

§ 423.1990

42 CFR Ch. IV (10–1–23 Edition)

or otherwise, is not a basis for reopening a determination or hearing decision regarding appeals under this section.

(2) An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

§ 423.1990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.* (1) For purposes of this section, a “review entity” means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Council does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) An enrollee may request EAJR in place of an ALJ hearing or Council review if the following conditions are met:

(i) An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with § 423.2002 and a decision, dismissal order, or remand order of the ALJ or an attorney adjudicator has not been issued; or

(ii) An ALJ or attorney adjudicator has made a decision and the enrollee

has filed a request for Council review in accordance with § 423.2102 and a final decision, dismissal order, or remand order of the Council has not been issued.

(2) The requestor is an enrollee.

(3) The amount remaining in controversy meets the threshold requirements specified in § 423.2006.

(4) If there is more than one enrollee to the hearing or Council review, each enrollee concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the enrollee considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the enrollee is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid; or

(ii) A CMS Ruling that the enrollee considers invalid.

(3) Include a copy of the IRE reconsideration and of any ALJ or attorney adjudicator decision that the enrollee has received;

(4) If the IRE reconsideration or ALJ or attorney adjudicator decision was based on facts that the enrollee is disputing, state why the enrollee considers those facts to be immaterial; and

(5) If the IRE reconsideration or ALJ or attorney adjudicator decision was based on a provision of a law, regulation, or CMS Ruling in addition to the one the enrollee considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request.*

(1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his

or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

(2) Time of filing request. The enrollee may file a request for EAJR—

(i) If the enrollee has requested a hearing, at any time before receipt of the notice of the ALJ's or attorney adjudicator's decision; or

(ii) If the enrollee has requested Council review, at any time before receipt of notice of the Council's decision.

(e) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 calendar days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance with paragraph (f) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (f) of this section or denying the request is not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the timeframe specified in paragraph (e)(2) of this section, then the enrollee may bring a civil action in Federal District Court within 60 calendar days of the end of the timeframe.

(f) *Certification by the review entity.* If an enrollee meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the appeal are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation or CMS Ruling;

(4) But for the provision challenged, the enrollee would receive a favorable decision on the ultimate issue; and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(g) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (f) of this section:

(1) The enrollee that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The enrollee has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal District Court.

(3) The enrollee must satisfy the requirements for venue under section 205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under § 423.2136.

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c), and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the