

**§ 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