CMS Response to Public Comments Received for CMS-10518

The Centers for Medicare and Medicaid Services (CMS) received comments from an individual beneficiary, a pharmaceutical supplier, and a joint response from a patient advocacy foundation and two clinical societies with interest in IVIG. These latter two sets of comments were largely duplicative. Below are responses to each of the comments made.

Comment:

A beneficiary from Florida submitted a comment unrelated to the demonstration regarding a need for information about Part B enrollment and potential penalties.

Response:
CMS staff responded directly to the beneficiary clarifying that the question was unrelated to the PRA package and we were unable to provide the information requested. However, sources for additional assistance and information were offered. The beneficiary responded via email that her issue had been resolved and she had the information needed.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a pharmaceutical supplier recommending that an introductory statement about the demonstration be added to the application.

Response:
CMS will be adding a brief introductory statement to the revised application. The application will be distributed with a brochure and fact sheet that provides additional information for the beneficiary. CMS believes that to reproduce the information in this literature on the application would be redundant and add to the length of the application.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a pharmaceutical supplier, a patient advocacy group and 2 clinical societies suggesting that the order of Questions 12 & 13 be reversed so as to keep all IVIG questions in one column separate from questions about subcutaneous medication separate.

Response:
CMS appreciates the suggestion and has incorporated it into the revised application form. Please note that the numbering of some of the questions has also been adjusted.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a patient advocacy group and 2 clinical societies suggesting that the wording in Questions 12 and 13 be revised to reflect how the patient currently receives their medication as distinct from how they might receive it if they participate in the demonstration

Response:
CMS appreciates the suggestion and has incorporated it into the revised application form.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a patient advocacy group and 2 clinical societies identifying a typographical error in two of the response options for Question 14.

Response:
CMS has incorporated the correction into the revised application form.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a pharmaceutical supplier, a patient advocacy group and 2 clinical societies asking why the application directs questions toward patients who receive their medication subcutaneously since the demonstration covers intravenous administration of immune globulin.

Response:
Although the demonstration will cover nursing and supplies related to the administration of IVIG, there is the potential that some beneficiaries who currently self-administer the drug subcutaneously may wish to switch to intravenous administration with the availability of coverage under the demonstration. One of the purposes of the questions on the application is to collect baseline data on all beneficiaries that may potentially apply to the demonstration, regardless of how they currently receive the medication.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received a comment from a pharmaceutical supplier, a patient advocacy group and two clinical societies regarding the answer options for Question 14. It was noted that the primary concern for most primary immune deficiency patients is safety and additional answer options related to reduction of risk of exposure to infection and reactions to infusion were suggested.

Response:
CMS appreciates the suggestions and has incorporated them into the revised application.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier, a patient advocacy group and two clinical societies suggesting that where an answer is "Other", more space should be provided to write in responses.

Response:
CMS appreciates the suggestion and has incorporated more space for applicants to write in responses to the questions. In addition, this application will be available to complete online which will also allow for more space, as needed.

Comment:
The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier, a patient advocacy group and two clinical societies suggesting that in question 15 we replace the word "administering this drug" with "nursing and supplies associated with this drug." It was also suggested that an "I don't know" option be provided as a possible response.

Response:
CMS appreciates the suggestions and has incorporated them into the revised application.

Comment:
The Centers for Medicare and Medicaid Services (CMS) received comments from a patient advocacy group and two clinical societies suggesting that in question 16 one option be "Veterans Benefits" and that applicants be allowed to select as many options as applicable.

Response:
CMS appreciates the suggestion and has incorporated it into the revised application.

Comment:
The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier, a patient advocacy organization and two clinical societies suggesting that the application needs to more clearly accommodate newly diagnosed patients as well as those already receiving immune globulin.

Response:
CMS appreciates the suggestion and has revised the wording on several questions to make clear that they apply to persons currently receiving immune globulin for primary immune deficiency disease as well as those newly diagnosed.

Comment:
The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier, a patient advocacy organization and two clinical societies suggesting that the application include information regarding how the form should be submitted.

Response:
The application will be accompanied by a guide that will have detailed information about how to complete the application and submit it and how to get additional information. In the interest of space, we did not want to repeat all of this information on the application form. However, we appreciate the suggestion and have added submission instructions on the revised application as well as contact information should applicants or their physicians have further questions.

Comment:
The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier, a patient advocacy organization and two clinical societies asking that we add a question regarding whether the patient has experienced adverse reactions during previous IVIG infusions that would require that their care be continued in a setting other than home.

Response:
CMS appreciates the concern that beneficiaries applying to participate in the demonstration be appropriate for home-based infusion. That is why we have required that the patient have their physician sign the application. The application includes an attestation statement above the physician's signature: "I attest that I am treating this patient, that the patient has primary immune deficiency disease, and is a candidate for home IVIG." We believe that this is sufficient and that physicians may consider a multitude of factors in determining the appropriateness of a beneficiary's participation in the demonstration.

Comment:
The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier regarding the need for providers to have clear instructions on billing.

Response:
CMS agrees and has prepared a "Medlearn Matters" article outlining all of the billing requirements. "Medlearn Matters" articles are regularly distributed by CMS to all providers and suppliers with information about payment and billing for Medicare services. The article specific to the IVIG Demonstration will be published closer to the time that the demonstration is scheduled to start and will outline the codes to be used as well as the payment rate. No special documentation will be required along with the claim as long as the beneficiary is

enrolled in the demonstration and eligible to receive the IVIG medication under Part B.

Comment:

The Centers for Medicare and Medicaid Services (CMS) received comments from a pharmaceutical supplier, a patient advocacy organization and two clinical societies expressing concern about the sufficiency of the payment rate. Concern was expressed that the payment rate should be sufficient to insure that suppliers will participate and that necessary services and supplies will be covered.

Response:

CMS has developed a bundled payment rate to cover nursing and supplies to administer the IVIG in accordance with the requirements in the statute. As outlined in an "Open Door Forum" held in 2013, the rate will be based on the LUPA for nursing services and assume an average infusion time of 4-4 ½ hours, recognizing that some infusions are shorter and some are longer. We believe that the rate, which will be published when the start date for the demonstration is finalized, will be appropriate to the setting and services rendered.