

hearing is also binding and not subject to judicial review.

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

**§ 423.2118 Obtaining evidence from the Council.**

An enrollee may request and receive a copy of all or part of the record of the ALJ's or attorney adjudicator's action, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. However, the enrollee may be asked to pay the costs of providing these items. If an enrollee requests evidence from the Council and an opportunity to comment on that evidence, the time beginning with the Council's receipt of the request for evidence through the expiration of the time granted for the enrollee's response will not be counted toward the adjudication deadline.

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

**§ 423.2120 Filing briefs with the Council.**

Upon request, the Council will give the enrollee requesting review a reasonable opportunity to file a brief or 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