

§ 423.2600

§ 423.2600 Payment appeals.

If the Part D RAC did not apply its stated payment methodology correctly, a Part D plan sponsor may appeal the findings of the applied methodology. The payment methodology itself is not subject to appeal.

§ 423.2605 Request for reconsideration.

(a) *Time for filing a request.* The request for reconsideration must be filed with the designated independent reviewer within 60 calendar days from the date of the demand letter received by the Part D plan sponsor.

(b) *Content of request.* (1) The request for reconsideration must be in writing and specify the findings or issues with which the Part D plan sponsor disagrees.

(2) The Part D plan sponsor must include with its request all supporting documentary evidence it wishes the independent reviewer to consider.

(i) This material must be submitted in the format requested by CMS.

(ii) Documentation, evidence, or substantiation submitted after the filing of the reconsideration request will not be considered.

(c) *CMS Rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's reconsideration request.

(1) The rebuttal must be submitted within 30 calendar days of the review entity's notification to CMS that it has received the Part D plan sponsor's reconsideration request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the independent reviewer.

(d) *Review entity.* An independent reviewer conducts the reconsideration. The independent reviewer reviews the demand for repayment, the evidence and findings upon which it was based, and any evidence that the Part D plan sponsor or CMS submitted in accordance with this section.

(e) *Notification of decision.* The independent reviewer informs CMS and the Part D plan sponsor of its decision in writing.

(f) *Effect of decision.* A reconsideration decision is final and binding unless the Part D plan sponsor requests a hearing official review in accordance with § 423.2610.

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(g) *Right to hearing official review.* A Part D plan sponsor that is dissatisfied with the independent reviewer's reconsideration decision is entitled to a hearing official review as provided in § 423.2610.

§ 423.2610 Hearing official review.

(a) *Time for filing a request.* A Part D plan sponsor must file with CMS a request for a hearing official review within 30 calendar days from the date of the independent reviewer's issuance of a determination.

(b) *Content of the request.* (1) The request must be in writing and must provide evidence or reasons or both to substantiate the request.

(2) The Part D plan sponsor must submit with its request all supporting documentation, evidence, and substantiation that it wants to be considered.

(3) No new evidence may be submitted.

(4) Documentation, evidence, or substantiation submitted after the filing of the request will not be considered.

(c) *CMS rebuttal.* CMS may file a rebuttal to the Part D plan sponsor's hearing official review request.

(1) The rebuttal must be submitted within 30 calendar days of the Part D plan sponsor's submission of its hearing official review request.

(2) CMS sends its rebuttal to the Part D plan sponsor at the same time it is submitted to the hearing official.

(d) *Conducting a review.* A CMS-designated hearing official conducts the hearing on the record.

(1) The hearing is not to be conducted live or via telephone unless the hearing official, in his or her sole discretion, requests a live or telephonic hearing.

(2) In all cases, the hearing official's review is limited to information that meets one or more of the following:

(i) The Part D RAC used in making its determinations.

(ii) The independent reviewer used in making its determinations.

(iii) The Part D plan sponsor submits with its hearing request.

(iv) CMS submits in accordance with paragraph (c) of this section.

(3) Neither the Part D plan sponsor nor CMS may submit new evidence.

(e) *Hearing official decision.* The CMS hearing official decides the case within