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 Tuesday, 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.

Under this demonstration, Medicare will issue 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.

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. 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 Congressionally mandated under Title I of the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012".

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. 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 will subsequently be used to facilitate the evaluation. Any additional data collection that is determined to later be needed for the evaluation will have a separate PRA application.

2. Purpose and Use of the Information Collection

The demonstration application will request basic demographic information necessary to determine eligibility for participation in the demonstration as well as ask some questions about how and where the beneficiary is currently receiving immunoglobulin and related services. This latter information will be used to support the mandated evaluation.

3. Use of Improved Information Technology and Burden Reduction

CMS has hired an implementation support contractor to assist in conducting the application process in addition to beneficiary and provider outreach and education. Shortly after receiving approval to use the application form, CMS plans to conduct beneficiary and provider outreach campaign followed by a 30 day open enrollment period during which beneficiaries may submit applications to participate in the demonstration.

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 will require 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 implement 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

CMS shall list the OMB control number on the front page of the application. We do not anticipate any special circumstances that would require the need for other means to inform potential respondents of the OMB control number associated with this application.

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

The 60-day Federal Register notice was published on March 7, 2014. Three comments were received: one was from a beneficiary that was unrelated to the demonstration, one was from a pharmaceutical supplier, and the third was a joint response from a patient advocacy group and two clinical societies. As a result of these comments, CMS has made adjustments to the application form which are described under Item 15. There is no impact on the projected burden of completing the form.

9. Explanation of Any Payment or Gift to Respondents

The benefit to beneficiary respondents will be the potential of being selected 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 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 1,000 (4,000 respondents x .25 hour per response). The cost per hour of beneficiary response time is based on the median Medicare income level as provided in The Henry J. Kaiser Family Foundation, Medicare Chartbook, Fourth Edition.[1]

[1] *Taken from the median Medicare income level as provided in The Henry J. Kaiser Family Foundation, Medicare Chartbook, Fourth Edition, 2010, http://www.kff.org/medicare/upload/8103.pdf ; $12.45*.25=$3.1125 per response.*

	Total # Respondents	# Responses / Respondent	Time / Response	Total Hours	Cost / Response	Total Cost Burden *(one time only- not annual)*
TOTAL	4,000	1	0.25 hrs. (15 min.)	1,000	$ 3.1125*	$ 12,450

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. For purposes of planning we have preliminarily allocated $5 million for contractual support for both the implementation and evaluation of the demonstration. The remaining $40 million will be reserved to pay for benefits over the three year course of the demonstration.

The evaluation contract has not yet been awarded. The implementation support work has been awarded to NHIC, one of the DME Medicare Administrative Contractors (MACs). Included in NHIC's contract is $75,000 to develop, implement and process applications. This does not include other costs to support implementation which are not expected to exceed $2 million over the course of the demonstration.

In addition, it is estimated that .35 FTE GS-15 senior project officer and .25 FTE GS–11 staff will be required to implement and monitor the demonstration. Based on the mid-range salary for these staff, CMS annual salary expenses will be approximately $68,460.[1]

15. Explanation for Program Changes or Adjustments

As a result of the comments received, CMS revised the order of the questions on the application form as well as some of the wording of questions and response options. The number of questions on the application remains unchanged. The purpose of the changes was to improve the flow of the questions and to clarify how newly diagnosed patients who may not yet be taking IVIG should respond. In addition, more response options related to safety were provided on the question related the potential demonstration impact on the beneficiary. An introductory statement describing the purpose of the application was also inserted.

[1] *Salaries based on DC/Baltimore 2014 GS wage rates. The mid-range was defined as mid-way between steps 5 and 6. For GS-11 this is $72,556 /FTE. For GS-15 this is 143,744/FTE.*

Finally, information on how to submit the application was added to the end of the form. Previously this information was intended to be provided in a separate document. Providing it on the application itself will make sure that the beneficiary has complete information readily available when the application is completed without having to reference any other document.

16. Plans for Tabulation and Publication and Project Time Schedule

The statute 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 not later than three years after the date of enactment. A final evaluation is due to Congress not later than one year after the date of completion of the demonstration project. 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.