

Supporting Statement A

Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration

A. Background

This section provides background on Primary Immune Deficiency Disease (PIDD), the Medicare Patient Intravenous Immunoglobulin (IVIG) Demonstration legislation, the objectives of the evaluation, and an overview of the evaluation's data collection methods.

Primary Immune Deficiency Diseases (PIDD)¹ are caused by genetic defects that result in a lack of and/or impaired antibody function. Without antibodies, the body's immune system is not able to function effectively. Immunoglobulin (IG) therapy is used to temporarily replace some of the antibodies (immunoglobulins) that are missing or not working properly in people with PIDD (Immune Deficiency Foundation, 2013).

By special statutory provision, Medicare Part B covers intravenous immunoglobulin (IVIG) for persons with PIDD who wish to receive the drug in-home, but does not allow for Medicare to cover any of the items and services needed to administer the drug unless the person is homebound or otherwise receiving services under a Medicare home health episode of care. Therefore, most beneficiaries with PIDD receive treatment at hospital outpatient departments, physicians' offices, and other outpatient settings. A current alternative to IVIG is subcutaneous immunoglobulin (SCIG), a product that permits some beneficiaries to self-administer the immunoglobulin (IG) safely at home without an attending healthcare professional. SCIG at home is reimbursed by Medicare. However, there are limitations to SCIG—e.g., the need for more frequent administration and higher volumes of solution, which can reach a maximum absorbable level for some patients that is below their optimum IG treatment level—that inhibit more widespread use of SCIG.

Under the Medicare Patient IVIG Access Demonstration project, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option that is most appropriate for the beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration.

The Medicare Patient IVIG Access Demonstration project mandates CMS to:

1. Evaluate the impact of the Medicare IVIG Access Demonstration project on Medicare beneficiary access to IVIG at home,

[For purposes of the evaluation of the Medicare Patient IVIG Demonstration Project, impact is defined as the effect of offering in home administration of IVIG to Medicare beneficiaries with

¹ PIDD diseases included in the demonstration project include common variable immunodeficiency, selective IgM immunodeficiency, Wiskott-Aldrich syndrome, congenital hypogammaglobulemia, and immunodeficiency with increased IgM.

PIDD on their healthcare utilization (i.e. treatments, hospitalizations, emergency room visits), treatment experience (i.e., side effects, wait times, switching medications, access to treatment), health outcomes (i.e., infections, complications) and Medicare costs over the 3-year Demonstration period. Access is defined as receiving the desired treatment without delay in the setting selected by the beneficiary and physician.]

2. Determine the appropriateness of implementing a new methodology for payment for IVIG in all settings under Part B, and

[For purposes of the evaluation, an analysis of new payment models will be conducted to determine the feasibility of paying for IVIG under Part B in all care settings. Appropriateness of the payment model is defined as whether the model saves or incurs additional Medicare costs, and is viable.]

3. An update of the existing 2007 Office of the Assistant Secretary for Planning and Evaluation (ASPE) report *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)* (2007 ASPE Report).

[ASPE published a report in 2007 that investigated the shortage of IVIG and other IVIG access problems under Medicare reimbursement. The report addressed the IVIG market dynamics and IVIG access problems among 3 components: suppliers and manufacturers; demand for and utilization of IVIG products including how it is prescribed, administered and paid for; and physician and patient problems with access to IVIG. Anecdotally, there has been several changes in market dynamics and access to IVIG since the report was released, but no systematic formal study has been conducted. As such, this systematic formal study, will inform CMS and Congress of any changes since 2007.]

To accomplish these objectives, this evaluation includes three main data collection approaches:

- 1.) Interviews to provide perspectives on the Demonstration program, including access and barriers to care, benefits and disadvantages of different treatment site options, health outcomes and consequences, and cost and reimbursement issues;
- 2.) Survey of Medicare beneficiaries to compare treatment experiences of beneficiaries participating and not participating in the Demonstration; and
- 3.) Medicare claims analysis to examine health and cost outcomes longitudinally

Table 1 below summarizes the purpose and the respondents for each type of data collection.

Table 1: Purpose and Respondents for Data Collection Activities

Data collection	Purpose	Respondents
Interviews	<ul style="list-style-type: none">• To examine the market dynamics including benefits and disadvantages of different sites of treatment, including health consequences of delays or postponement of treatment, switching treatment, convenience,	<ul style="list-style-type: none">• Providers (physicians and nurses) treating patients with IVIG• Caregivers of beneficiaries with PIDD• Manufacturers of IG• Patient advocate groups for IVIG beneficiaries• IG distributors

Data collection	Purpose	Respondents
	<p>ease of use, and barriers and facilitators of treatment</p> <ul style="list-style-type: none"> • To assess IVIG supply, demand, access, utilization, cost, and reimbursement issues and changes since 2007 	<ul style="list-style-type: none"> • Group purchasing organization (GPO) representatives • Infusion centers that administer IVIG
Surveys	<ul style="list-style-type: none"> • To determine the experiences of Medicare beneficiaries with PIDD who are receiving IVIG treatment over the 3-year Demonstration period, including difficulty obtaining treatment and changes in treatment 	<ul style="list-style-type: none"> • Medicare beneficiaries with PIDD who have Medicare claims for IVIG including beneficiaries who participated and those who did not participate in the Demonstration
Administrative claims	<ul style="list-style-type: none"> • To examine IVIG utilization and healthcare utilization (hospital admission/readmission, ER, specialty care, antibiotics) of Medicare beneficiaries with PIDD over the 3-year Demonstration period • To examine Medicare costs under Part B to inform the payment methodology analysis 	<ul style="list-style-type: none"> • Medicare beneficiaries with PIDD who have claims for IVIG

The contract for the evaluation of the Medicare Patient IVIG Access Demonstration project was awarded in September 2014. Interviews and survey data collection will occur in 2017.

B. Justification

Need and Legal Basis

Section 101 of H.R. 1845 Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012, Public Law 112-242, mandates the establishment, implementation, and evaluation of a three-year Medicare Patient Intravenous Immunoglobulin (IVIG) Access Demonstration Project under Part B of title XVIII of the Social Security Act.

Purpose and Use of the Information Collection

The evaluation study will use a mixed methods approach using interviews, surveys, and administrative claims information. This section describes the purpose, use, and design of each type of information collection, defines the measures that will be collected, and lists our hypotheses.

The purpose and use of interviews with providers, nurses, informal caregivers and patient advocates is to provide their perspectives on the Demonstration program, including the advantages and disadvantages of different treatment options, perspectives on access, quality, cost, convenience, ease of use, safety, and health outcomes for beneficiaries using the services provided under the Demonstration. These cross-sectional, semi-structured interviews will provide rich contextual information to supplement the survey and claims data.

The purpose and use of interviews with manufacturers, distributors, large GPOs, and home infusion therapy companies is to assess changes to date in the current IVIG market dynamics, including IVIG supply, distribution, demand, and access. Access is defined as the receiving the desired treatment without delay in the setting selected by the beneficiary and physician. ***We hypothesize that compared to 2007, there is improved IVIG supply, distribution, demand, and access.***

The purpose and use of information collected through surveys is to determine the effect of offering in home administration of IVIG to Medicare beneficiaries with PIDD on their treatment experience over the 3-year Demonstration period. The survey will assess the experience of beneficiaries participating in the Demonstration and those not enrolled in the Demonstration. The purpose of the survey is to assess beneficiaries' experiences prior to and during the demonstration. Additional questions will include assessing why the beneficiary enrolled (or did not enroll) in the Demonstration. ***We hypothesize that beneficiaries participating in the Demonstration will have increased access to IVIG treatment compared to non participating beneficiaries.***

The purpose and use of information using administrative claims is twofold: 1.) to determine healthcare utilization and spending for beneficiaries with PIDD using IVIG during the 3-year Demonstration, and 2.) to inform new payment methods for IVIG under Part B in all care settings. Health care utilization is defined as a combination of hospital admission and readmission; use of emergency rooms, specialty care, and other post-acute care; and antibiotic use and will be measured using claim codes. Medicare costs are defined as Medicare payments, and beneficiary cost-sharing during the demonstration period. Medicare cost will be measured as Medicare payment per beneficiary per treatment per month. We will also analyze healthcare utilization and spending data for both Demonstration and comparison groups for both pre and post-Demonstration periods and will use a difference-in-differences approach to compare the groups. ***We hypothesize that beneficiaries participating in the Demonstration will have better health outcomes, lower healthcare utilization, and lower costs for IVIG care compared to beneficiaries not participating in the Demonstration.***

Institutional Review Board (IRB) Approval and Informed Consent

IRB exemption has been approved for the research project which is conducted pursuant to the specific federal statutory authority Section 101 of H.R. 1845 Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012, Public Law 112-242.

In requesting an IRB exemption, the study team disclosed all informed consent procedures for both the interview and survey data collection. For the interviews, each individual will be provided with an interview protocol in advance of the interview that will summarize the purpose of the interviews and

emphasize that participation is voluntary and response to any single question is not required. As no signatures confirming informed consent will be gathered, participation in the interview will serve as a proxy for informed consent. Similarly, for the beneficiary survey, beneficiaries will receive the survey package and introductory cover letter and can choose to participate (there is no requirement for participation). The survey cover letter informs the participant of the purpose of the survey and how the information provided will be used; therefore, a beneficiary's completion and submission of the survey is considered a proxy for informed consent. The IRB has confirmed that these methods for informed consent are appropriate.

Use of Information Technology and Burden Reduction

The interviews with physicians, nurses, caregivers and advocates for patients with PIDD receiving IVIG; and IVIG manufacturers, distributors, Group Purchasing Organizations (GPOs), and infusion companies will be administered over the telephone and will not be relying on information technology. These interviews will not be available electronically, and the respondents' signature will not be required. The project team does not expect to make the interview data collection process available electronically, as it would pose a higher burden on the participant to complete each of the questions in writing.

For the beneficiary survey, each respondent will have the option to complete the survey online. A unique username and password will be provided to all beneficiaries to enable them to access the survey online if they prefer to complete the survey online rather than mail back a hard copy. The online survey software eliminates the respondents' burden of manually following the survey's skip patterns, as the software follows the skip patterns automatically. The online survey will also have explanatory mouse-over pop-up balloons that explain some terms identified as potential frequently asked questions (FAQs). This feature, will reduce respondent difficulty and burden. The online survey can be submitted electronically instead of printed and mailed in the return envelope via US Postal mail, which also reduces respondent burden.

Duplication of Efforts

This information collection does not duplicate any other effort.

Small Businesses

The interviews will likely involve small businesses, as approximately 98 percent of physician offices are small (SBA, 2014; Census Bureau, 2012). The interviews for the manufacturers, distributors, GPOs, infusion suite companies, and patient advocate groups may be large or small businesses. To reduce the burden on small businesses, the interviews will be conducted with the use of a written interview protocol that will be provided to each interviewee in advance of the interview (typically provided when the interview time is scheduled). This will allow the interviewee to review the content of the interview in advance (likely days or even weeks in advance, depending on how quickly the interview can be scheduled from the time approval for participation is obtained). The use of the written protocol will keep the interview focused and targeted to the information needed. As the interviews will require approximately 45 minutes of the respondent's time, the interviews will be scheduled prior to or after regular business hours

to further reduce the burden on small businesses and not interrupt patient care or scheduled appointments. If interviewees prefer, we can also schedule the meetings during business hours when no patient care or appointments are scheduled.

The beneficiary survey will not impact small businesses.

Less Frequent Collection

Less frequent collection will impact the ability to fulfill the legislative mandates of the evaluation of the three-year Medicare Patient IVIG Demonstration project.

Special Circumstances

There are no special circumstances for this data collection effort.

Federal Register/Outside Consultation

The 60-day Federal Register notice published on: February 10, 2016. The 30-day Federal Register notice was published on May 22, 2016. There were no comments received. There will be no outside consultation in this evaluation effort.

Payments/Gifts to Respondents

No payments or gifts will be offered to participants in the interviews.

All participants in the survey will receive a \$2 cash incentive enclosed in the survey package as a means to increase their likelihood of response. Although some earlier published studies reported ambiguous results from enclosing small, noncontingent (i.e., the incentive is not contingent on participation) cash incentives with mailed surveys, more recent studies and meta-analyses have refined this view. Mercer et al. (2015) analyzed results from over 40 research efforts and reported that surveys with a \$2 noncontingent incentive resulted in a 10 percent higher response rate than those with no incentive. Parsons and Manierre (2014), in their study of incentives, response rates, and nonresponse bias, referenced Millar and Dillman (2011), who found that a mailed survey notification with a \$2 incentive elevated response rates among college students to a web survey from 21.2 percent (notification without incentive) to 38.2 percent. Parsons and Manierre further stated: “Overall, the research in this area suggests that unconditional incentives reduce nonresponse bias.” Gneezy and Rey-Biel (2014) assessed the impact of incentives in increments from zero to \$30 and found that a \$1 incentive doubled the response rate obtained without incentive (i.e., a 100 percent increase), and that a \$2 incentive increased the no-incentive rate by over 140 percent.

Confidentiality

The data collected through the interviews and survey will be maintained as required by the Privacy Act of 1974 (5 U.S.C. 552a). In addition, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule defines the standards for protecting individuals’ sensitive and private health

information and covers all settings, personnel, and procedures that have access, handle, or share individuals' health care information. Dobson DaVanzo & Associates, LLC and its team received annual mandatory HIPAA training on handling of personal health information (PHI) and personal identifiable information (PII). In addition, Dobson DaVanzo & Associates, LLC and its team are trained in HIPAA compliance procedures when transmitting or sharing information that might contain PHI or PII. These procedures include:

- De-identifying records by removing enough PII so that the remaining information does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual. De-identified records can be used when full records are not necessary, such as for examinations of correlations and trends;
- Controlling access to PII through access control policies and access enforcement mechanisms, such as access control lists and data encryption and keeping the information protected in highly restricted and locked locations;
- Prohibiting access to PII from portable and mobile devices, such as laptops, cell phones, and personal digital assistants (PDAs), which are generally higher-risk than non-portable devices, such as desktop computers at the organization's facilities;
- Protecting the security of transmitted PII by implementing encryption methodologies and mechanism during communications or by encrypting the information before it is transmitted; and
- Monitoring and reporting events that affect the confidentiality of PII, such as inappropriate access to PII.

Interviews

Each interviewee will be given a unique identification (ID) number. This ID number will be the only information that is recorded on data-collection instruments, and the data-collection instruments will be stored separately from other data collected within this project. Contact information (names, telephone numbers, and email addresses) of interviewees will be stored separately from interview data files and will only be access by authorized team members for scheduling purposes. All team members have been trained in protecting information and data security procedures.

Interviewers will conduct the interview in a private setting with only staff involved with that interview. The interviewer will not be able to control the setting of the interviewee, but will suggest that they talk somewhere private without the presence of anyone else. Interviews will be recorded using a telephone service with the interviewee's permission and then transcribed. Recordings and transcription files will be encrypted and only accessible to team members for data validation and analysis. Any hard copies of files will be stored in a locked filing cabinet.

When data are entered or transcribed, personal identifiers will not be used and any identifying information of individuals will be removed and replaced with a qualifying codename. Interview data that has been de-identified will be entered into NVivo, the qualitative data software, and stored on the Dobson DaVanzo & Associates, LLC secure SharePoint site that is only accessible to authorized members. Reports on data collected will be presented in aggregate form only. At the end of the project, the Project

Investigator will arrange for the proper storage and destruction of all data in compliance with all relevant government regulations and policies.

Survey

The survey solicits medical information that is subject to protection under the HIPAA Privacy Rule, which, in §164.502(d), permits a covered entity or its business associate to create information that is not individually identifiable by following the de-identification standard and implementation specifications in §164.514(a)-(b). CMS is a covered entity under the Act, and the CMS contractors administering the survey and interviews are covered as business associates of the covered entity.

Survey respondents will be de-identified through the use of randomly-assigned respondent ID numbers, which will also be their usernames for the on-line version of the survey. No one outside the Dobson DaVanzo & Associates, LLC team will have access to the individual survey responses, nor will anyone outside the team be able to identify any individual respondent with their responses. All covered information will be maintained in password-secured files on its internal server (i.e., only members of the team will have access to the files). The contractor's internal servers are protected by Sonic firewall, and the servers are housed in a locked room accessible only to IT staff.

The printing and mailing tasks associated with the survey (e.g., survey forms, letters, and envelopes) will be distributed in such a way that no outside printer(s) will be able to identify an individual respondent as a Medicare beneficiary or a PIDD patient.

Completed surveys will have the option to be mailed to a dedicated mailbox or submitted electronically, via Qualtrics, an on-line survey software. Qualtrics uses Transport Layer Security (TLS) encryption (also known as HTTPS) for all transmitted data. Qualtrics will also protect surveys with passwords (provided by the team) and HTTP referrer checking. Qualtrics services are hosted by trusted data centers, which are independently audited using the industry standard SSAE-16 method, to ensure the highest protection as per HITECH requirements. Qualtrics deploys the general requirements set forth by several federal Acts, including the FISMA Act of 2002, and meets or exceeds the minimum requirements as outlined in FIPS Publication 200.

Undeliverable survey packages will be returned directly to the CMS by the U.S. postal service.

Surveys submitted by mail will be opened and data-entered only by Dobson DaVanzo & Associates, LLC team members. Data entry will be via Qualtrics. Only assigned team members will be able to crosswalk respondents' names with their usernames. Upon completion of the survey field work and appropriate data cleaning steps, the identifiers that link a survey respondent with the respondent's name and contact information will be destroyed. All assigned team members have acknowledged and signed the required Code of Business Conduct and Ethics, which (among other things) enforces to maintain the integrity, confidentiality, and accuracy of all data and information obtained during the course of this data collection effort. At the end of the Demonstration, Dobson DaVanzo & Associates, LLC team will ensure the proper storage and destruction of all data in compliance with all relevant government regulations and policies.

Sensitive Questions

There are no sensitive questions.

Burden Estimates (Hours & Wages)

The burden estimates are divided into interviews and survey data collection.

Interviews

For the nurse interviews, the estimated number of interviewees includes a total of 60 nurse interviews. No individual nurse will be interviewed more than once. The burden hours for the interviews are based on the planned length of the interviews (30 minutes). The wages used for nurse interviewees reflect a median hourly wage of \$32.04 for nurses (specifically *SOC 29-1141 Registered Nurses*). We then calculated a loaded hourly wage, with benefits and overhead accounting for 100 percent of the total hourly wage. This results in a loaded hourly wage of \$64.08.

The estimated number of physician interviewees includes a total of 36 physician interviews. No individual physician will be interviewed more than once. The burden hours for the interviews are based on the planned length of the interviews (30 minutes). The wages used for physician interviewees reflect a mean hourly wage of \$91.60 for physicians (specifically *SOC 29-1063 Internists, General*). We then calculated a loaded hourly wage, with benefits and overhead accounting for 100 percent of the total hourly wage. This results in a loaded hourly wage of \$183.20 for physicians.

The estimated number of caregiver interviewees includes a total of 36 interviews. No individual caregiver will be interviewed more than once. The burden hours for the interviews are based on the planned length of the interviews (45 minutes). The wages used for caregivers reflect the median hourly wage for all occupations in the US, \$17.09 (BLS, 2014a). We then calculated a loaded hourly wage, with benefits and overhead accounting for 100 percent of the total hourly wage. This results in a loaded hourly wage of \$34.18.

For the manufacturer and distributor interviews, the estimated number of interviewees includes six IVIG manufacturers, nine primary or secondary distributors of IVIG, nine of the largest GPOs, and nine home infusion therapy companies. These individuals will be interviewed once. The burden hours are based on the planned length of the interviews (45 minutes). The wage used for manufacturer and distributor interviewees reflects a median hourly wage of \$46.75 (for *SOC 11-000 Management Occupations*). We then calculated a loaded hourly wage, with benefits accounting for 100 percent of the total hourly wage (BLS, 2014). This results in a loaded hourly wage of \$93.50.

The patient advocate interviews will include six representatives from patient advocate organizations who will be interviewed once. The burden hours are based on the planned length of the interviews (45 minutes). The wage used for patient advocate interviewees reflects a median hourly wage of \$46.75 (for *SOC 11-000 Management Occupations*). We then calculated a loaded hourly wage, with benefits and overhead accounting for 100 percent of the total hourly wage. This results in a loaded hourly wage of \$93.50.

Survey

For the survey, the estimated number of respondents reflects the planned sample of 2,770 total Medicare beneficiaries with PIDD (reflecting a 100 percent response rate) who could potentially choose to take the survey (and thus incur a response burden). We selected this response rate to be conservative and estimate the maximum amount of potential burden.

The burden hour estimates for the survey are based on tests of the length of time each type of respondent is likely to need to read the survey invitation (5 minutes) and complete the survey questions (30 minutes), and the assumption that 100 percent of beneficiaries who receive the survey will complete it. The wages used for survey respondents reflect the median hourly wage for all occupations in the US, \$17.09 (BLS, 2014a). The survey respondents are eligible for Medicare, and thus are likely to be over 65 years-old and more likely than the general population to be retired. For those who are currently in the workforce or who were once in the workforce, they might have had any number of occupations. The median hourly wage for all occupations in the United States is used to capture the variety of occupations they might currently hold or once have held. We then calculated a loaded hourly wage, with benefits and overhead accounting for 100 percent of the total hourly wage. This results in a loaded hourly wage of \$34.18.

For all data collection activities, the burden hours is calculated by multiplying the number of responses estimated for each year by the hours per response. These activities are expected to be initiated and completed within one calendar year (2017); therefore Table 2 can be considered an “annual” burden estimate for the one calendar year in which burden would be realized.

Table 2: Estimated Respondent Overall Burden

	Estimated Number of Total Responses	Estimated Number of Responses per Respondent	Average Burden per Response (in hours)	Estimated Total Annual Burden Hours
Interviews				
Nurses	60	1	0.50	30
Physicians	36	1	0.50	18
Caregivers	36	1	0.75	27
Manufacturers	6	1	0.75	5
Distributors	9	1	0.75	7
GPOs	9	1	0.75	7
Infusion Suite Companies	9	1	0.75	7
Patient Advocates	6	1	0.75	5
Survey				
Beneficiaries	2,770	1	0.58	1607

	Estimated Number of Total Responses	Estimated Number of Responses per Respondent	Average Burden per Response (in hours)	Estimated Total Annual Burden Hours
Grand Total (Overall Average)	2,941	1	0.58	1,711

Note: Totals may not sum and calculations may produce different results due to rounding and truncated inputs.

The total annual burden cost is calculated by multiplying the estimated annual burden hours by the loaded hourly wage rate to derive the total cost for all respondents (Table 3).

Table 3: Estimated Respondent Annual Burden Cost by Year and Overall

Type of Respondent	Hourly Wage Rate (including Benefits)	Average Burden per Response (in hours)	Average Cost per Response	Estimated Total Burden Cost
column	(1)	(2)	(3)=(1)*(2)	(4)
Interviews				
Nurses	\$64.08	0.50	\$32.04	\$1,922
Physicians	\$183.20	0.50	\$91.60	\$3,298
Caregivers	\$34.18	0.75	\$25.64	\$923
Manufacturers	\$93.50	0.75	\$70.13	\$421
Distributors	\$93.50	0.75	\$70.13	\$631
GPOs	\$93.50	0.75	\$70.13	\$631
Infusion Suite Companies	\$93.50	0.75	\$70.13	\$631
Patient Advocates	\$93.50	0.75	\$70.13	\$421
Survey				
Beneficiaries	\$24.48	0.58	\$14.20	\$54,914
Grand Total				\$63,791

Note: Totals may not sum and calculations may produce different results due to rounding and truncated inputs.

Capital Costs

There are no capital costs.

Cost to Federal Government

The cost of this information collection effort for each of the 3 years of the project and overall cost to the Federal government is provided in Table 4. While the survey will not be fielded until 2017 (Year 3), preparations will be made in 2016; therefore there is a cost to the federal government for data collection activities in all three years (2015-2017).

Table 4: Cost to the Federal Government

	Year 1 (2015)	Year 2 (2016)	Year 3 (2017)	Total (2015-2017)
Government Activity				
Reviewing and providing guidance on instruments, OMB clearance, and data collection approach ²	\$10,194	\$2,549	\$7,646	\$20,388
Contractor Activity³				
Interviews				
Design interview guide	\$6,614	\$0	\$0	\$6,614
Train interviewers	\$0	\$4,134	\$0	\$4,134
Administer interviews	\$0	\$0	\$20,049	\$20,049
Transcribe interviews	\$0	\$0	\$20,049	\$20,049
Code findings	\$0	\$0	\$16,535	\$16,535
Subtotal	\$6,614	\$4,134	\$56,633	\$67,380
Beneficiary Survey				
Survey instrument design	\$42,169	\$0	\$0	\$42,169
Data collection	\$0	\$27,334	\$137,506	\$164,840
Data analysis	\$0	\$0	\$55,804	\$55,804
Subtotal	\$42,169	\$27,334	\$193,310	\$262,813
Total Costs				
Total Costs	\$58,977	\$34,016	\$257,588	\$350,581

Changes to Burden

Not applicable as this is a new information collection.

Publication/Tabulation Dates

Planning for the evaluation of the three-year Demonstration started in September 2014. All evaluation activities will be completed by August 2019, with several data collection, analyses, and reporting activities occurring concurrently. Error: Reference source not found The findings from this three-pronged evaluation will be summarized in several reports during the course of the Demonstration evaluation, including:

1. **Beneficiary Experience Report** – Results on the beneficiary experience s based on the IVIG Demonstration project. The Beneficiary Experience Reports will include input from Medicare claims analyses as well as findings from the interviews and beneficiary survey.
2. **Payment Methodology Report** – Results of the analysis of Medicare costs under Part B to inform the payment methodology in various care settings. This report will be developed from April through September 2017, with a final version submitted at the end of September 2017.

² Assumes a single GS-14 staff. According to national industry-specific occupational employment and wage estimates, social scientist and related workers in “Management, Scientific, and Technical Consulting Services” (NAICS 541600) on average earned \$43.75 in 2011, which is approximately \$101.94 including overhead, fringe and general and administrative indirect rate (\$43.75 * 2.3). http://www.bls.gov/oes/current/naics4_541600.htm

³ Consists of contractor costs estimated at \$103.34 per hour on average, including labor and overhead charges.

3. **Analysis of Supply, Distribution, Demand, and Access Issues Report** – This report will include changes in market dynamics since the release of the 2007 ASPE report identified from interviews, the beneficiary survey and Medicare claims analyses. The final version will be submitted in at the end of December 2017.
4. **Final Report to Congress** – The findings from the reports 1, 2 and 3 will be incorporated into the Final Report to Congress, to be submitted by September 2018.
5. **Final Evaluation Report** – Final evaluation findings which will include lagged claims data and updated survey and/or interviews data will be reported the final report to be submitted by August 2019.

Table 5: Deliverable Schedule for Data Collection and Reporting Activities

Deliverables	Timeline
Data Collection and Analysis	
Conduct Interviews	1/1/2017-9/30/2017
Conduct Beneficiary Survey	1/1/2017 to 6/30/2017
Beneficiary Experience Report	9/30/2017
Payment Methodology Report	9/30/2017
Update 2007 ASPE Report	12/31/2017
Final Report to Congress	9/30/2018
Final Evaluation Report	8/31/2019

Expiration Date

The project team will display the expiration date on the front page of the survey and interview guides. Those participating in phone interviews will receive the interview guide by email before the scheduled interview. If an email address is not available, we will read the PRA statement to the participant at the beginning of the telephone interview.

Certification Statement

No exceptions are requested.

References:

Bureau of Labor Statistics (BLS). (2014a). May 2014 National Occupational Employment and Wage Estimates. Available at http://www.bls.gov/oes/current/oes_nat.htm. (Accessed March 25, 2015).

Bureau of Labor Statistics (BLS). (2014b). Employer Costs for Employee Compensation June 2014. Available at <http://www.bls.gov/news.release/ecec.nr0.htm>.

Census Bureau, (2012a). Statistics of U.S. Businesses. Available at <http://www.census.gov/programs-surveys/susb.html>.

Gneezy, U., and Rey-Biel, P. (2014). On the relative efficiency of performance pay and noncontingent incentives. *Journal of the European Economic Association*. February. 12(1):62-72. doi:10.1111/jeea.12062

Immune Deficiency Foundation. (2013). Patient & Family Handbook for Primary Immunodeficiency Diseases, 5th Edition. Available at <http://primaryimmune.org/patient-family-handbook/> (Accessed January 25, 2016)

Mercer, A.W., Caporaso, A., Cantor, D., Townsend, R. (2015). How much gets you how much? Monetary incentives and response rates in household surveys. *Public Opinion Quarterly*, 79(1, Spring), 105-129. doi:10.1093/poq/nfu059

Millar, M.M., and Dillman, D.A. (2011). Improving response to web and mixed-mode surveys. *Public Opinion Quarterly*, 75, 249-269. doi:10.1093/poq/nfr003

Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2007). Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV) (2007 ASPE Report). Available at <http://aspe.hhs.gov/sp/reports/2007/igiv/report.pdf>. (Accessed October 8, 2014).

Parsons, N.L., and Manierre, M.J. (2014). Investigating the relationship among prepaid token incentives, response rates, and nonresponse bias in a web survey. *Field Methods*, 26(2), 191-204. doi:10.1177/1525822X13500120

Schulman, Ronca & Bucuvalas, Inc. (2003). Primary Immune Deficiency Diseases in America: 2002. The second national survey of patients. Accessed from <https://primaryimmune.org/idf-publications/> on December 15, 2014.

Small Business Administration (SBA), (2014). Table of Small Business Size Standards Matched to North American Industry Classification System Codes. Available at <http://www.sba.gov/content/table-small-business-size-standards> (Accessed July 7, 2015).