

(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