

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 405.990, 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 attorney adjudicator or Council, 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 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) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *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.

(2) When the Secretary's decision is adverse to a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party 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.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005; 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1138 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 Council, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ or attorney adjudicator with instructions to take action and either issue a decision, take other action, or return the case to the Council with a recommended decision. If the Council remands a case, the procedures specified in § 405.1140 will be followed.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1140 Council review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with § 405.1138, when a case is remanded by a Federal district court for further consideration and the Council remands the case to an ALJ or attorney adjudicator, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the Council assumes jurisdiction.

(2) The Council may assume jurisdiction based on written exceptions to the decision of the ALJ or attorney adjudicator that a party files with the Council or based on its authority under paragraph (c) of this section.

(3) The Council 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 or attorney adjudicator for further proceedings.

(b) *A party files exceptions disagreeing with the decision of the ALJ or attorney adjudicator.* (1) If a party disagrees with an ALJ or attorney adjudicator decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the Council. Exceptions may be filed by submitting a written statement to the Council setting forth the reasons for disagreeing with the decision of the ALJ or attorney adjudicator. The party must file exceptions within 30 calendar days of the date the party receives the decision of the ALJ or attorney adjudicator or submit a