

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

§ 423.558 Scope.

(a) This subpart sets forth the requirements relating to the following:

(1) Part D plan sponsors with respect to grievances, coverage determinations, and redeterminations.

(2) Part D IRE with respect to reconsiderations.

(3) Part D enrollees' rights with respect to grievances, coverage determinations, redeterminations, and reconsiderations.

(4) Review of at-risk determinations made under a drug management program in accordance with § 423.153(f).

(b) The requirements regarding reopenings, ALJ hearings and ALJ and attorney adjudicator decisions, Council review, and judicial review are set forth in subpart U of this chapter.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5125, Jan. 17, 2017; 83 FR 16750, Apr. 16, 2018]

§ 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