

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 423.1094 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect—(1) ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in 423.1088.

[72 FR 68726, Dec. 5, 2007, as amended at 85 FR 72909, Nov. 16, 2020]

Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, Council Review, and Judicial Review

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and

ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

[82 FR 5125, Jan. 17, 2017]

§§ 423.1970–423.1976 [Reserved]

§ 423.1978 Reopening determinations and decisions.

(a) A coverage determination or re-determination made by a Part D plan sponsor, a reconsideration made by the independent review entity specified in § 423.600, or the decision of an ALJ or attorney adjudicator or the Council that is otherwise binding may be reopened and revised by the entity that made the determination or decision as provided in § 423.1980 through § 423.1986.

(b) The filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638 of this chapter.

(c) Once an entity issues a revised determination or decision, the revisions made by the decision may be appealed.

(d) A decision not to reopen by the Part D plan sponsor or any other entity is not subject to review.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. Consistent with § 423.1978(a), that action may be taken by—

(i) A Part D plan sponsor to revise the coverage determination or redetermination;

(ii) An IRE to revise the reconsideration;

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(3) Consistent with § 423.1978(b), the filing of a request for reopening does not relieve the Part D plan sponsor of its obligation to make payment or provide benefits as specified in § 423.636 or § 423.638.

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

(5) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for drug claims that were already reimbursed by the Part D plan sponsor is not a reopening.

(b) *Timeframes and requirements for reopening coverage determinations and redeterminations initiated by a Part D plan sponsor.* A Part D plan sponsor may reopen its coverage determination or redetermination on its own motion:

(1) Within 1 year from the date of the coverage determination or redetermination for any reason.

(2) Within 4 years from the date of the coverage determination or redetermination for good cause as defined in § 423.1986.

(3) At any time if there exists reliable evidence as defined in § 405.902 of this chapter that the coverage determination was procured by fraud or similar fault as defined in § 405.902.

(c) *Timeframe and requirements for reopening coverage determinations and redeterminations requested by an enrollee.* (1) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.

(2) An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the coverage determination or redetermination for good cause in accordance with § 423.1986.

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.* (1) An IRE may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with § 423.1986. If the IRE's reconsideration was procured by fraud or similar fault, then the IRE may reopen at any time.

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.* (1) An enrollee who received a reconsideration or a Part D plan sponsor may request that an IRE reopen its reconsideration decision within 180 calendar days from the date of the reconsideration for good cause in accordance with § 423.1986.

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 423.1980:

(1) The Part D plan sponsor, IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

(b) *Reopenings initiated at the request of an enrollee or a Part D plan sponsor.*

(1) The Part D plan sponsor, IRE, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the enrollee at his or her last known address.

(2) The IRE, ALJ or attorney adjudicator or the Council must mail its revised determination or decision to the Part D plan sponsor.

(3) An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5126, Jan. 17, 2017]

§ 423.1984 Effect of a revised determination or decision.

(a) *Coverage determinations.* The revision of a coverage determination is binding unless an enrollee submits a request for a redetermination that is accepted and processed in accordance with § 423.580 through § 423.590.

(b) *Redeterminations.* The revision of a redetermination is binding unless an enrollee submits a request for an IRE reconsideration that is accepted and

processed in accordance with § 423.600 through § 423.604.

(c) *Reconsiderations.* The revision of a reconsideration is binding unless an enrollee submits a request for an ALJ hearing that is accepted and processed in accordance with §§ 423.2000 through 423.2063.

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding unless an enrollee submits a request for a Council review that is accepted and processed as specified in §§ 423.2100 through 423.2130.

(e) *Council review.* The revision of a Council determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

(f) *Appeal of only the portion of the determination or decision revised by the reopening.* Only the portion of the coverage determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* Consistent with § 423.1978(c), a revised determination or decision is binding unless it is appealed or otherwise reopened.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.1986 Good cause for reopening.

(a) *Establishing good cause.* Good cause may be established when—

(1) There is new and material evidence that—

(i) Was not available or known at the time of the determination or decision; and

(ii) May result in a different conclusion; or

(2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

(b) *Change in substantive law or interpretative policy.* (1) *General rule.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent

or otherwise, is not a basis for reopening a determination or hearing decision regarding appeals under this section.

(2) An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

(c) *Third party payer error.* A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

§ 423.1990 Expedited access to judicial review.

(a) *Process for expedited access to judicial review.* (1) For purposes of this section, a “review entity” means an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary.

(2) In order to obtain expedited access to judicial review (EAJR), a review entity must certify that the Council does not have the authority to decide the question of law or regulation relevant to the matters in dispute and that there is no material issue of fact in dispute.

(3) An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

(b) *Conditions for making the expedited appeals request.* (1) An enrollee may request EAJR in place of an ALJ hearing or Council review if the following conditions are met:

(i) An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with § 423.2002 and a decision, dismissal order, or remand order of the ALJ or an attorney adjudicator has not been issued; or

(ii) An ALJ or attorney adjudicator has made a decision and the enrollee

has filed a request for Council review in accordance with § 423.2102 and a final decision, dismissal order, or remand order of the Council has not been issued.

(2) The requestor is an enrollee.

(3) The amount remaining in controversy meets the threshold requirements specified in § 423.2006.

(4) If there is more than one enrollee to the hearing or Council review, each enrollee concurs, in writing, with the request for the EAJR.

(5) There are no material issues of fact in dispute.

(c) *Content of the request for EAJR.* The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the enrollee considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the enrollee is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid; or

(ii) A CMS Ruling that the enrollee considers invalid.

(3) Include a copy of the IRE reconsideration and of any ALJ or attorney adjudicator decision that the enrollee has received;

(4) If the IRE reconsideration or ALJ or attorney adjudicator decision was based on facts that the enrollee is disputing, state why the enrollee considers those facts to be immaterial; and

(5) If the IRE reconsideration or ALJ or attorney adjudicator decision was based on a provision of a law, regulation, or CMS Ruling in addition to the one the enrollee considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary.

(d) *Place and time for an EAJR request.*

(1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his

or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

(2) Time of filing request. The enrollee may file a request for EAJR—

(i) If the enrollee has requested a hearing, at any time before receipt of the notice of the ALJ's or attorney adjudicator's decision; or

(ii) If the enrollee has requested Council review, at any time before receipt of notice of the Council's decision.

(e) *Determination on EAJR request.* (1) The review entity described in paragraph (a) of this section will determine whether the request for EAJR meets all of the requirements of paragraphs (b), (c), and (d) of this section.

(2) Within 60 calendar days after the date the review entity receives a request and accompanying documents and materials meeting the conditions in paragraphs (b), (c), and (d) of this section, the review entity will issue either a certification in accordance with paragraph (f) of this section or a denial of the request.

(3) A determination by the review entity either certifying that the requirements for EAJR are met pursuant to paragraph (f) of this section or denying the request is not subject to review by the Secretary.

(4) If the review entity fails to make a determination within the timeframe specified in paragraph (e)(2) of this section, then the enrollee may bring a civil action in Federal District Court within 60 calendar days of the end of the timeframe.

(f) *Certification by the review entity.* If an enrollee meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the appeal are not in dispute;

(2) Except as indicated in paragraph (f)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation or CMS Ruling;

(4) But for the provision challenged, the enrollee would receive a favorable decision on the ultimate issue; and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(g) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (f) of this section:

(1) The enrollee that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The enrollee has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal District Court.

(3) The enrollee must satisfy the requirements for venue under section 205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under § 423.2136.

(h) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c), and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises the enrollee in writing that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the

hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, CMS, or the IRE may participate in the proceedings on a request for an ALJ hearing as specified in § 423.2010.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If an enrollee waives his or her right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the enrollee to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In that event, however, the ALJ will give the enrollee the opportunity to appear when the testimony is given, but may hold the hearing even if the enrollee decides not to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017]

§ 423.2002 Right to an ALJ hearing.

(a) An enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ if—

(1) The enrollee files a written request for an ALJ hearing within 60 calendar days after receipt of the written notice of the IRE's reconsideration; and

(2) The enrollee meets the amount in controversy requirements of § 423.2006.

(b) An enrollee may request that the hearing before an ALJ be expedited if:

(1) The appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished;

(2) The enrollee submits a written or oral request for an expedited ALJ hearing within 60 calendar days of the date of the written notice of an IRE reconsideration determination. The request can only be submitted after the enrollee receives the written IRE reconsideration notice. The request should also explain why applying the standard timeframe may seriously jeopardize the life or health of the enrollee; and

(3) The enrollee meets the amount in controversy requirements of § 423.2006.

(c) OMHA must document all oral requests for expedited hearings in writing and maintain the documentation in the case files.

(d) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the written reconsideration, unless there is evidence to the contrary.

(e) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE's reconsideration.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2004 Right to a review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ or attorney adjudicator if—

(1) The enrollee files a written request for review within 60 calendar days after receipt of the notice of the IRE's dismissal.

(2) The enrollee meets the amount in controversy requirements of § 423.2006.

(3) For purposes of this section, the date of receipt of the IRE's dismissal is presumed to be 5 calendar days after the date of the written dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the IRE's dismissal.

(b) If the ALJ or attorney adjudicator determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration in accordance with § 423.2056.

(c) If the ALJ or attorney adjudicator affirms the IRE's dismissal of a reconsideration request, he or she issues a notice of decision affirming the IRE's dismissal in accordance with § 423.2046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of an IRE's dismissal in accordance with § 423.2052(b).

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5127, Jan. 17, 2017; 84 FR 19872, May 7, 2019]

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

(a) *ALJ review.* To be entitled to a hearing before an ALJ, an enrollee must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be \$100, increased by the percentage increase in the medical care component of the Consumer Price Index for All Urban Consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (a)(1) of this section is not a multiple of \$10, it is rounded to the nearest multiple of \$10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(b) *Judicial review.* To be entitled to judicial review, the enrollee must meet the amount in controversy requirements of this subpart at the time it requests judicial review. For review requests, the required amount remaining in controversy must be \$1,000 or more, adjusted as specified in paragraphs (a)(1) and (2) of this section.

(c) *Calculating the amount remaining in controversy.* (1) The amount remaining in controversy is computed as the projected value described in paragraph (c)(2) or (3) of this section, reduced by any cost sharing amounts, including deductible, coinsurance, or copayment

amounts that may be collected from the enrollee for the Part D drug(s).

(2) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, the projected value of those benefits is used to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(3) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f), the projected value of the drugs subject to the drug management program is used to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills prescribed for the drug(s) in dispute during the plan year.

(d) *Aggregating appeals to meet the amount in controversy*—(1) *Enrollee.* Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees.* Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

(i) The appeals have previously been reconsidered by an IRE;

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

[84 FR 19872, May 7, 2019, as amended at 86 FR 6121, Jan. 19, 2021]

§ 423.2008 Parties to the proceedings on a request for an ALJ hearing.

The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the proceedings on a request for an ALJ hearing.

[82 FR 5127, Jan. 17, 2017]

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS, the IRE, or the Part D plan sponsor may participate.* (1) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the proceedings on a request for an ALJ hearing upon filing a request to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

(b) *How a request to participate is made—*(1) *No notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation before it receives a notice of hearing, or when no notice is required, it must send written notice of its request to participate to

the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.

(2) *Notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation after the IRE and Part D plan sponsor receive a notice of hearing, it must send written notice of its request to participate to the ALJ and the enrollee, except that the request to participate may be made orally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

(3) *Timing of request.* CMS, the IRE, and/or the Part D plan sponsor must send its request to participate—

(i) If a standard request for hearing was filed, if no hearing is scheduled, within 30 calendar days after notification that a standard request for hearing was filed;

(ii) If an expedited hearing is requested, but no hearing has been scheduled, within 2 calendar days after notification that a request for an expedited hearing was filed;

(iii) If a non-expedited hearing is scheduled, within 5 calendar days after receiving the notice of hearing; or

(iv) If an expedited hearing is scheduled, within 1 calendar day after receiving the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(c) *The ALJ's or attorney adjudicator's decision on a request to participate.* The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate. The ALJ or attorney adjudicator must notify the entity requesting participation, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate within the following time frames—

(1) If no hearing is scheduled, at least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand;

(2) If a non-expedited hearing is scheduled, within 5 calendar days of receipt of a request to participate; or

(3) If an expedited hearing is scheduled, within 1 calendar of receipt of a request to participate.

(d) *Roles and responsibilities of CMS, the IRE, and/or the Part D plan sponsor as a participant.* (1) Participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee.

(2) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the enrollee, but the enrollee may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS, IRE, and/or Part D plan sponsor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a position paper and written testimony must be submitted—

(A) Within 14 calendar days for a standard appeal, or 1 calendar day for an expedited appeal, after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled; or

(B) No later than 5 calendar days prior to the hearing if a non-expedited hearing is scheduled, or 1 calendar day prior to the hearing if an expedited hearing is scheduled.

(ii) A copy of any position paper and written testimony that CMS, the IRE, or the Part D plan sponsor submits to OMHA must be sent within the same time frames specified in paragraph (d)(3)(i)(A) and (B) of this section to the enrollee.

(iii) If CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of its position paper or written testimony to the enrollee or fails to submit its position paper or written testimony within the time frames described in this section, the position paper or written

testimony will not be considered in deciding the appeal.

(e) *Invalid requests to participate.* (1) An ALJ or attorney adjudicator may determine that a CMS, IRE, and/or Part D plan sponsor request to participate is invalid under this section if the request to participate was not timely filed or the request to participate was not sent to the enrollee.

(2) If the request to participate is determined to be invalid, the written notice of an invalid request to participate must be sent to the entity that made the request to participate and the enrollee.

(i) If no hearing is scheduled or the request to participate was made after the hearing occurred, the written notice of an invalid request to participate must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a non-expedited hearing is scheduled, the written notice of an invalid request to participate must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

(iii) If an expedited hearing is scheduled, oral notice of an invalid request to participate must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

[82 FR 5127, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2014 Request for an ALJ hearing or a review of an IRE dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of an IRE dismissal must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(i) The name, address, telephone number, and Medicare number of the enrollee.

(ii) The name, address, and telephone number of the representative, as defined at § 423.560, if any.

(iii) The Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed.

(iv) The prescription drug in dispute.

(v) The plan name.

(vi) The reasons the enrollee disagrees with the IRE's reconsideration or dismissal being appealed.

(2) The enrollee must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) The enrollee must submit a statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. OMHA must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(c) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the enrollee will be provided with an opportunity to complete the request, and if an adjudication time frame applies it does not begin until the request is complete. If the enrollee fails to provide the information necessary to complete the request within the time frame provided, the enrollee's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(d) *When and where to file.* The request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration or dismissal being appealed.

(2) With the office specified in the IRE's reconsideration or dismissal.

(i) If the request for hearing is timely filed with an office other than the office specified in the IRE's reconsideration, the request is not treated as untimely, and any applicable time frame specified in § 423.2016 for deciding the appeal begins on the date the office specified in the IRE's reconsideration or dismissal receives the request for hearing.

(ii) If the request for hearing is filed with an office, other than the office specified in the IRE's reconsideration or dismissal, OMHA must notify the enrollee of the date the request was received in the correct office and the commencement of any applicable adjudication timeframe.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review is not filed within 60 calendar days of receipt of the written IRE's reconsideration or dismissal, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. OMHA must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must be filed with the office specified in the notice of reconsideration or dismissal, must give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of an IRE dismissal, or upon notice that the request may be dismissed because it was not timely filed.

(4) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of an IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of an IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of an IRE dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or

attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3) of this chapter.

(5) If a request for hearing is not timely filed, any applicable adjudication period in § 423.2016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(6) A determination granting a request to extend the filing deadline is not subject to further review.

[82 FR 5128, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019; 86 FR 6121, Jan. 19, 2021]

§ 423.2016 Timeframes for deciding an appeal of an IRE reconsideration.

(a) *Standard appeals.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

(2) The adjudication period specified in paragraph (a)(1) of this section begins on the date that a timely filed request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(3) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a)(1) of this section, the remanded appeal will be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand.

(b) *Expedited appeals*—(1) *Standard for expedited appeal.* An ALJ or attorney adjudicator issues an expedited decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or an ALJ or attorney adjudicator determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to re-

gain maximum function. An ALJ or attorney adjudicator may consider this standard as met if a lower level adjudicator has granted a request for an expedited decision.

(2) *Grant of a request.* If an ALJ or attorney adjudicator grants a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make the decision to grant an expedited appeal within 5 calendar days of receipt of the request for an expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request.* If an ALJ or attorney adjudicator denies a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that an ALJ or attorney adjudicator will process the enrollee's request using the 90 calendar day timeframe for non-expedited appeals; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) *Decision not appealable.* A decision on a request for expedited hearing may not be appealed.

(5) *Time frame for adjudication.* (i) If an ALJ or attorney adjudicator accepts a request for expedited hearing, an ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely provided, the date that an ALJ or attorney adjudicator grants any extension to the filing deadline.

(6) *Time frame for Council remands.* If the Council remands a case and the case was subject to an adjudication time frame under paragraph (b)(5) of this section, the remanded appeal will be subject to the same adjudication timeframe beginning on the date that OMHA receives the Council remand, if the standards for an expedited appeal continue to be met. If the standards for an expedited appeal are no longer met, the appeal will be subject to the adjudication time frame for a standard appeal.

(c) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the enrollee may waive the adjudication period specified in paragraphs (a)(1) and (b)(5) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the enrollee.

(2) The adjudication periods specified in paragraphs (a)(1) and (b)(5) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the matters at issue ordered by a court or tribunal of competent jurisdiction;

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an enrollee.

[82 FR 5129, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2018 Submitting evidence.

(a) *All appeals.* An enrollee must submit any written or other evidence that he or she wishes to have considered.

(1) An ALJ or attorney adjudicator will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination or at-risk determination was made.

(2) An ALJ or attorney adjudicator will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination or at-risk determination to be considered.

(b) *Non-expedited appeals.* (1) Except as provided in this paragraph, a represented enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 423.2014(a)(2), or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(3) The requirements of paragraph (b) of this section do not apply to unrepresented enrollees.

(c) *Expedited appeals.* (1) Except as provided in this section, an enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing, by the date specified in the request for hearing pursuant to § 423.2014(a)(2), or, if an expedited hearing is scheduled, within 2 calendar days of receiving the notice of the expedited hearing.

(2) If an enrollee submits written or other evidence later than 2 calendar days after receiving the notice of expedited hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 2 calendar days after receipt of the notice of expedited hearing and the day the evidence is received.

(d) *When this section does not apply.* The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

[82 FR 5130, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2020 Time and place for a hearing before an ALJ.

(a) *General.* The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made.* (1) *Appearances by unrepresented enrollees.* The ALJ will direct that the appearance of an unrepresented enrollee who filed a request for hearing be conducted by video-teleconferencing if the ALJ finds that video-teleconferencing technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented enrollee.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by represented enrollees.* The ALJ will direct that the appearance of an individual, other than an unrepresented enrollee who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by video-teleconferencing if he or she determines that video-teleconferencing is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) The video-teleconferencing and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to the enrollee, the Part D plan sponsor that issued the coverage determination or at-risk de-

termination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS, the IRE, or the Part D plan sponsor that requests to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b).

(1) As specified in § 423.2000, an ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If an ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

(e) *An enrollee's objection to time and place of hearing.* (1) If an enrollee objects to the time and place of the hearing, the enrollee must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The enrollee must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally, and except that the enrollee may orally request that a non-expedited hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral objections to the time and place of a hearing in writing and maintain the documentation in the case files.

(4) The ALJ may change the time or place of the hearing if the enrollee has good cause.

(5) If the enrollee's objection to the place of the hearing includes a request for an in-person or video-teleconferencing hearing, the objection and request are considered in paragraph (i) of this section.

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the enrollee's contention that—

(1) The enrollee or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.*

(1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the enrollee's reason for requesting the change, the facts supporting the request, and the impact of the change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing,

and whether any prior changes were granted the enrollee.

(3) Examples of other circumstances an enrollee might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The enrollee has attempted to obtain a representative but needs additional time.

(ii) The enrollee's representative was appointed within 10 calendar days of the scheduled hearing for non-expedited hearings (or 2 calendar days for expedited hearings) and needs additional time to prepare for the hearing.

(iii) The enrollee's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to an enrollee's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for an enrollee to travel to the hearing.

(vi) The enrollee is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language).

(vii) The enrollee or enrollee's representative has a prior commitment that cannot be changed without significant expense.

(viii) The enrollee or enrollee's representative asserts he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 423.2016.

(i) *An enrollee's request for an in-person or video-teleconferencing hearing.* (1) If an unrepresented enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, or a represented enrollee

who filed the request for hearing objects to a telephone or video-teleconferencing hearing, the enrollee or the enrollee's representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a video-teleconferencing or an in-person hearing.

(2) The enrollee must state the reason for the objection and state the time and/or place he or she wants an in-person or video-teleconferencing hearing to be held.

(3) The request must be in writing except for an expedited hearing for which the request may be provided orally. The ALJ must document all oral objections to an expedited video-teleconferencing or telephone hearing in writing and maintain the documentation in the case files.

(4) When an enrollee's request for an in-person or video-teleconferencing hearing is granted and an adjudication time frame applies in accordance with § 423.2016, the ALJ issues a decision, dismissal, or remand to the IRE within the adjudication time frame specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee if the request was for an in-person hearing, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person or by video-teleconference before the ALJ. Good cause is not required for a request for video-teleconferencing hearing made by an unrepresented enrollee who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with § 423.2022(a)(2).

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5130, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019]

§ 423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the enrollee and other potential participants, as provided in § 423.2020(c) at their last known addresses, or given by personal service, except to an enrollee or other potential participant who indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed, transmitted, or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed, transmitted, or served at least 3 calendar days before the hearing, unless the enrollee or other potential participant agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the non-expedited hearing or 3 calendar days before the expedited hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the coverage determination or at-risk determination, redetermination, or reconsideration that were not decided entirely in the enrollee's favor and that were specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 423.2032.

(2) The notice will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the enrollee fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

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(4) The enrollee will also be told if his or her appearance or that of any other witness is scheduled by video-teleconferencing, telephone, or in person. If the ALJ has scheduled the enrollee to appear at the hearing by video-teleconferencing, the notice of hearing will advise that the scheduled place for the hearing is a video-teleconferencing site and explain what it means to appear at the hearing by video-teleconferencing.

(5) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at § 423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the enrollee for an explanation.

(2) If the enrollee states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the enrollee and in accordance with OMHA procedures.

(3) The enrollee may request that the ALJ reschedule the hearing in accordance with § 423.2020(e).

[82 FR 5131, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2024 Objections to the issues.

(a) If an enrollee objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 calendar days before the hearing, except for expedited hearings in which the enrollee must submit written or oral notice of objection no later than 2 calendar days before the hearing. OMHA must document all oral objections in writing and maintain the documentation in the case files.

(b) The enrollee must provide the reasons for his or her objections.

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(c) The ALJ makes a decision on the objections either in writing, at a pre-hearing conference, or at the hearing.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5132, Jan. 17, 2017]

§ 423.2026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator may not adjudicate an appeal if he or she is prejudiced or partial to the enrollee or has any interest in the matter pending for decision.

(b) If an enrollee objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing if a non-expedited hearing is scheduled, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator must document all oral objections in writing and maintain the documentation in the case files. The ALJ or attorney adjudicator considers the enrollee's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the enrollee may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 423.2100 through § 423.2130. The Council will then consider whether the decision or dismissal should be revised or, if applicable, a new hearing held before another ALJ.

(d) If the enrollee objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by 14 calendar days for a standard appeal, or 2 calendar days for an expedited appeal.

[82 FR 5132, Jan. 17, 2017]

§ 423.2030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the enrollee and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept evidence that is material to the issues consistent with § 423.2018.

(2) The ALJ may limit testimony and argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the enrollee or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that the enrollee or enrollee's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the enrollee or representative to stop such behavior, the ALJ may excuse the enrollee or representative from the hearing and continue with the hearing to provide the participants with an opportunity to offer testimony and/or argument. If an enrollee or representative was excused from the hearing, the ALJ will provide the enrollee or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the enrollee or representative may request a recording of the hearing in accordance with § 423.2042 and respond in writing to any statements made by participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Effect of new evidence on adjudication period.* If an enrollee, other than an unrepresented enrollee in a standard

appeal, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 423.2016 is extended in accordance with § 423.2018(b) or (c), as applicable.

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 423.2022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the continuance and an adjudication time frame applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 423.2022, except that the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

[82 FR 5132, Jan. 17, 2017]

§ 423.2032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the appealed matter specified in the request for hearing that were brought out in the coverage

determination or at-risk determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor.

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS, the IRE, or the Part D plan sponsor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS, the IRE, or the Part D plan sponsor for the first time to the ALJ. The ALJ or the enrollee may raise a new issue; however, the ALJ may only consider a new issue relating to a determination or appealed matter specified in the request for hearing, including a favorable portion of a determination or appealed matter specified in the request for hearing, if its resolution could have a material impact on the appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the enrollee will have at least 10 calendar days in standard appeals or 2 calendar days in expedited appeals after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding coverage determinations to a pending appeal.* A coverage determination on a drug that was not specified in a request for hearing may only be added to a pending appeal if the coverage determination was adjudicated in the same reconsideration that is ap-

pealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on the reconsideration in accordance with § 423.2014(e).

[82 FR 5132, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019]

§ 423.2034 Requesting information from the IRE.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, the information may be requested from the IRE that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues, and official copies of dismissals of a request for redetermination or reconsideration, can be provided only by CMS, the IRE, and/or the Part D plan sponsor. Prior to issuing a request for information to the IRE, OMHA will confirm whether an electronic copy of the missing redetermination, reconsideration, or dismissal is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) “Can be provided only by CMS, the IRE, and/or the Part D plan sponsor” means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor Web site or information in an official CMS or HHS publication.

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The IRE has 15 calendar days for standard appeals, or 2 calendar days for expedited appeals, after receiving the request for information to furnish the information or otherwise respond to the information request directly or

through CMS or the Part D plan sponsor.

(d) If an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the date of the request for information and the date the IRE responds to the request or 20 calendar days after the date of the request for standard appeals, or 3 calendar days after the date of the request for expedited appeals, whichever occurs first.

[82 FR 5133, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) An enrollee has the right to appear at the hearing before the ALJ to present evidence and to state his or her position. An enrollee may appear by video-teleconferencing, telephone, or in person as determined under § 423.2020.

(2) An enrollee may also make his or her appearance by means of a representative, who may make his or her appearance by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(3) Witness testimony may be given and CMS, IRE, and Part D plan sponsor participation may also be accomplished by video-teleconferencing, telephone, or in person, as determined under § 423.2020.

(b) *Waiver of the right to appear.* (1) An enrollee may submit to OMHA a written statement indicating that he or she does not wish to appear at the hearing.

(i) For expedited hearings, an enrollee may indicate in writing or orally that he or she does not wish to appear at the hearing.

(ii) The OMHA hearing office must document all oral waivers in writing and maintain the documentation in the case files.

(2) The enrollee may subsequently withdraw his or her waiver in writing at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the enrollee agrees to an extension of the adjudication period as specified in § 423.2016, that may be necessary to schedule and hold the hearing.

(3) Even if the enrollee waives his or her right to appear at a hearing, the ALJ may require him or her to attend an oral hearing if the ALJ believes that a personal appearance and testimony by the enrollee is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* An enrollee or an enrollee's representative, as defined at § 423.560, may appear before the ALJ to state the enrollee's case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record.

(d) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the issues and allow the enrollee or his or her representative, as defined at § 423.560, to do so.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court. However, the ALJ may not consider evidence on any change in condition of an enrollee after a coverage determination or at-risk determination. If the enrollee wishes for the evidence to be considered, the ALJ must remand the case to the Part D IRE as set forth in § 423.2056(e).

(f)(1) *Subpoenas.* When it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative, issue subpoenas for the appearance and testimony of witnesses and for the enrollee and/or the 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. An ALJ may not issue a subpoena to CMS, or the IRE to compel an appearance, testimony, or the production of evidence, or to the Part D plan sponsor to compel an appearance or testimony.

(2) *Reviewability of an ALJ Subpoena.* A subpoena issued by an ALJ is not subject to immediate review by the Council. The subpoena may be reviewed

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solely during the Council's review specified in § 423.2102 and § 423.2110.

(3) *Exception.* To the extent a subpoena compels disclosure of a matter which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the Council may review immediately the ruling of the ALJ on the objections to the subpoena or that portion of the subpoena as applicable.

(i) Upon notice to the ALJ that the enrollee or a non-party, as applicable, intends to seek Council review of the ALJ's ruling on the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(ii) The proceedings are stayed for 15 calendar days or until the Council issues a written decision that affirms, reverses, or modifies the ALJ's subpoena, whichever comes first.

(iii) If the Council does not take action within the 15 calendar days, then the stay is lifted and the enrollee or non-party must comply with the ALJ's subpoena.

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

(ii) After submitting the enforcement request, the time period for the ALJ to issue a decision, dismissal or remand a case in response to a request for hearing is stayed for 15 calendar days or until the Secretary makes a decision with respect to the enforcement request, whichever occurs first.

(iii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the enrollee or person other than the enrollee subject to the subpoena.

(iv) The ALJ must promptly mail a copy of the notice and related documents to the individual or entity sub-

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ject to the subpoena, to the enrollee, and to any other affected person.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5133, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019; 86 FR 6121, Jan. 19, 2021]

§ 423.2038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s) prior notice and without an ALJ conducting a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Enrollee does not wish to appear.* (1) The ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available. OMHA must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS, the IRE, and/or the Part D plan sponsor submits a written statement or makes an oral statement at a hearing indicating the drug should be covered or payment may be made, or an enrollee's at-risk determination should be reversed, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the enrollee on the basis of the

statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

[82 FR 5133, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of the enrollee to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) For non-expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing, of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) All oral requests not to receive written notice of the conference must be documented in writing and the documentation must be made part of the administrative record.

(e) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice, if the enrollee consents to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(f) The ALJ issues an order to the enrollee and all participants who attended the conference stating all agreements and actions resulting from the conference. If the enrollee does not object within 10 calendar days of re-

ceiving the order for non-expedited hearings or 1 calendar day for expedited hearings, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on the enrollee.

[82 FR 5133, Jan. 17, 2017]

§ 423.2042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conference and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including but not limited to duplicative evidence submitted by the enrollee.

(3) An enrollee may request and receive a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if an enrollee seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, an enrollee may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of

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the audio recording of the oral proceedings. The enrollee may be asked to pay the costs of providing these items.

(2) If an enrollee requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 423.2016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the enrollee's response.

(3) If the enrollee requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the enrollee is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the enrollee obtains consent from the individual.

[82 FR 5134, Jan. 17, 2017]

§ 423.2044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the issue(s) may be more efficiently decided if the appeals are consolidated for hearing. In considering the enrollee's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an enrollee to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an enrollee to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hear-

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ing issued in accordance with §§ 423.2020 and 423.2022.

(b) *Consolidated decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the enrollee or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same enrollee, unless multiple enrollees aggregated appeals to meet the amount in controversy requirement in accordance with § 423.2006 and the enrollees have all authorized disclosure of information to the other enrollees.

[82 FR 5134, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing—*

(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(i) The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.

(ii) A copy of the decision should be mailed or otherwise transmitted to the

enrollee at his or her last known address.

(iii) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination or at-risk determination.

(2) *Content of the notice.* The decision must be provided in a manner calculated to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's or attorney adjudicator's decision is a new coverage determination under § 423.566.

(b) *Decisions on requests for review of an IRE dismissal—*(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of an IRE dismissal, or the dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the IRE's dismissal. OMHA mails or otherwise transmits a copy of the decision to the enrollee.

(2) *Content of the notice.* The decision must be written in a manner calculated

to be understood by an enrollee and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to the enrollee at his or her last known address.

[82 FR 5134, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018]

§ 423.2048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding unless—

(1) An enrollee requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 423.2110, and the Council issues a final decision or remand order;

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 423.1980;

(3) The expedited access to judicial review process at § 423.1990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 423.2138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of an IRE dismissal is binding on the enrollee unless the decision is reopened

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and revised by the ALJ or attorney adjudicator under the procedures explained in § 423.1980.

[82 FR 5135, Jan. 17, 2017]

§ 423.2050 Removal of a hearing request from OMHA to the Council.

If a request for hearing is pending before OMHA, the Council may assume responsibility for holding a hearing by requesting that OMHA send the hearing request. If the Council holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to the enrollee at his or her last known address informing him or her that the Council has assumed responsibility for the case.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5135, Jan. 17, 2017]

§ 423.2052 Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the enrollee that requested the hearing nor the enrollee's representative appears at the time and place set for the hearing, if—

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the enrollee acknowledged the notice of hearing, and the enrollee does not contact the ALJ within 10 calendar days after the hearing for non-expedited hearings and 2 calendar days after the hearing for expedited hearings, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the enrollee acknowledged the notice of hearing, the ALJ sends a notice to the enrollee at his or her last known address asking why the enrollee did not appear, and the enrollee does not respond to the ALJ's notice within 10 calendar days for non-expedited hearings or within 2 calendar days for expedited hearings after receiving the notice, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing. For expedited hear-

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ings, an enrollee may submit his or her response orally to the ALJ.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) the enrollee may have.

(2) The person requesting a hearing has no right to it under § 423.2002.

(3) The enrollee did not request a hearing within the stated time period and the ALJ has not found good cause for extending the deadline, as provided in § 423.2014(e).

(4) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(5) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because an IRE, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the enrollee's rights on the same facts and on the same issue(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The enrollee abandons the request for hearing. An ALJ may conclude that an enrollee has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the enrollee after making reasonable efforts to do so.

(7) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(b) *Dismissal of request for review of IRE dismissal.* An ALJ or attorney adjudicator dismisses a request for review of an IRE dismissal under any of the following conditions:

(1) The enrollee has no right to a review of the IRE dismissal under § 423.2004.

(2) The enrollee did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(3) The enrollee died while the request for review was pending and the request was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(4) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if the enrollee asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of an IRE dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing or review of the IRE dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 180 calendar days of the date of the notice of dismissal.

[82 FR 5135, Jan. 17, 2017, as amended at 84 FR 19873, May 7, 2019]

§ 423.2054 Effect of dismissal of a request for a hearing or request for review of an IRE's dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 423.2108(b), or vacated by the ALJ or attorney adjudicator under § 423.2052(e).

(b) The dismissal of a request for review of an IRE dismissal of a request for reconsideration is binding and not subject to further review unless vacated by the ALJ or attorney adjudicator under § 423.2052(e).

[82 FR 5136, Jan. 17, 2017]

§ 423.2056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed coverage determination or at-risk determination in accordance with § 423.2034, and the IRE, CMS, or Part D plan sponsor does not furnish the copy within the time frame specified in § 423.2034, an ALJ or attorney adjudicator may issue a remand directing the IRE or Part D plan sponsor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the IRE does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the IRE to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the IRE or Part D plan sponsor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the IRE issued a reconsideration and no redetermination was made with respect to the issue under appeal or the request for redetermination was dismissed, the reconsideration will be remanded to

the IRE, or its successor, to readjudicate the request for reconsideration, unless the request for redetermination was forwarded to the IRE in accordance with § 423.590(c) or (e) without a redetermination having been conducted.

(c) *Requested remand*—(1) *Request contents and timing*. At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the enrollee and CMS, the IRE, or the Part D plan sponsor may jointly request a remand of the appeal to the IRE. The request must include the reasons why the appeal should be remanded, and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request*. An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding an IRE's dismissal of a request for reconsideration*. (1) Consistent with § 423.2004(b), an ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that an IRE's dismissal of a request for reconsideration was in error.

(2) If an official copy of the notice of dismissal or case file cannot be obtained from the IRE, an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of this section.

(e) *Consideration of change in condition*. The ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that the enrollee wants evidence on his or her change in condition after the coverage determination or at-risk determination to be considered in the appeal.

(f) *Notice of a remand*. OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the enrollee at his or her last known address, and CMS, the IRE, and/or the Part D plan sponsor if a request to be a participant was granted by the ALJ or attorney adjudicator. The notice states that there is a right to request that the Chief ALJ or a designee review the remand, unless

the remand was issued under paragraph (d)(1) of this section.

(g) *Review of remand*. Upon a request by the enrollee or CMS, the IRE, or the Part D plan sponsor filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph (g) are not available for and do not apply to remands that are issued in paragraph (d)(1) of this section.

[82 FR 5136, Jan. 17, 2017, as amended at 83 FR 16754, Apr. 16, 2018; 84 FR 19873, May 7, 2019]

§ 423.2058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 423.2056(g).

[82 FR 5137, Jan. 17, 2017]

§ 423.2062 Applicability of policies not binding on the ALJ and Council.

(a) ALJs or attorney adjudicators and the Council are not bound by 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 a policy applies only to the specific coverage determination or at-risk determination being considered and does not have precedential effect.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137, Jan. 17, 2017; 83 FR 16754, Apr. 16, 2018]

§ 423.2063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare program, 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 CMS Administrator. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, and on all HHS components that 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, and all HHS components that adjudicate matters under the jurisdiction of CMS.

[82 FR 5137, Jan. 17, 2017]

§ 423.2100 Medicare Appeals Council review: general.

(a) An enrollee who is dissatisfied with 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) When the Council reviews an ALJ's or attorney adjudicator's written decision, it undertakes a de novo review.

(c) The Council issues a final decision, dismissal order, or remands a case to the ALJ or attorney adjudicator no later than the end of the 90 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited Council review.

(d) If an enrollee requests expedited Council review, the Council issues a final decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

[82 FR 5137, Jan. 17, 2017, as amended at 84 FR 19874, May 7, 2019]

§ 423.2102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

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

(2) An enrollee may request that Council review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the Council review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ's or attorney adjudicator's written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(ii) The Council must document all oral requests for expedited review in writing and maintain the documentation in the case files.

(3) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's written 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.

(4) 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) An enrollee 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 or, for expedited reviews, in writing or oral. The Council must document all oral requests in writing and maintain the documentation in the case file.

(2) The request 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) of this chapter.

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

[82 FR 5137, Jan. 17, 2017]

§ 423.2106 Where a request for review may be filed.

When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a written decision or dismissal, the request for review must be submitted to the entity specified in the notice of the ALJ's or attorney adjudicator's action. 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 enrollee of the date of receipt of the request and commencement of the adjudication timeframe.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137, Jan. 17, 2017]

§ 423.2108 Council Actions when request for review is filed.

(a) *General.* Except as specified in paragraph (c) of this section, when an enrollee 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 enrollee requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence admitted into 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 the ALJ or attorney adjudicator for further pro-

ceedings. Unless the Council's review is expedited as provided in paragraph (d) of this section, the Council must issue its action no later than 90 calendar days after receiving the request for review, unless the 90 calendar day period has been extended as provided in this subpart.

(b) *Review of ALJ's or attorney adjudicator's dismissal of a request for a hearing.* When an enrollee 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) *Council dismissal of request for review.* The Council will dismiss a request for review when the individual or entity requesting review does not have a right to a review by the MAC, 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) *Expedited reviews.* (1) *Standard for expedited reviews.* The Council must provide an expedited review if the appeal involves an issue specified in § 423.566(b), but does not include solely a request for payment of Part D drugs already furnished, enrollee's prescribing physician or other prescriber indicates, or the Council determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life or health or ability to regain maximum function. The Council may consider this standard as met if a lower level adjudicator has granted a request for an expedited appeal.

(2) *Grant of a request.* If the Council grants a request for expedited review, the Council must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Issue a decision, dismissal order or remand, as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received by the

entity specified in the ALJ's or attorney adjudicator's written notice of decision.

(3) *Denial of a request.* If the Council denies a request for expedited review, the Council must:

(i) Make this decision within 5 calendar days of receipt of the request for expedited review;

(ii) Give the enrollee and Part D plan sponsor within 5 calendar days of receiving the request written notice of the denial. The written notice must inform the enrollee of the denial and explain that the Council will process the enrollee's request using the 90 calendar day timeframe for non-expedited reviews.

(4) *Decision on a request.* A decision on a request for expedited review may not be appealed.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5137 Jan. 17, 2017]

§ 423.2110 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 the IRE may refer a case to the Council for it to consider reviewing under this authority any time within 60 calendar days of receipt of an ALJ's or attorney adjudicator's written decision or dismissal.

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

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's 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' or the IRE's 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 written decision or dismissal is received.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review—(1) Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate 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 or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA proceedings.* 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 or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal,

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may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

(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 5137, Jan. 17, 2017, as amended at 84 FR 19874, May 7, 2019]

§ 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 en-

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rollee 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.

(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 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, sub-

ject 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]

§ 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—

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(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 Council's decision 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 § 423.1990, 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 enrollee 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) *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 an enrollee due to an enrollee's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof an enrollee 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.

[74 FR 65363, Dec. 9, 2009, as amended at 82 FR 5139, Jan. 17, 2017; 84 FR 19874, May 7, 2019]

§ 423.2138 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 § 423.2140 will be followed.

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

§ 423.2140 Council Review of ALJ or attorney adjudicator decision in a case remanded by a Federal District Court.

(a) *General rules.* (1) In accordance with § 423.2138, 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 or attorney adjudicator 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 an enrollee 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) *An enrollee files exceptions disagreeing with the decision of the ALJ or attorney adjudicator.* (1) If an enrollee 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.

(2) 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.

(i) The enrollee must file exceptions within 30 calendar days of the date the enrollee receives the decision of the ALJ or attorney adjudicator or submit a written request for an extension within the 30 calendar day period.

(ii) 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 enrollee 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) of this chapter.

(3) If written exceptions are timely filed, the Council considers the enrollee'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.

(4) When an enrollee 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 written 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 the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the Council about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the Council will either issue a final decision 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 over the case within 60 calendar days after the date of the ALJ's or attorney adjudicator's written decision, the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand.

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

Subpart V—Part D Communication Requirements

SOURCE: 73 FR 54222, Sept. 18, 2008, unless otherwise noted.