

(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.