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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 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.

(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.

(i) *Automatic forwarding of redeterminations made under a drug management program.* If on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS within 24 hours of the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

(j) *Requests for review of a dismissal by the independent entity.* If the Part D plan sponsor dismisses a request for a reconsideration in accordance with § 423.582(e) or § 423.584(f), the enrollee or other proper party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the Part D plan sponsor's dismissal notice.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 75 FR 19823, Apr. 15, 2010; 83 FR 16752, Apr. 16, 2018; 86 FR 6120, Jan. 19, 2021]

§ 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. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the 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, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee), files an appeal or a determination is forwarded to the IRE by a Part D plan sponsor, the IRE is required to solicit the views of the prescribing physician or other prescriber.

(1) The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing.

(2) 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 record.

(c) In order for an enrollee or a prescribing physician or other prescriber (acting on behalf of 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 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.

(f) The party who files a request for reconsideration may withdraw it by filing a request with the IRE.

(g) The independent entity dismisses a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a reconsideration is not a proper party under paragraph (a) of this section.

(2) When the IRE determines the party failed to make out a valid request for reconsideration that substantially complies with paragraph (a) of this section.

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

(4) When an enrollee or the enrollee's representative files a request for reconsideration, 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 continue the appeal.

(5) When a party filing the reconsideration request submits a timely request for withdrawal of the request for a reconsideration with the IRE.

(h) The IRE mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the IRE vacate the dismissal action.

(3) The right to a review of the dismissal in accordance with § 423.2004.

(i) If good cause is established, the IRE may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(j) An enrollee has a right to have an IRE's dismissal reconsidered in accordance with § 423.2004.

(k) If the IRE determines that the Part D plan sponsor's dismissal was in error, the IRE vacates the dismissal and remands the case to the Part D plan sponsor for reconsideration consistent with § 423.590. The IRE's decision regarding an Part D plan sponsor's dismissal, including a decision to deny

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a request for review of a dismissal, is binding and not subject to further review.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1548, Jan. 12, 2009; 74 FR 65363, Dec. 9, 2009; 77 FR 22171, Apr. 12, 2012; 86 FR 6120, Jan. 19, 2021]

§ 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. When the prescribing physician or other prescriber requests the reconsideration on behalf of the enrollee, the IRE is also responsible for notifying the prescribing physician or other prescriber of its decision.

(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 or redetermination 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 § 423.2006;

(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; 77 FR 22171, Apr. 12, 2012; 83 FR 16752, Apr. 16, 2018; 84 FR 19872, May 7, 2019]

§ 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 § 423.2014.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 84 FR 19872, May 7, 2019]

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§§ 423.610–423.634 [Reserved]

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) *Reversals by the Part D plan sponsor—*(1) *Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(3) *Review of an at-risk determination.* If, on redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor—*(1) *Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the