

entity specified in the ALJ's or attorney adjudicator's written notice of decision.

(3) *Denial of a request.* If the Council denies a request for expedited review, the Council must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee and Part D plan sponsor within 5 calendar days of receiving the request written notice of the denial. The written notice must inform the enrollee of the denial and explain that the Council will process the enrollee's request using the 90 calendar day timeframe for non-expedited reviews.

(4) *Decision on a request.* A decision on a request for expedited review may not be appealed.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137 Jan. 17, 2017]

§ 423.2110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or the IRE may refer a case to the Council for it to consider reviewing under this authority any time within 60 calendar days of receipt of an ALJ's or attorney adjudicator's written decision or dismissal.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the Council if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the appeal or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the Council take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' or the IRE's referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney

adjudicator's written decision or dismissal is received.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review*—(1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA proceedings.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal,

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may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

(e) *Referral timeframe.* For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

[82 FR 5137, Jan. 17, 2017, as amended at 84 FR 19874, May 7, 2019]

§ 423.2112 Content of request for review.

(a)(1) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(2) The request for review must be in writing and may be made on a standard form, except for requests for expedited reviews which may be made orally.

(3) The Council must document all oral requests in writing and maintain the documentation in the case file.

(4) A written request that is not made on a standard form or, for expedited requests, an oral request, is accepted if it includes the enrollee's name and telephone number, the plan name; Medicare number; the ALJ appeal number; the specific Part D drug(s) for which the review is requested; a statement that the enrollee is requesting an expedited review, if applicable; and the name of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ or attorney adjudicator action with which the en-

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rollee requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. For purposes of this section only, a representative is either anyone with a valid appointment as the enrollee's representative or is a member of the enrollee's family, a legal guardian or an individual who routinely acts on behalf of the enrollee, such as a family member or friend who has a power of attorney.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 84 FR 19874, May 7, 2019]

§ 423.2114 Dismissal of request for review.

The Council dismisses a request for review if the enrollee requesting review did not file the request within the stated period of time and the time for filing has not been extended. The Council also dismisses the request for review if—

(a) The enrollee asks to withdraw the request for review;

(b) The individual or entity does not have a right to request Council review; or

(c) The enrollee died while the request for review is pending and the enrollee's estate or representative, if any, either has no remaining financial interest in the case or does not want to continue the appeal.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2116 Effect of dismissal of request for Council review or request for hearing.

The dismissal of a request for Council review or denial of a request for review of a dismissal issued by an ALJ or attorney adjudicator is binding and not subject to further review unless reopened and vacated by the Council. The Council's dismissal of a request for