

Supporting Statement Part A
Application for Enrollment in Part B Immunosuppressive
Drug Coverage (Part B-ID)
CMS-10798, OMB 0938-1428

Background

Medicare is a Federal program that provides health insurance to people age 65 and older, and those under 65 with certain disabilities or end-stage renal disease (ESRD). Section 226A(a) of the Social Security Act (the Act) provides that certain individuals who are medically determined to have ESRD and apply for Medicare coverage, are entitled to benefits under Medicare Part A and eligible to enroll in Part B. However, section 226A(b)(2) of the Act currently requires that an individual's entitlement under Part A and eligibility under Part B based on ESRD status ends with the 36th month after the month in which the individual receives a kidney transplant.

Section 402 of the Consolidated Appropriations Act, 2021 (CAA) amended section 226A(b)(2) (and made conforming changes to sections 1836, 1837, 1838, 1839, 1844, 1860D-1, 1902, and 1905 of the Act) to make certain individuals eligible for enrollment under Medicare Part B solely for purposes of coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Effective January 1, 2023, this provision will allow certain individuals whose Medicare entitlement based on ESRD would otherwise end after a successful kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act.

In order for an individual to be enrolled in the Part B-ID benefit, section 1836(b)(2)(B)(ii) (I) of the Act requires that an individual provide to the Commissioner an attestation that they are not enrolled and do not expect to enroll in other coverage that would make the individual ineligible for the Part B-ID benefit.

This information collection request is associated with our final rule (CMS-4199-F; RIN 0938-AU85). The rule provides the required attestation via telephone, completion and submission of website-accessed PDF- fillable forms, or completion of paper forms requested from CMS or SSA (the Social Security Administration), and eventually fax and online. Generally, for the telephonic attestation, an individual will contact SSA, and a representative, using a standard script, will repeat the requirements to the individual that are in the attestation form.

A. Justification

1. Need and Legal Basis

Sections 226A, 1836(b) and 1837(n) of the Act provide the statutory authority for this

new, limited Medicare entitlement program, and we are adding a description of this basis for the Part B-ID benefit at § 407.1(a)(6). Sections 1836(b) and 1837(n) of the Act and § 407.1(a)(6) of our final rule provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023, for eligible individuals whose benefits under Medicare Part A and eligibility to enroll in Part B on the basis of ESRD would otherwise end with the 36th month after the month in which the individual receives a kidney transplant by reason of section 226A(b)(2) of the Act.

2. Information Users

The CMS-10798 provides the necessary information to determine eligibility and to process the beneficiary's request for enrollment for in Part B-ID coverage. This form is only used for enrollment by beneficiaries whose Medicare entitlement based on ESRD would otherwise end after a successful kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs who already have Part A, but not Part B.

Form CMS-10798 is completed by the individual, or is completed by an SSA representative using information provided by the Medicare enrollee during a telephone interview. The form is owned by CMS, but not completed by CMS staff. SSA processes Medicare enrollments on behalf of CMS.

3. Use of Information Technology

The form CMS-10798 will be available on the internet at (<https://www.cms.gov>). Individuals complete the form and submit it to SSA, either via US mail or in person at a local field office for processing.

In addition to the paper application as described above, applicants may apply via interview with an SSA employee over the phone or at a field office. Although technology is used in the collection, processing and storage of the data, the burden is not reduced by the use of technology. The burden is in the interview to solicit and clarify information that is collected for the application.

4. Duplication of Efforts

This information does not duplicate any other effort, as the person with Medicare must initiate the request for enrollment into Part B-ID coverage. Use of this form or contacting SSA telephonically to enroll is the initial request by the individual.

This information is not available from any other source.

5. Small Businesses

Small businesses are not affected by the collection of this information.

6. Less Frequent Collection

This information is collected only as needed, and only when an individual requests to enroll in Part B-ID. Each individual respondent uses the form one time when he or she submits the request to enroll in Part B-ID. If this information is not collected, the individual cannot enroll in Part B-ID. Since the statute permits enrollment and specific data is necessary to determine eligibility, the burden cannot be minimized.

7. Special Circumstances

There are no special circumstances that would require an 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-4199-P; RIN 0938-AU85) published in the Federal Register on April 27, 2022 (87 FR 25090).

Based on public comments, the collection methods have changed, however, the form did not change. Specifically, telephonic enrollment was added as an enrollment method under § 407.59. A summary of the comments and our response is attached to this

package.

Our final rule (CMS-4199-F; RIN 0938-AU85) displayed at the Federal Register on August 28, 2022. The publication citation will be added upon publication of the rule.

9. Payment/Gift to Respondents

There are no payments or gifts provided to respondents.

10. Confidentiality

This collection will be used solely by SSA for the purpose of enrolling a beneficiary into Medicare Part B-ID. Both CMS and SSA are responsible for ensuring that all personally identifiable information (PII) remains confidential.

The completed form is not provided to CMS, rather it is stored with SSA Under Privacy Act System of Records Notice (SORN) 60-0090, entitled Master Beneficiary Record, as published in the Federal Register (FR) on January 11, 2006, at 71 FR 1826.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the 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. Collection of Information Requirements and Associated Burden Estimates

Wage Estimates

To derive average costs for individuals we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for our salary estimate (www.bls.gov/oes/current/oes_nat.htm).

We believe that the burden will be addressed under All Occupations (occupation code 00-0000) at \$28.01/hr since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. We are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

Requirements and Associated Burden Estimates

We estimate that there will be approximately 767 respondents annually requesting enrollment in Part B-ID using the form CMS-10798 or telephonic enrollment. This

estimate was provided by CMS actuaries based on historical information provided by SSA on the number of individuals who had prior Medicare Part A coverage and a kidney transplant between 2001 and 2019, and then making downward adjustments to account for those individuals who are deceased or who are anticipated to have other comprehensive coverage and would not be eligible for the Part B-ID benefit. The overall results of applying these assumptions is that roughly 1,800 individuals would be enrolled in the Part B-ID benefit in 2023, with an estimated growth of 250 enrollees each year thereafter. This would equate to approximately 2,300 individuals enrolling in the Part B- ID benefit from 2023 through 2025 (1,800 individuals + 250 individuals + 250 individuals), or an annual estimated enrollment of 767 individuals (2,300 individuals/3 years).

The average completion time for the paper CMS-10798 or telephonic enrollment is 10 minutes (0.167 hr). In aggregate we estimate an annual burden of 128 hours (767 responses x 0.167 hr/response) at a cost of \$3,585 (128 hr x \$28.01/hr) or \$4.67 per beneficiary (\$3,585 / 767 respondents).

Collection of Information Instruments and Instruction/Guidance Documents

- *Application for Enrollment in Part B Immunosuppressive Drug Coverage*

The form consists of five questions and an attestation that must be answered to determine an individual's eligibility for Part B-ID. The questions request information to identify the applicant and obtain contact information. The identity information includes name, address, phone number, and Social Security number (SSN) or Medicare Number if the applicant is already a Medicare recipient.

The applicant would attest that they are not enrolled and do not expect to enroll in any coverage that would make them individual ineligible for the Part B-ID benefit.

Our justification for requesting the SSN is attached to this collection of information request.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Wage Estimate

To derive average costs, we used data from the Office of Personnel Management 2022 General Schedule (GS) Locality Pay Table for all salary estimates (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary->

tables/22Tables/html/GS_h.aspx). We estimate that the average government employee at SSA to receive and record the collected data to be a Grade 11, Step 1 (GS-11-1) – which we believe is the most appropriate level for a SSA field office representative.

As the processing of this form occurs at the national level and not just one geographic location, we estimated the salary using the national base general schedule. Such an hourly wage is \$27.30/hr or \$56,983 annually.

Burden Estimates

Based on the information collected on the form, we estimate it will take a federal government employee 10 minutes (0.167 hr) to review and record the collected data (process the enrollment), either by paper form or telephonic enrollment.

In aggregate, we estimate a burden of 128 hours (767 responses x 0.167 hr/response) at a cost of \$3,495 (128 hr x \$27.30/hr).

15. Changes to Burden

Changes are not applicable since this is a new collection of information.

16. Publication/Tabulation Dates

The collected information is not published or tabulated.

17. Expiration Date

The form displays the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

Not applicable. There are no statistical methods.