Appendix B. Medicare IVIG Demonstration Evaluation Survey

This Appendix contains all beneficiary notifications, including: 1) a pre-notification letter; 2) a cover letter to be included in the survey package; 3) beneficiary survey Form A, for beneficiaries who are not enrolled in the Medicare In-home IVIG Demonstration; 4) beneficiary survey Form B, for beneficiaries who are enrolled; 5) the survey reminder letter; and 6) a survey reminder postcard. All notification letters and the postcard will contain the logos of CMS and the Department of Health and Human Services. The cover pages of the survey forms will bear the CMS logo.

B.1. Pre-Notification Letter

Nota: Estos materiales están disponibles en español. Para solicitar una copia de la encuesta en español, por favor llame al 1-800-674-7381. These materials are available in Spanish. To request a copy of the survey in Spanish, please call 1-800-674-7381.

NAME
ADDRESS
CITY, STATE ZIP

Dear [Medicare Beneficiary],

Medicare is surveying all beneficiaries being treated with immunoglobulin for Primary Immune Deficiency Disease (PIDD). Because our records show that you are receiving immunoglobulin for PIDD, you will soon be getting our survey package in the mail.

I am writing to urge you to take the time (about 30 minutes) to complete this important survey soon after you receive it. The results of the survey will help us improve our services to you and other Medicare beneficiaries.

You can complete the survey on line now, by going to the secure survey web site at www.IGsurvey.com. Your personal survey identifiers are:

Username: **XXXXX**

Password: **XXXXX**

Your answers and participation in this survey are PRIVATE, CONFIDENTIAL, and PROTECTED under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your answers to the survey will be grouped with answers from all other survey participants; your name and identifying information will not be linked to your answers.

Your participation in this survey is voluntary and will not affect any health care or benefits you receive.

The questions are mainly about your immunoglobulin treatment experiences—how long your treatment takes, your travel and waiting time (if any), how often you receive treatment, any trouble you've had getting the right medicine, any other difficulties you may have had getting treatment, and so on. The results of this survey will help Medicare improve services in the future.

Thank you in advance for participating in this important survey!

Sincerely,

Pauline Karikari-Martin, PhD., MPH, MSN
Centers for Medicare & Medicaid Services

410-786-1040 | pauline.karikarimartin@cms.hhs.gov

B.2. Cover Letter

Nota: Estos materiales están disponibles en español. Para solicitar una copia de la encuesta en español, por favor llame al 1-800-674-7381. These materials are available in Spanish. To request a copy of the survey in Spanish, please call 1-800-674-7381.
Dear [Medicare beneficiary],

Medicare is surveying all beneficiaries treated with immunoglobulin for Primary Immune Deficiency Disease (PIDD). We need your feedback to help us improve services for you and other people taking immunoglobulin for PIDD.

Medicare needs your help to improve our services to you and others. We want to learn more about beneficiaries' experiences with getting immunoglobulin treatment (intravenous or subcutaneous) for treatment of PIDD. We also want to know how people are doing with Medicare's in-home IVIG Demonstration, and why some people have enrolled and others haven't.

Your answers and participation in this survey are PRIVATE, CONFIDENTIAL, and PROTECTED under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your answers to the survey will be grouped with answers from all other survey participants; your name and identifying information will not be linked to your answers.

Your participation in this survey is voluntary and will not affect any health care or benefits you receive. If it's more convenient, you can **complete the survey on-line at www.IGsurvey.com.** The cover page of your survey form has your unique username and password.

Two versions of this survey are enclosed. Please fill out the form that applies to you and mail it back in the postage-paid envelope provided. Please call the survey helpline at 800-674-7381 if you have questions about which form to fill out.

If you ARE NOT ENROLLED in the Medicare in-home IVIG Demonstration* → **Complete Form A**

If you ARE ENROLLED in the Medicare in-home IVIG Demonstration* → **Complete Form B**

If you have any questions about the survey after reading the instructions, please call the survey helpline at 800-674-7381.

Thank you for participating in this survey. Please accept the enclosed $2.00 as a small gesture of our appreciation.

Sincerely,

Pauline Karikari-Martin, PhD, MPH, MSN
Center for Medicare & Medicaid Services
410-786-1040 | pauline.karikarimartin@cms.hhs.gov

* This demonstration provides in home IVIG services to enrolled beneficiaries. If you have any questions about the Medicare in-home IVIG Demonstration, please call the demonstration hotline toll-free at 1-844-625-6284, or visit www.medicarenhic.com.

B.3. Survey Instrument Form A - For beneficiaries not enrolled in the Medicare In-home IVIG Demonstration

Please complete Form A if you are NOT ENROLLED in the Medicare In-home IVIG Demonstration, or if you've applied but haven't heard yet from Medicare about your enrollment.

Want a quicker and easier way to fill out the survey?
Go to www.IGsurvey.com and sign in with this information:

Your Username: XXXX3
Your Password: XXXX3

IGsurvey.com is a SECURE website administered by a Medicare contractor.

OMB Control No. XXXX-XXXX. Approval expires XX/XX/20XX.
SURVEY OF MEDICARE BENEFICIARIES
TAKING IMMUNOGLOBULIN (IG) FOR PRIMARY
IMMUNE DEFICIENCY DISEASE (PIDD)

FORM A INFORMATION AND INSTRUCTIONS

IMPORTANT: If you have been continuously confined to your home since October 1, 2014, AND you have been continuously receiving all of your medical care at home since October 1, 2014 under Medicare's Home Health Prospective Payment System, you may be ineligible for this survey. Please call the survey helpline at 1-800-674-7381 if you think this applies to you.

- FOR CAREGIVERS AND/OR RELATIVES: If you're a caregiver or relative of the beneficiary and you're helping them with the survey, please tell us about their experiences when answering the questions.
- ALL RESPONSES ARE PROTECTED UNDER THE HIPAA PRIVACY RULE. The rules of the Health Insurance Portability and Accountability Act (HIPAA) ensure that we won't use or associate your name with your survey responses. We will combine the information you give with information from other people's surveys. No one outside of the project team will see your survey or your responses.
- QUESTIONS OR CONCERNS ABOUT THE SURVEY? Call the Survey Helpline at 800-674-7381. We'll be happy to assist you.
- QUESTIONS ABOUT ENROLLMENT IN THE DEMONSTRATION? Please call NHIC, Inc., the Medicare demonstration contractor, toll-free at 844-625-6284 or go to http://www.medicarenhic.com.
- INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE:
- Please read all the response options before moving on to the next question. Some questions ask you to Check all that apply. If you skip to the next question before reading all the options, you may be missing a response that applies to you.
- Watch for the GO TO and Continue arrows!
- The word "home" used in the questions throughout the survey refers to your primary residence—the address at which you received this survey package. This may be your house, an assisted living facility, a nursing home, or another location. Even if you reside in different locations throughout the year, please respond for your primary residence only.

- Please feel free to give an explanation for any of your responses if you feel it's necessary. There is space on the last page for your comments. If you comment on a particular question, please tell us the question number your comment refers to.
- ABBREVIATIONS AND DEFINITIONS:
- IVIG—intravenous immunoglobulin (infusion into a vein)
- SCIG—subcutaneous immunoglobulin (infusion under the skin)
- PIDD—primary immune deficiency disease
- Home—your primary residence

SURVEY ELIGIBILITY

IMPORTANT: If you have been continuously confined to your home since October 1, 2014, AND continuously receiving all of your medical care at home under Medicare's Home Health Prospective Payment System since October 1, 2014, you may be ineligible for this survey. If you think this applies to you, please call the survey helpline at 1-800-674-7381. Otherwise, please continue.

1. Please read each of the following questions and check YES, NO, or NOT SURE.

   1a. Have you been diagnosed with primary immune deficiency disease (PIDD)?

   ☐ Yes
   ☐ No
   ☐ Not sure

   1b. Do you require immunoglobulin for the treatment of PIDD?

   ☐ Yes
   ☐ No
   ☐ Not sure

   1c. Since October 1, 2014, have you been covered under Medicare Part A and Part B ("Original Medicare" coverage) at any time?

   ☐ Yes
   ☐ No
   ☐ Not sure

If you checked YES to all of these three questions PLEASE CONTINUE TO Q2. If you checked NO to any of these three questions, STOP and go to END. If you checked "NOT SURE," or have any questions about taking this survey, please call the Survey Helpline at 1-800-674-7381

YOUR PRIMARY IMMUNE DEFICIENCY DISEASE (PIDD) EXPERIENCE

2. In what year were you first diagnosed with primary immune deficiency disease (PIDD)?

   _____

3. Which type of PIDD are you diagnosed with now? Please check all that apply.

- ☐ Common Variable Immunodeficiency (CVID)
- ☐ Selective IgM Immunodeficiency
- ☐ Wiskott-Aldrick Syndrome (WAS)
- ☐ Congenital Hypogammaglobulinemia
- ☐ Immunodeficiency with Increased IgM
- ☐ Other (please specify)_____
- ☐ Don't know

4. In what year did you first start immunoglobulin (IG) treatment?

   _____

5. What type of immunoglobulin treatment did your doctor prescribe for your condition most recently?

   - ☐ Intravenous immunoglobulin (infusion into a vein-IVIG)
   - ☐ Subcutaneous immunoglobulin (infusion under the skin—SCIG)
   - ☐ I have prescriptions for both IVIG and SCIG
   - ☐ Other _____

6. Which brand(s) of immunoglobulin are you currently prescribed? If you have a prescription for both IVIG and SCIG, please check off your medicine under both categories.

Intravenous Immunoglobulin (IVIG) Brands:

- ☐ Bivigam (IVIG)
- ☐ Carimune NF (IVIG)
- ☐ Flebogamma DIF (IVIG)
- ☐ Gammagard (IVIG)
- ☐ Gammaked (IVIG)
- ☐ Gammaplex (IVIG)
- ☐ Gamunex-C (IVIG)
- ☐ Iveegam (IVIG)
- ☐ Octagam (IVIG)
- ☐ Panglobulin (IVIG)
- ☐ Polygam (IVIG)
- ☐ Privigen (IVIG)
- ☐ Venoglobulin (IVIG)
- ☐ Other (please specify) _____
- ☐ Don't know

Subcutaneous Immunoglobulin (SCIG) Brands:

- ☐ Gammagard (SCIG)
- ☐ Gammaked (SCIG)
- ☐ Gamunex-C (SCIG)
- ☐ Hizentra (SCIG)
- ☐ Other (please specify) _____
- ☐ Don't know

7. How often do you receive immunoglobulin treatment currently? Please check the ONE best response.

   - ☐ Every week
   - ☐ Every two weeks
   - ☐ Every three weeks
   - ☐ Every four weeks
   - ☐ Every five weeks
   - ☐ Every six weeks
   - ☐ Other (please specify) _____

8. Where do you usually receive immunoglobulin treatment now? Please check the ONE best response.

   - ☐ At a medical setting (such as an infusion center, doctor's office, or hospital)
   - ☐ At home
   - ☐ Sometimes at home and sometimes at a medical setting (such as an infusion center, doctor's office, or hospital)
   - ☐ Other (please specify) _____

9. About how long does your usual immunoglobulin treatment take per session? Do NOT include travel time or waiting room time, but DO include time required for any procedure or treatment that you get with your immunoglobulin treatment, such as hydrating fluids or Benadryl.) Please check the ONE best response.

   - ☐ Less than 2 hours
   - ☐ From 2 hours to 4 hours
   - ☐ From 4 hours to 6 hours
   - ☐ Six hours or more
   - ☐ Other (please specify)_____

10. How would you rate your overall health?

    - ☐ Excellent
    - ☐ Very Good
    - ☐ Good
    - ☐ Fair

☐ Poor

11. Since October 1, 2014, Medicare has offered beneficiaries the opportunity to enroll in a Medicare In-home IVIG Demonstration. This demonstration pays providers to administer IVIG in patients' homes even if the patient doesn't qualify for Medicare-covered home health care services.

    Did a provider—other than your doctor—ever express an opinion to you about whether or not you should enroll in the Medicare In-home IVIG Demonstration?

    ☐ Yes, a provider—other than my doctor— suggested I should enroll.

    ☐ Yes, a provider—other than my doctor— suggested I should NOT enroll.

    ☐ No, no provider—other than my doctor— has expressed an opinion to me about my enrollment.

    ☐ Other (please specify)_____

THE MEDICARE IN-HOME IVIG DEMONSTRATION

12. Did you apply for the Medicare In-home IVIG Demonstration?

    ☐ No, I did not apply. Continue to 13

    ☐ Yes, I applied but haven't heard back yet. GO TO 14

    ☐ Yes, I applied but my application was denied. GO TO END.

13. Why did you NOT apply to enroll in the Medicare In-home IVIG Demonstration? Please check all that apply.

    ☐ I wasn't aware it was available.

    ☐ I wasn't eligible because I was receiving Medicare covered home health services.

    ☐ I wasn't eligible because I was enrolled in a Medicare Advantage plan.

    ☐ I didn't think I could find a provider willing or able to give me infusions at home.

    ☐ I tried, but I couldn't find a provider willing or able to give me infusions at home.

    ☐ I was taking SCIG treatments at home and saw no need to enroll.

    ☐ I can't receive IVIG treatments at home for medical reasons.

    ☐ I prefer to receive my IVIG treatments at a medical setting (such as an infusion center, doctor's office, or hospital).

    ☐ My provider recommended that I not enroll.

    ☐ Other (please specify)_____

14. If you applied to the Medicare In-home IVIG Demonstration, but haven't heard back yet: Why did you apply for the Medicare in-home IVIG Demonstration? Please check all that apply.

    ☐ I wanted to receive IVIG in the comfort of my home.

    ☐ I wanted to cut out travel time and waiting time at my IVIG infusion site.

    ☐ I've had difficulty finding an infusion site.

    ☐ I wanted to avoid being exposed to sick patients in a health care setting.

    ☐ I previously had difficulty paying for the in-home service.

- ☐ I felt too sick to travel to an infusion site.
- ☐ It was recommended by my doctor or other health care professional.
- ☐ I had been taking SCIG at home but wanted to get IVIG instead.
- ☐ I wasn't sure I wanted to receive IVIG at home when I applied, but I wanted to enroll in the demonstration in case I change my mind in the future.
- ☐ I wanted to have access to the demonstration as a backup to my usual immunoglobulin treatment.
- ☐ Other (please specify)_____

15. Since October 1, 2014, did you miss any immunoglobulin treatments?

- ☐ Yes, I have missed approximately _____ treatments since October 1, 2014. Continue to 16
- ☐ No GO TO 17
- ☐ Other (please specify)_____

16. Why did you miss treatment(s)? Please check all that apply.

- ☐ My usual provider (infusion clinic, doctor's office, etc.) cancelled one or more scheduled treatment(s).
- ☐ I switched providers and missed a treatment as a result.
- ☐ I had transportation problems that caused one or more missed treatment(s).
- ☐ My travel schedule caused me to miss one or more treatment(s).
- ☐ I was too sick to travel to my usual treatment setting.
- ☐ Other (please specify) _____

HOW YOU TAKE YOUR IMMUNOGLOBULIN

17. Since you were first diagnosed with PIDD, have you ever switched treatment methods from intravenous immunoglobulin (IVIG) to subcutaneous immunoglobulin (SCIG)?

- ☐ Yes Continue to 18
- ☐ No GO TO 19

18. Why did you switch from IVIG to SCIG? Please check all that apply.

- ☐ SCIG was recommended by my doctor.
- ☐ I wanted to lessen the side effects from IVIG.
- ☐ I wanted to use SCIG in the comfort of my home.
- ☐ I wanted to cut out travel time to the IVIG infusion facility.
- ☐ I had difficulty finding an infusion facility.
- ☐ I wanted to avoid being exposed to sick patients in a health care setting.
- ☐ SCIG costs me less.
- ☐ Other (please specify)_____

19. Since you were first diagnosed with PIDD, have you ever switched treatment methods from SCIG to IVIG?

- ☐ Yes Continue to 20
- ☐ No GO TO 21

20. Why did you switch from SCIG to IVIG? Please check all that apply.

- ☐ IVIG was recommended by my doctor.
- ☐ I had difficulty with self-administration of SCIG.
- ☐ I switched from SCIG to IVIG so I could be eligible for the demonstration and get help with infusions at home.
- ☐ I wanted to have less frequent treatments.
- ☐ I preferred to receive IVIG in a health care setting.
- ☐ IVIG costs me less.
- ☐ Other (please specify)_____

21. Since October 1, 2014, has the brand of immunoglobulin medicine you usually receive changed?

- ☐ Yes Continue to 22
- ☐ No GO TO 25

22. Why was there a change in the brand of immunoglobulin medicine you receive? Please check all that apply.

- ☐ My former immunoglobulin product became unavailable or hard to get.
- ☐ My insurance reimbursement was reduced.
- ☐ Insurance did not cover or stopped covering my former product.
- ☐ My co-pays and/or other out-of-pocket expenses were too high.
- ☐ My doctor recommended changing because my former product was not working well.
- ☐ I switched from IVIG to SCIG.
- ☐ I switched from SCIG to IVIG.
- ☐ Other (please specify)_____
- ☐ Don’t know

23. After you changed brands of immunoglobulin medicine, did you experience any of the following side effects? Please check all that apply.

- ☐ Chills
- ☐ Fainting
- ☐ Fever
- ☐ Headaches
- ☐ High blood pressure
- ☐ Hives

- ☐ Nausea
- ☐ Rash
- ☐ Shortness of breath
- ☐ Vomiting
- ☐ Other (please specify)_____
- ☐ None

24. Which of the following best describes your experience with the brand of immunoglobulin medicine you switched to? Please check the ONE best response.

- ☐ There was no difference in side effects between my new and previous medicine.
- ☐ My new brand caused fewer side effects than my previous one.
- ☐ My new brand caused more side effects than my previous one.
- ☐ Other (please specify)_____

IMMUNOGLOBULIN TREATMENT LOCATION

25. Between September 30, 2012 and October 1, 2014, where were you usually receiving your immunoglobulin treatments? Please check the ONE location where you received most of your treatments.

- ☐ At home
- ☐ Doctor's private office
- ☐ Hospital, as an inpatient
- ☐ Hospital outpatient clinic
- ☐ Infusion clinic
- ☐ I was not receiving immunoglobulin treatments at that time.
- ☐ Other (please specify)_____
- ☐ Don't know

26. Since October 1, 2014, has your usual immunoglobulin treatment location changed?

- ☐ Yes Continue to 27
- ☐ No GO TO 28

27. Where are you getting your immunoglobulin treatments now? Please check all that apply.

- ☐ At home
- ☐ Doctor's private office
- ☐ Hospital, as an inpatient
- ☐ Hospital outpatient clinic
- ☐ Infusion clinic
- ☐ I am not receiving immunoglobulin treatments now.

☐ Other (please specify)_____

FLUIDS FOR HYDRATION

28. Before October 1, 2014, did you usually receive hydrating fluids when you had immunoglobulin treatment? Please read each statement and check YES or NO.

    Before October 1, 2014, I usually received hydrating fluids intravenously before, during, or after receive immunoglobulin.

    ☐ Yes
    ☐ No
    ☐ Not sure

    Before October 1, 2014, I was instructed to drink extra fluids on the day of my immunoglobulin treatment.

    ☐ Yes
    ☐ No
    ☐ Not sure

    Before October 1, 2014, I usually drank extra fluids on the day of my immunoglobulin treatment on my own.

    ☐ Yes
    ☐ No
    ☐ Not sure

    Before October 1, 2014, I did not usually drink extra fluids or receive hydrating fluids intravenously before, during, or after immunoglobulin treatment.

    ☐ Yes
    ☐ No
    ☐ Not sure
    ☐ Other (please specify)_____
    ☐ Don't know

29. After October 1, 2014, have you usually been receiving hydrating fluids when you get immunoglobulin treatment? Please read each statement and check YES or NO.

    Since October 1, 2014, I usually received hydrating fluids intravenously before, during, or after receive immunoglobulin.

    ☐ Yes
    ☐ No
    ☐ Not sure

Since October 1, 2014, I have been instructed to drink extra fluids on the day of my immunoglobulin treatment.

- ☐ Yes
- ☐ No
- ☐ Not sure

Since October 1, 2014, I usually drink extra fluids on the day of my immunoglobulin treatment on my own.

- ☐ Yes
- ☐ No
- ☐ Not sure

Since October 1, 2014, I do not usually drink extra fluids or receive hydrating fluids intravenously before, during, or after immunoglobulin treatment.

- ☐ Yes
- ☐ No
- ☐ Not sure
- ☐ Other (please specify)_____
- ☐ Don't know

IMMUNOGLOBULIN TREATMENT FREQUENCY

30. Since October 1, 2014, how many of your immunoglobulin treatments have been postponed?

- ☐ None, no treatments have been postponed. GO TO 32
- ☐ One treatment was postponed. Continue to 31
- ☐ Two or three treatments were postponed. Continue to 31
- ☐ Four or more treatments were postponed. Continue to 31

31. Why was treatment postponed? Please check all that apply.

- ☐ I postponed my treatment to accommodate my personal schedule.
- ☐ I was too sick to travel to my treatment.
- ☐ My doctor recommended postponement.
- ☐ My provider postponed treatment.
- ☐ My insurance reimbursement was reduced.
- ☐ My insurance wouldn't cover all of the treatments.
- ☐ I was unable to afford the cost of co-pays and/or other out-of-pocket expenses.
- ☐ Immunoglobulin wasn't available.
- ☐ Other (please specify)_____

☐ Don’t know

32. Since October 1, 2014, has the usual time between your immunoglobulin treatments gotten longer? That is, are you getting treatments less often?

☐ Yes Continue to 33

☐ No, the time between my immunoglobulin treatments has not increased. GO TO 34

33. IF YOU CHECKED YES TO 32: Why did the time interval between your immunoglobulin treatments increase? Please check all that apply.

☐ My doctor recommended it.

☐ I switched from SCIG to IVIG, so time between treatments increased.

☐ My insurance reimbursement was reduced.

☐ My insurance wouldn’t cover all of the treatments.

☐ Higher co-pays and/or other out-of-pocket expenses caused me to get treatment less often.

☐ Immunoglobulin wasn’t available.

☐ My dosage increased, so I got treatment less often.

☐ Other (please specify) _____

☐ Don’t know

34. Since October 1, 2014, has the time between your immunoglobulin treatments gotten shorter? That is, are you getting treatments more often?

☐ Yes Continue to 35

☐ No, the time between my immunoglobulin treatments has not gotten shorter. GO TO 36

☐ Don’t know/Not sure

35. IF YOU CHECKED YES TO 34: Why are you getting treatments more often since October 1, 2014? Please check all that apply.

☐ My doctor recommended it.

☐ My dosage had to be decreased, so I needed treatments more often.

☐ I switched from IVIG to SCIG, so I started having treatments more often.

☐ Other (please specify)_____

☐ Don’t know

IMMUNOGLOBULIN TREATMENT DURATION

36. Since October 1, 2014, have your immunoglobulin treatment sessions gotten longer, shorter, or do they take about the same amount of time? DO NOT include travel or waiting time, if any. DO include time required for any procedure or treatment that you get with your immunoglobulin infusion, such as hydrating fluids or Benadryl.

☐ My immunoglobulin treatment sessions have gotten longer since October 1, 2014.

☐ My immunoglobulin treatment sessions have gotten shorter since October 1, 2014.

- ☐ My immunoglobulin treatment sessions take about the same amount of time since October 1, 2014.
- ☐ My immunoglobulin treatment sessions are sometimes shorter and sometimes longer since October 1, 2014.
- ☐ Other (please specify) _____

TRAVEL TIME

37. During the summer of 2014, about how long did it normally take you to travel to and from your immunoglobulin treatment location? DO NOT include the time you spent being treated or time spent on other activities. Please read each statement and check the ONE best response.

- ☐ No travel time—during the summer of 2014, I was getting ALL of my immunoglobulin treatments at home.
- ☐ No travel time— during the summer of 2014, I was too sick to travel to receive treatment.
- ☐ No travel time— during the summer of 2014, I was not getting any immunoglobulin treatments.
- ☐ Less than one hour total travel time per treatment.
- ☐ One to two hours total travel time per treatment.
- ☐ More than two hours, up to three hours total travel time per treatment.
- ☐ More than three hours total travel time per treatment.

38. Since October 1, 2014, about how long does it normally take you to travel to and from your immunoglobulin treatment location? DO NOT include the time you spend being treated or time you spend on other activities.

- ☐ No travel time—I have been getting ALL of my immunoglobulin treatments at home since October 1, 2014.
- ☐ Less than one hour total travel time per treatment.
- ☐ One to two hours total travel time per treatment.
- ☐ More than two hours, up to three hours total travel time per treatment.
- ☐ More than three hours total travel time per treatment.

AMOUNT OF IMMUNOGLOBULIN PER TREATMENT

39. Since October 1, 2014, has the number of grams of immunoglobulin per treatment you receive been REDUCED for any reason? That is, did you receive less medicine per treatment at any time since October 1, 2014?

- ☐ Yes Continue to 40
- ☐ No GO TO 41
- ☐ Don’t know GO TO 41

40. Why was the amount of immunoglobulin per treatment reduced? Please check all that apply.

- ☐ My doctor recommended a reduction.
- ☐ My dose was reduced because of side effects.

- ☐ My insurance reimbursement was reduced, so I had to get less medicine.
- ☐ My insurance wouldn't cover all of my treatments.
- ☐ The cost of co-pays and/or of other out-of-pocket expenses went up, so I had to get less medicine.
- ☐ Immunoglobulin wasn't available.
- ☐ I switched to SCIG, so required less immunoglobulin per treatment.
- ☐ The time interval between treatments decreased.
- ☐ Other (please specify)_____
- ☐ Don't know

PROBLEMS WITH IMMUNOGLOBULIN TREATMENT

41. Since October 1, 2014, have you had less trouble overall, or more trouble overall getting immunoglobulin treatments than before?

- ☐ More trouble
- ☐ Less trouble
- ☐ No change

42. In the two years between October 1, 2012 and October 1, 2014, did you experience any of the following health issues? Please read each item and check YES or NO.

During the two years between October 1, 2012 and October 1, 2014…

I had to be hospitalized.

- ☐ Yes
- ☐ No

I experienced more infections than I had in the previous two years.

- ☐ Yes
- ☐ No

I required increased use of antibiotics.

- ☐ Yes
- ☐ No

I experienced additional/new side effects.

- ☐ Yes
- ☐ No

I had pneumonia.

- ☐ Yes

☐ No

I had bronchitis.

☐ Yes

☐ No

I had other health issue(s) (please specify)_____

☐ Yes

☐ No

☐ None of the above

☐ Can't remember

43. Since October 1, 2014, did you experience any of the following health issues? Please read each item and check YES or NO.

Since October 1, 2014…

I had to be hospitalized.

☐ Yes

☐ No

I experienced more infections than I had in the previous two years.

☐ Yes

☐ No

I required increased use of antibiotics.

☐ Yes

☐ No

I experienced additional/new side effects.

☐ Yes

☐ No

I had pneumonia.

☐ Yes

☐ No

I had bronchitis.

☐ Yes

☐ No

I had other health issue(s) (please specify)_____

☐ Yes

☐ No

☐ None of the above

☐ Can't remember

BACKGROUND INFORMATION

44. Which of the following types of health insurance do you currently have? Please check all that apply.

☐ Original Medicare (Part A and Part B)

☐ Medicare Advantage (like an HMO or PPO)

☐ Original Medicare Supplement Insurance (Medigap)

☐ Medicaid or Medi-Cal

☐ Private health insurance (like Blue Cross Blue Shield, Aetna, United Healthcare, etc.)

☐ COBRA

☐ TRICARE

☐ Other (please specify)_____

45. What year were you born?

_____

46. Please check the response that best describes your level of education.

☐ Some high school

☐ High school graduate or GED

☐ Some college or technical/vocational school

☐ Two-year college graduate (Associate's degree)

☐ Four-year college graduate (Bachelor's degree)

☐ Technical/vocational school graduate

☐ Post-graduate school or degree

47. Do you live alone?

☐ Yes

☐ No

48. Are you of Hispanic or Latino origin or descent?

- ☐ Yes
- ☐ No

49. What is your race? Please check all that apply.

- ☐ Asian
- ☐ Black or African-American
- ☐ Native American or Alaska native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White

50. What language do you usually speak at home?

- ☐ English
- ☐ Spanish
- ☐ Other (please specify) _____

END

Thank you for participating in this important survey!

Please return this form in the enclosed postage-paid envelope to:

Eastern Research Group, Inc.
Attn: Medicare Immunoglobulin Survey
110 Hartwell Avenue
Lexington, MA 02421

We welcome any additional comments or remarks from you. Please write in the space below or attach another sheet of paper with any comments or remarks you may have.

B.4. Survey Instrument Form B - For beneficiaries not enrolled in the Medicare In-home IVIG Demonstration

Please complete Form B if you are ENROLLED in the Medicare In-home IVIG Demonstration, even if you haven't yet received a treatment under the demonstration.

Want a quicker and easier way to fill out the survey?
Go to www.IGsurvey.com and sign in with this information:

Your Username: XXXX3
Your Password: XXXX3

IGsurvey.com is a SECURE website administered by a Medicare contractor.

OMB Control No. XXXX-XXXX. Approval expires XX/XX/20XX.
SURVEY OF MEDICARE BENEFICIARIES
TAKING IMMUNOGLOBULIN (IG) FOR PRIMARY
IMMUNE DEFICIENCY DISEASE (PIDD)

FORM B INFORMATION AND INSTRUCTIONS

IMPORTANT: If you have been continuously confined to your home since October 1, 2014, AND you have been continuously receiving all of your medical care at home since October 1, 2014 under Medicare's Home Health Prospective Payment System, you may be ineligible for this survey. Please call the survey helpline at 1-800-674-7381 if you think this applies to you.

- FOR CAREGIVERS AND/OR RELATIVES: If you're a caregiver or relative of the beneficiary and you're helping them with the survey, please tell us about their experiences when answering the questions.
- ALL RESPONSES ARE PROTECTED UNDER THE HIPAA PRIVACY RULE. The rules of the Health Insurance Portability and Accountability Act (HIPAA) ensure that we won't use or associate your name with your survey responses. We will combine the information you give with information from other people's surveys. No one outside of the project team will see your survey or your responses.
- QUESTIONS OR CONCERNS ABOUT THE SURVEY? Call the Survey Helpline at 800-674-7381. We'll be happy to assist you.
- QUESTIONS ABOUT ENROLLMENT IN THE DEMONSTRATION? Please call NHIC, Inc., the Medicare demonstration contractor, toll-free at 844-625-6284, or go to http://www.medicarenhic.com.
- INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE:
- Please read all the response options before moving on to the next question. Some questions ask you to Check all that apply. If you skip to the next question before reading all the options, you may be missing a response that applies to you.
- Watch for the GO TO and Continue arrows!
- The word "home" used in the questions throughout the survey refers to your primary residence—the address at which you received this survey package. This may be your house, an assisted living

facility, a nursing home, or another location. Even if you reside in different locations throughout the year, please respond for your primary residence only.

- Please feel free to give an explanation for any of your responses if you feel it's necessary. There is space on the last page for your comments. If you comment on a particular question, please tell us the question number your comment refers to.
- ABBREVIATIONS AND DEFINITIONS:
- IVIG—intravenous immunoglobulin (infusion into a vein)
- SCIG—subcutaneous immunoglobulin (infusion under the skin)
- PIDD—primary immune deficiency disease
- Home—your primary residence

SURVEY ELIGIBILITY

IMPORTANT: If you have been continuously confined to your home since October 1, 2014, AND continuously receiving all of your medical care at home under Medicare's Home Health Prospective Payment System since October 1, 2014, you may be ineligible for this survey. If you think this applies to you, please call the survey helpline at 1-800-674-7381. Otherwise, please continue.

1. Please read each of the following questions and check YES, NO, or NOT SURE.

   1a. Have you been diagnosed with primary immune deficiency disease (PIDD)?

   ☐ Yes

   ☐ No

   ☐ Not sure

   1b. Do you require immunoglobulin for the treatment of PIDD?

   ☐ Yes

   ☐ No

   ☐ Not sure

   1c. Since October 1, 2014, have you been covered under Medicare Part A and Part B ("Original Medicare" coverage) at any time?

   ☐ Yes

   ☐ No

   ☐ Not sure

If you checked YES to all of these three questions PLEASE CONTINUE TO Q2. If you checked NO to any of these three questions, STOP and go to END. If you checked "NOT SURE," or have any questions about taking this survey, please call the Survey Helpline at 1-800-674-7381

YOUR PRIMARY IMMUNE DEFICIENCY DISEASE (PIDD) EXPERIENCE

2. In what year were you first diagnosed with primary immune deficiency disease (PIDD)?

   _____

3. Which type of PIDD are you diagnosed with now? Please check all that apply.

   - ☐ Common Variable Immunodeficiency (CVID)
   - ☐ Selective IgM Immunodeficiency
   - ☐ Wiskott-Aldrick Syndrome (WAS)
   - ☐ Congenital Hypogammaglobulinemia
   - ☐ Immunodeficiency with Increased IgM
   - ☐ Other (please specify)_____
   - ☐ Don't know

4. In what year did you first start immunoglobulin (IG) treatment?

   _____

5. What type of immunoglobulin treatment did your doctor prescribe for your condition most recently?

   - ☐ Intravenous immunoglobulin (infusion into a vein-IVIG)
   - ☐ Subcutaneous immunoglobulin (infusion under the skin—SCIG)
   - ☐ I have prescriptions for both IVIG and SCIG
   - ☐ Other _____

6. Which brand of immunoglobulin are you currently prescribed? If you have a prescription for both IVIG and SCIG, please check off your medicine under both categories.

Intravenous immunoglobulin (IVIG) Brands:

- ☐ Bivigam (IVIG)
- ☐ Carimune NF (IVIG)
- ☐ Flebogamma DIF (IVIG)
- ☐ Gammagard (IVIG)
- ☐ Gammaked (IVIG)
- ☐ Gammaplex (IVIG)
- ☐ Gamunex-C (IVIG)
- ☐ Iveegam (IVIG)
- ☐ Octagam (IVIG)
- ☐ Panglobulin (IVIG)
- ☐ Polygam (IVIG)
- ☐ Privigen (IVIG)
- ☐ Venoglobulin (IVIG)
- ☐ Other (please specify) _____
- ☐ Don't know

Subcutaneous immunoglobulin (SCIG) Brands

- ☐ Gammagard (SCIG)
- ☐ Gammaked (SCIG)
- ☐ Gamunex-C (SCIG)
- ☐ Hizentra (SCIG)
- ☐ Other (please specify) _____
- ☐ Don't know

7. How often do you receive immunoglobulin treatment currently? Please check the ONE best response.

   - ☐ Every week
   - ☐ Every two weeks
   - ☐ Every three weeks
   - ☐ Every four weeks
   - ☐ Every five weeks
   - ☐ Every six weeks
   - ☐ Other (please specify)_____

8. Where do you usually receive immunoglobulin treatment currently? Please check the ONE best response.

   - ☐ At a medical setting (such as an infusion center, doctor's office, or hospital)
   - ☐ At home
   - ☐ Sometimes at home and sometimes at a medical setting (such as an infusion center, doctor's office, or hospital)
   - ☐ Other (please specify)_____

9. About how long does your usual immunoglobulin treatment take per session? Do NOT include travel or waiting room time. DO include time required for any procedure or treatment that you get with your immunoglobulin treatment, such as hydrating fluids or Benadryl. Please check the ONE best response.

   - ☐ Less than 2 hours
   - ☐ From 2 hours to 4 hours
   - ☐ From 4 hours to 6 hours
   - ☐ Six hours or more
   - ☐ Other (please specify)_____

10. How would you rate your overall health?

    - ☐ Excellent
    - ☐ Very Good
    - ☐ Good

☐ Fair

☐ Poor

11. Since October 1, 2014, Medicare has offered beneficiaries the opportunity to enroll in a Medicare In-home IVIG Demonstration. This demonstration pays providers to administer IVIG in patients' homes, even if the patient doesn't qualify for Medicare-covered home health care services.

    Did a provider—other than your doctor—ever express an opinion to you about whether or not you should enroll in the Medicare In-home IVIG Demonstration?

    ☐ Yes, a provider—other than my doctor— suggested I should enroll.

    ☐ Yes, a provider—other than my doctor— suggested I should NOT enroll.

    ☐ No, no provider—other than my doctor— has expressed an opinion to me about my enrollment.

    ☐ Other (please specify)_____

THE MEDICARE IN-HOME IVIG DEMONSTRATION

12. When did you apply for the Medicare In-home IVIG Demonstration?

    _____ _____
    Month Year

13. Why did you apply for the Medicare In-home IVIG Demonstration? Please check all that apply.

    ☐ I wanted to receive IVIG in the comfort of my home.

    ☐ I wanted to cut out travel and waiting time at my IVIG infusion facility.

    ☐ I've had difficulty finding an infusion facility.

    ☐ I wanted to avoid being exposed to sick patients in a health care setting.

    ☐ I previously had difficulty paying for the in-home service.

    ☐ I felt too sick to travel to an infusion facility.

    ☐ It was recommended by my doctor or other health care provider.

    ☐ I had been taking SCIG at home but wanted to receive IVIG instead.

    ☐ I wasn't sure I wanted to receive IVIG at home when I applied, but I wanted to enroll in the demonstration in case I change my mind in the future.

    ☐ I wanted to have access to the demonstration as a backup to my usual immunoglobulin treatment.

    ☐ Other (please specify)_____

14. After your application to the Demonstration was approved, did you experience any of the following issues regarding in-home IVIG treatments? Please read each statement and check YES or NO.

    I had trouble getting an in-home IVIG treatment provider.

    ☐ Yes

    ☐ No

I missed one or more immunoglobulin treatments because of problems finding or scheduling an in-home IVIG treatment provider.

☐ Yes

☐ No

I had to get IVIG at a treatment location away from home one or more times because of problems finding or scheduling an in-home IVIG treatment provider.

☐ Yes

☐ No

I had to get IVIG at a treatment location away from home one or more times because of my travel commitments.

☐ Yes

☐ No

My in-home IVIG treatment provider stopped performing the service, and I had to look for a new in-home IVIG treatment provider.

☐ Yes

☐ No

I switched over to SCIG because of problems getting an in-home IVIG treatment provider.

☐ Yes

☐ No

I had no trouble getting or maintaining an in-home IVIG treatment provider.

☐ Yes

☐ No

I haven't tried to schedule any treatments at home yet.

☐ Yes

☐ No

Other (please specify)_____

15. After you enrolled in the Demonstration, did you miss any immunoglobulin treatments?

☐ Yes, I missed approximately _____ treatments since enrolling. Continue to 16

☐ No, I haven't missed any treatments since enrolling. GO TO 18

☐ Other (please specify)_____

16. Where were you expecting to have the immunoglobulin treatment(s) that you missed? Please check all that apply.

- ☐ In my home
- ☐ At my doctor's office
- ☐ At an infusion clinic or other medical setting
- ☐ Other (please specify)_____
- ☐ Not sure

17. Why did you miss treatment(s) after you enrolled in the in-home Demonstration? Please check all that apply.

    - ☐ I had trouble getting an in-home provider.
    - ☐ My in-home provider cancelled a scheduled treatment(s).
    - ☐ My usual medical setting (infusion clinic, doctor's office, etc.) cancelled a scheduled treatment(s).
    - ☐ I was too sick to travel to my usual treatment setting (infusion clinic, doctor's office, etc.)
    - ☐ I had transportation problems that caused one or more missed treatment(s).
    - ☐ My travel schedule caused me to miss one or more treatment(s).
    - ☐ Other (please specify)_____

18. Have you received IVIG treatment at home under the Medicare In-home IVIG Demonstration?

    - ☐ Yes. Continue to 19
    - ☐ No. GO TO 21
    - ☐ Not sure (please explain, then GO TO 22)_____

19. About how long after you were enrolled in the Demonstration did you have your first in-home IVIG treatment under the Demonstration?

    - ☐ 1 to 2 weeks
    - ☐ 3 to 4 weeks
    - ☐ 5 to 6 weeks
    - ☐ 6 to 8 weeks
    - ☐ More than 8 weeks (please enter approximate number of weeks) _____

20. How satisfied are you with the in-home IVIG administration service you've had since you enrolled in the Demonstration? Please check the ONE best response, THEN GO TO 22

    - ☐ Very satisfied
    - ☐ Satisfied
    - ☐ Neither satisfied nor dissatisfied
    - ☐ Unsatisfied
    - ☐ Very unsatisfied

21. If you haven't yet received an in-home IVIG treatment under the Demonstration, Medicare would like to know why not? Please check all that apply.

- ☐ I contacted one or more in-home IVIG treatment providers, but haven't heard back from them.
- ☐ I spoke with an in-home IVIG treatment provider, but haven't yet gotten an appointment scheduled.
- ☐ I haven't been able to find a provider that will agree to provide my in-home IVIG treatments.
- ☐ I have an in-home IVIG treatment provider and have an appointment for my first in-home IVIG treatment.
- ☐ After I enrolled, my doctor decided that in-home IVIG treatments wouldn't be a good idea for me.
- ☐ I decided I would rather take SCIG at home.
- ☐ I decided I would rather receive IVIG at a medical setting (such as an infusion center, doctor's office, or hospital).
- ☐ I haven't had time to arrange in-home treatments yet.
- ☐ I receive immunoglobulin treatments at home under my state Medicaid.
- ☐ I enrolled to reserve a spot in the demonstration in case I changed my mind, but am not currently interested in receiving in-home IVIG treatments.
- ☐ Other (please specify)_____
- ☐ Don't know

HOW YOU TAKE YOUR IMMUNOGLOBULIN

22. Since you were first diagnosed with PIDD, have you ever switched treatment methods from intravenous immunoglobulin (IVIG) to subcutaneous immunoglobulin (SCIG)?

- ☐ Yes. Continue to 23
- ☐ No. GO TO 24

23. Why did you switch from IVIG to SCIG? Please check all that apply.

- ☐ SCIG was recommended by my doctor.
- ☐ My in-home IVIG treatment provider stopped performing the in-home infusion service.
- ☐ I wanted to lessen the side effects from IVIG.
- ☐ I wanted to cut out travel time to the IVIG infusion facility.
- ☐ I had difficulty finding an infusion facility.
- ☐ I wanted to avoid being exposed to sick patients in a health care setting.
- ☐ SCIG costs me less.
- ☐ Other (please specify)_____

24. Have you ever switched treatment methods from SCIG to IVIG? Please check all that apply.

- ☐ Yes Continue to 25
- ☐ No GO TO 26

25. Why did you switch from SCIG to IVIG? Please check all that apply.

- ☐ IVIG was recommended by my doctor.
- ☐ I had difficulty with self-administration of SCIG.
- ☐ I switched from SCIG to IVIG so I could be in the demonstration and get help with in-home infusions.
- ☐ I wanted to have less frequent treatments.
- ☐ I preferred to receive IVIG in a health care setting.
- ☐ IVIG costs me less.
- ☐ Other (please specify)_____

26. Since you enrolled in the Demonstration, has the brand of immunoglobulin medicine you usually receive changed?

- ☐ Yes Continue to 27
- ☐ No GO TO 30

27. Why was there a change in the brand of immunoglobulin medicine you receive? Please check all that apply.

- ☐ My former immunoglobulin product became unavailable or hard to get.
- ☐ My insurance reimbursement was reduced.
- ☐ Insurance did not cover, or stopped covering, my former product.
- ☐ My co-pays and/or other out-of-pocket expenses were too high.
- ☐ My doctor recommended changing because my former product was not working well.
- ☐ I switched from IVIG to SCIG.
- ☐ I switched from SCIG to IVIG.
- ☐ Other (please specify)_____
- ☐ Don’t know

28. After you changed brands of immunoglobulin medicine, did you experience any of the following side effects? Please check all that apply.

- ☐ Chills
- ☐ Fainting
- ☐ Fever
- ☐ Headaches
- ☐ High blood pressure
- ☐ Hives
- ☐ Nausea
- ☐ Rash
- ☐ Shortness of breath

- ☐ Vomiting
- ☐ Other (please specify)_____
- ☐ None

29. Which of the following best describes your experience with the brand of immunoglobulin medicine you switched to? Please check the ONE best response.

- ☐ There was no difference in side effects between my new brand and my previous medicine.
- ☐ My new brand caused fewer side effects than my previous one.
- ☐ My new brand caused more side effects than my previous one.
- ☐ Other (please specify)_____

IMMUNOGLOBULIN TREATMENT LOCATION

30. During the 2 years before you enrolled in the Demonstration, where were you usually receiving your immunoglobulin treatments? Please check the ONE location where you received most of your treatments.

- ☐ At home
- ☐ Doctor's private office
- ☐ Hospital, as an inpatient
- ☐ Hospital outpatient clinic
- ☐ Infusion clinic
- ☐ I was not receiving immunoglobulin treatments before I enrolled.
- ☐ Other (please specify)_____
- ☐ Don't know

31. Since you enrolled in the Demonstration, has your usual immunoglobulin treatment location changed?

- ☐ Yes. Continue to 32
- ☐ No. GO TO 34

32. Where are you getting your immunoglobulin treatments now? Please check all that apply.

- ☐ At home
- ☐ Doctor's private office
- ☐ Hospital, as an inpatient
- ☐ Hospital outpatient clinic
- ☐ Infusion clinic
- ☐ I am not receiving immunoglobulin treatments now.
- ☐ Other (please specify)_____

33. What is your understanding of the main reason for the change in your usual treatment location? Please check the ONE best response.

- ☐ I started getting IVIG treatments at home.
- ☐ I started taking SCIG at home.
- ☐ My former location closed.
- ☐ My former location stopped providing IVIG.
- ☐ I changed locations for convenience.
- ☐ I became unhappy with the service at the former location.
- ☐ My doctor recommended a different location.
- ☐ My out of pocket costs increased too much.
- ☐ Other (please specify)_____
- ☐ Don't know

FLUIDS FOR HYDRATION

34. Before you enrolled in the Demonstration, did you usually receive hydrating fluids when you had immunoglobulin treatment? Please read each statement and check YES or NO.

Before I enrolled in the Demonstration, I usually received hydrating fluids intravenously before, during, or after receive immunoglobulin.

- ☐ Yes
- ☐ No
- ☐ Not sure

Before I enrolled in the Demonstration, I was instructed to drink extra fluids on the day of my immunoglobulin treatment.

- ☐ Yes
- ☐ No
- ☐ Not sure

Before I enrolled in the Demonstration, I usually drank extra fluids on the day of my immunoglobulin treatment on my own.

- ☐ Yes
- ☐ No
- ☐ Not sure

Before I enrolled in the Demonstration, I did not usually drink extra fluids or receive hydrating fluids intravenously before, during, or after immunoglobulin treatment.

- ☐ Yes
- ☐ No

☐ Not sure

☐ Other (please specify)_____

☐ Don't know

35. Since you enrolled in the Demonstration, have you usually been receiving hydrating fluids when you get immunoglobulin treatment? Please read each statement and check YES or NO.

Since I enrolled in the Demonstration, I usually received hydrating fluids intravenously before, during, or after receive immunoglobulin.

☐ Yes

☐ No

☐ Not sure

Since I enrolled in the Demonstration, I have been instructed to drink extra fluids on the day of my immunoglobulin treatment.

☐ Yes

☐ No

☐ Not sure

Since I enrolled in the Demonstration, I usually drink extra fluids on the day of my immunoglobulin treatment on my own.

☐ Yes

☐ No

☐ Not sure

Since I enrolled in the Demonstration, I do not usually drink extra fluids or receive hydrating fluids intravenously before, during, or after immunoglobulin treatment.

☐ Yes

☐ No

☐ Not sure

☐ Other (please specify)_____

☐ Don't know

IMMUNOGLOBULIN TREATMENT FREQUENCY

36. Since you enrolled in the Demonstration, how many of your immunoglobulin treatments have been postponed?

☐ None, no treatments have been postponed.GO TO 38

- ☐ One treatment was postponed.Continue to 37
- ☐ Two or three treatments were postponed.Continue to 37
- ☐ Four or more treatments were postponed.Continue to 37

37. Why was treatment postponed? Please check all that apply.

- ☐ I postponed my treatment to accommodate my personal schedule.
- ☐ My doctor recommended postponement.
- ☐ My in-home provider postponed treatment.
- ☐ My doctor's office, infusion clinic, or other provider postponed treatment.
- ☐ My insurance wouldn't cover all of the treatments.
- ☐ I was unable to afford the cost of co-pays and/or other out-of-pocket expenses.
- ☐ Immunoglobulin wasn't available.
- ☐ Other (please specify)_____
- ☐ Don't know.

38. Since you enrolled in the Demonstration, has the usual time between your immunoglobulin treatments gotten longer? That is, are you getting treatments less often?

- ☐ Yes. Continue to 39
- ☐ No, the time between my immunoglobulin treatments has not gotten longer. GO TO 40

39. Why are you getting treatments less often since you enrolled? Please check all that apply.

- ☐ I have had trouble scheduling an in-home IVIG treatment provider, causing delayed or missed treatments.
- ☐ My doctor recommended it.
- ☐ I switched from SCIG to IVIG, so time between treatments increased.
- ☐ My insurance wouldn't cover all of the treatments.
- ☐ Higher co-pays and/or other out-of-pocket expenses caused me to get treatment less often.
- ☐ Immunoglobulin wasn't available.
- ☐ My dosage increased, so I got treatments less often.
- ☐ Other (please specify)_____
- ☐ Don't know

40. Since you enrolled in the Demonstration has the time between your immunoglobulin treatments gotten shorter? That is, are you getting treatments more often?

- ☐ Yes. Continue to 41
- ☐ No, the time between my immunoglobulin treatments has not gotten shorter. GO TO 42

41. Why did the time interval between your immunoglobulin treatments decrease? Please check all that apply.

- ☐ My doctor recommended it.
- ☐ My dosage had to be decreased, so I needed treatments more often.
- ☐ I switched from IVIG to SCIG, so I started having treatments more often.
- ☐ Other (please specify)_____
- ☐ Don't know

IMMUNOGLOBULIN TREATMENT DURATION

42. Since you enrolled in the Demonstration, have your immunoglobulin treatment sessions gotten longer, shorter, or do they take about the same amount of time? Do not include travel or waiting time, if any. DO include time required for any procedure or treatment that you get with your immunoglobulin infusion, such as hydrating fluids or Benadryl. Please check the ONE best response.

- ☐ My immunoglobulin treatment sessions have gotten longer since I enrolled.
- ☐ My immunoglobulin treatment sessions have gotten shorter since I enrolled.
- ☐ My immunoglobulin treatment sessions take about the same amount of time since I enrolled.
- ☐ My immunoglobulin treatment sessions are sometimes shorter and sometimes longer since I enrolled.
- ☐ Other (please specify) _____

TRAVEL TIME

43. During the 3 months before you enrolled in the Demonstration, about how long did it normally take you to travel to and from your immunoglobulin treatment location? Don't include the time you spent being treated or time spent on other activities.

- ☐ No travel time—during the summer of 2014, I was getting ALL of my immunoglobulin treatments at home.
- ☐ No travel time— during the summer of 2014, I was too sick to travel to receive treatment.
- ☐ No travel time— during the summer of 2014, I was not getting any immunoglobulin treatments.
- ☐ Less than one hour total travel time per treatment.
- ☐ One to two hours total travel time per treatment.
- ☐ More than two hours, up to three hours total travel time per treatment.
- ☐ More than three hours total travel time per treatment.
- ☐ I was getting ALL of my immunoglobulin treatments at home and had no travel time.

44. Since you enrolled in the Demonstration, about how long does it normally take you to travel to and from your immunoglobulin treatment location for those immunoglobulin treatments you DO NOT receive at home (if any)? Don't include the time you spend being treated or time you spend on other activities.

- ☐ No travel time—I have been getting ALL of my immunoglobulin treatments at home since I enrolled.
- ☐ No travel time—I have not had an immunoglobulin treatment since I enrolled.
- ☐ Less than one hour total travel time per treatment.
- ☐ One to two hours total travel time per treatment.
- ☐ More than two hours, up to three hours total travel time per treatment.
- ☐ More than three hours total travel time per treatment.

AMOUNT OF IMMUNOGLOBULIN PER TREATMENT

45. Since you enrolled in the Demonstration, has the number of grams of immunoglobulin per treatment you receive been REDUCED for any reason?

- ☐ Yes. Continue to 46
- ☐ No. GO TO 47

46. Why was the amount of immunoglobulin reduced? Please check all that apply.

- ☐ My doctor recommended a reduction.
- ☐ My dose was reduced because of side effects.
- ☐ My insurance reimbursement was reduced, so I had to get less medicine.
- ☐ My insurance wouldn't cover all of my treatments.
- ☐ The cost of co-pays and/or of other out-of-pocket expenses went up, so I had to get less medicine.
- ☐ Immunoglobulin wasn't available.
- ☐ I switched to SCIG, so required less immunoglobulin per treatment.
- ☐ The time interval between my treatments decreased.
- ☐ Other (please specify)_____
- ☐ Don't know

PROBLEMS WITH IMMUNOGLOBULIN TREATMENT

47. Since your enrollment in the Demonstration, have you had less trouble overall, or more trouble overall getting immunoglobulin treatments than before?

- ☐ More trouble
- ☐ Less trouble
- ☐ No change

48. During the 2 years <u>before</u> you enrolled in the Demonstration, did you experience any of following health issues? Please read each item and check YES or NO.

During the 2 years before I enrolled in the Demonstration…

I had to be hospitalized.

☐ Yes

☐ No

I experienced more infections than I had in the previous two years.

☐ Yes

☐ No

I required increased use of antibiotics.

☐ Yes

☐ No

I experienced additional/new side effects.

☐ Yes

☐ No

I had pneumonia.

☐ Yes

☐ No

I had bronchitis.

☐ Yes

☐ No

I had other health issue(s) (please specify)_____

☐ Yes

☐ No

☐ None of the above

☐ Can't remember

49. After you enrolled in the Demonstration, did you experience any of following health issues? Please read each item and check YES or NO.

Since I enrolled in the Demonstration…

I had to be hospitalized.

☐ Yes

☐ No

I experienced more infections than I had in the previous two years.

☐ Yes

☐ No

I required increased use of antibiotics.

☐ Yes

☐ No

I experienced additional/new side effects.

☐ Yes

☐ No

I had pneumonia.

☐ Yes

☐ No

I had bronchitis.

☐ Yes

☐ No

I had other health issue(s) (please specify)_____

☐ Yes

☐ No

☐ None of the above

☐ Can't remember

BACKGROUND INFORMATION

50. Which of the following types of health insurance do you currently have? Please check all that apply.

☐ Original Medicare (Part A and Part B)

☐ Medicare Advantage (like an HMO or PPO)

☐ Original Medicare Supplement Insurance (Medigap)

☐ Medicaid or Medi-Cal

☐ Private health insurance (like Blue Cross Blue Shield, Aetna, United Healthcare, etc.)

☐ COBRA

☐ TRICARE

☐ Other (please specify)_____

51. What year were you born?

_____

52. Please check the response that best describes your level of education.

- ☐ Some high school
- ☐ High school graduate or GED
- ☐ Some college or technical/vocational school
- ☐ Two-year college graduate (Associate's degree)
- ☐ Four-year college graduate (Bachelor's degree)
- ☐ Technical/vocational school graduate
- ☐ Post-graduate school or degree

53. Do you live alone?

- ☐ Yes
- ☐ No

54. Are you of Hispanic or Latino origin or descent?

- ☐ Yes
- ☐ No

55. What is your race? Please check all that apply.

- ☐ Asian
- ☐ Black or African-American
- ☐ Native American or Alaska native
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White

56. What language do you usually speak at home?

- ☐ English
- ☐ Spanish
- ☐ Other (please specify) _____

END

Thank you for participating in this important survey!

Please return this form in the enclosed postage-paid envelope to:

Eastern Research Group, Inc.
Attn: Medicare Immunoglobulin Survey

110 Hartwell Avenue
Lexington, MA 02421

We welcome any additional comments or remarks from you. Please write in the space below or attach another sheet of paper with any comments or remarks you may have.

B.5. Survey Reminder Letter

Nota: Estos materiales están disponibles en español. Para solicitar una copia de la encuesta en español, por favor llame al 1-800-674-7381. These materials are available in Spanish. To request a copy of the survey in Spanish, please call 1-800-674-7381.

Dear [Medicare Beneficiary],

Recently, we sent you a survey package asking for your help in our effort to gather information about the experiences of Medicare beneficiaries receiving immunoglobulin treatment for primary immune deficiency disease (PIDD). As of today, we have not yet received your completed questionnaire. (If you have already returned the questionnaire, please accept our thanks.)

If you have not completed the survey, please take a few minutes to complete the appropriate form and return it in the enclosed postage-paid envelope. Your feedback is important because it will help improve the PIDD-related services we provide. The results of the survey will help us improve our services to you and other Medicare beneficiaries.

If you need help, please call the survey help line at 800-674-7381.

Your answers and participation in this survey are PRIVATE, CONFIDENTIAL, and PROTECTED under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your answers to the survey will be grouped with answers from all other survey participants; your name and identifying information will not be linked to your answers.

Your participation in this survey is voluntary and will not affect any health care or benefits you receive.

If it's more convenient, you can **complete the survey on-line at www.IGsurvey.com.** The cover page of your survey form has your unique username and password.

Two versions of this survey are enclosed. Please fill out the form that applies to you and mail it back in the postage-paid envelope provided.

If you ARE NOT ENROLLED in the Medicare in-home IVIG Demonstration* → **Complete Form A**

If you ARE ENROLLED in the Medicare in-home IVIG Demonstration* → **Complete Form B**

Thank you in advance for participating in this important survey!

Sincerely,

Pauline Karikari-Martin, PhD, MPH, MSN
Centers for Medicare & Medicaid Services
410-786-1040 | pauline.karikarimartin@cms.hhs.gov

* This demonstration provides in home IVIG services to enrolled beneficiaries. If you have any questions about the Medicare in-home IVIG Demonstration, please call the demonstration hotline toll-free at 1-844-625-6284, or visit www.medicarenhic.com.

B.6. Survey Reminder Postcard

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Nota: Estos materiales están disponibles en español. Para solicitar una copia de la encuesta en español, por favor llame al 1-800-674-7381. These materials are available in Spanish. To request a copy of the survey in Spanish, please call 1-800-674-7381.

Dear [Medicare Beneficiary]

We recently mailed you Medicare's *2016 Survey of Beneficiaries Using Immunoglobulin for Treatment of PIDD*. This card is to remind you that **YOUR PARTICIPATION IS HIGHLY IMPORTANT.**

THIS IS AN OPPORTUNITY FOR YOU TO HAVE YOUR VOICE HEARD BY MEDICARE. Medicare needs your feedback to understand the needs of beneficiaries taking immunoglobulin, and how we can improve our services.

THE SURVEY SHOULD TAKE LESS THAN 30 MINUTES TO COMPLETE.

- You can complete the survey we mailed to you.
- **OR: You can take the survey on line at: www.IGsurvey.com Your password is: _____**
- OR: You can download another copy at: **www.IGsurvey.com** (Click the link at the bottom of the second page.)
- OR: You can request another survey by emailing us at **IGsurvey@erg.com**.

Your participation and responses are PRIVATE, CONFIDENTIAL, and PROTECTED UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT of 1996 (HIPAA). Your participation in this survey is voluntary and will not affect any health care or benefits you receive.

ANY QUESTIONS OR CONCERNS? Email Pauline Karikari-Martin at: pauline.karikarimartin@cms.hhs.gov or call 410 786 1040.

This reminder has been sent by Eastern Research Group, Inc. (ERG), under contract by Medicare to conduct this survey (OMB Approval No._____).