

(3) Any enforcement request by the Council must consist of a written notice to the Secretary describing in detail the Council's findings of non-compliance and its specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or other person or entity subject to the subpoena.

(4) The Council must promptly mail a copy of the notice and related documents to the enrollee or other person or entity subject to the subpoena, and to any other affected person.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018]

§ 423.2124 Oral argument.

An enrollee may request to appear before the Council to present oral argument.

(a) The Council grants a request for oral argument if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone.

(b) The Council may decide on its own that oral argument is necessary to decide the issues in the case. If the Council decides to hear oral argument, it informs the enrollee of the time and place of the oral argument at least 10 calendar days before the scheduled date or, in the case of an expedited review, at least 2 calendar days before the scheduled date.

(c) In case of a previously unrepresented enrollee, a newly hired representative may request an extension of time for preparation of the oral argument and the Council must consider whether the extension is reasonable.

(d) The Council may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to appear before it if the Council determines that it may be helpful in resolving the issues in the case.

(e) The Council cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in the oral argument.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017]

§ 423.2126 Case remanded by the Council.

(a) *When the Council may remand a case to the ALJ or attorney adjudicator.*

(1) The Council may remand a case in which additional evidence is needed or additional action by the ALJ or attorney adjudicator is required. The Council will designate in its remand order whether the ALJ or attorney adjudicator will issue a decision or a recommended decision on remand.

(2) *Action by ALJ or attorney adjudicator on remand.* The ALJ or attorney adjudicator will take any action that is ordered by the Council and may take any additional action that is not inconsistent with the Council's remand order.

(3) *Notice when case is returned with a recommended decision.* When the ALJ or attorney adjudicator sends a case to the Council with a recommended decision, a notice is mailed to the enrollee at his or her last known address. The notice tells the enrollee that the case was sent to the Council, explains the rules for filing briefs or other written statements with the Council, and includes a copy of the recommended decision.

(4) *Filing briefs with the Council when ALJ or attorney adjudicator issues recommended decision.* (i) An enrollee may file with the Council briefs or other written statements about the facts and law relevant to the case within 20 calendar days of the date on the recommended decision or with the request for review for expedited appeals. An enrollee may ask the Council for additional time to file a brief or written statement. The Council will extend this period, as appropriate, if the enrollee shows that he or she has good cause for requesting the extension.

(ii) All other rules for filing briefs with and obtaining evidence from the Council follow the procedures explained in this subpart.

(5) *Procedures before the Council.* (i) The Council, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(ii) If the Council determines that more evidence is required, it may again remand the case to an ALJ or attorney

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adjudicator for further inquiry into the issues, rehearing if applicable, receipt of evidence, and another decision or recommended decision. However, if the Council decides that it can get the additional evidence more quickly, it will take appropriate action.

(b) *When the Council must remand a case to the Part D IRE.* The Council will remand a case to the appropriate Part D IRE if the Council determines that the enrollee wishes evidence on his or her change in condition after the coverage determination or at-risk determination to be considered in the appeal.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018]

§ 423.2128 Action of the Council.

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

(b) The Council may adopt, modify, or reverse the ALJ or attorney adjudicator decision or recommended decision.

(c) The Council 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.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

§ 423.2130 Effect of the Council's decision.

The Council's decision is final and binding unless a Federal District Court issues a decision modifying the Council'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 Council's decision.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

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§ 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 Council.

(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 Council uses the standards specified in §§ 405.942(b)(2) or (b)(3) of this chapter.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017]

§ 423.2136 Judicial review.

(a) *General rule—*(1) *Review of Council decision.* To the extent authorized by sections 1876(c)(5)(B) and 1860D–4(h) of the Act, an enrollee may obtain a court review of a Council decision if—

(i) It is a final decision of the Secretary; and

(ii) The amount in controversy meets the threshold requirements of § 423.2006.

(2) *Review of ALJ's or attorney adjudicator's decision.* To the extent authorized by sections 1876(c)(5)(B) and 1860D–4(h) of the Act, the enrollee may request judicial review of an ALJ's or attorney adjudicator's decision if—

(i) The Council denied the enrollee's request for review; and

(ii) The amount in controversy meets the threshold requirements of § 423.2006.

(b) *Court in which to file civil action.* (1) 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