

(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 60 days and sends a written decision to the Part D plan sponsor and CMS, explaining the basis for the decision.

(f) *Effect of hearing official decision.* The hearing official's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with §423.2610.

§423.2615 Review by the Administrator.

(a) *Request for review by Administrator.* If a Part D plan sponsor is dissatisfied with the hearing official's decision, it

may request that the CMS Administrator review the decision.

(1) The request must be filed with the CMS Administrator within 30 calendar days of the date of the hearing official's decision.

(2) The request must provide evidence or reasons to substantiate the request.

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

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

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

(c) *Discretionary review.* After receiving a request for review, the CMS Administrator has the discretion to review the hearing official's decision in accordance with paragraph (e) of this section or to decline to review said decision.

(d) *Notification of decision whether to review.* The CMS Administrator notifies the Part D plan sponsor within 45 days of receiving the Part D plan sponsor's hearing request of whether he or she intends to review the hearing official's decision. If the Administrator agrees to review the hearing official's decision, CMS may file a rebuttal statement within 30 days of the Administrator's notice to the plan sponsor that the request for review has been accepted. CMS sends its rebuttal statement to the plan sponsor at the same time it is submitted to the Administrator. If the CMS Administrator declines to review the hearing official's decision, the hearing official's decision is final and binding.

(e) *Administrator review.* If the CMS Administrator agrees to review the hearing official's decision, he or she determines, based upon this decision, the hearing record, and any arguments submitted by the Part D plan sponsor or CMS in accordance with this section, whether the determination should be upheld, reversed, or modified. The CMS Administrator furnishes a written decision, which is final and binding, to the Part D plan sponsor and to CMS.