

(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).

[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]

§ 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.* (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)) 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, 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 7 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 7 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 sponsor 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 re-

sponsible 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.* (1) A person or persons who were not involved in making the coverage determination 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, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

(ii) For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

(4) Comply with any other notice requirements specified by CMS.

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(h) *Form and content of a completely favorable redetermination notice.* The notice of any completely favorable determination under paragraphs (a)(1), (d)(1) or (d)(2) of this section must explain the conditions of the approval in a readable and understandable form.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010]

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. An enrollee must file a written request for reconsideration with the IRE within 60 calendar days of the date of the redetermination by the Part D plan sponsor.

(b) When an enrollee files an appeal, the IRE is required to solicit the views of the prescribing physician or other prescriber. The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing. A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE's record.

(c) In order for an enrollee to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide for a Part D drug that is not on the formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

(d) The independent review entity must conduct the reconsideration as expeditiously as the enrollee's health condition requires but must not exceed the deadlines applicable in § 423.590, including those deadlines that are applicable when a request for an expedited reconsideration is received and granted.

(e) When the issue is the denial of coverage based on a lack of medical necessity (or any substantively equivalent

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term used to describe the concept of medical necessity), the reconsideration 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 reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician or other prescriber.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009]

§ 423.602 Notice of reconsideration determination by the independent review entity.

(a) *Responsibility for the notice.* When the IRE makes its reconsideration determination, it is responsible for mailing a notice of its determination to the enrollee and the Part D plan sponsor, and for sending a copy to CMS.

(b) *Content of the notice.* The notice must—

(1) State the specific reasons for the IRE's decision in understandable language;

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.1970;

(3) Describe the procedures that must be followed to obtain an ALJ hearing; and

(4) Comply with any other requirements specified by CMS.

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

§ 423.604 Effect of a reconsideration determination.

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.1972.

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