

(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.