

§ 423.553

42 CFR Ch. IV (10–1–06 Edition)

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.

Grievance means any complaint or dispute, other than one that involves a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

Physician has the meaning given the term in section 1861(r) of the Act.

Projected value means the charges incurred by the enrollee and future charges that are incurred within 12 months from the date the request for coverage determination or exception is received by the plan. Projected value includes enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

Reconsideration means a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

§ 423.562 General provisions.

(a) *Responsibilities of the Part D plan sponsor.* A Part D plan sponsor must meet all of the following requirements.

(1) A Part D plan sponsor, for each Part D plan that it offers, must establish and maintain—

(i) A grievance procedure as described in § 423.564 for addressing issues that do not involve coverage determinations;

(ii) A procedure for making timely coverage determinations, including determinations on requests for exceptions to a tiered cost-sharing structure or to a formulary; and

(iii) Appeal procedures that meet the requirements of this subpart for issues that involve coverage determinations.

(2) A Part D plan sponsor must ensure that all enrollees receive written information about the—

(i) Grievance and appeal procedures that are available to them through the Part D plan sponsor; and

(ii) Complaint process available to the enrollee under the QIO process as set forth under section 1154(a)(14) of the Act.

(3) A Part D plan sponsor must arrange with its network pharmacies to post or distribute notices instructing enrollees to contact their plans to obtain a coverage determination or request an exception if they disagree with the information provided by the pharmacist.

(4) In accordance with subpart K of this part, if the Part D plan sponsor delegates any of its responsibilities under this subpart to another entity or individual through which the Part D plan sponsor provides covered benefits, the Part D plan sponsor is ultimately responsible for ensuring that the entity or individual satisfies the relevant requirements of this subpart.

(b) *Rights of enrollees.* In accordance with the provisions of this subpart, enrollees have all of the following rights under Part D plans:

(1) The right to have grievances between the enrollee and the Part D plan sponsor heard and resolved by the plan sponsor, as described in § 423.564.

(2) The right to a timely coverage determination by the Part D plan sponsor, as specified in § 423.566 and § 423.568, including the right to request from the Part D plan sponsor an exception to its tiered cost-sharing structure or formulary, as specified in § 423.578.

(3) The right to request from the Part D plan sponsor an expedited coverage determination, as specified in § 423.570.

(4) If dissatisfied with any part of a coverage determination, all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of a redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.