

determination to be considered in the appeal.

**§ 423.2128 Action of the MAC.**

(a) After it has reviewed all the evidence in the administrative record and any additional evidence received, subject to the limitations on MAC consideration of additional evidence in § 423.2122, the MAC will make a decision or remand the case to an ALJ.

(b) The MAC may adopt, modify, or reverse the ALJ hearing decision or recommended decision.

(c) The MAC mails a copy of its decision to the enrollee at his or her last known address, to CMS, to the IRE, and to the Part D plan sponsor.

**§ 423.2130 Effect of the MAC's decision.**

The MAC's decision is final and binding unless a Federal District Court issues a decision modifying the MAC's decision or the decision is revised as the result of a reopening in accordance with § 423.1980. An enrollee may file an action in a Federal District Court within 60 calendar days after the date the enrollee receives written notice of the MAC's decision.

**§ 423.2134 Extension of time to file action in Federal District Court.**

(a) An enrollee may request that the time for filing an action in a Federal District Court be extended.

(b) The request must:

(1) Be in writing.  
(2) Give the reasons why the action was not filed within the stated time period.

(3) Be filed with the MAC.

(c) If the enrollee shows that he or she had good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the MAC uses the standards specified in §§ 405.942(b)(2) or (b)(3) of this chapter.

**§ 423.2136 Judicial review.**

(a) *General rule.* To the extent authorized by sections 1876(c)(5)(B) and 1860D-4(h) of the Act and consistent with § 423.1976, an enrollee may obtain a court review of a MAC decision if the amount in controversy meets the threshold requirement estimated annually by the Secretary.

(b) *Court in which to file civil action.*

(1) Consistent with § 423.1976(c), any civil action described in paragraph (a) of this section must be filed in the District Court of the United States for the judicial district in which the enrollee resides.

(2) If the enrollee does not reside within any judicial district, the civil action must be filed in the District Court of the United States for the District of Columbia.

(c) *Time for filing civil action.* (1) Any civil action described in paragraph (a) of this section must be filed within the time periods specified in § 423.2130 or § 423.2134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the MAC's decision shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 423.1990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or MAC, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff enrollee will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

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(2) When the Secretary's decision is adverse to an enrollee due to an enrollee's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof an enrollee must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

**§ 423.2138 Case remanded by a Federal District Court.**

When a Federal District Court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in § 423.2140 will be followed.

**§ 423.2140 MAC Review of ALJ decision in a case remanded by a Federal District Court.**

(a) *General rules.* (1) In accordance with § 423.2138, when a case is remanded by a Federal District Court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that an enrollee files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *An enrollee files exceptions disagreeing with the decision of the ALJ.* (1) If an enrollee disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC.

(2) Exceptions may be filed by submitting a written statement to the

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MAC setting forth the reasons for disagreeing with the decision of the ALJ.

(i) The enrollee must file exceptions within 30 calendar days of the date the enrollee receives the decision of the ALJ or submit a written request for an extension within the 30 calendar day period.

(ii) The MAC will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the MAC finds good cause under the standard established in §§ 405.942(b)(2) or (b)(3) of this chapter.

(3) If written exceptions are timely filed, the MAC considers the enrollee's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the written decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the MAC about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the MAC