Supporting Statement

Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration

A. 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."*

B.

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 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. While existing beneficiaries enrolled in the demonstration as of September 30, 2017 will be automatically re-enrolled, in order to continue to enroll new beneficiaries into the demonstration, an application is required. The original enrollment and financial limits remain and CMS will continue to monitor both to assure that statutory limitations are not exceeded.

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 implement the demonstration and ensure that statutory 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. With this submission, CMS is seeking OMB approval for the reinstatement of the Application for Participation in the Intravenous Immune Globlulin (IVIG) Demonstration under OMB control number 0938-1246.

Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who do not participate will continue to be eligible to receive all of the regular Medicare Part B benefits that they are would be eligible for in the absence of the demonstration.

Part B. Justification

1. Need and Legal Basis

As noted above, this demonstration was originally Congressionally mandated under Title I of the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012. The ''Disaster Tax Relief and Airport and Airway Extension Act of 2017'' extends the demonstration through December 31, 2020.

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. The application is not changing from that originally approved for use through August 31, 2017, (CMS-10518) Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstrationnsert. Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who do not participate will continue to be eligible to receive all of the regular Medicare Part B benefits that they are would be eligible for in the absence of the demonstration.

This data collection only applies to the application form that will be used to enroll eligible beneficiaries and provide some baseline data that is being used to facilitate the evaluation. Any additional data collection that is required for the evaluation will have a separate PRA application.

2. Purpose and Use of the Information Collection

The Medicare IVIG Demonstration application requests basic demographic information necessary to determine eligibility for participation in the demonstration. It also includes some questions about how and where the beneficiary is currently receiving immunoglobulin and related services which is used to provide information to support the demonstration evaluation. This application was previously approved for use through August 31, 2017 (OMB no. 0938-1246 (CMS-105184). The application is not changing with this new request.

3. Use of Improved Information Technology and Burden Reduction

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

Applications will be able to be downloaded from the demonstration web site or, upon request, may 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 of the demonstration and the desire to re-start the demonstration quickly, to have a fully automated on-line application submission process.

4. Efforts to Identify Duplication and Use of Similar Information

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

5. Impact on Small Businesses or Other Small Entities

Beneficiaries will be required to have their doctor's 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 insure 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. Consequences of Collecting the Information Less Frequently

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 Relating to the Guidelines of 5 CFR 1320.5

None.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

CMS is seeking an emergency approval to use the previously approved application. This will be followed by a FR 60-day notification for a regular renewal of approval to use the form.

9. Explanation of Any Payment or Gift to Respondents

The benefit to beneficiary respondents will be the potential of being allowed to participate in the demonstration and receiving the additional demonstration services for the administration of IVIG in the home. There will be no other payments or incentives to respondents or their providers.

10. Assurance of Confidentiality Provided to Respondents

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 will be 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 a 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. Justification for Sensitive Questions

The proposed application asks for information necessary to confirm the identity of the Medicare beneficiary and validate their eligibility for the demonstration. Additional non demographic information that will be collected will be related to how they are currently receiving immune globulin and their perceived benefit from participating in the demonstration and will be used to conduct the statutorily mandated demonstration evaluation.

Neither CMS nor its contractors will identify any individual beneficiary or provider in any published reports or presentations.

12. Estimates of Annualized Burden Hours and Costs

Estimates of survey burden in terms of hours and annualized costs for this one-time application are shown in the table below. The estimated total number of respondents is based on the most recent enrollment trends during the last year of the demonstration 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 375 (40 respondents per month x 37.5 additional months (October 1, 2017 – November 15, 2020, the last date applications can be accepted) 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	1500	1	0.25 hrs. (15 min.)	375	$ 3.15*	$ 4,725

13. Capital costs.

There are no capital costs.

14. Annualized Cost to the Federal Government

The demonstration is limited to $45 million, including benefit and administrative costs. As of October 1, CMS has allocated approximately $3.7 million for the evaluation and implementation support. Through September 22, 2017, $ 6,076,903 has been expended to pay for claims under the demonstration. The Disaster Tax Relief and Airport and Airway Extension Act of 2017 does not provide additional funding. While additional funding will be needed to support the continued implementation support for and evaluation of the demonstration, we will continue to monitor enrollment and total expenditures closely in order to stay within the statutory limits.

In addition, it is estimated that .35 FTE GS-15 senior project officer will be required to implement and monitor the demonstration. Based on the mid-range salary for this staff, CMS annual salary expenses for implementation will be approximately $53,037.[2]

[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.*

[2] *Salaries based on DC/Baltimore 2017 GS wage rates. The mid-range was defined as mid-way between steps 5 and 6. For GS-15 this is 151,534/FTE.*

15. Explanation for Program Changes or Adjustments

No changes in the application form from that previously approved are being requested. The respondents have decreased from 4,000 to 1,500. The burden hours have dereased from 1,000 to 375.

16. Plans for Tabulation and Publication and Project Time Schedule

The statute originally authorizing this demonstration requires an interim Report to Congress 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 on CMMI's web site (*https://innovation.cms.gov/initiatives/ivig/).* A 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.

Although summary level data on applications submitted and beneficiaries enrolled in the demonstration may be included in these reports, any additional data collection necessary to support this demonstration will be covered under a separate PRA application.

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

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not applicable. The OMB expiration date will be displayed on all applications.