

known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(6) If the physician provides an oral supporting statement, the Part D plan sponsor may require the physician to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

(c) *Requirements for exceptions*—(1) *General rule.* A decision by a Part D plan sponsor concerning an exceptions request under this section constitutes a coverage determination as specified at § 423.566.

(2) When a Part D plan sponsor does not make a timely decision. If the Part D plan sponsor fails to make a decision on an exceptions request and provide notice of the decision within the timeframe required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication timeframe.

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under § 423.578(a) is approved, the Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies for preferred drugs, and may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(i) The enrollee's prescribing physician continues to prescribe the drug;

(ii) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(iii) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(4) *When a non-formulary exceptions request is approved.* Whenever an exceptions request made under § 423.578(b) is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).

(d) *Notice regarding formulary changes.* Whenever a Part D plan sponsor removes a covered part D drug from its formulary or makes any changes in the preferred or tiered cost-sharing status of such a drug, the Part D plan sponsor must provide notice in accordance with § 423.120(b)(5).

(e) *Limitation of the exceptions procedures to Part D drugs.* Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug.

(f) *Implication of the physician's supporting statement.* Nothing in this section should be construed to mean that the physician's supporting statement required for an exceptions request will result in an automatic favorable determination.

§ 423.580 Right to a redetermination.

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.634) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. An enrollee or an enrollee's prescribing

§ 423.582

42 CFR Ch. IV (10–1–07 Edition)

physician (acting on behalf of an enrollee) may request an expedited redetermination specified in § 423.584.

§ 423.582 Request for a standard redetermination.

(a) *Method and place for filing a request.* An enrollee must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, an enrollee must file a request for a redetermination within 60 calendar days from the date of the notice of the coverage determination.

(c) *Extending the time for filing a request—*(1) *General rule.* If an enrollee shows good cause, the Part D plan sponsor may extend the timeframe for filing a request for redetermination.

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor. The request for redetermination and to extend the timeframe must—

- (i) Be in writing; and
 - (ii) State why the request for redetermination was not filed on time.
- (d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a written request with the Part D sponsor.

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b). (This does not include requests for payment of drugs already furnished.)

(b) *How to make a request.* (1) To ask for an expedited redetermination, an enrollee or a prescribing physician acting on behalf of an enrollee must submit an oral or written request directly to the Part D plan sponsor or, if applicable, to the entity responsible for making the redetermination, as directed by the Part D plan sponsor.

(2) A prescribing physician may provide oral or written support for an enrollee's request for an expedited redetermination.

(c) *How the Part D plan sponsor must process requests.* The Part D plan sponsor must establish and maintain the following procedures for processing requests for expedited redetermination:

(1) *Handling of requests.* The Part D plan sponsor must establish an efficient and convenient means for individuals to submit oral or written requests, document all oral requests in writing, and maintain the documentation in the case file.

(2) *Prompt decision making.* The Part D plan sponsor must promptly decide whether to expedite the redetermination or follow the timeframe for standard redetermination based on the following requirements:

(i) For a request made by an enrollee, the Part D plan sponsor must provide an expedited redetermination if it determines that applying the standard timeframe for making a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) For a request made or supported by a prescribing physician, the Part D plan sponsor must provide an expedited redetermination if the physician indicates that applying the standard timeframe for conducting a redetermination may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(d) *Actions following denial of a request.* If a Part D plan sponsor denies a request for expedited redetermination, it must take the following actions:

(1) Make the determination within the 7-day timeframe established in § 423.590(a). The 7-day period begins the day the Part D plan sponsor receives the request for expedited redetermination.

(2) Give the enrollee prompt oral notice of the denial that—

- (i) Explains that the Part D plan sponsor processes the enrollee's request using the 7-day timeframe for standard redetermination;
- (ii) Informs the enrollee of the right to file an expedited grievance if he or