

standards outlined at § 405.942(b)(2) and (3) of this chapter.

(c) An enrollee does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to an IRE, or an ALJ's or attorney adjudicator's affirmation of an IRE's dismissal of a request for reconsideration, or dismissal of a request to review an IRE dismissal.

[82 FR 5137, Jan. 17, 2017]

§ 423.2106 Where a request for review may be filed.

When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a written decision or dismissal, the request for review must be submitted to the entity specified in the notice of the ALJ's or attorney adjudicator's action. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the enrollee of the date of receipt of the request and commencement of the adjudication timeframe.

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

§ 423.2108 Council Actions when request for review is filed.

(a) *General.* Except as specified in paragraph (c) of this section, when an enrollee requests that the Council review an ALJ's or attorney adjudicator's decision, the Council will review the ALJ's or attorney adjudicator's decision de novo. The enrollee requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence admitted into the administrative record. Upon completion of its review, the Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or remand the case to the ALJ or attorney adjudicator for further pro-

ceedings. Unless the Council's review is expedited as provided in paragraph (d) of this section, the Council must issue its action no later than 90 calendar days after receiving the request for review, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *Review of ALJ's or attorney adjudicator's dismissal of a request for a hearing.* When an enrollee requests that the Council review an ALJ's or attorney adjudicator's dismissal of a request for a hearing, the Council may deny review or vacate the dismissal and remand the case to the ALJ or attorney adjudicator for further proceedings.

(c) *Council dismissal of request for review.* The Council will dismiss a request for review when the individual or entity requesting review does not have a right to a review by the MAC, or will dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request for hearing.

(d) *Expedited reviews.* (1) *Standard for expedited reviews.* The Council must provide an expedited review if the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, enrollee's prescribing physician or other prescriber indicates, or the Council determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. The Council may consider this standard as met if a lower level adjudicator has granted a request for an expedited appeal.

(2) *Grant of a request.* If the Council grants 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 prompt oral notice of this decision; and

(iii) Issue a decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received by the

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,