of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

(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.

(iv) If the IRE affirms the plan's adverse coverage determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.1970.

(v) If the ALJ affirms the IRE's adverse coverage determination, in whole or in part, the right to request MAC review of the ALJ hearing decision, as specified in § 423.1974.

(vi) If the MAC affirms the ALJ's adverse coverage determination, in whole or in part, the right to judicial review of the hearing decision if the amount in controversy meets the requirements in § 423.1976.

(c) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 422, subpart M of this chapter (concerning the administrative review and hearing processes under titles II and XVIII, and representation of parties under title XVIII of the Act) and any interpretive rules or CMS rulings issued under these regulations, apply under this subpart to the extent they are appropriate.

(d) *Relation to ERISA Requirements.* Consistent with section 1860D–22(b) of the Act, provisions of this subpart may, to the extent applicable under the regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 76 FR 21575, Apr. 15, 2011]

§ 423.564 Grievance procedures.

(a) *General rule.* Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits under any Part D plan it offers.

(b) *Distinguished from appeals.* Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

(c) *Distinguished from the quality improvement organization complaint process.* Under section 1154(a)(14) of the Act, the quality improvement organization (QIO) must review enrollees' written complaints about the quality of services they have received under the Medicare program. This process is separate and distinct from the grievance procedures of the Part D plan sponsor. For quality of care issues, an enrollee may file a grievance with the Part D plan sponsor, file a written complaint with

the QIO, or both. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(d) *Method for filing a grievance.* (1) An enrollee may file a grievance with the Part D plan sponsor either orally or in writing.

(2) An enrollee must file a grievance no later than 60 calendar days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification.* (1) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 calendar days after the date the Part D plan sponsor receives the oral or written grievance.

(2) The Part D plan sponsor may extend the 30 calendar day timeframe by up to 14 calendar days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay.

(3) The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint.

(f) *Expedited grievances.* A Part D plan sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves a refusal by the Part D plan sponsor to grant an enrollee's request for an expedited coverage determination under § 423.570 or an expedited redetermination under § 423.584, and the enrollee has not yet purchased or received the drug that is in dispute.

(g) *Record keeping.* The Part D plan sponsor must have an established process to track and maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the enrollee was notified of the disposition.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009]

§ 423.566 Coverage determinations.

(a) *Responsibilities of the Part D plan sponsor.* Each Part D plan sponsor must have a procedure for making timely coverage determinations in accordance with the requirements of this subpart regarding the prescription drug benefits an enrollee is entitled to receive under the plan, including basic prescription drug coverage as specified in § 423.100 and supplemental benefits as specified in § 423.104(f)(1)(ii), and the amount, including cost sharing, if any, that the enrollee is required to pay for a drug. The Part D plan sponsor must have a standard procedure for making determinations, in accordance with § 423.568, and an expedited procedure for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum function, in accordance with § 423.570.

(b) *Actions that are coverage determinations.* The following actions by a Part D plan sponsor are coverage determinations:

(1) A decision not to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excludable under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

(2) Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

(3) A decision concerning an exceptions request under § 423.578(a);