Appendix A. Screeners and Interview Guides

A.1. Nurses Treating Beneficiaries with Primary Immune Deficiency Disorder (PIDD)

A.1.a. Screeners

1. Screening Email for Nurses who Administer IVIG

Dear [Insert name and title]:

I am writing on behalf of the Centers for Medicare and Medicaid Services (CMS). We are conducting interviews with nurses who administer intravenous immunoglobulin (IVIG) for patients with primary immune deficiency disorder. CMS is collecting this information to provide better care for patients and to simplify billing and reimbursement. CMS is conducting a trial to provide better access to IVIG for those who need it, and we are interested in talking with nurses who provide IVIG in different settings, including home administration of IVIG.

Would you be able to participate in an interview that would take approximately 30 minutes? If you can spare the time for this important interview, please respond to the questions below. If you meet the criteria for this round of interviews, we will schedule a convenient time for an interview with you. We will not use your name in the report and everything you tell us would be used only for the purposes of this research. If you cannot help in this study, kindly forward this email to colleagues who qualify.

Please answer these questions in your reply (you can delete to leave the correct response to the Yes/No questions):

1. What is your primary occupation and specialty?
2. Do you have certification or training in IVIG? Yes/No
3. In your role as a nurse, do you administer IVIG? Yes/No
4. Have you ever administered IVIG in a home setting? Yes/No
5. If YES: How long have been administering IVIG to patients either at home or in other settings?
6. If YES: Approximately how many IVIG patients do you see in a typical month?
7. Do you have experience administering IVIG to Medicare beneficiaries? Yes/No
8. What is the best number to contact you to set up an interview?
9. Can you recommend any of your colleagues to interview? If so, please provide their name and as much contact information as possible.

We thank you in advance for your time and help. Your input will be very valuable to this research.

Sincerely,

[Insert name, title and contact information]

2. Screening Call (to be used in place of Screening Email if phone number is available)

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services or CMS. The purpose of the call is to ask if you can participate in interviews we are conducting with nurses who administer intravenous immunoglobulin, otherwise known as IVIG, for patients with primary immune deficiency disorder. CMS is collecting this information to provide better care for patients and to simplify billing and reimbursement. CMS is conducting a trial to provide better access to IVIG for those who need it, and we are interested in talking with nurses who provide IVIG in home settings. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. What is your primary occupation and specialty? Do you have certification or training in IVIG?
2. Do you have certification or training in IVIG? Yes/No
3. In your role as a nurse, do you administer IVIG? Yes/No
4. Have you ever administered IVIG in a home setting? Yes/No
5. If YES: How long have been administering IVIG to patients either at home or in other settings?
6. If YES: Approximately how many IVIG patients/beneficiaries do you see in a typical month?
7. Do you have experiencing administering IVIG to Medicare beneficiaries?

[If YES to questions 2 and 3, continue; If NO to questions 2 and 3, thank and terminate interview]

Thank you very much for answering my questions. I would like to interview you at a time that's convenient to you about your observations of the IVIG patients. The interview would take approximately 30 minutes. The information we collect from the interviews will help CMS evaluate the effectiveness of expanding access to patients in different settings, including the home, and simplifying how to charge for services and products, so your input would be very valuable. We will not use your name in the report and everything you tell us would be used only for the purposes of this research.

8. Would you be willing to participate in an interview?

[If yes, proceed to next question. If no, thank and terminate.]

Scheduling

We will conduct this interview over the phone. It will need a 30-minute block of time. Please make sure you will be in private/quiet place with few distractions.

9. When would you like to schedule this interview? Date: _____ Time: _____

We will send you a reminder email you the day before to remind you of your interview. Could we have your email address and the best number to reach you?

Contact information (phone and email): _____

Thank you! I look forward to talking with you.

A.1.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

We are doing research on the Centers for Medicare and Medicaid Services (CMS) Intravenous Immunoglobulin (IVIG) Demonstration program for CMS/Medicare, and I would like to talk to you about your experiences working with people who receive IG therapy, either through IV or subcutaneously (SCIG). Specifically, we would like to learn your perspective of treating Medicare beneficiaries who receive IV/SCIG treatments. Our assessment will investigate your opinions of the IVIG program, your experiences with Medicare beneficiaries to whom you provide IVIG, what works well for them, what needs improvement, and we'll also ask you some treatment-related questions.

We appreciate your time and help with these interviews. The information you will share is very valuable for our project. This interview should take about 30 minutes. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of your patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from you will not be attributed to you, nor will we ever link your responses to you.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

A.1.c. Interview Guide

We want to start out with asking you about your experience administering IVIG in different settings.

1. In addition to the home setting, do you now or have you in the past administered IVIG to patients…

    a. At a hospital? Yes/No

    b. At a specialty pharmacy infusion center or clinic? Yes/No

    c. At a physician's office? Yes/No

    d. At another location? Yes/No. If YES where? _____

    e. [If yes, refer to these for comparisons to the interview setting throughout the interview]

2. Can you briefly describe the key steps you go through when you administer IVIG (from the point of administration to the patient)?

    Probe for:

    a. Checking that the patient/ beneficiary takes any prescribed pre-medications, has appropriate lab values, has no allergies/contra-indications

    b. Making sure the IVIG is room temperature before it is infused

    c. Hydrating the patient/ beneficiary unless it's contraindicated

    d. Taking baseline vital signs

    e. Taking vital signs at least every 30 minutes

    f. Any other health monitoring (such as monitoring and reporting adverse IVIG reactions)

    g. Disposal of hazardous materials (blood-soaked bandages, discarded surgical gloves, discarded sharps)

3. Are any of these steps administering IVIG easier or more difficult for you to complete in a home setting compared to clinical settings?

4. Do you use an infusion pump for one or more of your IVIG patients? Yes/No

    [If YES]:

a. Do you use one with all patients/beneficiaries or just some?

b. [If not all]: What are the reasons for using a pump with some patients/beneficiaries but not others?

c. [If not all]: On average, what is the time difference using and not using a pump?

d. [If not all]: How do the experiences differ for the patient/beneficiary when you use or don't use a pump?

e. Do you have to take steps, like submitting an extra form, for the patient/beneficiary to be reimbursed for the pump?

5. Have any of your patients/beneficiaries undergoing IVIG treatment had health problems or adverse events related to receiving IVIG? [PROBE: infections, hospitalizations, a need for increased antibiotics, any unpleasant side effects, delayed infusions, or some other health problems?]

   a. If YES: In which setting/s were these patients receiving IVIG treatments?

6. Have you observed any health consequences from patients/beneficiaries transitioning to receiving IVIG infusions to their home? YES/NO

   a. If YES: What types of changes in health have they experienced?

7. From your perspective, what would you say are the top benefits for patients/beneficiaries when they receive IVIG treatment at home versus in another setting? [PROBE: How does receiving care in the home setting impact the quality of life for patients and their families?]

8. What would you say are the top *disadvantages* for patients/beneficiaries when they receive IVIG treatment at home versus in another setting?

9. Have you seen cases when a patient's/beneficiary's IVIG treatment has been postponed or delayed?

   a. IF YES: Do you know the reasons behind postponing/delaying treatment?

   b. PROBE: doctor's advice, insurance reimbursement, cost of co-pays, IVIG was unavailable, bad weather or illness, or another reason?

10. Have you worked with patients/beneficiaries who have had to switch brands of IVIG or have you recommended that patients with primary immune deficiency disorder (PIDD) switch brands?

a. If YES: What were the reasons for changing brands? (e.g. supply issues, insurance reimbursement, side effects, copay costs?)

b. If YES: What effects, if any, did you observe or do they mention to you from having to switch brands?

c. If YES: Are there any potential health consequences of having to switch IVIG brands or products?

d. Do you have experience with patients who use SCIG?

If YES:

a. Have you noticed a difference in the effectiveness or ease of in-home administration of IVIG or in-home SCIG administration?

b. Have you noticed a difference in adverse events or secondary complications for patients receiving in-home administration of IVIG or in-home administration SCIG? Please explain.

11. What role do you play in your organization for getting reimbursed from Medicare? [PROBE: Do you have to log in codes? Are you responsible for checking or submitting invoices?]

    a. In your opinion, what can cause challenges to Medicare reimbursement steps in the home setting? [PROBE: time constraints, supply issues, patient adhering to pre-meds, delayed or refused treatments?]

12. Are you aware of the IVIG Demonstration Project? [If NO, provide brief explanation and SKIP TO Q.15

    a. If YES: Have you expressed an opinion to your patients/beneficiaries whether they should or should not enroll in the Medicare IVIG Demonstration? If YES, please explain.

    b. How is the Medicare IVIG Demonstration working in your opinion? [PROBE for observations related to access, quality, cost, convenience, ease of use, safety, and health outcomes]

    c. What, if anything, is not working well in the Medicare IVIG Demonstration?

    d. In your opinion, is the IVIG Demonstration meeting your beneficiaries' needs? How so? / Why not?

    e. If you could change one thing in the IVIG Demonstration, what would you change? Please explain why.

13. Is there anything more you would like to add that you think would be helpful for us to know?

14. Could you recommend any other physicians or nurses for us to contact who are experienced with administering IVIG in home settings to patients with PIDD? Please provide us their names and contact information so we can see if they would be interested in participating in an interview. If you prefer, you could provide them with our name and contact information and ask them to contact us.

Thank you for your time and sharing your experiences with IVIG treatment. Your comments are very helpful and insightful.

Other Topics Discussed:

Any Documents Obtained:

Post Interview Comments or Questions:

A.1.d. Reminder Communications for Participants Treating Beneficiaries with Primary Immune Deficiency Disorder (PIDD)

Dear [Insert name and title]:

Thank you for agreeing to take the time to talk to us for the Centers for Medicare & Medicaid Services (CMS) Intravenous Immunoglobulin (IVIG) Access Demonstration Project. We are interested in hearing about your experiences working with patients with Primary Immune Deficiency Disorder (PIDD) who receive IVIG or subcutaneous immunoglobulin (SCIG) in the home setting. In addition, we would like to learn your perspectives of treating Medicare beneficiaries who receive IV/SCIG treatments and who are participating in the IVIG Access Demonstration Project. This 3-year demonstration project provides a bundled payment for the items and services used for in-home administration of IVIG for non-homebound Medicare beneficiaries with primary immune deficiency disorder.

Your 30 minute interview is scheduled for:

[Insert date and time (EST)].

[Insert Interviewer name] will call you at [Insert telephone number]. Please find a private place to take the call where you can talk freely without distraction.

If you have a conflict and need to reschedule, please email me or call me at [Insert telephone number].

Thank you,

[Insert name, title, and contact information]

A.1.e. Communication of Thanks for Participants Treating Beneficiaries with Primary Immune Deficiency Disorder (PIDD)

Dear [Insert name and title]:

Thank you for taking the time to talk to us about the CMS IVIG Access Demonstration Project. We greatly appreciate your time and help with this project. Your insights are very valuable for the evaluation of this project.

For more information about the project, please see http://innovation.cms.gov/initiatives/ivig/.

If you have any additional comments or further questions about the project, please feel free to contact us.

Sincerely,

[Insert name, title and contact information]

A.2. Physicians Treating Beneficiaries with Primary Immune Deficiency Disorder (PIDD)

A.2.a. Screeners

1. Screening Email

Dear [Insert name and title]:

I am writing on behalf of the Centers for Medicare and Medicaid Services (CMS). We are conducting interviews physicians who prescribe intravenous immunoglobulin (IVIG) for patients with primary immune deficiency disorder (PIDD) to participate in a short questionnaire/interview. CMS is collecting this information to provide better care for patients and to simplify billing and reimbursement. You have been referred to us by our research partners at Eastern Research Group (ERG), who previously interviewed you for an analysis of IVIG supply, demand, and distribution study they conducted in 2006 for the Office of the Assistant Secretary for Planning and Evaluation at the U.S. Department of Health and Human Services.

We would greatly appreciate your participation in this important effort. The interview would take approximately 30 minutes. If you can invest the time and participate, we would like your feedback to the questions below. If you meet the criteria for this round of interviews, we will schedule a convenient time for an interview with you. We will not use your name or other personal identifiable information in the report and everything you tell us would be used only for the purposes of this research.

Please answer these questions in your reply (you can delete to leave the correct response to the Yes/No questions):

1. For Medicare patients receiving IVIG treatments, do you currently or have you in the past recommended that they receive treatment:

    a. In the patient's/beneficiary's home? Yes/No

    b. At a hospital? Yes/No

    c. At a specialty pharmacy infusion center or clinic? Yes/No

    d. At a physician offices? Yes/No

    e. At another location? Yes/No [If YES] Where? _____

Medicare's Intravenous Immunoglobulin (IVIG) Demonstration project provides reimbursement of IVIG administration services in the home setting for non-homebound Medicare beneficiaries with primary immune deficiency disorder (PIDD). In order to be eligible for the project, beneficiaries must be covered under the original Medicare fee-for-service program and not enrolled in a Medicare Advantage plan, have Medicare Part B, and require IVIG for the treatment of PIDD.

1. Do you currently have any patients that are part of this program? Yes/No

a. [If YES] How many patients are participating in the Medicare IVIG Demonstration? Number: ___

b. [If NO] Why not? [e.g. patients are not eligible, medical reasons, unaware of demonstration project, personal preferences, medical risk, other reasons.]
_____

2. Please provide us with the best number to contact you to set up an interview:
_____

3. Can you recommend any of your colleagues that are currently prescribing IVIG products patients with PIDD to participate in this study/interview? If so, please provide their name and as much contact information as possible.
_____

We thank you in advance for your time and help. Your input will be extremely valuable to this research.

Sincerely,

[Insert name, title and contact information]

2. Screening Call (to be used in place of Screening Email if phone number is available)

[Note that physicians will be pre-screened for prescribing IVIG]

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services (CMS) or Medicare. The purpose of the call is to ask if you can participate in interviews we are conducting with physicians who prescribe immunoglobulin for patients with primary immune deficiency disorder. CMS is collecting this information to provide better care for patients and to simplify billing and reimbursement. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. For patients receiving IVIG treatments, do you recommend that patients/beneficiaries receive treatment:

    a. In the patient's/beneficiary's home? Yes/No

    a. At a hospital? Yes/No

    b. At a specialty pharmacy infusion center or clinic? Yes/No

    c. At a physician offices? Yes/No

    d. At another location? Yes/No [If YES] Where? _____

2. Are you aware of Medicare's Intravenous Immunoglobulin (IVIG) demonstration project that provides reimbursement of IVIG infusion in the home setting?

[If no, provide this explanation and ask question again] The 3-year demonstration project is called the "Medicare Intravenous Immunoglobulin Demonstration" and it involves a bundled payment for the items and services used for in-home administration of IVIG for non-homebound Medicare beneficiaries with primary immune deficiency disorder (PIDD). In order to be eligible for the project, beneficiaries must be covered under the original Medicare fee-for-service program and not enrolled in a Medicare Advantage plan, have Medicare Part B, and require IVIG for the treatment of PIDD.

If YES:

3. Do you currently have any patients that are part of this program or who are eligible for this program?

    a. [If YES] About how many patients are participating?

    b. [If NO] Why is that? [Check if patients were eligible, medical reasons, payment reasons, etc.]

    c. [If YES to question 3, continue; If NO to question 3, thank and terminate interview]

Thank you very much for answering my questions. I would like to interview you at a time that's convenient to you about the project. The interview would take approximately 30 minutes. The information we collect from the interviews will help CMS evaluate the effectiveness of having access to in-home service and providing a bundled payment for IVIG in physician offices or clinics, so your input would be very valuable. We will not use your name in the report and everything you tell us would be used only for the purposes of this research.

Would you be willing to participate in an interview? [If yes, ask for the best way to schedule the interview, either directly with physician or through an administrative assistant and then schedule. If no, thank and terminate].

We will conduct this interview over the phone. Please make sure you will be in private/quiet place with few distractions. We will send you a reminder email you the day before to remind you of your interview. Could we have your email address and the best number to reach you?

Contact information (phone and email): _____

To terminate: Thank you for your time today. Have a good day.

A.2.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

We are doing research on the Centers for Medicare and Medicaid Services (CMS) Intravenous Immunoglobulin (IVIG) Demonstration program for CMS/Medicare, and I would like to talk to you about your experiences working with people who receive immunoglobulin (IG) therapy, either through IV or subcutaneously. Specifically, we would like to learn your perspective of treating Medicare beneficiaries who receive IV/SCIG treatments. Our assessment will investigate your opinions of the IVIG program, your experiences with Medicare beneficiaries to whom you provide IVIG, what works well for them, what needs improvement, and we'll also ask you some treatment-related questions.

We appreciate your time and help with these interviews. The information you will share is very valuable for our project. This interview should take about 30 minutes. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of your patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from you will not be attributed to you, nor will we ever link your responses to you.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

Appendix 13

A.2.c. Interview Guide

First I would like to ask you some general questions about your work with patients/beneficiaries with primary immune deficiency disorder (PIDD) who receive intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG) in different care settings.

1. What criteria do you use to determine whether patients/beneficiaries receive IVIG treatment at home, in your office, in hospitals or infusion pharmacies?

2. What criteria do you use to determine whether patients/beneficiaries receive IVIG or SCIG? [PROBE: Do you consider effectiveness, safety, the patient's preferences, the patient's health status and possible functional limitations, medical reimbursements from insurance (including reimbursement for pump or hydration, if needed), or any other circumstances?]

3. From your perspective, what would you say are the top benefits for patients/beneficiaries when they receive IVIG treatment at home versus in another setting? [PROBE: How does receiving care in the home setting impact the quality of life for patients and their families?]

4. What would you say are the top *disadvantages* for patients/beneficiaries when they receive IVIG treatment at home versus in another setting?

5. How would you compare the safety and effectiveness of in-home administration of IVIG with settings in medical offices or facilities? What would make it safer or less safe to receive IVIG at home? [PROBE for checking for use of pre-medications, making sure IVIG is room temperature, disposal of hazardous materials, etc.]

6. Have any of your patients/beneficiaries undergoing IVIG treatment had health problems or adverse events related to receiving IVIG? [PROBE: infections, hospitalizations, a need for increased antibiotics, any unpleasant side effects, delayed infusions, or some other health problems?]

    a. If YES; In which setting/s were these patients receiving IVIG treatments?

7. Have you noticed any difference in effectiveness, adverse events, or secondary complications in patients receiving <u>in-home</u> IV administration or <u>in-home</u> SCIG administration?

    a. IF YES: Please explain

8. Have you observed any health consequences from people transitioning to receiving IVIG infusions to their home? YES/NO

    a. If YES: What types of changes in health have they experienced?

9. Across all settings (home, hospital, physician's office, etc.), have you seen cases when a patient's IVIG treatment has been postponed or delayed? YES/NO

    If YES:

a. Do you know the reasons behind postponing/delaying treatment? (PROBE: for example, insurance reimbursement, cost of co-pays, IVIG was unavailable, bad weather, infection, or another reason?)

b. What types of health consequences arise from postponing or delaying treatment?

10. Have you worked with patients/beneficiaries who have had to switch brands of IVIG or have you recommended that patient with PIDD switch brands?

    a. If YES: What were the reasons for changing brands? (e.g. supply issues, insurance reimbursement, side effects, copay costs?)

    b. What effects, if any, did you observe or do they mention to you from having to switch brands?

    c. Are there any potential health consequences of having to switch IVIG brands or products?

11. What types of additional medications or hydrating fluids do you prescribe for patients with primary immune deficiency disorder (PIDD) receiving IVIG, if any?

    a. Do you typically recommend premedication or hydration for IVIG patients? Why or why not?

    b. Do you recommend using a pump to regulate IVIG administration for some or all of your patients? Why or why not?

Now I would like to ask you some questions about the CMS IVIG Demonstration.

12. [If not answered in the screener] Do you recommend that beneficiaries in your care who are eligible for the program enroll in the program? Why or why not? [If not recommending enrollment in Demonstration, skip to Q. 16]

[For physicians with patients in the Demonstration]

13. How is the Medicare IVIG Demonstration working, in your opinion? [PROBE: how is the demonstration working when you think about access, quality, cost, convenience, ease of use, safety, and health outcomes]

    a. In your opinion, how well is the IVIG Demonstration meeting the beneficiaries' needs?

14. Have any of the beneficiaries in your care switched from SCIG to IVIG under the Demonstration?

    a. IF YES: What feedback about the Demonstration do you get from these beneficiaries?

15. If you could change anything in the IVIG Demonstration, what would you change? [If change suggested]: Please explain.

16. Is there anything more you would like to add that you think would be helpful for us to know?

17. Could you recommend any other physicians or nurses for us to contact who are experienced with administering IVIG in home settings to patients with PIDD? Please provide us their names and

contact information so we can see if they would be interested in participating in an interview. If you prefer, you could provide them with our name and contact information and ask them to contact us.

Thank you for your time and sharing your experiences with IVIG treatment. Your comments are very helpful and insightful.

Other Topics Discussed:

Any Documents Obtained:

Post Interview Comments or Questions:

A.3. IG Manufacturers

A.3.a. Screener

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services (CMS) or Medicare. The purpose of the call is to ask if you can participate in interviews we are conducting with companies that manufacture immunoglobulin for intravenous or subcutaneous use (IVIG and SCIG). CMS is collecting this information as part of a study on Medicare beneficiaries with primary immune deficiency disorder (PIDD) who receive IVIG and SCIG. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. Does your company manufacture IVIG or SCIG?

    a. If YES to Q1, proceed to invitation and scheduling. Else, thank and terminate interview.

I would like to interview you at a time that's convenient to you about the project. The interview would take approximately 30-45 minutes. The information we collect from the interviews will help CMS understand the IVIG and SCIG market, so your input would be very valuable. We will not use your name in the report and everything you tell us would be used only for the purposes of this research.

2. Would you be willing to participate in an interview? If yes, ask to be transferred to an administrative assistant for scheduling. If no, thank and terminate.

To terminate: Thank you for your time today. Have a good day.

A.3.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

[For manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations:] We are conducting a research evaluation of the CMS IVIG Demonstration project for the Centers for Medicare and Medicaid Services, and I would like to talk to you about the manufacture/distribution of immunoglobulin therapy. Our questions are aimed at characterizing the IVIG supply chain.

I would like to thank you up front for taking the time to talk to us, the information you will share is very valuable for our project. This interview should take about [30 minutes for physicians and nurses] [45 minutes for manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations]. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from a

specific participant will not be attributed to that person, nor will we ever link responses to any individual or use their name in any of our reporting.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

A.3.c. Interview Guide

1. Which IVIG products do you currently manufacture?
    a. What are the brand names?
    a. Do you have any products you have discontinued or have plans to discontinue any of your products?
    b. Do you have any products in the pipeline?
2. Do you have any inventory of products that are discontinued?
    a. If so, how much?
3. Please describe your IVIG manufacturing process.
4. How many grams of IVIG does a liter of plasma yield?
5. What is your manufacturing capacity (grams/year by product)?
6. Do you have any plans of expanding/contracting your manufacturing capacity?
7. What are your distribution channels (e.g., GPOs, distributors, specialty pharmacies, exports)?
8. Approximately how many entities do you distribute to in each channel and how much of total production (in percentage terms)?
    a. Could we get the company names?
    b. Has the composition of your distribution channels changed since 2007?
9. How much of your product is for export and how much is for U.S. consumption?
10. Have your IVIG exports grown over recent years?
11. Do you have any knowledge of the secondary, or gray, market for distribution that you can share

with us? How are products ending up in the gray market?

12. What is the average price you charge for your products?

13. What is the average price you charge for the unencumbered market relative to the encumbered one?

14. Can you share with us any supply and/or pricing data for your products for the past 7 years?

15. How do you report your sales prices to CMS? [Note: According to MMA, nominal sales of a product do not have to be included in the ASP calculation. What constitutes nominal?]

16. What percent of your product is encumbered/unencumbered?

17. Has the distribution of your products between these two channels (i.e., encumbered versus unencumbered) changed in recent years? Please explain why.

18. What is your understanding of actual demand versus measured demand (through sales of product)?

19. Do you think there is a shortage of your IVIG products?

20. Do you have projections of expected IVIG demand that you can share with us?

21. Over the last seven years, how has the cost of plasma collection changed?

22. Do you self-source your plasma needs?

23. Have you had any challenges in meeting demand for your products?

24. What systems do you have in place for meeting emergency requests for products?

25. What are the criteria that need to be met before you would meet such emergency requests?

26. How often do you receive and fill such requests? How much product is distributed in this manner?

27. How dependent is your production decisions on the market for other plasma products, such as Albumin, Factor VIII, etc.?

A.4. IG Distributors

A.4.a. Screener

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services (CMS) or Medicare. The purpose of the call is to ask if you can participate in interviews we are conducting with companies that distribute immunoglobulin for intravenous or subcutaneous use (IVIG and SCIG). CMS is collecting this information as part of a study on Medicare beneficiaries with primary immune deficiency disorder (PIDD) who receive IVIG and SCIG. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. Does your company distribute IVIG or SCIG?

If YES to Q1, proceed to invitation and scheduling. Else, thank and terminate interview.

I would like to interview you at a time that's convenient to you about the project. The interview would take approximately 30-45 minutes. The information we collect from the interviews will help CMS understand the IVIG and SCIG market, so your input would be very valuable. We will not use your name in the report and everything you tell us would be used only for the purposes of this research.

2. Would you be willing to participate in an interview? If yes, ask to be transferred to an administrative assistant for scheduling. If no, thank and terminate.

To terminate: Thank you for your time today. Have a good day.

A.4.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

[For manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations:] We are conducting a research evaluation of the CMS IVIG Demonstration project for the Centers for Medicare and Medicaid Services, and I would like to talk to you about the manufacture/distribution of immunoglobulin therapy. Our questions are aimed at characterizing the IVIG supply chain.

I would like to thank you up front for taking the time to talk to us, the information you will share is very valuable for our project. This interview should take about [30 minutes for physicians and nurses] [45 minutes for manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations]. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from a

specific participant will not be attributed to that person, nor will we ever link responses to any individual or use their name in any of our reporting.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

A.4.c. Interview Guide

1. Which IVIG products do you currently purchase?
    a. What are the brand names?
    b. Do you have any products you have discontinued or have plans to discontinue any of your products?
2. Do you have any inventory of products that are discontinued? If so, how much?
3. Who do you purchase your products from?
4. Who do you distribute to (e.g., hospitals, distributors, specialty pharmacies, etc.)?
5. Approximately how many entities do you distribute to in each channel and how much of total IVIG products (in percentage terms)?
6. Has the composition of your distribution channels changed over the past 7 years?
7. What is the average price markup for IVIG products by brand?
    a. Has this changed over the course of the last 7 years?
8. Do you receive discounts for prompt payment or for high-volume purchases?
9. Can you share with us any pricing data for your products for the past 6 to 8 years?
    a. Do these vary by channel and how much?
10. Over the last six/eight years, how have the prices paid for IVIG changed?
11. Are your IVIG purchases encumbered, unencumbered, or combination of both?

a. Has the share of your product purchases between encumbered and unencumbered changed in recent years? Please explain why.

12. What is your understanding of actual demand versus measured demand (through sales of product)?

13. Do you think there is a shortage of your IVIG products?

14. Do you have projections of expected IVIG demand that you can share with us?

15. Have you had any challenges in meeting demand for your products?

16. Do you have a system in place for meeting emergency requests for IVIG products?

17. What are the criteria that need to be met before you would meet such emergency requests?

18. How often do you receive and fill such requests? How much product is distributed in this manner)?

A.5. Group Purchasing Organizations (GPO)

A.5.a. Screener

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services (CMS) or Medicare. The purpose of the call is to ask if you can participate in interviews we are conducting with companies that purchase immunoglobulin for intravenous or subcutaneous use (IVIG and SCIG). CMS is collecting this information as part of a study on Medicare beneficiaries with primary immune deficiency disorder (PIDD) who receive IVIG and SCIG. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. Does your company purchase IVIG or SCIG?

   If YES to Q1, proceed to invitation and scheduling. Else, thank and terminate interview.

I would like to interview you at a time that's convenient to you about the project. The interview would take approximately 30-45 minutes. The information we collect from the interviews will help CMS understand the IVIG and SCIG market, so your input would be very valuable. We will not use your name in the report and everything you tell us would be used only for the purposes of this research.

2. Would you be willing to participate in an interview? If yes, ask to be transferred to an administrative assistant for scheduling. If no, thank and terminate.

To terminate: Thank you for your time today. Have a good day.

A.5.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

[For manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations:] We are conducting a research evaluation of the CMS IVIG Demonstration project for the Centers for Medicare and Medicaid Services, and I would like to talk to you about the manufacture/distribution of immunoglobulin therapy. Our questions are aimed at characterizing the IVIG supply chain.

I would like to thank you up front for taking the time to talk to us, the information you will share is very valuable for our project. This interview should take about [30 minutes for physicians and nurses] [45 minutes for manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations]. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from a

specific participant will not be attributed to that person, nor will we ever link responses to any individual or use their name in any of our reporting.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

A.5.c. Interview Guide

1. Which IVIG products do you currently contract for?
    a. What are the brand names?
2. What is the size of your membership?
3. Who are your members (e.g., hospitals, physician offices, etc.)?
    a. How has your membership changed over the past 7 years?
4. How much IVIG product do you contract for annually for your members (in grams)?
5. Has your purchasing volume changed in the past 6 to 8 years?
6. Do you have any estimates of the total volume of IVIG contracted for by GPOs?
7. How many distributors do you work with?
    a. Approximately how many entities do they distribute to and how much of total IVIG products (in percentage terms)?
8. Has the composition of your membership (hospital vs. physician office) changed over the past few years?
9. Do you have any knowledge of the secondary, or gray, market for distribution that you can share with us? How are products ending up in the gray market?
10. Do you purchase IVIG from secondary distributors if the need arises?
11. Do you have any practices designed to prevent the products you have contracted for from ending up in the gray market?
12. Do you have any estimates of how much product is currently being diverted to the gray market? Has this changed over the time and why?

13. Can you share with us any pricing data for products you contracted for the past 7 years?
14. What is the typical duration of contracts you have with IVIG manufacturers?
    a. Are the terms, price and volume, of these contracts fixed or do they fluctuate?
15. Are IVIG contracts tied with other plasma products, such as Albumin, and recombinant factors?
    a. What are the terms?
16. What is the average fee you receive from your distributors?
17. What is your understanding of actual demand versus measured demand (through sales of product)?
18. Do you think there is a shortage of IVIG products?
19. Do you have projections of expected IVIG demand that you can share with us?
20. Have you had any challenges in meeting demand for IVIG products?
21. Have you requested more IVIG products from manufacturers and what has been their response?
22. Have you had requests for additional product from your members in excess of allocation?
    a. How do you respond to those requests?

A.6. Infusion Companies

A.6.a. Screener

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services or CMS. The purpose of the call is to ask if you can participate in interviews we are conducting with companies that administer immunoglobulin to Medicare beneficiaries with primary immune deficiency disorder. CMS is collecting this information to provide better care for Medicare beneficiaries and to simplify billing and reimbursement. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. To start off, are you aware of Medicare's Intravenous Immunoglobulin (IVIG) demonstration project that provides reimbursement of IVIG infusion in the home setting?

[**If no**, provide this explanation and ask question again] The 3-year demonstration project is called the "Medicare Intravenous Immunoglobulin Demonstration" and it involves a bundled payment for the items and services used for in-home administration of IVIG.

If YES:

a. Do you currently have any patients that are part of this project? About how many patients are participating?

b. [If no patients are participating] Did you have patients who were eligible but decided against it? Why was that?

2. If YES to Q1 and 1a or 1b, proceed to invitation and scheduling. Else, thank and terminate interview.

To terminate: Thank you for your time today. Have a good day.

A.6.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

[For manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations:] We are conducting a research evaluation of the CMS IVIG Demonstration project for the Centers for Medicare and Medicaid Services, and I would like to talk to you about the manufacture/distribution of immunoglobulin therapy. Our questions are aimed at characterizing the IVIG supply chain.

I would like to thank you up front for taking the time to talk to us, the information you will share is very valuable for our project. This interview should take about [30 minutes for physicians and nurses] [45 minutes for manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations]. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept

confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of your patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from a specific participant will not be attributed to that person, nor will we ever link responses to any individual or use their name in any of our reporting.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

A.6.c. Interview Guide

1. Which IVIG products do you carry?
    a. What are the brand names?
2. How much IVIG product do you use annually (in grams)?
    a. Has this changed over the past 7 years?
3. Through which channels do you acquire IVIG?
4. Do you have any knowledge of the secondary or gray market for distribution that you can share with us? How are products ending up in the gray market?
5. Do you get solicitations/advertisements from individuals who claim to have IVIG available, on a regular basis?
    a. How frequently?
    b. Has the frequency of these decreased/increased over the past few years?
    c. Has there been a change in the amount of IVIG touted as being available over the past few years/months?
6. Do you end up purchasing IVIG from these secondary distributors or directly from health care entities if the need arises?
7. Do you receive requests from distributors to purchase some of your supplies?
8. Do you seek emergency supplies of IVIG at times?

a. Which emergency network do you use?

9. What is the markup you typically pay over the average sale price (ASP) to distributors?

    a. What is this markup for purchases from secondary distributors?

    b. Does the markup over ASP vary significantly by IVIG brand?

10. Do you work with GPOs or directly with manufacturers?

11. What is your understanding of actual demand for IVIG?

12. Do you think there is a shortage of IVIG products?

13. Do you have projections of expected IVIG demand that you can share with us?

14. Have you had any challenges in meeting demand for IVIG products?

    a. Have you had any problems getting your product allotment from your suppliers (any delays)?

    b. What do you do in those situations?

15. Do you keep an inventory of the product? How much?

16. Have you had requests for additional product in excess of what you have?

    a. How do you respond to those requests?

    b. How frequently do you receive these requests?

17. Have you requested more IVIG products from your regular supplier(s) and what has(ve) been their response?

18. Are you forced to switch IVIG products for the Medicare beneficiaries you treat due to access problems?

    a. What portion of this is IVIG supply versus reimbursement related in your opinion?

    b. What are the health consequences of switching IVIG products?

19. Are health care providers forced to prescribe reduced dosages or fewer treatments for Medicare beneficiaries?

    a. What are the health consequences of this?

20. Are there any estimates of the number of patients experiencing adverse health outcomes from switching products, switching site of service, dosage reductions, and less frequent IVIG administration?

21. Do you have any estimates of the number of patients who are refused IVIG therapy?

22. How does the cost of administration in your setting compare to that in a hospital outpatient

setting?

23. Do IVIG availability and reimbursement vary from one US region to the other? What is the source of this variation?

24. How long does it typically take to provide a PIDD patient with an IVIG infusion?

25. Do you pre-screen patients before deciding whether to provide them IVIG at home?

    a. What characteristics are important to consider?

26. Is the amount of reimbursement provided under CMS' IVIG demonstration sufficient to cover the labor cost of providing IVIG infusions at the patient's home? Please explain.

A.7. Patient Advocates

A.7.a. Screener

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services or CMS. The purpose of the call is to ask if you can participate in interviews we are conducting with organizations that advocate for Medicare beneficiaries with primary immune deficiency disorder who rely on IVIG. CMS is collecting this information to provide better care for Medicare beneficiaries and to simplify billing and reimbursement. Would you mind answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

1. To start off, are you aware of Medicare's Intravenous Immunoglobulin (IVIG) demonstration project that provides reimbursement of IVIG infusion in the home setting?

[**If no**, provide this explanation and ask question again] The 3-year demonstration project is called the "Medicare Intravenous Immunoglobulin Demonstration" and it involves a bundled payment for the items and services used for in-home administration of IVIG.

If YES:

a. Do you currently know of patients that are part of this project? About how many patients that you know are participating?

b. [If no patients are participating] Do you know of patients who were eligible but decided against it? Why was that?

2. If YES to Q1 and 1a or 1b, proceed to invitation and scheduling. Else, thank and terminate interview.

To terminate: Thank you for your time today. Have a good day.

A.7.b. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

[For manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations:] We are conducting a research evaluation of the CMS IVIG Demonstration project for the Centers for Medicare and Medicaid Services, and I would like to talk to you about the manufacture/distribution of immunoglobulin therapy. Our questions are aimed at characterizing the IVIG supply chain.

I would like to thank you up front for taking the time to talk to us, the information you will share is very valuable for our project. This interview should take about [30 minutes for physicians and nurses] [45 minutes for manufacturers, distributors, GPOs, home infusion therapy providers, and patient advocacy organizations]. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research

team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of patients, please do not mention any patients by name or disclose any other identifying personal or health information. We will remove all names and identifying information from the transcript and we won't use any names in our reports. Any comments made from a specific participant will not be attributed to that person, nor will we ever link responses to any individual or use their name in any of our reporting.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question, talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

A.7.c. Interview Guide

1. What are some of the significant concerns individuals and families living with primary immunodeficiency diseases (PIDD) face?
    a. Has this changed over the past 7 years? If yes, how so?
    b. Has this changed as a result of the Medicare IVIG Access Demonstration?
2. What are the ways your organization advocates for patients with PIDD?
3. Does your organization provide educational programs for patients and families with PIDD?
    a. (If YES) Can you describe these various efforts?
4. Does your organization work with the Centers for Medicare and Medicaid Services (CMS)?
    a. (If YES) In what ways?
5. Do you work with physicians and/or nurses who treat patients with PIDD? How and in what capacity?
6. Does your organization ever seek or procure supplies of IVIG for patients or providers?
    a. (If YES) Which networks do you use?
    b. (If YES) Have you encountered any challenges in obtaining IVIG for patients or providers?
7. What is your understanding of actual demand for IVIG?
8. Do you think there is a shortage of IVIG products?
9. (If YES) Do you know of providers who have not been able to obtain IVIG products from their

regular supplier(s) and what have they done?

10. Now I would like to focus on patients who are Medicare beneficiaries. Have you heard about providers having to switch IVIG products for their Medicare beneficiaries due to access problems?

    a. What portion of this is IVIG supply versus reimbursement related in your opinion?

    b. What are the health consequences of switching IVIG products?

11. Are health care providers forced to prescribe reduced dosages or fewer treatments for Medicare beneficiaries?

    a. What are the health consequences of this?

12. Are there any estimates of the number of Medicare patients experiencing adverse health outcomes from switching products, switching site of service, dosage reductions, and less frequent IVIG administration?

13. Do you have any estimates of the number of Medicare patients who are refused IVIG therapy?

14. Do IVIG availability and reimbursement vary from one US region to the other? What is the source of this variation?

15. Is the amount of reimbursement provided under CMS' IVIG demonstration sufficient to cover the labor cost of providing IVIG infusions at the patient's home? Please explain.

16. Are there additional issues related to IVIG access that your organization is currently working on?

A.8. Caregivers of PIDD Patients Receiving IVIG or SCIG

A.8.a. Website Recruitment Advertisement

To recruit caregivers of Medicare patients with PIDD receiving IVIG and SCIG to participate in interviews, we plan to request permission to advertise our interviews on patient websites, such as the Immune Deficiency Foundation and Jeffrey Modell websites. We will use the following language to recruit potential caregivers:

Do you care for a family member or friend with Primary Immune Deficiency Disorder (PIDD) who receives intravenous immunoglobulin (IVIG) or subcutaneous immunoglobulin (SCIG)? Does your family member or friend also have Medicare Part B health insurance? If you answered yes to both questions, we would like to talk with you! The Centers for Medicare & Medicaid Services (CMS) is interviewing caregivers of Medicare patients with PIDD to improve their care and evaluate the potential of providing IVIG at home. If you are interested in participating in a 45 minute interview, please contact [INSERT CONTACT NAME AND NUMBER].

A.8.b. Screening Call

Good day. My name is _____ and I am calling today on behalf of the Centers for Medicare and Medicaid Services (CMS) or Medicare. The purpose of the call is to ask if you can participate in an interview for caregivers of Medicare patients that receive **intravenous immunoglobulin** (IVIG) or subcutaneous immunoglobulin (SCIG) for the treatment of primary immune deficiency disorders (PIDD). We received your name from [your physician] who said you would be interested in participating in an interview and that you gave your permission to contact you. CMS is collecting this information to identify challenges and improve the level of care offered to patients receiving IVIG and evaluate the potential of providing IVIG at home. Would you mind first answering just a few questions to see if you meet our criteria? This will take only a couple minutes of your time.

17. Do you provide any type of care for a Medicare beneficiary receiving immunoglobulin (IG) products:

    b. Yes [If YES continue to next question]

    c. No [terminate the interview?]

18. Do you provide care to more than one person with PIDD?

[If more than one person] For the remainder of the questions, I would like you to think about only the one person for whom you provide the greatest amount of care.

19. Are you related to this person, or is it a friend that you help? [Refer to the relation throughout the rest of the interview]

20. Does your [relative/friend] receive the IG through an intravenous drip (IVIG) or through subcutaneous injections (SCIG)?

d. Intravenous (IVIG)

e. Subcutaneous (SCIG)

f. I do not know

21. Is the IG provided at home, in a hospital, infusion clinic, specialty pharmacy, or another setting?

g. Home setting

h. Hospital, specialty pharmacy, infusion center, clinic, etc.

i. At another location?

22. Is your [relative/friend] homebound, i.e. is he/she unable to leave the house with reasonable effort for grocery shopping or other errands?

j. Yes [Terminate interview]

k. No [Continue]

23. Does he/she have a Medicare Advantage plan (Part C)?

l. Yes [Terminate interview]

m. No [Continue]

n. Don't know [Ask if they can find out and arrange a follow-up call to continue]

[If beneficiary is receiving IVIG at home] Do you know whether your [relative/friend] is in the Medicare Intravenous Immunoglobulin (IVIG) Demonstration that provides eligible beneficiaries IVIG infusion in the home? [Provide this explanation if needed: The 3 year demonstration project is called the "Medicare Intravenous Immunoglobulin Demonstration" and it involves a bundled payment for the items and services used for in-home administration of IVIG for non-homebound Medicare beneficiaries with primary immune deficiency disorder (PIDD). In order to be eligible for the demonstration, beneficiaries must be covered under the original Medicare fee-for-service program and have Medicare Part B and not be enrolled in a Medicare Advantage plan.

[If the answer is no or don't know, ask if they can check with the beneficiary about their eligibility and arrange a follow-up call.]

[If after following-up the beneficiary receiving IVIG at home is NOT in the demonstration, terminate the interview.]

[If in the Demonstration or eligible] Thank you very much for answering my questions. I would like to interview you at a time that's convenient to you about the project. The interview would take approximately 45 minutes. The information we collect from the interviews will help CMS evaluate the effectiveness and benefits of providing IVIG treatment in different settings and improve the level of care and quality of life for these Medicare beneficiaries. We will not use your name in the report and everything you tell us would be used only for the purposes of this research.

Would you be willing to participate in an interview? [If yes, ask for the best way to schedule the interview, either directly with physician or through an administrative assistant and then schedule. If no, thank and terminate].

We will conduct this interview over the phone. Please make sure you will be in private/quiet place with few distractions. We will send you a reminder email the day before to remind you of your interview. Could we have your email address and the best number to reach you?

24. Contact information (phone and email):

_____

To terminate: Thank you for your time today. Have a good day.

A.8.c. Interview Introduction and Informed Verbal Consent

I want to thank you for taking the time to talk to us today. My name is _____ and I am calling from _____ and my colleague _____is here to help take notes during the interview.

We are doing research on the Centers for Medicare and Medicaid Services (CMS) Intravenous Immunoglobulin (IVIG) Demonstration program, and I would like to talk to you about your experiences providing care to your [relative/friend] who receives immunoglobulin (IG) therapy, either through IV or subcutaneously. Specifically, we would like to learn your perspective of challenges faced by Medicare beneficiaries who receive IG treatments. Our interview will ask about your opinions of the IVIG program, your experiences with your [relative/friend], what works well for them and for you, and what needs improvement. We are interested in learning how it is going for you as a caregiver and how you think it is going for your [relative/friend] since we will not be able to talk with them directly.

We appreciate your time and help with these interviews. The information you will share is very valuable for our project. This interview should take about 45 minutes. I would like to record the interview with your permission because I don't want to miss any of your comments. Although my colleague and I will be taking notes during the session, we want to make sure we're capturing your key comments. It is important that you know all responses will be kept confidential to the best of our ability. This means that your comments will only be shared with research team members and we will ensure that any information we include in our report does not identify you as the participant. To protect the privacy of your friend or relative, please do not mention their name or any other information that could identify them. We will remove all names and identifying information from the transcript and we won't use any names in our reports. If we use quotes from you, they will not be attributed to you, nor will we ever link your responses to you.

Finally, your participation in this interview is voluntary. This means that you do not have to answer every question or talk about anything you don't want to, and you may end the interview at any time.

Do you have any questions about the interview? Do we have your permission to record the interview and proceed?

Interviewee (ID number)	Interviewer	Date

According the Paperwork Reduction Act of 1995 (PRA), no persons are required to respond to a collection of information unless such a collection displays a valid OMB Control number. We are required by the PRA to inform you that the public reporting burden for this collection of information is voluntary and is estimated to average 45 minutes per completed interview, including the time for reviewing instructions and completing and reviewing the collection of information. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, please send them to Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C3-21-28 Baltimore, Maryland 21244.

A.8.d. Interview Guide

First I would like to ask you some general questions about the type of care you provide to your [relative/friend] with primary immune deficiency disorder (PIDD) who receives IG treatment.

1. How often do you provide care to your [relative/friend]: [check one]

    a. Daily

    b. Weekly

    c. Bi-weekly

    d. Monthly

    e. Other: _____

    1A. How long have you been providing care to your [relative/friend]?

2. How do you help with your [relative's/friend's] IG treatment? [open-ended, check off as mentioned]

    a. Transportation to the IVIG infusion center or clinic

        i. [If yes] How long does it take for you to travel from your home or workplace to pick up your [relative/friend] and take them to the IG treatment site?

        ii. Do you travel by car, public transportation, or taxi? What are your estimated transportation costs for each trip?

        iii. How much time do you spend at the [hospital/physician clinic/infusion clinic]?

b. Helping with hydration

c. Helping with the infusion or injection

d. Helping with painkillers after IG treatment

e. Helping to purchase the IG

f. Helping to schedules appointments

g. Helping to fill out Medicare paperwork

h. Other

QUESTIONS 3-7 are for beneficiaries enrolled in the demonstration
For IVIG beneficiaries *not enrolled* in the demonstration skip to QUESTION 8
For SCIG beneficiaries skip to QUESTION 8

3. What do you think are the *advantages* to your [relative/friend] receiving IVIG treatment at home instead of in another setting? [open-ended, check off as mentioned]

    a. Quality of life improvement [ask for specific examples]

    b. Ease of administration

    c. Reduced risk of secondary infections

    d. Better coordination with other family members

    e. Reduced emotional distress

    f. Other

        3A. From those that you mentioned, what is the top benefit?

4. What would you say are the *disadvantages* for your relative/friend when they receive IVIG treatment at home versus in another setting? [open-ended, check off as mentioned]

    a. Not seeing a registered nurse or physician during treatments

    b. Difficulty locating a supplier

    c. Difficulty getting the appointment scheduled for regular administration

    d. More adverse events or side effects compared to treatment in other settings

    e. Other

        4A. From those that you mentioned, what is the top issue or disadvantage?

5. What are the *advantages* for you, the caregiver, since your [relative/friend] began receiving IG treatment at home?

    a. Saving time [ask for an approximate estimate of time saved per week or month]

    b. Saving money from not needing transport the beneficiary to/from clinical settings

    c. More productive time at work or school

    d. Other

        5A. From those that you mentioned, what is the top benefit?

6. What are the *disadvantages* for you as the caregiver, if any, since your [relative/friend] began receiving IG treatment at home?

a. More responsibility/burden on the caregiver in caring for the patient at home

b. Stress/strain if there is an adverse event

6A. From those that you mentioned, what is the top issue or disadvantage?

7. Have you had, or will you want, specific training for assisting your [relative/friend] for in-home IVIG administration?

a. Yes, I have had training

b. Yes, I want training

c. No, I do not have and I will not want training

SKIP TO QUESTION 17

8. [For beneficiaries *not* in the demonstration] Have you heard of the Medicare Intravenous Immunoglobulin (IVIG) Demonstration that provides eligible beneficiaries IVIG infusion in the home?

YES/NO

[Provide this explanation if needed] The 3 year demonstration project is called the "Medicare Intravenous Immunoglobulin Demonstration" and it involves a bundled payment for the items and services used for in-home administration of IVIG for non-homebound Medicare beneficiaries with primary immune deficiency disorder (PIDD). In order to be eligible for the demonstration, beneficiaries must be covered under the original Medicare fee-for-service program and have Medicare Part B and not be enrolled in a Medicare Advantage plan.

QUESTIONS 9-12 are for IVIG beneficiaries not in the Demonstration For SCIG beneficiaries, skip to QUESTION 13

9. What do you think are the *advantages* to your [relative/friend] receiving IVIG treatment at [hospital/infusion clinic/physician's office] instead of at home? [open-ended, check off as mentioned]

a. Access to nurse or doctor in case of adverse event

b. Seeing other people at the treatment setting

c. Getting outside of the house

d. Easier to make an appointment

e. Other

9A. From those that you mentioned, what is the top *advantage*?

10. What do you think are the *disadvantages* to your [relative/friend] receiving IVIG treatment at [hospital/infusion clinic/physician's office] instead of at home? [open-ended, check off as mentioned]

    a. Transportation challenges (if they go alone)

    b. Feeling uncomfortable about inconveniencing the caregiver for transportation

    c. Long wait times for treatment

    d. Quality of care at treatment facilities can vary depending on the staff

    e. Higher risk of secondary infections compared to home treatments

    f. More adverse events post-treatment compared to at-home treatment

    g. Loss of work hours for the person with PIDD

    h. Emotional distress for the patient

    i. Other

    10A. From those that you mentioned, what is the top issue or disadvantage compared to receiving treatment at home?

11. What would be the *advantages* for you as the caregiver if your [relative/friend] was in the demonstration and receiving treatment at home?

    a. Saving time [ask for an approximate estimate of time saved per week or month]

    b. Saving money from not needing transport the beneficiary to/from clinical settings

    c. More productive time at work or school

    d. Other

    11A. From those that you mentioned, what would be the top benefit?

12. What would be the *disadvantages* for you, the caregiver, if your [relative/friend] began receiving IG treatment at home?

    12A. From those that you mentioned, what would be the top disadvantage?

SKIP TO QUESTION 17

QUESTIONS 13 - 16 are for SCIG beneficiaries

For IVIG beneficiaries, skip to QUESTION 17

13. Do you think there would be any advantages for your [relative/friend] if s/he enrolled in the demonstration to receive IVIG at home? [open ended, check off as mentioned]

a. Less frequent treatments

b. Not needing as many needle sticks

c. Less skin problems at needle stick sites

d. Having a professional administer IVIG

e. Feeling healthier

f. Better quality of life

g. Other

13A. What would be the top benefit?

14. Do you think there would be any *disadvantages* for your [relative/friend] if s/he enrolled in the demonstration to receive IVIG at home? [open ended, check off as mentioned]

a. Needing to schedule appointments

b. Losing control/autonomy of treatments

c. More "peaks and valleys" of IG between infusions

d. More headaches from infusion compared to SCIG

e. Other

14A. What would be the top disadvantage?

15. What would be the *advantages* to you as the caregiver if your [relative/friend] was in the demonstration and receiving IVIG treatment at home?

15A. From those that you mentioned, what would be the top benefit?

16. What would be the *disadvantages* for you, the caregiver, if your [relative/friend] began receiving IVIG treatment at home?

16A. From those that you mentioned, what would be the top disadvantage?

QUESTIONS 17-20 are for all beneficiaries

17. Has your [relative/friend] had health problems or adverse events related to receiving IG treatment?

a. [If YES] Can you tell me something about what happened?

b. In which setting/s was your [relative/friend] receiving IG treatments when the adverse events occurred?

a. Home

b. Outside the home (infusion clinic, hospital, specialty infusion clinic)

18. [If YES to adverse events] How often have you seen adverse events or side effects with your [relative/friend] related to them receiving IG treatment?

    a. During each visit

    b. Periodically

    c. Always

    d. Never

    e. Other

19. Do you have a plan in place in case your [relative/friend] experiences an adverse event? How do you manage adverse events?

20. Have you had any difficulties or delays in getting supplies or treatment for your [relative/friend] in different settings? Please explain.

21. Across all settings (home, hospital, physician's office, etc.), where do you think your [relative/friend] would prefer to receive care?

    a. Home

    b. Hospital

    c. Physician's office

    d. Infusion clinic

    e. Other

22. Is there anything more you would like to add that you think would be helpful for us to know?

Thank you for your time and sharing your experiences providing care for PIDD patients receiving IVIG treatment. Your comments are very helpful and insightful.

Other Topics Discussed:

Any Documents Obtained:

Post Interview Comments or Questions: