

§ 423.2518

(1) Experience covering low-income beneficiaries, including but not limited to enrolling and providing coverage to low-income subsidy individuals as defined in § 423.34;

(2) Pharmacy access as outlined in § 423.120;

(3) Past performance, including Star Ratings (as detailed in § 423.186), previous intermediate sanctions (as detailed in § 423.750), and consistent with past performance in § 423.503(b); and

(4) Ability to meet the requirements listed in § 423.505 that are not waived under § 423.2536.

(c) *Term of appointment.* The term of the appointment will be ongoing provided mutual agreement between CMS and the selected party, subject to an annual contracting and bid process (per § 423.2524(b)) to determine payment rates for the upcoming year.

§ 423.2518 Intermediate sanctions for the LI NET sponsor.

In the event it is determined that the LI NET sponsor violated its contract, CMS may impose intermediate sanctions as outlined in subpart O of this part.

§ 423.2520 Non-renewal or termination of appointment.

(a) *Notice of non-renewal.* If the LI NET sponsor decides for any reason to non-renew its existing contract, it must notify CMS by January 1 of the year before the next contract year. Except as provided in paragraph (c) of this section, if CMS decides for any reason to non-renew the existing contract with the incumbent LI NET sponsor, CMS notifies the LI NET sponsor by January 1 of the year before the next contract year.

(b) *Selection of successor and transition period.* After a notice of non-renewal or termination, CMS selects a successor for the LI NET contract from among potentially eligible entities (as detailed in § 423.2516). The outgoing LI NET sponsor must coordinate with the successor for a period of no less than 3 months to ensure seamless transition of the LI NET program, including timely transfer of any data or files.

(c) *Immediate termination for cause.* (1) Notwithstanding paragraph (a) of this section, CMS may immediately termi-

42 CFR Ch. IV (10–1–24 Edition)

nate the existing LI NET contract for any of the reasons specified at § 423.509(a)(4)(i) and (xii) or § (b)(2)(i)(A) and (B).

(2) CMS sends notice of an immediate termination as specified at § 423.509(b)(2)(ii).

(d) *Appeal rights.* Subpart N of this part applies to a termination under paragraph (c) of this section.

§ 423.2524 Bidding and payments to LI NET sponsor.

(a) *Source of payments.* CMS payments under this section are made from the Medicare Prescription Drug Account.

(b) *Submission of bids and related information.* (1) The submission of LI NET bids and related information must follow the requirements and limitations in § 423.265(b), (c), (d)(1), (d)(2)(i), (ii), (iv), and (v), (d)(4) and (6), and (e).

(2) The review, negotiation, and approval of the LI NET bid would follow the provisions in § 423.272(a) and (b)(1) and (4).

(3) Basic rule for bid. The bid must reflect the LI NET sponsor's estimate of its revenue needs for Payment Rates A and B per paragraph (c) of this section.

(c) *Monthly payments.* CMS provides advance monthly LI NET payments equal to the sum of Payment Rates A and B as established in the LI NET sponsor's approved bid, as outlined in paragraph (b) of this section. LI NET payments are made on a prospective per-member, per-month basis.

(1) Payment Rate A is an annual rate of payment for projected administrative costs. An annual percentage-based cap on Payment Rate A limiting the year over year increase to Payment Rate A is set as part of the bid review and negotiation under § 423.272(a).

(i) For the 2024 plan year, the LI NET sponsor includes in its bid the assumption that Payment Rate A cannot exceed a 2% increase from the prior year's Payment A, which is a figure CMS will provide to the LI NET sponsor.

(ii) For the 2025 plan year and subsequent plan years, the LI NET sponsor will specify its assumption for any increase needed to the prior year's Payment Rate A, submitting justification

to CMS in their bid if the cap exceeds 2%.

(2) Payment Rate B reflects the projected net costs of the Part D drugs dispensed to individuals who receive the LI NET benefit.

(d) *Payment reconciliation and risk corridors*—(1) *Reconciliation*. CMS conducts LI NET payment reconciliation each year for Payment Rates A and B after the annual PDE data submission deadline has passed and makes the resulting payment adjustment consistent with § 423.343(a).

(2) *Risk corridors*. As part of LI NET payment reconciliation, CMS will apply risk corridors to Payment Rate B as follows:

(i) There will be no risk sharing in the symmetrical 1% risk corridor around the target amount as defined in § 423.308.

(ii) There will be symmetrical risk sharing of 0.1% beyond the 1% risk corridor.

(iii) To carry out this section, § 423.336(c) applies to LI NET.

(e) *Reopening*. The LI NET contract will be subject to payment reopenings per § 423.346 as applicable.

(f) *Payment appeals*. The LI NET sponsor can appeal under § 423.350.

(g) *Overpayments*. The overpayment provisions at §§ 423.352 and 423.360 apply to LI NET.

§ 423.2536 Waiver of Part D program requirements.

CMS waives the following Part D program requirements for the LI NET program:

(a) *General information*. Paragraphs (1) and (3)(B) of section 1860D-4(a) of the Act (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(b) *Formularies*. Subparagraphs (A) and (B) of section 1860D-4(b)(3) of the Act (relating to requirements on development and application of formularies; formulary development) and formulary requirements in §§ 423.120(b) and 423.128(e)(5) and (6).

(c) *Cost control and quality improvement requirements*. Provisions under subpart D of this part, including requirements about medication therapy

management, are waived except for the provisions in § 423.2508(c)(1) through (5).

(1) Section 423.153(b) and (c) for dispensing and point-of-sale safety edits;

(2) Section 423.154 for appropriate dispensing of prescription drugs in long-term care facilities;

(3) Sections 423.159 and 423.160 for electronic prescribing, excepting the requirements pertaining to formulary standards in § 423.160(b)(5);

(4) Section 423.162 for QIO activities; and

(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

§ 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.

42 CFR Ch. IV (10–1–24 Edition)

(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