

§ 423.584

42 CFR Ch. IV (10–1–24 Edition)

(d) *Withdrawing a request.* The person who files a request for redetermination may withdraw it by filing a request with the Part D sponsor.

(e) *Dismissing a request.* A Part D plan sponsor dismisses a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 423.580.

(2) When the Part D plan sponsor determines the party failed to make out a valid request for redetermination that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) When the enrollee or the enrollee's representative files a request for redetermination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(5) When a party filing the redetermination request submits a timely request for withdrawal of the request for a redetermination with the Part D plan sponsor.

(f) *Notice of dismissal.* The Part D plan sponsor must mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(g) *Vacating a dismissal.* If good cause is established, a Part D sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless the enrollee or other party requests review by the IRE or the deci-

sion is vacated under paragraph (g) of this section.

[74 FR 1547, Jan. 12, 2009, as amended at 74 FR 65363, Dec. 9, 2009; 83 FR 16752, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024]

§ 423.584 Expediting certain redeterminations.

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in § 423.566(b) or an at-risk determination made under a drug management program in accordance with § 423.153(f). (This does not include requests for payment of drugs already furnished.)

(b) *Procedure and timeframe for filing a request.* A request for a redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or at-risk determination notice. (1) To ask for an expedited redetermination, an enrollee or a prescribing physician or other prescriber 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 or other prescriber may provide oral or written support for an enrollee's request for an expedited redetermination.

(3) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified in the Part D plan sponsor's written coverage determination or at-risk determination.

(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 or other prescriber, the Part D plan sponsor must provide an expedited redetermination if the physician or other prescriber 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 calendar day timeframe established in § 423.590(a). The 7 calendar 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 calendar day timeframe for standard redetermination;

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the decision by the Part D plan sponsor not to expedite;

(iii) Informs the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support; and

(iv) Provides instructions about the expedited grievance process and its timeframes.

(3) Subsequently deliver, within three calendar days, equivalent written notice.

(e) *Action following acceptance of a request.* If a Part D plan sponsor grants a request for expedited redetermination, it must conduct the redetermination and give notice in accordance with § 423.590(d).

(f) *Dismissing a request.* The Part D plan sponsor dismisses an expedited redetermination in accordance with § 423.582.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 74 FR 1547, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009; 83 FR 16752, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021; 89 FR 30841, Apr. 23, 2024; 89 FR 63828, Aug. 6, 2024]

§ 423.586 Opportunity to submit evidence.

The Part D plan sponsor must provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing. In the case of an expedited redetermination, the opportunity to present evidence is limited by the short timeframe for making a decision. Therefore, the Part D plan sponsor must inform the enrollee or the prescribing physician or other prescriber of the conditions for submitting the evidence.

[74 FR 1548, Jan. 12, 2009]

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits or review of an at-risk determination.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1) or (3) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in

whole or in part, its adverse coverage determination or at-risk determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) *Standard redetermination—request for payment.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 14 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 14 calendar days from the date it receives the request for redetermination.

(c) *Effect of failure to meet timeframe for standard redeterminations.* If the Part D plan sponsor fails to provide the enrollee with a redetermination within the timeframes specified in paragraphs (a) or (b) of this section, the failure constitutes an adverse redetermination decision, 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.

(d) *Expedited redetermination—(1) Timeframe.* A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician or other prescriber involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Confirmation of oral notice.* If the Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited redetermination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

(3) How the Part D plan sponsor must request additional information. If the Part D plan sponsor must receive medical information, the Part D plan spon-

sor must request the necessary information within 24 hours of the initial request for an expedited redetermination. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the timeframe and notice requirements.

(e) *Failure to meet timeframe for expedited redetermination.* If the Part D plan sponsor fails to provide the enrollee or the prescribing physician or other prescriber, as appropriate, with the results of its expedited redetermination within the timeframe described in paragraph (d) of this section, the failure constitutes an adverse redetermination decision, 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.

(f) *Who must conduct the review of an adverse coverage determination or at-risk determination.* (1) A person or persons who were not involved in making the coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f) must conduct the redetermination.

(2) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the redetermination need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

(g) *Form and content of an adverse redetermination notice.* The notice of any adverse determination under paragraphs (a)(2), (b)(2), (d)(1) or (d)(2) of this section must—

(1) Use approved notice language in a readable and understandable form;

(2) State the specific reasons for the denial;

(3) Inform the enrollee of his or her right to a reconsideration;

(i) For adverse drug coverage redeterminations, or redeterminations related to a drug management program in accordance with § 423.153(f), describe both