

Supporting Statement – Part A
Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-
Income Beneficiaries through the Limited Income Newly Eligible Transition (LI NET)
Program
(CMS-10831, OMB 0938-1441)

Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173) enacted on December 8, 2003, established the Medicare Part D prescription drug benefit, which became effective on January 1, 2006. Prior to 2006, beneficiaries who were eligible for both Medicaid and Medicare (dually eligible) received prescription drug benefits through Medicaid. When the MMA went into effect, dually eligible beneficiaries began receiving their prescription drug benefits through Medicare Part D.

In 2010, the Centers for Medicare & Medicaid Services (CMS) established the Medicare Part D Demonstration for Retroactive and Point-of-Sale Coverage for Certain Low-Income Beneficiaries (also known as Medicare’s Limited Income Newly Eligible Transition (LI NET) demonstration). The LI NET demonstration consolidates administration of transitional and retroactive Part D coverage for eligible beneficiaries to a single Part D sponsor. The LI NET demonstration provides an exception to the 36-month maximum period of retroactive enrollment if there is a Medicaid determination within the last 90 days that confers Medicaid eligibility going back further than 36 months. In these situations, LI NET enrollment under the demonstration goes back to the start of Medicaid eligibility.

Section 118 of the Consolidated Appropriations Act, 2021 (CAA) (Public Law 116-260) enacted on December 27, 2020, amended Section 1860D-14 of the Social Security Act (the Act) (42 U.S.C. 1395w-114) and authorized CMS to make transitional coverage and retroactive Medicare Part D coverage for certain low-income beneficiaries, called the Limited Income Newly Eligible Transition (LI NET) program a permanent part of the Part D program. The LI NET program under this statute must begin no later than January 1, 2024.

This New collection of information request is associated with our April 12, 2023 (88 FR 22120) final rule (CMS-4201-F; RIN 0938-AU96). The rule revises the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, and other programmatic areas. The rule also codifies regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, section 11404 of the Inflation Reduction Act, and includes other provisions that codifies existing sub-regulatory guidance in the Part C, Part D, and PACE programs.

See section 12 of this Supporting Statement for a more complete discussion of the collection of information requirements and burden estimates. The requirements include two forms for beneficiaries use:

- Application to Enroll in the Limited Income Newly Eligible Transition (LI NET) Program
- Direct Reimbursement Request for the Limited Income Newly Eligible Transition (LI NET) Program

There are no private sector forms for pharmacists and for LI NET sponsors.

The purpose of this submission is to comply with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.).

A. Justification

1. Need and Legal Basis

Section 118 of the CAA amended Section 1860D-14 of the Act with a new subsection (e) to provide transitional Part D coverage for LI NET eligible individuals. Section 1860D-14(e)(2) of the Act provides that an LI NET eligible individual is a Part D eligible individual who (1) meets the requirements of clauses (ii) and (iii) of subsection (a)(3)(A); and (2) has not yet enrolled in a prescription drug plan or a Medicare Advantage Prescription Drug plan, or, who has so enrolled, but with respect to whom coverage under such plan has not yet taken effect.

CMS regulations (CMS-4201-F) provide Transitional Coverage and Retroactive Medicare Part D Coverage for Certain Low-Income Beneficiaries through the LI NET Program at 42 CFR 423.2500 - 423.2536.

CMS enrolls most LI NET beneficiaries automatically, with no information provided directly by beneficiaries. Under our policies, those who are not automatically enrolled may enroll in LI NET 1) at the point-of-sale, 2) by submitting a direct reimbursement request, or 3) completing and submitting an LI NET application form.

- 1) Point-of-sale. Individuals 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. Ideally, these beneficiaries would be able to show documentation of their pending low-income subsidy (LIS) status, such as a letter from the State showing the beneficiary's LIS status. However, we do not believe an absence of documentation in hand at the point-of-sale should be a barrier to entry to LI NET for immediate need individuals. This is because our experience in the demonstration is that 80 percent of immediate need individuals do have their eligibility confirmed, and we would not want to turn away these individuals who imminently require access to their prescription drugs.
- 2) Direct reimbursement request. Individuals who submit a direct reimbursement request form, receipts for reimbursement for eligible claims paid out of pocket, and optional documentation of LIS eligibility listed in 42 CFR 423.2504(a)(3) 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. This typically occurs when a beneficiary is retroactively enrolled in LI NET and may have incurred

expenses that LI NET would have covered had they been enrolled at the time. These beneficiaries may complete a form available online, and return by mail or fax, together with their receipt, to the LI NET sponsor.

- 3) LI NET application form. An individual who is not enrolled automatically by CMS or through point-of-sale or direct reimbursement request may submit an application form to the LI NET sponsor with optional documentation of LIS eligibility listed in 42 CFR 423.2504(a)(3). If no documentation is submitted and accepted, the LI NET sponsor will periodically check for eligibility and enroll applicants once LIS eligibility is confirmed.

Point-of-sale, direct reimbursement requests, and LI NET application forms represent a small portion of LI NET beneficiaries as CMS automatically enrolls 90-95% of LI NET beneficiaries based on low-income data we maintain in our systems. Most beneficiaries pay their zero or reduced cost-sharing at point-of-sale and have no reason to seek direct reimbursement from the LI NET sponsor.

2. Information Users

As described above, Part D beneficiaries may be enrolled in LI NET: (1) automatically by CMS, (2) at the point-of-sale, (3) by submitting a direct reimbursement request, or (4) by completing and submitting an LI NET application form. Pharmacies, the LI NET sponsor, and CMS will use the information collected to determine eligibility for enrollment into LI NET.

3. Improved Information Technology

The information provided by LI NET beneficiaries is largely paper-based, such as showing a Medicaid eligibility letter to a pharmacist or sending a signed direct reimbursement request through the mail or by fax. Beneficiaries could also opt to e-mail a digital copy of their documentation to the LI NET sponsor. We believe the flexibility to allow either paper or digital supporting documentation is desirable, and would not want to add to beneficiary burden by restricting the submission to solely paper or solely digital. We may explore developing capacity for online submission of these documents in the future, but have not done so because the numbers of individuals engaging in these activities are modest compared to the size of the program. In 2021, about 37,000 individuals out of about 600,000 people enrolled due to immediate need, and an unknown subset of these individuals chose to present documentation of their low-income status. About 250 people submitted direct reimbursement requests and only 10 submitted LI NET application forms.

For supporting documentation related to point-of-sale enrollments, CMS reviews it and makes an LI NET eligibility determination.

4. Duplication of Similar Information

This collection does not contain duplication of similar information.

5. Small Businesses

Some pharmacies and Part D sponsors are small businesses so there is potential they may be affected if they fill claims for beneficiaries at the point-of-sale or become an LI NET sponsor.

6. Less Frequent Collection

This collection does not set out any daily, weekly, monthly, or annual requirements. Rather, this information is collected as needed to support the administration of the LI NET program.

7. Special Circumstances

There are no special circumstances that would require this information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Serving as the 60-day notice, our proposed rule (CMS-4201-P; RIN 0938-AU96) published in the Federal Register on December 27, 2022 (87 FR 79452). Comments were received on the proposed rule, but none pertained to the COI section of the rule or the PRA.

Our final rule (CMS-4201-F; RIN 0938-AU96) published in the Federal Register on April 12, 2023 (88 FR 22120).

9. Payments/Gifts to Respondents

In accordance with § 423.2504, approved direct reimbursement requests will result in the LI NET sponsor reimbursing beneficiaries for claims paid out of pocket during their period of LI NET eligibility.

10. Confidentiality

The information collected from Medicare beneficiaries and contained in medical records, and other health and enrollment information, is disclosed as specified in the System of Records Notice (SORN) “Medicare Advantage Prescription Drug (MARx)”, System No. 09-70-0588 (February 14, 2018; 83 FR 6591). Sections 1851 and 1860D-1 of the Act and 42 CFR 423.30 and 423.32 authorize the collection of this information including all Federal and State laws regarding confidentiality and disclosure.

11. Sensitive Questions

This collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

Wage Estimates

Private Sector Wages: To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2021 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Wage (\$/hr)
Business operations specialists (all others)	13-1199	38.1	38.1	76.20
Pharmacist	29-1051	60.43	60.43	120.86

As indicated in the preceding table, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Beneficiaries: We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of \$20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of \$998, divided by 40 hours to calculate

an hourly pre-tax wage rate of \$24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of \$20.71/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

Information Collection Requirements and Associated Burden Estimates

This New collection of information request is associated with our April 12, 2023 (88 FR 22120) final rule (CMS-4201-F; RIN 0938-AU96). We are setting out that rule's PRA related requirements and burden estimates to comply with the requirements of the PRA.

Section II.D.2 of the final rule describes the eligibility and enrollment in the LI NET program. While CMS automatically enrolls most LI NET beneficiaries, about 90-95% of LI NET beneficiaries, based on low-income data we maintain in our systems, we expect that some beneficiaries, about five to ten percent of LI NET beneficiaries, will enroll in LI NET using methods that may entail providing information. Some beneficiaries may enroll in LI NET at the point-of-sale (POS) at a pharmacy because: 1) they are likely eligible for the low-income subsidy (LIS), have immediate need for their prescription, and do not have Part D coverage or 2) present documentation with their LIS status at the pharmacy and do not have Part D coverage. Some beneficiaries submit receipts for reimbursement for claims paid out of pocket; if they are eligible for LI NET they will be retroactively enrolled into the LI NET program by the LI NET sponsor. Another way for beneficiaries to potentially enrollment into LI NET is by complete an LI NET application form.

To estimate the total burden, we consider the burden for enrollees, pharmacists, and Part D sponsors separately. Each consideration entails counting the number of documents arising from point of sale enrollments, direct reimbursement forms, and LI NET application forms.

For Beneficiaries: To estimate the information collection burden for beneficiaries, we have estimated the number of beneficiaries submitting information to LI NET and time related to handling the information. We have not included burden estimates for individuals who would not be providing documentation, such as those CMS automatically enrolls into LI NET, individuals whose eligibility for LI NET is confirmed independently by the LI NET sponsor, or for those who opt not to provide evidence.

When enrolling in LI NET at POS, possible forms of evidence for LIS eligibility include but are not limited to, a Medicaid card or award letter from the State or SSA showing LIS or "Extra Help" status. We estimate that it would take an individual approximately 15 minutes (0.25 hr) to gather supporting documentation. There are 36,722 individuals enrolled in the LI NET demonstration at POS in 2021 who will apply at the point of sale. Based on our experience with the LI NET demonstration, we estimate approximately 250 beneficiaries would submit receipts for reimbursement for claims paid out of pocket. These beneficiaries may complete a direct reimbursement request form available online, and return by mail, e-mail, or fax, together with their receipt, to the LI NET sponsor. In the LI NET demonstration, approximately ten beneficiaries per year complete the LI NET application form, which is available online, and

return it to the LI NET sponsor by mail, e-mail, or fax. Thus, in total we expect 36,982 beneficiaries (36,722 (99.3%) at point of sale plus 250 (0.67%) through direct reimbursement plus 10 (0.03%) applying via the LI NET application form) to spend 15 minutes (0.25 hr) resulting in an aggregate burden of 9,246 hours (36,982 enrollees * 0.25 hr) at an aggregate cost of \$191,485 (9,246 hr * \$20.71/hr).

For the Private Sector (Pharmacists): We estimate that it will take 2 minutes (0.0333 hr) for a pharmacy to fax the documentation to the LI NET sponsor. However, pharmacists will not process the forms of enrollees who use direct reimbursement or the LI NET application form. Thus, pharmacists will only process the 36,722 enrollees at point of sale. Thus, the aggregate burden for pharmacists is 1,223 hours (36,722 enrollees * 0.0333 hr) at an aggregate cost of \$147,812 (1,223 hr * \$120.86/hr).

For LI NET Sponsor: The LI NET sponsor will process the documents received from all 36,982 enrollees. Part D sponsors are estimated to spend about 2 minutes (0.0333 hr) to process and fax information to CMS. Thus, the aggregate burden for Part D sponsors is 1,232 hours (36,982 enrollees * 0.0333 hr) at an aggregate cost of \$93,878 (1,232 hr * \$76.20/hr).

Burden Summary

Section(s) in Part 42 of the CFR	Respondents	Total Number of Responses	Time Per Response (hr)	Total Annual Time (hr)	Hourly Labor Cost (\$/hr)	Total Cost (\$)
423.2504	36,982 Beneficiaries	36,982	0.25	9,246	20.71	191,485
423.2504	36,722 Pharmacists	36,722	0.0333	1,223	120.86	147,812
423.2504	1 (one) Sponsor	36,982	0.0333	1,232	76.20	93,878
TOTAL	73,705	110,686	Varies	11,701	Varies	433,175

Collection of Information Instruments and Instruction/Guidance Documents

The following forms are for beneficiaries use. There are no private sector forms.

- Application to Enroll in the Limited Income Newly Eligible Transition (LI NET) Program
- Direct Reimbursement Request for the Limited Income Newly Eligible Transition (LI NET) Program

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to the Federal Government

CMS' role related to LI NET involves existing systems and processes and the relevant information collection would not impart additional cost. Pharmacies and the LI NET sponsor are responsible for the information collection requirements in this package. LI NET sponsor receives

the information, determines eligibility, makes a determination if the enrollment is accepted, denied, or incomplete and finally communicates the decision to the beneficiary within specified timeframes. CMS systems provide automated responses to sponsor submitted transactions on a transaction reply report, which includes no additional burden or cost. There is no change to the process CMS uses for the sponsor to submit the enrollment and, therefore, there is no additional cost to the Federal Government.

Regardless, the following is an assessment of the costs incurred in the normal course of business operations.

CMS Central Office Staff: 1 FTE (GS-13 Step 1) working at 5% of assigned duties.

Annual Time: 104 hours (2,080 hr x 0.05)

Adjusted Hourly Wage: \$94.40/hr (\$47.20/hr + \$47.20/hr)

Annual Cost: = \$9,818 (\$94.40/hr) x (104 hr)

\$47.20/hr is derived from OPM's 2023 Salary Table at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/RUS_h.pdf

\$94.40/hr is calculated from 100% of the hourly wage (\$47.20/hr x 2) to account for fringe benefits and overhead.

15. Program/Burden Changes

Not applicable. There are no changes since this is a new collection of information request.

16. Publication/Tabulation Dates

There are no publication/tabulation dates.

17. Expiration Date

The expiration date will be displayed on the forms listed under section 12 of this Supporting Statement.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.