

November 22, 2006

### CMS Response to Public Comments Received for CMS-10197

The Centers for Medicare & Medicaid Services (CMS) received comments on CMS-10201 from Virginia Tobiason. She is Senior Director, Corporate Reimbursement, Abbott Laboratories, a diversified healthcare company whose main lines of business are global pharmaceuticals, nutritional and medical products, including diagnostics and cardiovascular devices. We found many useful comments in her statement, and we have made numerous changes to the instruments in response. Below is our summary of and response to each comment.

#### COMMENT:

Tracking Information by DMEPOS Category

The beneficiary survey should be able to identify problems with quality or access associated with particular categories of medical equipment and supplies that are included in competitive bidding. CMS should issue a separate survey for each product category or add a question at the beginning of Section A listing the product categories included in bidding in the beneficiary's competitive bidding area (CBA) and asking beneficiaries to check the categories of products they use.

*Response: We agree with this comment and have revised the project's plan for surveying beneficiaries about "other DMEPOS". We plan to develop four (4) customized surveys for each of four (4) product categories, in addition to the oxygen survey. We will select four (4) of the most important DMEPOS categories in the competitive bidding program, in terms of volume and utilization. We will make this decision after the categories are finalized by CMS later this year. A list of important categories was included in the Notice of Proposed Rulemaking for the competitive bidding program (Federal Register-May 1, 2006). We will ensure a varied range of categories is selected. Pending these decisions, we have developed, for illustrative purposes only, a survey for power wheelchairs to demonstrate how the surveys can be customized. As shown in the illustrative example, specific answer choices will be developed that make sense for the particular product category that is the focus of the customized survey. In addition to improving access and quality impact measurements, another benefit of customizing the separate surveys is improved reliability of the survey information. Many questions will remain constant across all surveys. The revised PRA package contains the full surveys for Oxygen users and as customized for Power Wheelchair users. We have provided a comparative summary of the survey content for both surveys at the end of this document.*

*The following are the specific questions that were customized to power wheelchair survey:*

A1a. Why did you stop using your power wheelchair? (Please check all that apply)

- <sub>1</sub> My condition got better so I didn't need it anymore
- <sub>2</sub> My condition got worse so I couldn't use it anymore
- <sub>3</sub> I was embarrassed to use it
- <sub>4</sub> I was not comfortable sitting in it
- <sub>5</sub> I did not feel safe driving it

- <sub>6</sub> I just didn't like using it
- <sub>7</sub> It was too cumbersome
- <sub>8</sub> It was too complicated to drive
- <sub>9</sub> It kept breaking down
- <sub>10</sub> I had no place to charge it and/or store it
- <sub>11</sub> I did not have the features I needed
- <sub>12</sub> I have never used a power wheelchair ( → Skip to SECTION F on page)
- <sub>13</sub> Other (Please specify:) \_\_\_\_
- <sub>14</sub> Don't remember

A3. Did your doctor or health care provider (e.g. physical therapist) ever explain to you why you needed to use a power wheelchair?

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>98</sub> I don't know
- <sub>99</sub> Not Applicable

A4. Did your doctor or health care provider (e.g. physical therapist) ever explain to you the different types of power wheelchairs, controls options and accessories that exist?

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>98</sub> I don't know
- <sub>99</sub> Not Applicable

A5. Did your doctor or health care provider (e.g. physical therapist) ever suggest that you contact your supplier about your options?

- <sub>1</sub> Yes
- <sub>2</sub> No
- <sub>98</sub> I don't know
- <sub>99</sub> Not Applicable

A9a. What do you want to do that your current power wheelchair does not allow you to do?  
(Please check all that apply)

- <sub>1</sub> Nothing
- <sub>2</sub> Maneuver the chair more easily inside my home
- <sub>3</sub> Maneuver the chair more easily outside of my home
- <sub>4</sub> Put the chair in a car/taxi to go places

- <sub>5</sub> Sit comfortably in it for a longer time
- <sub>6</sub> Be able to transfer in and out of the wheelchair easily
- <sub>6</sub> Other (please tell us what else):
- <sub>8</sub> Not sure
- <sub>9</sub> Not Applicable

A10a. What is it about your power wheelchair that makes it difficult or uncomfortable?

- <sub>1</sub> It is not difficult or uncomfortable
- <sub>2</sub> I cannot sit comfortably in it
- <sub>3</sub> I cannot maneuver it well
- <sub>4</sub> I can't transfer in and out of it easily
- <sub>5</sub> I can't put it in the car or taxi
- <sub>6</sub> It goes too slow or too fast
- <sub>7</sub> It is too heavy and cumbersome to use
- <sub>8</sub> I have trouble charging it

A13b. Can you describe the kind of problem(s) that you had? (Please check all that apply)

- <sub>1</sub> Wheelchair failed/did not work
- <sub>2</sub> Other (Please specify:) \_\_\_\_\_
- <sub>3</sub> Don't remember

A14a. Why did you make this (these) change(s)? (Please check all that apply)

- <sub>1</sub> Wheelchair needed to be replaced because the original one didn't work
- <sub>2</sub> My medical condition changed, so I needed something different
- <sub>3</sub> Found a new wheelchair that was better for me
- <sub>4</sub> Found new features/accessories that were better for me
- <sub>5</sub> Doctor/ health care provider prescribed a different type of wheelchair
- <sub>6</sub> Other (Please specify:) \_\_\_\_

B2. What features did you buy with your own money? (Please check all that apply)

- <sub>1</sub> Seat or back cushions
- <sub>2</sub> Tires
- <sub>3</sub> Crutch holder
- <sub>4</sub> Lap tray
- <sub>5</sub> Repairs
- <sub>6</sub> Routine Maintenance
- <sub>7</sub> Other (specify) \_\_\_\_\_

C4. How did you get your power wheelchair? (Please check all that apply)

- <sub>1</sub> Delivered to my home by my supplier
- <sub>2</sub> Mailed to my home by my supplier
- <sub>3</sub> I picked it up from my supplier
- <sub>4</sub> I picked it up at a seating clinic or rehabilitation center

<sub>5</sub> Some other way (Specify):

D5. What kind of training or help did the supplier give you or the person who takes care of you? (Please check all that apply)

Did he/she...

- <sub>1</sub> Give you written instructions on how to use the power wheelchair
- <sub>2</sub> Show you how to use the power wheelchair
- <sub>3</sub> Choose a safe and convenient place to store and charge the power wheelchair
- <sub>4</sub> Show you how to clean and maintain the power wheelchair
- <sub>5</sub> Show you how to use the power wheelchair safely
- <sub>6</sub> Let you practice how to use and maintain your power wheelchair while they watched
- <sub>7</sub> Gave me the manufacturer's customer assistance toll-free telephone number
- <sub>8</sub> I didn't get any training or help from my supplier (→ Skip to D5)
- <sub>9</sub> Don't remember (→ Skip to D5)
- <sub>10</sub> Not Applicable (→ Skip to D5)

*Information about access and quality impacts on product categories other than those selected for the beneficiary survey will be obtainable from nonstatistical data collection methods in the project plan, namely, our interviews and focus groups with suppliers, referral agents, and beneficiary group representatives (see focus group guides and discussion guides included in the PRA package). In selecting participants to invite to focus groups and key informant discussions, we will ensure that product categories not covered by the survey will also be included. Our experience evaluating the 1998-2002 DME competitive bidding demonstration indicates that such sources were useful for uncovering specific product quality issues.*

COMMENT:

Beneficiary Access to Appropriate Products

Products under a given HCPCS code are not necessarily interchangeable, and may incorporate different types of medically necessary features that enhance medical care and compliance for beneficiaries with specific needs. CMS should ensure that beneficiaries have access to equipment with medically-necessary features. The survey should include questions to elicit whether the equipment has the appropriate features and whether there are difficulties with access to supplies that are used with specific equipment.

*Response: We agree with these suggestions. We have added a new response category, "It doesn't have the features I need" to the question, A2a. Why did you stop using your power wheelchair? We have also added a response category to the question: A13a. Why did you make changes to your power wheelchair? The new response is, "found new features/accessories that were better for me". We will also add the following question to the appropriate versions of the survey (pending customization for the four product categories): "Do you have trouble obtaining the right supplies to use with your equipment?"*

COMMENT:

Beneficiary Access to Local Suppliers

The survey content should allow CMS to study whether competitive bidding affected access to retail suppliers and pharmacies, particularly if blood glucose monitoring or enteral nutritional products are included in bidding. For example, beneficiaries who rely on enteral nutrients must have a variety of suppliers in close proximity if an emergency situation arises, such as if an immediate change in products is necessary to sustain life or if there is a serious medical complication associated with tube feeding.

*Response: We agree. The survey was designed to address this issue by including several questions aimed at access impacts. See the following questions in the accompanying sample survey for power wheelchair users: C4. How did you get your power wheelchair? D3. Did you have a choice of suppliers?; E4. Did you need emergency service or advice from you supplier in the past three (3) months?; E4b. Did you get the advice or services you needed? In addition, we have added the following question: C1. Do you have more than one supplier for your power wheelchair, accessories, parts, maintenance, and repairs? The same questions, appropriately modified, will be included in each customized survey we develop after the product lines selected for competitive bidding are known.*

*Another aspect of the analytic plan involves examining changes, if any, in the number of suppliers in a market subsequent to competitive bidding. We will use claims-level data aggregated to the supplier level to analyze supplier statistics that are likely related to beneficiary access. For example , we will track the number of suppliers, the supplier-to-beneficiary ratio, the number of new suppliers, the number of inactive suppliers, the size of suppliers, the geographic location of suppliers, and so forth.*

**COMMENT:**

**Supplier Services/Access to Manufacturer Support**

Unlike many other segments of the DMEPOS industry, education of and technical support for patients using blood glucose monitoring systems ideally is performed by the manufacturer, rather than by the DMEPOS supplier, because of wide differences in models on the market. Misuse could lead to erroneous treatment decisions. Disclosure of manufacturer contact information by the supplier to the beneficiary is an aspect of service quality that should be covered in the survey.

*Response: We agree with the suggestion. We have added the following response category to question: D4. What kind of training or help did the supplier give you or the person who takes care of you?: “Give you information on manufacturer toll-free patient assistance hotline numbers”. Also, we have added questions about the beneficiary’s experience contacting the supplier after regular business hours.(E5, E5a)*

**COMMENT:**

**Overall Beneficiary Satisfaction**

In order to gauge overall beneficiary satisfaction under competitive bidding compared to before competitive bidding, CMS should add the following question: How satisfied are you with how Medicare provides your medical equipment compared to last year?

*Responses: We did not add the recommended question, because our project plan fundamentally incorporates a design that permits us to assess change in satisfaction and other policy objectives of the Medicare program. As described in the data collection plan, we will administer the survey to two independent samples, one before the program commences, and another after the program commences. We will analyze the change in satisfaction between the two sets of surveys, while controlling for secular effects that could affect beneficiary satisfaction. We will control for such effects by conducting the survey in comparable areas where competitive bidding is not in effect. This method has greater reliability than asking the beneficiary to recall their satisfaction level of one year ago.*

COMMENT:  
Nursing home patients

CMS appears to be excluding nursing home patients from the beneficiary survey. We recommend that CMS ensure that nursing home residents, if included in competitive bidding, are also adequately represented in the evaluation report through beneficiary surveys, resident and staff interviews, or other appropriate mechanisms.

*Response: We agree that the experiences of nursing home residents' obtaining their needed DMEPOS are important. However, interviewing the nursing home population is a complicated and expensive process, and it is not clear if data collected from nursing home residents or proxies would be consistent with data collected from Medicare beneficiaries living at home. Also, there are many differences between the experiences of nursing home residents and beneficiaries who live at home with regard to obtaining DMEPOS that would have implications for the evaluation. First, some products (e.g., manual wheelchairs) are supplied by the nursing home as part of the resident's bed rate and are often stock items. Second, when residents do obtain DMEPOS products they most often do so through an intermediary, i.e. nursing home staff. Third, many services such as training in the use of the equipment or maintenance may be provided by nursing home staff in addition to or instead of the DMEPOS supplier. Fourth, some DMEPOS items may not be used directly by nursing home resident. For example, the nursing home staff may use the beneficiary's diabetic supplies (e.g. monitor, test strips, and lancets), instead of the beneficiary using these items directly. Each of these differences could significantly impact the analysis of the survey data.*

*As mentioned above, a beneficiary in a nursing home may not be able to complete a survey independently and many questions would not apply. Many would require a proxy to complete the survey. Thus, we are unable to overcome the significant barriers to studying this population systematically, through a survey. Special data collection methods would be needed for the nursing home situation.*

*However, in response to this comment, we have made a change to our qualitative data collection plan (focus groups and interviews). Our project plan now calls for including some nursing home staff members as key informants. In our original design we stated that we would recruit from "An organization with a large rehabilitation unit or a nursing home" for participation in the referral agent focus group. However, as we agree with the recommendation to include a nursing*

*home staff person in the referral agent focus groups, we will recruit a nursing home staff person involved in helping residents with Medicare obtain DMEPOS in that setting. (See PRA statement, Appendix C, for focus group guides.)*

COMMENT:

Clarification of Application of Certain Questions to Non-Oxygen Suppliers

CMS should clarify on page 8, Questions C1-C4, that these questions in the general medical equipment and supplies survey are not limited to oxygen suppliers.

*Response: This was a typographical error. The survey will be corrected to reference the supplier of the particular item category we are addressing in the survey.*

COMMENT:

Recommendations Regarding the Supporting Statement for Paperwork Reduction Act Submission

Any evaluation or estimates of Medicare program savings should include an analysis of offsetting increases in hospital and other Part A costs or increased Part B physician services associated with adverse clinical outcomes related to competitive bidding. Specifically, CMS should compare Part A hospital admission rates and Part B physician services spending in CBAs to spending in comparable areas that are not subject to competitive bidding to determine if the new program is having unintended, adverse impacts requiring the need for hospital care or additional physician visits.

*Response: The commenter raises a worthwhile question, but one that is very difficult to study scientifically. Tracing health outcomes to medical equipment quality is highly problematic. Frequently, there are too many intervening variables, particularly physician quality, that affect the final outcome but that cannot be accounted for in the analysis. Further, studies can be hindered by lack of data on specific physiological measures, such as test results, upon which depend downstream effects such as treatment decisions and, eventually, outcomes. Because of the expense and complexity of data collection required to conduct such studies, and because the state of the art is not well developed, a properly conceived study, whose success is not assured, is not within the scope of the evaluation. A study based on administrative data, akin to the kind suggested by the commenter, is a potential part of the evaluation plan, but results would likely have to be heavily qualified because of such limitations as important missing variables and inadequate quality of data available for risk adjustment. We have made no final decision on whether to conduct such a correlational study, pending further development of data collection and analysis plans. The plans will be carefully reviewed to determine whether an expenditure of funds on the activity is a worthwhile use of project funds.*

COMMENT:

The evaluation of the competitive bidding program should reflect the range of supplier types participating in the program, including small retail suppliers, large chain suppliers, mail order suppliers, specialty providers, supplier networks, and hospital-owned suppliers. It would be important for CMS to have data regarding whether beneficiary satisfaction and other outcomes

vary depending on supplier type.

Response: The supplier survey is designed to reflect the range of supplier types participating in the program. The supplier sampling plan calls for a representative sample of suppliers who bill the Medicare program for the items selected for study, provided that they have a substantial market presence in the study area (see PRA statement, Section C1). The purpose of the supplier survey is to obtain information on quality, in accordance with the goal of the evaluation to study impacts on beneficiaries. It would not be an efficient use of funds to survey suppliers with little Medicare business volume in the area, because they have little impact on the quality experienced by beneficiaries in the area. We expect to obtain responses from at least 105 suppliers per study area in the baseline survey, and similar numbers in the follow-up survey. This large sample is expected to be representative of the target population of suppliers of the items to be studied (i.e., Medicare suppliers with significant item business volume in the study area). Responses will be adjusted to ensure that respondents represent the actual distribution of utilization among the suppliers in the area. Responses will be adjusted based on supplier size, but will not be adjusted for supplier type (mail order, specialty providers, etc), as we do not have these data available to us.

The evaluation also includes data collection via focus groups of suppliers, groups that will be constituted to reflect the range of suppliers active in the program.

We do not believe that analysis of outcomes according to form of business organization is an appropriate objective for the evaluation, which is a relatively short-term study. Longer-term routine data collection on quality can be used for this purpose. CMS has proposed and issued for public comment a routine beneficiary survey for DMEPOS that is now under revision. Data from this instrument can provide the kind of information being sought in the comment. However, at this time, we have no reason to believe that program outcomes will differ by form of business organization. Pursuant to the congressional mandate in the MMA 2003, the competitive bidding program proposed to date has been designed to provide for participation by all types of suppliers in such a way that no beneficiary population will be disadvantaged by impacts on suppliers.

COMMENT:

CMS should monitor the impact of competitive bidding on Medicaid beneficiaries and privately-insured individuals. We are concerned that many suppliers who are not winning Medicare bidders will not be able to continue supplying DMEPOS in competitive bidding areas, which would affect the availability of needed medical equipment and supplies for the non-Medicare population.

*Response: We appreciate the comment. Effects on other insured populations are important questions, but they are beyond the scope of the CMS evaluation. The charge for this project in the Medicare Modernization Act of 2003 is to study specific impacts on the Medicare program. Another provision of the law is a study by the Government Accountability Office of impacts on suppliers. Future studies such as that one may provide information about effects beyond the Medicare population.*



### Comparative Summary of Beneficiary Surveys

Power Wheelchairs Question #	Oxygen Question #	Content
A1	A1	Do you use.....?
A1a	A1a	If not, why stopped?
A2	A2	Someone help you?
A3	A3	Doc explain--why?
	A4	Doc explain how much O2
A4		Doc explain--different options
	A5	Doc explain when?
	A6	Doc explain options?
A5	A7	Doc suggest--contact supplier
A6	A8	How long expect to use?
A7	A9	Last time saw provider to discuss?
A8	A10	Right----for you?
A9	A11	Able to do what you want?
A9a	A11a	What do you want to do that you can't?
A10	A12	Difficult or uncomfortable to use?
A10a	A12a	What about it makes it difficult or uncomfortable?
	A14	Make you feel better?
A14	A15	Same equipment as when you first started therapy?
A14b	A15a	Why did you make changes?
	B1, C1	Use stationary O2?, Use portable O2
	B2, C2	Type of stationary O2?; Type of port O2
	B3	Type of delivery system?
A11	B4, C3	How often do you use?
A12	B5, C4	Hours per day used
	B6, C5	Using less than prescribed?
	B6a, C5a	Why?
A13	B7	Problems that made you go without it?
A13a	B75a	How often have problems?
A13b	B7b	What problems?
	C6	How often get refills for portable?
	C6a	# tanks/delivery
	C7	Use intermittent flow device?

	C7a	Who adjusted and tested intermittent flow device?
B1	D1	Buy something with own money?
B2	D2	What did you buy?
B3	D3	How much did you spend?
C1	E1	More than 1 supplier?
C2	E2	Rate supplier
C3	E3	Recommend supplier to friend?
C4	E4	How do you get equipment?
C5	E5	Time and energy to get equipment?
D1	F1	Used for less than 6 months?
D2	F2	When first prescribed, any problems finding supplier?
D2a	F2a	Type of problems?
D3	F3	Have a choice of suppliers?
D4	F4	How long after ordered did you receive?
D5	F5	Training supplier gave you?
D5a	F5a	As a result of training, feel comfortable?
D6	F6	Received answers you could understand?
D7	F7	Told you as much as you wanted to know?
D8	F8	Spend as much time as you wanted?
	G1	How often send respiratory therapist to home to check breathing? (past 3 mos)
	G2	How often send someone to check equipment? (past 3 mos)
E1		Supplier send someone to your home? (past 3 mos)
E2	G3	Supplier reliable making deliveries/repairs? (past 3 mos)
E3	G4	Contact supplier with complaint or problem? (past 3 mos)
E3a	G4a	Complaint settled satisfactorily?
E4	G5	Contact for emergency services from supplier? (past 3 mos)
E4a	G5a	Get emergency service you needed?
E4b	G5b	How fast respond to emergency?
E5	G6	Need to contact supplier after business hours? (past 3 mos)
E5b	G6a	Get service you needed after business hours?
E6	G7	How reliable is equipment? (past 3 mos)

E7	G8	Changed supplier? (past 3 mos)
E7a	G8a	Why change supplier? (past 3 mos)
F1	H1	Rate overall health
F2	H2	Health compared to one year ago
F3	H3	Living situation
F4	H4	Education
F5	H5	Income
F6	H6	Hispanic/Latino
F7	H7	Race
G1	I1	Who completed survey
G2	I2	If helper, how helped