

§ 423.2108

42 CFR Ch. IV (10–1–13 Edition)

filed with an entity other than the entity specified in the notice of the ALJ's action, the MAC'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 action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the MAC sends written notice to the enrollee of the date of receipt of the request and commencement of the adjudication timeframe.

§ 423.2108 MAC Actions when request for review is filed.

(a) *General.* Except as specified in paragraph (c) of this section, when an enrollee requests that the MAC review an ALJ's decision, the MAC will review the ALJ's decision de novo. The enrollee requesting review does not have a right to a hearing before the MAC. The MAC will consider all of the evidence admitted into the administrative record. Upon completion of its review, the MAC may adopt, modify, or reverse the ALJ's decision or remand the case to the ALJ for further proceedings. Unless the MAC's review is expedited as provided in paragraph (d) of this section, the MAC 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 dismissal.* When an enrollee requests that the MAC review an ALJ's dismissal, the MAC may deny review or vacate the dismissal and remand the case to the ALJ for further proceedings.

(c) *MAC dismissal of request for review.* The MAC 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 could have dismissed the request for hearing.

(d) *Expedited reviews.* (1) *Standard for expedited reviews.* The MAC 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 MAC 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 MAC 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 MAC grants a request for expedited review, the MAC 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 written notice of decision.

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

§ 423.2110 MAC reviews on its own motion.

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

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the MAC if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the

claim or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the MAC take own motion review of a case if—

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

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

(2) CMS' or the IRE's referral to the MAC is made in writing and must be filed with the MAC no later than 60 calendar days after the ALJ's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the MAC 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 ALJ.

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

(iv) An enrollee submitting comments to the MAC 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 ALJ level.* If CMS or the IRE participated or requested to participate in an appeal at the ALJ level, the MAC 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, 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 MAC will limit its consideration of the ALJ'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 ALJ proceedings.* The MAC 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 MAC will limit its consideration of the ALJ's action to those exceptions raised by CMS or the IRE.

(d) *MAC's action.* (1) If the MAC 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 MAC may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ for further proceedings or may dismiss a hearing request.

(3) The MAC 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 MAC 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 MAC declines to review a decision or dismissal on its own motion, the ALJ's decision or dismissal is binding.

§ 423.2112 Content of request for review.

(a)(1) The request for MAC review must be filed with the entity specified in the notice of the ALJ'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 MAC 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 health insurance claim 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 and signature of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ action with which the enrollee requesting review