

**§ 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