

(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

enrollee must pay for the drug coverage, as defined in § 423.566(b). Appeal also includes the review of at-risk determinations made under a drug management program in accordance with § 423.153(f). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (Council), and judicial reviews.

At-risk determination means a decision made under a plan sponsor's drug management program in accordance with § 423.153(f) that involves the identification of an individual as an at-risk beneficiary for prescription drug abuse; a limitation, or the continuation of a limitation, on an at-risk beneficiary's access to coverage for frequently abused drugs (that is, a beneficiary specific point-of-sale edit or the selection of a prescriber and/or pharmacy and implementation of lock-in, or); and information sharing for subsequent plan enrollments.

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 or at-risk 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.

Other prescriber means a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

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

Projected value of a Part D drug or drugs includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. 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 or at-risk 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 or at-risk 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.

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 filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, 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.

Specialty tier: (1) Before January 1, 2022, means a formulary cost-sharing tier dedicated to very high cost Part D drugs that exceed a cost threshold established by the Secretary; and

(2) Beginning January 1, 2022, has the meaning given the term in § 423.104.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1546, Jan. 12, 2009; 82 FR 5125, Jan. 17, 2017; 83 FR 16750, Apr. 16, 2018; 86 FR 6119, Jan. 19, 2021]

§ 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) Use a single, uniform exceptions and appeals process which includes procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128(b)(7) and (d)(1)(iv).