

(f) *Enrollee access to information.* Each Part D plan sponsor must make the information reported to CMS under this section available to its enrollees upon reasonable request.

**§ 423.516 Prohibition of midyear implementation of significant new regulatory requirements.**

CMS may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

**Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract**

**§ 423.551 General provisions.**

(a) *Change of ownership.* The following constitute a change of ownership:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer.* Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation.* The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception.* Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement.* If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

**§ 423.552 Novation agreement requirements.**

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed

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copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

- (i) The proposed new owner is in fact a successor in interest to the contract.
- (ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.
- (iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

- (i) Guarantee performance of the contract by the new owner during the contract period; or
- (ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

**§ 423.553 Effect of leasing of a PDP sponsor's facilities.**

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor,

it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

**Subpart M—Grievances, Coverage Determinations, and Appeals**

**§ 423.560 Definitions.**

As used in this subpart, unless the context indicates otherwise—

*Appeal* means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

*Appointed representative* means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.

*Drug Use* means an enrollee is receiving the drug in the course of treatment, including time off if it is part of the treatment.

*Enrollee* means a Part D eligible individual who has elected or has been enrolled in a Part D plan.