

§ 423.2600

42 CFR Ch. IV (10–1–23 Edition)

(5) Section 423.165 for compliance deemed on the basis of accreditation.

(d) *Out-of-network access.* Section 423.124 Special rules for out-of-network access to Part D drugs at out-of-network pharmacies, except for § 423.124(a)(2), which applies to LI NET.

(e) *Medicare contract determinations and appeals.* Subpart N, except for the provisions that apply to LI NET in § 423.2520(d).

(f) *Risk-sharing arrangements.* Section 423.336(a), (b), and (d).

(g) *Certification of accuracy of data for price comparison.* Section 423.505(k)(6).

(h) *Part D communication requirements.* Portions of subpart V of this part related to Part D communication requirements that are inapplicable to LI NET, including:

(1) Section 423.2265(b)(4), (5), (11), and (13);

(2) Section 423.2265(c);

(3) Section 423.2266(a);

(4) Section 423.2267(e)(3) through (5), (9) through (12), (14) through (17), (25), (29), and (33); and

(5) Section 423.2274.

(i) *Medicare Coverage Gap Discount Program.* Subpart W of this part.

(j) *Requirements for a minimum medical loss ratio.* Subpart X of this part.

(k) *Recovery audit contractor Part C appeals process.* Subpart Z of this part.

[88 FR 22342, Apr. 12, 2023; 88 FR 34780, May 31, 2023]

Subpart Z—Recovery Audit Contractor Part D Appeals Process

SOURCE: 79 FR 29967, May 23, 2014, unless otherwise noted.

§ 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.

(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 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.