

(b) *Review by an ALJ or attorney adjudicator.* (1) An ALJ or attorney adjudicator may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ or attorney adjudicator may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the Council.* (1) The Council may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The Council may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 82 FR 5121, Jan. 17, 2017]

§ 405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5121, Jan. 17, 2017]

§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[82 FR 5121, Jan. 17, 2017]

MEDICARE APPEALS COUNCIL REVIEW

§ 405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90

calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

[82 FR 5122, Jan. 17, 2017]

§ 405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

(2) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) A party requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the Council; and

(3) It explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§ 405.1100 through 405.1140),

unless specifically excepted, the term "party", includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, "appellant," does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

[82 FR 5122, Jan. 17, 2017]

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100

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until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

[82 FR 5122, Jan. 17, 2017]

§ 405.1108 Council actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party requests that the Council review an ALJ's or attorney adjudicator's decision, the Council will review the ALJ's or attorney adjudicator's decision *de novo*. The party requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence in the administrative record. Upon completion of its review, the Council may adopt, modify, or reverse the ALJ's or attorney adjudicator's decision or remand the case to an ALJ or attorney adjudicator for further proceedings.

(b) When a party requests that the Council review an ALJ's or attorney adjudicator's dismissal of a request for a hearing, the Council may deny review or vacate the dismissal and remand the case to the ALJ or attorney adjudicator for further proceedings.

(c) The Council will dismiss a request for review when the party requesting review does not have a right to a review by the Council, or will dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request for hearing.

(d) When an appellant requests escalation of a case from the OMHA level to the Council, the Council may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the Council determines are necessary to issue a decision.

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(3) Remand the case to OMHA for further proceedings, including a hearing.

(4) Dismiss the request for Council review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5122, Jan. 17, 2017]

§ 405.1110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days of receipt of an ALJ's or attorney adjudicator's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and

(ii) In CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's decision or dismissal is received. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file

exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings or may dismiss a hearing request. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, issue its action before the 20 calendar day comment period has ex-

pired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

(e) *Referral timeframe.* For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

[82 FR 5122, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1112 Content of request for review.

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's or attorney adjudicator's decision or dismissal order, if any; and the name of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator's action with which the party 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. For example, if the party requesting review believes that the ALJ's or attorney adjudicator's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented

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beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

[82 FR 5123, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1114 Dismissal of request for review.

The Council dismisses a request for review if the party 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 party asks to withdraw the request for review;

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

(c) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(1) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the Council considers whether the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue;

(2) No other individual or entity with a financial interest in the case wishes to pursue an appeal under § 405.1102;

(3) No other party to the ALJ's or attorney adjudicator's action filed a valid and timely review request under §§ 405.1102 and 405.1112.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017; 84 FR 19871, May 7, 2019]

§ 405.1116 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

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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.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017]

§ 405.1118 Obtaining evidence from the Council.

A party 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 party may be asked to pay the costs of providing these items. If a party 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 party's response will not be counted toward the 90 calendar day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009; 82 FR 5123, Jan. 17, 2017]

§ 405.1120 Filing briefs with the Council.

Upon request, the Council will give the party requesting review, as well as all other parties, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. Any party who submits a brief or statement must send a copy to all of the other parties. Unless the party 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 § 405.1100. The Council may also request, but not require, CMS or its contractor to file a brief or position paper if the Council determines that it is necessary to resolve the issues in the case. The Council will not draw any adverse inference if CMS or a contractor either

participates, or decides not to participate in Council review.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017]

§405.1122 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 limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ or attorney adjudicator. However, if the ALJ's or attorney adjudicator's decision decides a new issue that the parties were 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.

(b) *Appeal before Council as a result of appellant's request for escalation.* (1) If the Council is reviewing a case that is escalated from the OMHA level to the Council, the Council will decide the case based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) If the Council receives additional evidence with the request for escalation that is material to the question to be decided, or determines that additional evidence is needed to resolve the issues in the case, and the record provided to the Council indicates that the previous decision-makers did not attempt to obtain the evidence before escalation, the Council may remand the case to an ALJ or attorney adjudicator to consider or obtain the evidence and issue a new decision.

(c) *Evidence related to issues previously considered by the QIC.* (1) If new evidence related to issues previously considered by the QIC is submitted to the

Council by a provider, supplier, or a beneficiary represented by a provider or supplier, the Council must determine if the provider, supplier, or the beneficiary represented by a provider or supplier had good cause for submitting it for the first time at the Council level.

(2) If the Council determines that good cause does not exist, the Council must exclude the evidence from the proceeding, may not consider it in reaching a decision, and may not remand the issue to an ALJ or attorney adjudicator.

(3) The Council must notify all parties if it excludes the evidence. The Council may remand to an ALJ or attorney adjudicator if—

(i) The ALJ or attorney adjudicator did not consider the new evidence submitted by the provider, supplier, or beneficiary represented by a provider or supplier because good cause did not exist; and

(ii) The Council finds that good cause existed under §405.1028 and the ALJ or attorney adjudicator should have reviewed the evidence.

(iii) The new evidence is submitted by a party that is not a provider, supplier, or a beneficiary represented by a provider or supplier.

(d) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, the Council may, on its own initiative or at the request of a party, issue subpoenas requiring a party 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 its contractors, on its own initiative or at the request of a party, to compel the production of evidence.

(2) A party's request for a subpoena must—

(i) Give a sufficient description of the documents to be produced;

(ii) State the important facts that the documents are expected to prove; and

(iii) Indicate why these facts could not be proven without issuing a subpoena.

(3) A party to the Council review on escalation that wishes to subpoena documents must file a written request that complies with the requirements set out in paragraph (d)(2) of this section within 10 calendar days of the request for escalation.

(4) A subpoena will issue only where a party—

- (i) Has sought discovery;
- (ii) Has filed a motion to compel;
- (iii) Has had that motion granted; and
- (iv) Nevertheless, has still not received the requested discovery.

(e) Reviewability of subpoena rulings—

(1) *General rule.* A Council ruling on a subpoena request is not subject to immediate review by the Secretary.

(2) *Exception.* 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 portion of the subpoena.

(3) Upon notice to the Council that a party or non-party, as applicable, intends to seek Secretary review of the subpoena, the Council must stay all proceedings affected by the subpoena.

(4) The Council determines the length of the stay under the circumstances of a given case, but in no event is less than 15 calendar days after the day on which the Council received notice of the party or non-party's intent to seek Secretary review.

(5) If the Secretary grants a request for review, the subpoena or portion of the subpoena, as applicable, is stayed until the Secretary issues a written decision that affirms, reverses, modifies, or remands the Council's action for the subpoena.

(6) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the Council's action stands.

(f) *Enforcement.* (1) If the Council determines, whether on its own motion or at the request of a party, that a party or non-party 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) 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 party or nonparty subject to the subpoena.

(3) The Council must promptly mail a copy of the notice and related documents to the party or non-party subject to the subpoena, and to any other party and affected non-party to the appeal.

(4) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the subpoena stands.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009; 82 FR 5123, Jan. 17, 2017]

§ 405.1124 Oral argument.

A party 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 tells the parties of the time and place of the oral argument at least 10 calendar days before the scheduled date.

(c) In case of a previously unrepresented beneficiary, 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 or its contractor to appear before it if the Council determines that it may be helpful in resolving the issues in the case.

(e) The Council will not draw any inference if CMS or a contractor decides

not to participate in the oral argument.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1126 Case remanded by the Council.

(a) *When the Council may remand a case.* Except as specified in § 405.1122(c), 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.

(b) *Action by ALJ 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.

(c) *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 parties at their last known address. The notice tells them 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.

(d) *Filing briefs with the Council when ALJ or attorney adjudicator issues recommended decision.* (1) Any party to the recommended decision 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. Any party may ask the Council for additional time to file briefs or statements. The Council will extend this period, as appropriate, if the party shows that it has good cause for requesting the extension.

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

(e) *Procedures before the Council.* (1) The Council, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

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

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1128 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 § 405.1122, 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's or attorney adjudicator's decision or recommended decision.

(c) The Council mails a copy of its decision to all the parties at their last known addresses. For overpayment cases involving multiple beneficiaries where there is no beneficiary liability the Council may choose to send written notice only to the appellant. In the event the decision will result in a payment to a provider or supplier, the Medicare contractor must issue any electronic or paper remittance advice notice to that provider or supplier.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1130 Effect of the Council's decision.

The Council's decision is final and binding on all parties 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 § 405.980. A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the Council's decision.

[74 FR 65338, Dec. 9, 2009, as amended at 82 FR 5124, Jan. 17, 2017]

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§ 405.1132 Request for escalation to Federal court.

(a) If the Council does not issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ or attorney adjudicator dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the Council may—

(1) Issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or

(2) If the Council is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the Council's notice that the Council is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ or attorney adjudicator dismissal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1134 Extension of time to file action in Federal district court.

(a) Any party to the Council's decision or to a request for EAJR that has been certified by the review entity other than CMS 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 party shows that he or she had good cause for missing the dead-

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line, 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).

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1136 Judicial review.

(a) *General rules.* (1) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a Council decision, or an appellant who requests escalation to Federal district court if the Council does not complete its review of the ALJ's or attorney adjudicator's decision within the applicable adjudication period, may obtain a court review if the amount remaining in controversy satisfies the requirements of § 405.1006(c).

(2) If the Council's adjudication period set forth in § 405.1100 expires and the appellant does not request escalation to Federal district court, the case remains with the Council until a final decision, dismissal order, or remand order is issued.

(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 party resides or where such individual, institution, or agency has its principal place of business.

(2) If the party does not reside within any judicial district, or if the individual, institution, or agency does not have its principal place of business within any such 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 § 405.1130, § 405.1132, or § 405.1134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the Council's decision or the Council's notice that it is not able to issue a decision within the statutory timeframe shall be presumed to be 5 calendar days after the date of the notice, unless there is a reasonable showing to the contrary.

(3) Where a case is certified for judicial review in accordance with the expedited access to judicial review process in § 405.990, the civil action must be filed within 60 calendar days after receipt of the review entity's certification, except where the time is extended by the ALJ or attorney adjudicator or Council, as applicable, upon a showing of good cause.

(d) *Proper defendant.* (1) In any civil action described in paragraph (a) of this section, the Secretary of HHS, in his or her official capacity, is the proper defendant. Any civil action properly filed shall survive notwithstanding any change of the person holding the Office of the Secretary of HHS or any vacancy in such office.

(2) If the complaint is erroneously filed against the United States or against any agency, officer, or employee of the United States other than the Secretary, the plaintiff will be notified that he or she has named an incorrect defendant and is granted 60 calendar days from the date of receipt of the notice in which to commence the action against the correct defendant, the Secretary.

(e) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *Standard of review.* (1) Under section 205(g) of the Act, the findings of the Secretary of HHS as to any fact, if supported by substantial evidence, are conclusive.

(2) When the Secretary's decision is adverse to a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005; 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1138 Case remanded by a Federal district court.

When a Federal district court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the Council, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ or attorney adjudicator with instructions to take action and either issue a decision, take other action, or return the case to the Council with a recommended decision. If the Council remands a case, the procedures specified in § 405.1140 will be followed.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1140 Council review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with § 405.1138, when a case is remanded by a Federal district court for further consideration and the Council remands the case to an ALJ or attorney adjudicator, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the Council assumes jurisdiction.

(2) The Council may assume jurisdiction based on written exceptions to the decision of the ALJ or attorney adjudicator that a party files with the Council or based on its authority under paragraph (c) of this section.

(3) The Council either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ or attorney adjudicator for further proceedings.

(b) *A party files exceptions disagreeing with the decision of the ALJ or attorney adjudicator.* (1) If a party disagrees with an ALJ or attorney adjudicator decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the Council. Exceptions may be filed by submitting a written statement to the Council setting forth the reasons for disagreeing with the decision of the ALJ or attorney adjudicator. The party must file exceptions within 30 calendar days of the date the party receives the decision of the ALJ or attorney adjudicator or submit a

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written request for an extension within the 30 calendar day period. The Council will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the party needs the additional time and may be granted if the Council finds good cause under the standard established in § 405.942(b)(2) or (b)(3).

(2) If written exceptions are timely filed, the Council considers the party's reasons for disagreeing with the decision of the ALJ or attorney adjudicator. If the Council concludes that there is no reason to change the decision of the ALJ or attorney adjudicator, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ or attorney adjudicator is warranted. In this instance, the decision of the ALJ or attorney adjudicator is the final decision of the Secretary after remand.

(3) When a party files written exceptions to the decision of the ALJ, the Council may assume jurisdiction at any time. If the Council assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or attorney adjudicator or remanding the case to an ALJ or attorney adjudicator for further proceedings, including a new decision. The new decision of the Council is the final decision of the Secretary after remand.

(c) *Council assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the decision of the ALJ or attorney adjudicator, the Council may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to all parties at their last known address.

(3) The parties will be provided with the opportunity to file briefs or other written statements with the Council about the facts and law relevant to the case.

(4) After the briefs or other written statements are received or the time allowed (usually 30 calendar days) for submitting them has expired, the Council will either issue a final deci-

sion of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ or attorney adjudicator for further proceedings, including a new decision.

(d) *Exceptions are not filed and the Council does not otherwise assume jurisdiction.* If no exceptions are filed and the Council does not assume jurisdiction of the cases within 60 calendar days after the date of the ALJ's or attorney adjudicator's decision, the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

SOURCE: 69 FR 69624, Nov. 26, 2004, unless otherwise noted.

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of treatment prescribed in a discrete increment, regardless of whether the beneficiary agrees that the services should end. A termination does not include a reduction in services. A termination also does not include the termination of one type of service by the provider if the beneficiary continues to receive other Medicare-covered services from the provider.

(b) *Advance written notice of service terminations.* Before any termination of services, the provider of the service must deliver valid written notice to