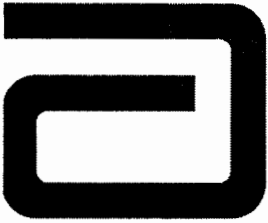


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August 14, 2006

VIA OVERNIGHT MAIL

Ms. Melissa Musotto
Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – A
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

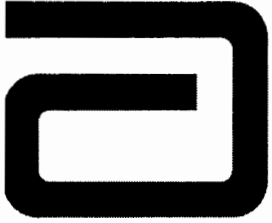
**RE: Evaluation of the Medicare National Competitive Bidding Program for DME:
CMS-10197/OMB# 0938-New**

Dear Ms. Musotto:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed evaluation of the Medicare National Competitive Bidding Program for durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). This letter supplements our comments on the separate CMS proposed rule to establish the DMEPOS competitive bidding program ("Proposed Rule"); a copy of our comments on the Proposed Rule is attached for your reference.

Abbott is a global, broad-based health care company devoted to discovering new medicines, new technologies and new ways to manage health. Our products span the continuum of care, from medical devices and nutritional products through laboratory diagnostics and pharmaceutical therapies. The company employs 65,000 people and markets its products in more than 130 countries. The competitive bidding program is of particular interest to two Abbott divisions – Abbott Diabetes Care and the Ross Products Division. Abbott Diabetes Care manufactures diabetes care products, including self-monitoring blood glucose systems, test strips, data management software, and accessories that help individuals with diabetes obtain the diagnostic information they need to control their disease. The Ross Products Division is a dedicated leader in the research and development of specialized enteral nutritional products, which provide therapeutic nutritional support to patients with acute and chronic conditions who cannot swallow and/or digest and absorb adequate nutrition.

In our comments on the Proposed Rule, we detailed the patient care and operational reasons why CMS should exclude blood glucose monitoring systems and enteral nutritionals from competitive bidding. However, if CMS does include either product category in competitive bidding, it is essential to assess the resulting impact on quality of care, access to the most medically-appropriate equipment, and overall health care spending. The evaluation of the DMEPOS competitive bidding program will provide policymakers with critical information that will help CMS and Congress assess the need for refinements to the program in future years. Thus, it is important for the information collected to provide a complete and accurate picture of the impact of the new program.



We therefore provide a number of suggestions for ways to enhance the quality, utility, and clarity of the information to be collected. In particular, we recommend a number of changes to (1) the CMS Survey of Beneficiaries Using Medical Equipment and Supplies, and (2) the Supporting Statement for Paperwork Reduction Act Submission.

I. **Recommendations for Survey of Beneficiaries Using Medical Equipment & Supplies**

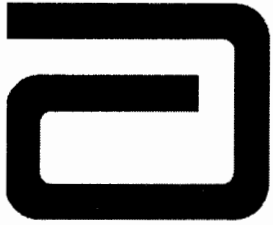
Tracking Information by DMEPOS Category

CMS, through its contractor, is proposing to use one beneficiary survey for beneficiaries using oxygen equipment and another for all other medical equipment and supplies. It is unclear whether the non-oxygen beneficiary survey will specifically identify the product category the patient received or whether this general survey will apply to all of the beneficiary's medical equipment and supplies. We believe that it is important for CMS to be able to identify problems with quality or access associated with particular categories of medical equipment and supplies that are included in competitive bidding. If CMS does not issue a separate survey for each product category, we recommend that CMS 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. CMS then should analyze information received to identify trends applicable to particular product categories.

Beneficiary Access to Appropriate Products

There is a wide variety of blood glucose monitoring systems on the market, including many with a variety of medically-necessary features that enhance medical care and compliance for Medicare beneficiaries. For instance, some monitoring systems prevent false glucose level readings that could lead to ineffective or potentially harmful medical interventions, offer multiple body site testing capabilities or require smaller blood sample size (thereby minimizing pain associated with testing and enhancing beneficiary compliance with testing regimens), and/or provide verbal instructions and results for safe and effective testing by individuals with vision impairment. Likewise, many of the HCPCS codes for enteral nutrition formulas, equipment, and supplies contain products that are not interchangeable, and in many cases have significant differences among them; differences include a range in technology and features that may be critical to a patient's medical care as well as packaging to enhance safety

In evaluating the competitive bidding program, CMS should ensure that beneficiaries have convenient access to equipment with medically-necessary features. To that end, we recommend that CMS include the following questions and additional responses in its beneficiary survey:



Does the equipment supplied have all of the features you needed?

Do you have trouble obtaining the right supplies to use with your equipment?

A7b1 Is there anything about your medical equipment and supplies that makes [it/them] difficult for you to use [it/them] or is uncomfortable for you?

It doesn't have the features I want.

A12b.*Can you describe the kind of problem(s) that you had?

I could not find, or there was a delay in finding, a supplier that could provide equipment with the features or in the form I needed.

I did not know how to use the equipment

Beneficiary Access to Suppliers

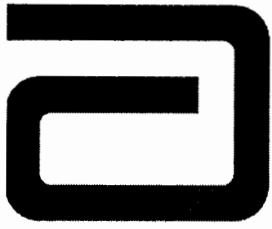
It is important for CMS to ensure that beneficiaries in each CBA have convenient access to retail suppliers and pharmacies, particularly if blood glucose monitoring or enteral nutritional products are included in bidding. With regard to blood glucose monitoring products, beneficiaries rely on their pharmacies to assist in the management of their total diabetes care needs, including treatment for the comorbidities that so often accompany diabetes, and CMS should ensure that competitive bidding does not disrupt this important network for beneficiaries. Likewise, beneficiaries who rely on enteral nutrients need convenient access to their life-sustaining food supply; they also 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.

To enhance the information CMS is collecting about convenient beneficiary access to suppliers, we recommend adding the following new questions to section C:

How far do you need to travel in order to obtain your medical equipment and supplies?

How many suppliers and/or pharmacies do you need to use to obtain all of the products you need to manage your health care?

Were your equipment and supplies available from a local supplier or pharmacy, or did you have to use a mail order supplier?



Supplier Services/Access to Manufacturer Support

Unlike many other segments of the DMEPOS industry, education of and technical support for patient using blood glucose monitoring systems ideally is performed by the manufacturer, rather than by the DMEPOS supplier. There currently are more than 30 blood glucose monitoring systems available to suppliers and beneficiaries; a single supplier simply cannot know the technical intricacies of every monitoring system. Such manufacturer-specific knowledge is critical, since a misunderstanding or misinterpretation of results could lead to erroneous treatment decisions resulting in adverse health outcomes (such as the potentially deadly administration of too much insulin). Manufacturers of high-quality blood glucose monitoring systems like Abbott provide 24-hour/7-day-a-week manufacturer support lines staffed by intensely-trained professionals that provide technical support and professional guidance on how to operate the equipment, assist beneficiaries with their questions regarding effective management of their diabetes, and often encourage patient follow-up with health care providers. We have recommended that CMS require all Medicare suppliers to provide beneficiaries with information regarding how to access the manufacturer's 24-hour/7-day-a-week customer service lines, and to only accept submit bids for blood glucose monitors or test strips under competitive bidding if the products offer 24-hour/7-day-a-week manufacturer support. To ensure that beneficiaries receive information from suppliers regarding this support information, we recommend that CMS add the following response option to question D4:

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?

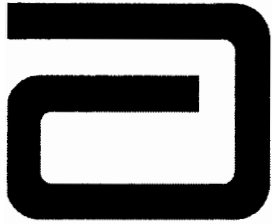
Overall Beneficiary Satisfaction

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?

Nursing home patients

Abbott has recommended that CMS exclude enteral products furnished to patients in the nursing home setting from competitive bidding because it would jeopardize access to quality care for SNF residents and interfere with efficient SNF operations, while not resulting in significant savings to Medicare. If SNF residents are included in competitive bidding, however, it is important to assess the impact of the program on their care. Yet CMS appears to be excluding nursing home patients from the beneficiary survey on the very first page, when



CMS states that the survey can be returned uncompleted because the survey was mailed to a person who is "in a nursing home or other institution and cannot complete the 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.

Clarification of Application of Certain Questions to Non-Oxygen Suppliers

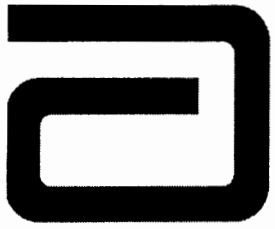
CMS should clarify on page 8, Questions C1-C4, that these questions in the general medical equipment and supplies survey are not limited to oxygen suppliers.

II. Recommendations Regarding the Supporting Statement for Paperwork Reduction Act Submission

One of the goals of the evaluation report is to quantify any Medicare program savings attributable to DMEPOS competitive bidding. The Supporting Statement indicates that CMS's contractor plans to review Medicare claims data to determine Medicare expenditures and savings associated with the demonstration. We recommend that any such 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 – which is a particular risk if blood glucose monitoring supplies or enteral nutritionals are included in 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.

We also recommend that CMS ensure that its evaluation of the competitive bidding program reflects 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.

In addition, as part of its initial and ongoing impact analyses, we recommend that CMS 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.



Please feel free to contact me if you have any questions or if you need additional information.

Sincerely,

Virginia Tobiason /sr

Virginia Tobiason
Senior Director
Corporate Reimbursement

Enclosure