Supporting Statement – Part A

Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration
(CMS-10518, OMB 0938-1246)

Background

Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office or in an outpatient hospital setting.

On January 3, 2012, the President signed into law the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012". Title I of the act states:

> *"The Secretary shall establish and implement a demonstration project under part B of title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globulin for the treatment of primary immune deficiency disease."*

The statute limited the demonstration to 4,000 beneficiaries and $45 million, including administrative expenses for implementation and evaluation as well as benefit costs. The statute also required that an evaluation of the demonstration would be conducted.

On September 29, 2017, the ''Disaster Tax Relief and Airport and Airway Extension Act of 2017'' was enacted into law. Section 302 of this legislation extends the Medicare IVIG Demonstration through December 31, 2020. Existing beneficiaries enrolled in the demonstration as of September 30, 2017 were automatically re-enrolled in the demonstration for that extension. Congress again extended the demonstration on December 21, 2020 for three additional years under the "Consolidated Appropriations Act, 2021," Division CC, Section 104, Extension of Medicare Patient IVIG Access Demonstration Project. The legislation also instructs that 6,500 eligible beneficiaries can participate in the demonstration, and is an increase from the initial 4,000 eligible beneficiaries as instructed in the original legislation. The original financial limits (funding) remains and CMS will continue monitoring both to assure that statutory limitations on funding and the new enrollment cap are not exceeded under this second extension.

Under this demonstration, Medicare pays under Part B, a bundled payment for all medically necessary supplies and services to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound, and receiving home health care benefits. The exact payment amount is updated annually in January.

In order to continue to enroll new beneficiaries into the demonstration, an application is required. Beneficiaries complete this application in order to enroll in the demonstration. The collection of information referenced under this submission is for the application to participate in the demonstration. With this submission, CMS is seeking OMB to reapprove the extension of the Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration under OMB control number 0938-1246.

Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who participate in the demonstration will continue to be eligible to receive all of the regular Medicare Part B benefits that they are eligible for in the absence of the demonstration.

A. Justification

1. Need and Legal Basis

As noted above, this demonstration was mandated by Congress under Title I of the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012". Section 302 of the ''Disaster Tax Relief and Airport and Airway Extension Act of 2017'' extended the Medicare IVIG Demonstration through December 31, 2020, and finally, the demonstration was extended again under the "Consolidated Appropriations Act, 2021" through December 31, 2023 or until the financial and/or enrollment statutory limits are met.

In order to implement the demonstration and ensure that statutory enrollment and cost limits are not exceeded, it is necessary to positively enroll beneficiaries in the demonstration. The collection of information referenced under this submission is for the application to participate in the demonstration. There are no changes to the currently approved applications (English or Spanish) for use through May 31, 2021.

This extension application is a renewal of an application that had been used successfully since the demonstration's inception. As the demonstration was originally scheduled to end on September 30, 2017, and then again on December 31, 2020, no efforts to re-evaluate the application were planned or conducted. However, during the course of the demonstration, CMS has worked with patient advocacy groups, suppliers, and providers and no problems in the use of the application have been identified. Therefore, no changes are being proposed.

2. Information Users

The Medicare IVIG Demonstration application requests basic demographic information necessary to determine eligibility for participation in the demonstration. This information is used by CMS' implementation support contractor to determine eligibility for the demonstration and to set up a demonstration eligibility record that is used by the Medicare claims system when processing claims for demonstration services.

The application also includes some questions about how and where the beneficiary is currently receiving immunoglobulin and related services. This data is being used by the evaluation contractor to conduct its evaluation and to better understand which beneficiaries are electing to enroll in the demonstration.

3. Use of Information Technology

CMS has hired an implementation support contractor to assist in the processing of applications as well as to respond to any provider, supplier or beneficiary inquiries.

Applications can be downloaded from the demonstration web site at the following url: https://med.noridianmedicare.com/web/ivig, or upon request, can be mailed to a beneficiary by the CMS implementation support contractor. Completed applications may be returned by mail or fax.

Because the application requires the signature of the beneficiary as well as his/her provider, it is not practical, given the limited size and duration of the demonstration, to have a fully automated on-line application submission process.

4. Duplication of Efforts

This is the only way for beneficiaries to apply to participate in this demonstration. There is no other collection of similar information.

5. Small Businesses

Beneficiaries will be required to have their doctors co-sign the application. This ensures that there is communication between the beneficiary and the provider regarding the appropriateness of receiving this drug at home. It also allows the provider to confirm that the beneficiary has primary immune deficiency disease (PIDD) which is a requirement for participation.

Some of the doctors who will be asked to co-sign applications for their patients will work for or own small businesses (i.e., physicians' offices). However, the impact of this data collection

on small businesses over and above what would be done during a routine patient visit will be minimal, and will ensure better communication between patient and provider. Beyond their signature confirming that the patient has the required diagnosis of PIDD, no other information is being requested from the provider.

6. Less Frequent Collection

This is a one-time request for data. It could not be requested less frequently, and still enable CMS to conduct the demonstration.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register TBD (86 FR).

9. Payments/Gifts to Respondents

There are no gifts provided to respondents.

10. Confidentiality

Confidentiality of patient-specific data will be maintained as provided by the Privacy Act of 1974 (5 U.S.C.552a). The implementation support contractor is a DME-MAC that currently processes Medicare claims. This contractor currently meets all requirements for handling personally identifiable data in a secure and confidential manner. All personnel who will have access to data collected through this application will be trained on the significance and protection of confidentiality and respondent information will be maintained in a confidential manner to the fullest extent possible. The application database will be stored on a secured server with access-limiting firewall protections, including encryption and password requirements. Data collected through this application will be retained only long enough to perform analyses associated with CMS's implementation and evaluation of the IVIG Demonstration, and will then be destroyed.

These data collection activities are covered under the Centers for Medicare & Medicaid Services System of Records: "Master Demonstration, Evaluation, and Research Studies for the Office of Research, Development and Information" (System No. 09-70-0591). The System of Records Notice was published in the Federal Register on April 19, 2007 (Volume 72, page 19705).

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Estimates of survey burden in terms of hours and costs for this one-time application are shown in the table below. The estimated number of respondents is based on recent enrollment trends during the most recent year of the demonstration, the number of months that will be remaining in the demonstration during the period this application will be used, and the statutorily mandated limit on enrollment. Each beneficiary will only need to complete the application once and it is expected to take no more than 15 minutes to do so. Thus the total projected hours required will be no more than 1,625 (if the total number of beneficiaries who are eligible for the demonstration enroll) x .25 hour per response). The cost per hour of beneficiary response time is based on the median Medicare income level as provided by The Henry J. Kaiser Family Foundation, "Income and Assets of Medicare Beneficiaries, 2016-2035"[1].

	Total # Respondents	# Responses / Respondent	Time / Response	Total Hours	Cost / Response	Total Cost Burden *(one time only- not annual)*
TOTAL	6,500	1	0.25 hrs. (15 min.)	1,625	$ 3.15*	$5,118.75

13. Capital Costs

There are no capital costs

14. Cost to Federal Government

The original statute authorizing this demonstration limited total expenditures to $45 million, including benefit and administrative costs (implementation support and evaluation). The statute authorizing extension of the demonstration did not provide any additional funding. To date, the following expenses have been incurred:

[1] *Taken from the median Medicare income level as provided in the Henry J. Kaiser Family Foundation, http://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/ ($26,200 median annual income/ (2080 hours/year)=12.60/hour*.25=$3.15 per response).*

Implementation Support (dollars spent through 11/30/2020	$1,255,596
Evaluation (contract fully funded through 09/30/2021	$3,659,577
Total Administrative Costs awarded to date	**$4,915,173**
Paid Claims (processed through 01/08/2021	$20,439,162.92
Total Expenditures	**$ 25,354,335.92**

Total costs are not expected to exceed the statutorily authorized amount even with the extension period. Weekly reports provided by the implementation support contractor allow for close monitoring of claims expenditures to ensure that the statutory limits are not exceeded. Based on total projected claims and implementation expenses, it is projected that for the next year, the annual expenditures will be approximately $7.6 million. Total spending will continue to be monitored closely to ensure that we do not exceed the authorized spending limits over the course of the demonstration extension.

15. Changes to Burden

The burden rate for filling out the beneficiary application form has not changed for the individual beneficiary because nothing on the application form has changed. The time allotted is 15 minutes that was originally stated to fill out the application for enrollment into the demonstration. What has changed is the number of potential beneficiaries who can enroll into the demonstration. The original legislation mandated the number of beneficiaries who can enroll into the program to be no more than 4,000. In the IVIG extension legislation approved by Congress on December 21, 2020 ("Consolidated Appropriations Act, 2021"), up to 6,500 eligible beneficiaries may enroll in the demonstration. The calculation in the table under Section 12 "*Burden Estimate (Hours and Wages)"* has changed but that is because of the number of potential beneficiaries has increased. There is no additional burden to the beneficiaries.

16. Publication/Tabulation Dates

The statute originally authorizing this demonstration requires an interim Report to Congress (RTC) on the impact of the demonstration on access for Medicare beneficiaries to items and services needed for the in-home administration of IVIG. This interim report was published in March 2016 and is posted on CMMI's web site (https://innovation.cms.gov/initiatives/ivig/). A second RTC report is due no later than December 2023 and the final evaluation is due to Congress not later than one year after the date of completion of the demonstration project. Nothing in the legislation extending the demonstration changes these requirements.

No personally identifiable beneficiary or provider level data will be published in any of the evaluation reports.

17. Expiration Date

The OMB expiration date will be displayed on all applications.

18. Certification Statement

There are no exceptions.