

other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time beginning with the date of receipt of the request to submit the brief and ending with the date the brief is received by the Council will not be counted toward the adjudication timeframe set forth in § 423.2100. The Council may also request, but not require, CMS, the IRE, and/or the Part D plan sponsor to file a brief or position paper if the Council determines that it is necessary to resolve the issues in the case. The Council cannot draw any adverse inference if CMS, the IRE, and/or the Part D plan sponsor either participates, or decides not to participate in Council review.

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

§ 423.2122 What evidence may be submitted to the Council.

(a) *Appeal before the Council on request for review of ALJ's or attorney adjudicator's decision.* (1) If the Council is reviewing an ALJ's or attorney adjudicator's decision, the Council will consider the evidence contained in the record of the proceedings before the ALJ or attorney adjudicator, and any new evidence that relates to the period before the coverage determination or at-risk determination. If the ALJ's or attorney adjudicator's decision decides a new issue that the enrollee was not afforded an opportunity to address at the OMHA level, the Council considers any evidence related to that issue that is submitted with the request for review.

(2) If the Council determines that additional evidence is needed to resolve the issues in the case and the administrative record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ or attorney adjudicator to obtain the evidence and issue a new decision.

(3) The Council will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination or at-risk determination is made. The Council will remand a case to the Part D IRE if the Council determines that the enrollee wishes to have evidence on his or her

change in condition after the coverage determination or at-risk determination considered.

(b) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, the Council may, on its own initiative, issue subpoenas requiring an enrollee or Part D plan sponsor to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. The Council may not issue a subpoena to CMS, or the IRE to compel the production of evidence.

(1) To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality or undue burden, was made before the Council, the Secretary may review immediately that subpoena or a portion of the subpoena.

(2) Upon notice to the Council that an enrollee or Part D plan sponsor intends to seek the Secretary review of the subpoena, the Council must stay all proceedings affected by the subpoena, tolling the time period for the Council to issue a final action or remand a case in response to a request for review for 15 calendar days or until the Secretary makes a decision with respect to the review request, whichever occurs first.

(3) If the Secretary does not grant review within the time allotted for the stay, the stay is lifted and the subpoena stands.

(c) *Enforcement.* (1) If the Council determines that an enrollee or other person or entity subject to a subpoena issued under this section has refused to comply with the subpoena, the Council may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(2) After submitting the enforcement request, the time period for the Council to issue a final action or remand a case in response to a request for review is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(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