

§ 423.2480 MLR review and non-compliance.

To ensure the accuracy of MLR reporting, CMS conducts selected review of data submitted under § 423.2460 to determine that the MLRs and remittance amounts under § 423.2410(b) and sanctions under § 423.2410(c) and (d), were accurately calculated, reported, and applied.

(a) The reviews will include a validation of amounts included in both the numerator and denominator of the MLR calculation reported to CMS.

(b) Part D sponsors are required to maintain evidence of the amounts reported to CMS and to validate all data necessary to calculate MLRs.

(c)(1) Documents and records must be maintained for 10 years from the date such calculations were reported to CMS with respect to a given contract year.

(2) Part D sponsors must require any third party vendor supplying drug cost contracting and claim adjudication services to the Part D sponsors to provide all underlying data associated with MLR reporting to that Part D sponsor in a timely manner, when requested by the Part D sponsor, regardless of current contractual limitations, in order to validate the accuracy of MLR reporting.

(d) Data submitted under § 423.2460, calculations, or any other MLR submission required by this subpart found to be materially incorrect or fraudulent—

(1) Are noted by CMS;

(2) Appropriate remittance amounts are recouped by CMS; and

(3) Sanctions may be imposed by CMS as provided in § 423.752.

[78 FR 31310, May 23, 2013, as amended at 83 FR 16756, Apr. 16, 2018]

§ 423.2490 Release of Part D MLR data.

(a) *Terminology.* Subject to the exclusions in paragraph (b) of this section, Part D MLR data consists of the information submitted under § 423.2460.

(b) *Exclusions from Part D MLR data.* For the purpose of this section, the following items are excluded from Part D MLR data:

(1) Narrative descriptions that Part D sponsors submit to support the information reported to CMS pursuant to

the reporting requirements at § 423.2460, such as descriptions of expense allocation methods.

(2) Information that is reported at the plan level, such as the number of member months associated with each plan under a contract, including information submitted for a contract consisting of only one plan.

(3) Any information that could be used to identify Medicare beneficiaries or other individuals.

(4) MLR review correspondence.

(5) Any information for a contract for those contract years for which the contract is determined to be non-credible, as defined in accordance with § 423.2440(d).

(c) *Data release.* CMS releases to the public Part D MLR data, for each contract for each contract year, no earlier than 18 months after the end of the applicable contract year

[81 FR 80558, Nov. 15, 2016, as amended at 83 FR 16756, Apr. 16, 2018]

Subpart Y—Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries Through the Limited Income Newly Eligible Transition (LI NET) Program

SOURCE: 88 FR 22342, Apr. 12, 2023, unless otherwise noted.

§ 423.2500 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D-14 of the Social Security Act.

(b) *Scope.* This subpart sets forth the requirements for the Limited Income Newly Eligible Transition (LI NET) program that begins no later than January 1, 2024. Under this program, eligible individuals are provided transitional coverage for Part D drugs.

§ 423.2504 LI NET eligibility and enrollment.

(a) *Eligibility.* An individual is eligible for LI NET coverage if they satisfy the criteria at paragraph (a)(1) or (2) of this section.

(1) *LIS-eligible.* The individual is a low-income subsidy eligible individual as defined at § 423.773 and—

(i) Has not yet enrolled in a prescription drug plan or an MA–PD plan; or

(ii) Has enrolled in a prescription drug plan or MA–PD plan but their coverage has not yet taken effect.

(2) *Immediate need individuals.* An individual who states their eligibility for LIS and immediate need for their prescription, but whose eligibility as defined at § 423.773 cannot be confirmed at the point-of-sale, will be granted immediate need LI NET coverage.

(3) *Documentation of LIS eligibility.* Individuals may provide documentation to the LI NET sponsor to demonstrate LIS eligibility. Documentation may include, but is not limited to:

(i) A copy of the beneficiary’s Medicaid card that includes their name and the eligibility date;

(ii) A copy of a letter from the State or SSA showing LIS or “Extra Help” status;

(iii) The date that a verification call was made to the State Medicaid Agency, the name and telephone number of the State staff person who verified the Medicaid period, and the Medicaid eligibility dates confirmed on the call;

(iv) A copy of a State document that confirms active Medicaid status;

(v) A screen-print from the State’s Medicaid systems showing Medicaid status; or

(vi) Evidence at point-of-sale of recent Medicaid billing and payment in the pharmacy’s patient profile.

(4) *Confirmation of LIS eligibility.* CMS uses documentation submitted under paragraph (a)(3) of this section to confirm LIS eligibility.

(5) *Inability to confirmation of eligibility.* If CMS cannot confirm an immediate need individual’s eligibility during the period of LI NET coverage, the individual will not be auto-enrolled into a standalone Part D plan in accordance with § 423.34(d) following their LI NET coverage.

(b) *Enrollment.* Individuals who are eligible for LI NET as defined in § 423.2504 are enrolled into the LI NET program as follows:

(1) *Automatic enrollment.* Beneficiaries who are LIS-eligible and whose auto-enrollment into a Part D plan (as outlined in § 423.34(d)(1)) has not taken effect will be automatically enrolled by CMS into the LI NET program unless

the beneficiary has affirmatively declined enrollment in Part D per § 423.34(e);

(2) *Point-of-sale enrollment.* An individual who is not automatically enrolled in accordance with paragraph (b)(1) of this section and whose claim is submitted at the point-of-sale and accepted by the LI NET sponsor will be enrolled into the LI NET program by the LI NET sponsor; or

(3) *Direct reimbursement request.* An individual described in paragraph (a)(1) of this section who is not automatically enrolled in accordance with paragraph (b)(1) or at the point-of-sale as provided in paragraph (b)(2) of this section and who submits a direct reimbursement request form, receipts for reimbursement for eligible claims paid out of pocket (with and optional documentation of LIS eligibility listed in paragraph (a)(3) of this section), will be retroactively enrolled into the LI NET program by the LI NET sponsor. The LI NET sponsor has 14 calendar days to reply with a coverage decision; or

(4) *LI NET application form.* An individual who is not enrolled through one of the methods in paragraphs (b)(1) through (3) of this section may submit an LI NET application form to the LI NET sponsor (with optional documentation of LIS eligibility listed in paragraph (a)(3) of this section). If no documentation is submitted and accepted, the LI NET sponsor will periodically check for eligibility and enroll applicants once LIS eligibility is confirmed.

(c) *Duration of LI NET enrollment.* (1) Enrollment begins on the first day of the month an individual is identified as eligible under this section and ends after 2 months, with a longer LI NET enrollment for those with retroactive coverage per paragraph (c)(2) of this section.

(2) Retroactive LI NET coverage begins on the date an individual is identified as eligible for a low-income subsidy as a full-benefit dual eligible or an SSI benefit recipient, or 36 months prior to the date such individual enrolls in (or opts out of) Part D coverage, whichever is later. LI NET coverage ends with enrollment into a Part D plan or opting out of Part D coverage.

(d) *Ending LI NET enrollment.* An individual's enrollment in the LI NET program ends when:

(1) The individual is auto-enrolled into a standalone Part D plan in accordance with the guidelines at § 423.34(d) and that coverage has taken effect.

(2) The individual elects another Part D plan and that coverage has taken effect.

(3) The individual voluntarily disenrolls from the LI NET program.

(4) The individual is involuntarily disenrolled under § 423.44(b).

(5) LIS eligibility for an individual in LI NET due to an immediate need cannot be confirmed within the period of LI NET coverage.

§ 423.2508 LI NET benefits and beneficiary protections.

(a) *Formulary.* The LI NET program provides access to all Part D drugs under an open formulary.

(b) *Network.* The LI NET sponsor must allow its network and out-of-network pharmacies that are in good standing to process claims under the program. Licensed pharmacies are considered to be in good standing for the LI NET program so long as they: are not revoked from Medicare under § 424.535; do not appear on the Office of Inspector General's list of entities excluded from Federally funded health care programs pursuant to section 1128 of the Act or from Medicare and State health care programs under section 1156 of the Act (unless waived by the OIG); do not appear on the preclusion list as defined at § 423.100; and do not have a determination by the LI NET sponsor of a credible allegation of fraud as defined at § 423.4.

(c) *Safety.* The following provisions necessary to improve patient safety and ensure appropriate dispensing of medication apply to the LI NET program and LI NET sponsor, as applicable:

(1) Sections 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) *Cost sharing.* (1) LI NET beneficiaries under § 423.2504(a)(1) will pay the applicable cost sharing for their low-income category as established for each year in the Rate Announcement publication specified in § 422.312 of this chapter.

(2) LI NET beneficiaries under § 423.2504(a)(2) will pay the cost sharing associated with the category of non-institutionalized full-benefit dual eligible individuals with incomes above 100% of the Federal poverty level and full-subsidy-non-FBDE individuals. If the beneficiary is later confirmed to belong to a different LIS category, the LI NET sponsor must reimburse the beneficiary for the difference between the cost sharing they paid versus what they would have paid in their LIS category.

(e) *Appeals.* LI NET enrollees have rights with respect to Part D grievances, coverage determinations, and appeals processes set out in subpart M of this part.

§ 423.2512 LI NET sponsor requirements.

The LI NET program is administered by one or more Part D sponsor(s) that meet all of the requirements in paragraphs (a) through (c) of this section.

(a) *Pharmacies and access to Part D drugs.* (1) The LI NET sponsor must be a PDP sponsor that has an established contracted pharmacy network in all geographic areas of the United States in which low-income subsidies are available.

(2) The LI NET sponsor must meet the requirements for providing access to Part D drugs under § 423.120(a), (c), and (d).

(b) *Experience.* The LI NET sponsor must have a minimum of two consecutive years contracting with CMS as a Part D sponsor.

(c) *Other LI NET sponsor requirements.* The LI NET sponsor must:

(1) Have the technical capability and the infrastructure to provide immediate, current, and retroactive coverage for LI NET enrollees;

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(2) Have the technical capability to develop the infrastructure necessary for verifying Medicaid dual eligibility status for presumed eligible LI NET enrollees.

(3) Identify, develop, and conduct outreach plans in consultation with CMS targeting key stakeholders to inform them about the LI NET program.

(4) Establish and manage a toll-free customer call center per § 423.128(d)(1) and fax line that can be accessed by pharmacy providers and beneficiaries, or others acting on their behalf, for purposes that include but are not limited to: handling inquiries about services under the LI NET program, providing the status of eligibility or claims, and having the ability to accept supporting documentation.

(5) Timely respond to beneficiary requests for reimbursement of claims by issuing reimbursement for eligible claims submitted by beneficiaries no later than 30 days after receipt, or, if the drug is not covered, the LI NET sponsor has 14 days to send communication to the beneficiary with a reason for the denial.

(6) Adjudicate claims from out-of-network pharmacies that are in good standing (as defined in § 423.2508(b)) according to the LI NET sponsor's standard reimbursement for their network pharmacies.

§ 423.2516 Selection of LI NET sponsor and contracting provisions.

(a) *Appointment by CMS.* CMS appoints a Part D sponsor that meets the requirements at § 423.2512 to serve as the LI NET sponsor.

(b) *Selection criteria.* In appointing a LI NET sponsor, CMS evaluates the following:

(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 terminate 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 result-

ing 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

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(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.