. 15, 2008; 75 FR 19822, Apr. 15, 2010; 76 FR 21575, Apr. 15, 2011]

§ 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.* (1) 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.

42 CFR Ch. IV (10–1–11 Edition)

(2) During the same 2-year period specified in (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating 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 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.

(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.

[70 FR 4525, Jan. 28, 2005, as amended at 76 FR 21575, Apr. 15, 2011]

§ 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:

(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.