

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

Background

Medicare is a federal program to provide health insurance for 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 would 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.

Pursuant to 42 CFR 407.59, an individual can provide the required attestation verbally, electronically (online or telephone), by fax, or by completing paper forms requested from CMS or SSA. Generally, for the telephonic attestation, an individual will contact the Social Security Administration (SSA), and a representative, using a standard script, will repeat the requirements to the individual that are in the CMS-10798 attestation form.

To increase the beneficiary application experience, this form can be completed physically and mailed, during a phone interview with an SSA employee, and in person at field offices. The enrollment data from 2023 demonstrates a successful ability for individuals to gain immunosuppressive drug coverage benefits.

CMS is revising enrollment forms to improve usability for the general public. Attestations have been separated and clarified to make sure individuals are separately attesting first that they don't have other health coverage at the point of enrollment and

second that they will contact SSA if they get other health coverage. This 2024 iteration is a revision that does not propose any program changes.

CMS also plans to have these forms translated into Spanish, Vietnamese, Chinese and Korean to increase accessibility for the Medicare population.

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. It is stated in § 407.1(a)(6) that, sections 1836(b) and 1837(n) of the Act 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

Federal Register Notice

The 60-day notice published in the Federal Register on 12/23/2024 (89 FR 104545) One comment was received during the 60-day comment period. The commentor agreed with the importance of the form and the associated benefit. The commenter stated that access to Part B-ID will make an impact on individuals recovering from kidney transplants.

The 30-day notice published in the Federal Register on TBD (90 FR)

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. Burden Estimate (Hours & Wages)

Burden Estimates

There were approximately 1,019 respondents annually requesting enrollment in Part B-ID using the form CMS-10798 or telephonic enrollment. The data represents the most current information based on enrollment in Part B-ID since January 1, 2023, via the CMS Medicare Beneficiary Database (MBD.)

The average completion time for the paper CMS-10798 or telephonic enrollment is 10 minutes (0.17). In aggregate we estimate an annual burden of 173 hours (1,019 respondents x 0.17hours/response) at a cost of \$3,998 (173x \$23.11/hr) or \$3.92 per beneficiary (\$3,998/1,019respondents). We believe that the burden will be addressed under All Occupations (occupation code 00-0000) 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.

To derive average costs for individuals we used data from the U.S. Bureau of Labor Statistics' May 2023 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 \$23.11/hr.

We are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

Number of applications	Time required	Total burden hours	Wage costs	Total cost
1,019	10 mins (0.17 hours)	173	\$23.11/hr	\$3,998

Collection of Information Instruments and Instruction/Guidance Documents

The form consists of seven 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, email address, 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 ineligible for the Part B-ID benefit and that if they do, they will notify SSA within 60 days.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Processing Costs

Based on the information collected on the form, we estimate it takes the federal government employee 10 minutes (0.17) to review and record the collected data (process the enrollment), either by paper form or telephonic enrollment.

The burden is computed as follows:

It is calculated that the burden hours for 1,019 responses to be reviewed and recorded in 10 minutes per response to be 173 total hours. $(1,019 \times 0.17 \text{ hours (10 minutes)}) = 173$ total burden hours)

To derive average costs, we used data from the Office of Personnel Management 2024 General Schedule (GS) Locality Pay Table for all salary estimates (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2024/general-schedule/>). 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 \$29.76/hr or \$62,107 annually. Therefore, the total cost to the government to complete the annual volume of responses is \$5,148.48 $(173 \text{ hours} \times \$29.76/\text{hr} = \$5,148.48)$

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1,019	10 mins (0.17 hours)	173	\$29.76/hr	\$5,148.48

15. Changes to Burden

The burden from the 2023 approved submission increased in cost from \$3,495 to \$5,148.48 for federal government costs – a change of \$1,653.48. The hourly burden from the 2023 approved submission increased from 128 hours to 173 hours – a change of 45. The change is due to a marginal increase in applicants from the 2023 submission to the 2024 submission and a slight increase in the salary of a government employee at SSA.

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This form has been improved for increased usability for the general public. Attestations have been separated and clarified to make sure individuals are separately attesting first that they don't have other health coverage at the point of enrollment and second that they will contact SSA if they get other health coverage.

16. Publication/Tabulation Dates

This information is not published or tabulated.

17. Display of Information

The form displays the expiration date below the OMB control number in the upper right corner of the first page of the document.

18. Certification Statement

There are no exceptions to the certification statement.

19. **Collection of Information Employing Statistical Methods**

Not applicable. There are no statistical methods.