

**§ 423.2112 Content of request for review.**

(a)(1) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(2) The request for review must be in writing and may be made on a standard form, except for requests for expedited reviews which may be made orally.

(3) The Council must document all oral requests in writing and maintain the documentation in the case file.

(4) A written request that is not made on a standard form or, for expedited requests, an oral request, is accepted if it includes the enrollee's name and telephone number, the plan name; Medicare number; the ALJ appeal number; the specific Part D drug(s) for which the review is requested; a statement that the enrollee is requesting an expedited review, if applicable; and the name of the enrollee or the representative of the enrollee.

(b) The request for review must identify the parts of the ALJ or attorney adjudicator action with which the enrollee requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the enrollee in the request for review, unless the enrollee is unrepresented. For purposes of this section only, a representative is either anyone with a valid appointment as the enrollee's representative or is a member of the enrollee's family, a legal guardian or an individual who routinely acts on behalf of the enrollee, such as a family member or friend who has a power of attorney.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5138, Jan. 17, 2017; 84 FR 19874, May 7, 2019]

**§ 423.2114 Dismissal of request for review.**

The Council dismisses a request for review if the enrollee requesting review did not file the request within the stated period of time and the time for filing has not been extended. The Council

also dismisses the request for review if—

(a) The enrollee asks to withdraw the request for review;

(b) The individual or entity does not have a right to request Council review; or

(c) The enrollee died while the request for review is pending and the enrollee's estate or representative, if any, either has no remaining financial interest in the case or does not want to continue the appeal.

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

**§ 423.2116 Effect of dismissal of request for Council review or request for hearing.**

The dismissal of a request for Council review or denial of a request for review of a dismissal issued by an ALJ or attorney adjudicator is binding and not subject to further review unless reopened and vacated by the Council. The Council's dismissal of a request for 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 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.