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June 28, 2006

VIA FEDERAL EXPRESS

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P -- Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

Abbott welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed rule to implement the Medicare durable medical equipment ("DME"), prosthetics, orthotics, and supplies ("DMEPOS") competitive bidding program ("Proposed Rule").

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 Proposed Rule 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 ("SMBG") systems, test strips, data management software, and accessories that help individuals with diabetes obtain the diagnostic information they need to control their disease. Through effective self-monitoring of blood glucose levels, individuals can take charge of their day-to-day diabetes care by adjusting medications, diet, and/or activity levels to achieve optimal diabetes self-management. 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 who cannot swallow and/or digest and absorb adequate nutrition from traditional nutrient sources. Integrating the appropriate enteral nutritional intervention into care plans is essential to the health outcomes of patients with severe and chronic diseases like cancer, HIV/AIDS, chronic obstructive pulmonary disease ("COPD"), diabetes, and kidney disease. In most cases, enteral nutritionals are the prime source of the individual's nutrition, and the beneficiaries depend on the enteral products to live.

Abbott fully supports the Congressional goals of promoting high-quality care for Medicare beneficiaries while achieving improved management of costs, and we believe that the Proposed Rule must ensure that it balances both of these key Congressional objectives. We also agree with Congressional drafters of the competitive bidding statute that the program

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needs to be phased in judiciously, both geographically and through careful selection of products for inclusion in each phase of bidding. We are very concerned, however, that the proposed DMEPOS competitive bidding rule is overly broad and does not comply with Congressional directives to tailor competitive bidding in a way that protects the quality of care for Medicare beneficiaries. CMS's Proposed Rule could restrict beneficiary access to medically-necessary blood glucose monitoring and enteral nutrition products, resulting in adverse impacts on patient health care outcomes.

Our specific concerns and recommendations are highlighted in our Executive Summary and discussed in greater detail in our comments below. We appreciate the opportunity to offer constructive comments on how to structure competitive bidding in a way that will protect the availability of medically-necessary diabetes and enteral products, ensure beneficiary choice of home medical equipment suppliers, and promote high quality care for Medicare beneficiaries.

Executive Summary: Abbott's Comments on Proposed Competitive Bidding Rule

1. CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries and that have been successfully tested in a competitive bidding demonstration. Enteral nutrition and blood glucose monitoring systems represent two categories of products that CMS should exclude from competitive bidding.

   As discussed in detail in our comments, blood glucose monitoring products should be excluded because:

   - It would limit access to medically-necessary blood glucose monitoring equipment, which would compromise the beneficiary's ability to control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life.
   - These products have never been tested in a competitive bidding demonstration, and the impact on patient outcomes has not been assessed; and
   - It would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program.

   Likewise, enteral nutrition products should be excluded from competitive bidding because:

   - They are the beneficiary's sole source of nutrition, and necessary for the Medicare beneficiary to survive. If a patient does not have adequate access to specific enteral products, it could have an adverse clinical impact on the patient's overall health status and jeopardize patient safety.

- Enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested.[1]

- The majority of Medicare enteral nutrition patients reside in skilled nursing facilities, which raises distinct clinical, quality, and operational issues that have not been successfully tested or resolved.

2. If CMS considers including blood glucose monitoring or enteral nutrition products in any future phase of competitive bidding, we recommend that CMS:

   - First do so on a limited basis in a single competitive bidding area ("CBA") in order to monitor the impact on beneficiary care and ensure certain key operational issues are resolved, as discussed below,

   - Include only products furnished in the home care setting (i.e., not products furnished in the skilled nursing facility setting);

   - Establish appropriate subcategories to preserve access to blood glucose monitoring products with medically-necessary and distinct features, and require suppliers to include in their bids certain medically-necessary item features within the enteral product codes;

   - Exclude from competitive bidding those specially-formulated enteral nutritional products (B4153, B4154, and B4155) that are designed for beneficiaries with a particular medical condition, since there is a serious medical risk associated with inappropriate substitutions of the disease-specific formulas in this category; and

   - Include enteral equipment in the grandfathering process, clarify that CMS intends to establish separate payment amounts for each enteral nutritional product and supply HCPCS code (rather than a bundled payment), and maintain current enteral pump rental payment policy.

3. We recommend that CMS establish final supplier quality standards and ensure that suppliers are accredited before implementing bidding in any region.

4. We recommend that CMS adopt retail supplier proximity standards based on the Part D prescription drug program pharmacy access standards to preserve adequate patient access to medically-necessary blood glucose monitoring systems and enteral nutritionals, equipment, and supplies.

5. We support the voluntary, rather than mandatory, use of mail order suppliers.

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1 Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, Final Evaluation Report, prepared by the Center for Health Systems Research and Analysis and RTI International, November 2003, at 252.

6. We support CMS's proposed requirement that suppliers fill prescriptions with the brand or mode of delivery specified by the physician or prescribing clinician.

7. We recommend that CMS exclude the bids of limited service DMEPOS suppliers (e.g., SNFs and physicians), mail order suppliers, and unaccredited suppliers when establishing pivotal bids and single payment amounts to promote fair and realistic pricing determinations and ultimately ensure beneficiary access to an adequate number of suppliers.

8. We recommend that CMS establish payment amounts in the first phase of competitive bidding after excluding outlier bids, and test alternatives to the use of the median price (e.g., mean and weighted mean).

9. We recommend that CMS not apply competitive bidding prices outside of competitive bidding areas until the results of the first phases of competitive bidding are fully assessed, the mandated reports have been submitted, and a separate rulemaking with public comment period is issued to adopt a suitable framework for the policy.

10. CMS should issue a separate rulemaking if it seeks to refine the current "gap fill" pricing methodology, and should not adopt "functional technology assessments" as currently proposed.

Detailed Comments: Table of Contents

Abbott's Detailed Comments on Proposed DMEPOS Competitive Bidding Rule

I. Comments Related to Blood Glucose Monitoring Products

A. Legal and Policy Rationale for Exclusion of Blood Glucose Monitoring Products [Criteria for Item Selection]

Abbott Recommendation: CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve the Congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries. Moreover, CMS should include in the first phase of competitive bidding only those products that have been successfully tested in prior competitive bidding demonstrations. Because blood glucose monitoring products have not been tested at all, and because inclusion of these products could compromise quality of care for beneficiaries with diabetes, CMS should not include blood glucose monitoring products in the first phase of the competitive bidding program. If CMS considers including blood glucose monitoring products in any future phase of competitive bidding, we recommend that CMS first do so on a limited basis in a single competitive bidding area in order to monitor the impact on beneficiary care and ensure certain key operational issues are resolved.

1. Overview of Statutory Authority for Limitation of Products in Competitive Bidding

The Medicare Modernization Act of 2003 ("MMA") authorizes CMS to select products from within three statutory categories of DMEPOS to include in various CBAs. The MMA does not mandate that all products in these categories be included in competitive bidding. To the contrary, the MMA gives the Secretary considerable flexibility in establishing which products will be included in each area. Specifically, the MMA provides that CBAs "may differ for different items and services," recognizing that all products will not be included in bidding. CMS acknowledges this authority in the Proposed Rule, stating that it "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding."[2]

The MMA also expressly excludes certain products from competitive bidding. In the related legislative history, Congress notes that it is excluding from competitive bidding certain products because they "sustain or support life . . . or present potential unreasonable risk . . . ."[3] While this legislative history pertains specifically to Class III devices, it also identifies a Congressional intent to exclude from competitive bidding certain products that raise significant patient safety concerns, and this intent should guide CMS in selecting products for competitive bidding. Abbott demonstrates in detail below that certain Medicare beneficiaries rely on specific blood glucose monitoring products to sustain or support life.

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2 71 Fed. Reg. 25,670.

3 Conference Report to Accompany MMA Report, 108-391 at page 575.

For instance, approximately half of individuals on dialysis have diabetes. They depend on blood glucose monitoring systems that avoid what the Food and Drug Administration ("FDA") characterizes as the "potential for life-threatening falsely elevated glucose readings" in the presence of certain dialysis solutions since it can be life-threatening if the falsely elevated glucose reading is treated with aggressive insulin therapy. As explained by an FDA advisory[4]:

> We recently received a report of a patient who suffered irreversible brain damage following an aggressive insulin treatment that was given for elevated glucose readings. Unfortunately, the elevated glucose readings were incorrect because the glucose monitoring device, which was unable to distinguish between glucose and maltose, was reacting to the maltose in the intravenous immunoglobulin solution that the patient was receiving.

Competitive bidding for these products would present an unreasonable risk of adverse clinical impact. There clearly are unique, patient-critical operational issues associated with blood glucose monitoring products, stemming from the complex therapeutic needs of the Medicare beneficiaries with diabetes and the need to protect access to certain medically-necessary product features, among others. Using Congress' own standards for exclusion, blood glucose monitoring products should be excluded from competitive bidding.

In addition, under section 1847(b)(7), in a section entitled "Consideration in Determining Categories for Bids," Congress recognized the need to take into account clinical issues and the impact on patient care in determining products to be included in bidding. Specifically, the statute provides the following:

> (7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

CMS should exercise this statutory authority to exclude certain blood glucose monitoring products from the initial phase of competitive bidding that have greater therapeutic advantages for individuals. Such products include: those that prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen; those that prevent falsely elevated glucose readings in dialysis patients receiving certain dialysis solutions, those that have multiple body site testing capabilities; and those that require small blood sample size and therefore minimize pain associated with testing. The therapeutic advantages of these products are discussed below.

CMS also has the statutory authority to exclude products from competitive bidding if "the application of competitive acquisition is not likely to result in significant savings." As we discuss below, inclusion of blood glucose monitoring products would not achieve cost savings, since complications associated with inappropriate diabetes care would result in higher overall health care costs for the Medicare program, and thus they can and should be excluded from competitive bidding.

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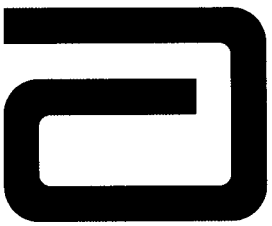
4 http://www.fda.gov/cdrh/oivd/news/glucosefalse.html.



If CMS decides to include any blood glucose monitoring products in Phase I, it should be done on a limited basis (i.e., one initial CBA) to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care of beneficiaries with diabetes.

2. Blood Glucose Monitoring Supplies and Equipment Were Not Tested in Competitive Bidding Demonstrations

CMS should include in the first round of competitive bidding only those products that have been successfully tested in a prior competitive bidding demonstration project to ensure that CMS has adequate information regarding the impact of competitive bidding on patient access, medical outcomes, and beneficiary satisfaction. We note that CMS lists as a factor it will consider when determining whether a product is appropriate for competitive bidding the "Savings in the DMEPOS Demonstrations" associated with that product.[5] We agree with CMS that this is an important factor for consideration in product selection.

CMS did not include blood glucose monitoring systems in the DMEPOS demonstration. We believe that CMS had strong policy and patient care reasons for not including blood glucose monitoring products in the demonstration; those reasons still apply. Equally important, CMS has no experience with the impact inclusion of such products would have on beneficiary care or overall health care spending. While the products that were included in the Polk County and San Antonio demonstrations generated a great deal of data, including information on beneficiary satisfaction, access to products, pricing, and supplier capacity issues, and this information has been subject to evaluation and careful review by CMS, its contractors, and the public, such data is completely lacking for blood glucose monitoring products.

CMS therefore should not include blood glucose monitoring products in the first phase of the competitive bidding program. Instead it would be more prudent for CMS to concentrate on those products that were successfully tested in the previous demonstrations. If CMS decides to include blood glucose monitoring systems in any future phase of competitive bidding, it should first test its impact on a limited scale (i.e., in one CBA).

3. Complexity of Diabetes Patient Care Needs

According to the American Diabetes Association ("ADA"), diabetes is one of the nation's most debilitating, deadly, and costly diseases. There currently are 20.8 million Americans – or 7 percent of the population – with diabetes, and the pace of new cases is increasing. More than 10 million individuals age 60 years or older, or 20.9 percent of all people in this age group, have diabetes. Diabetes is the leading cause of kidney disease, adult-onset blindness, and lower limb amputations and a significant cause of heart disease and stroke. Diabetes contributed to 224,092 deaths in 2002. The mortality rate due to diabetes has increased by 45 percent since 1987 – at the same time the mortality rates due to heart disease, stroke, and cancer have actually declined.[6] Effective management of diabetes – including monitoring and regulating blood glucose levels – is key to preventing numerous serious complications,

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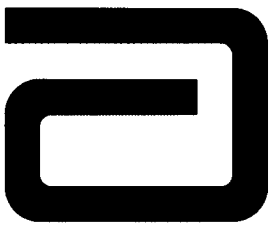
5 71 Fed. Reg. 25,671.

6 American Diabetes Association, available at www.diabetes.org.



including blindness, kidney and nerve damage, diabetic ketoacidosis, hyperosmolar (nonketotic) coma, and even death.[7]

Proper glucose monitoring requires careful selection of the meters and strips that are medically appropriate for the beneficiary's condition, taking into account the patient's comorbidities, interfering substances, and other health factors (such as visual impairments) that could affect the choice of a particular system. There currently are more than 30 blood glucose monitoring systems on the market. As discussed below, among these systems there are a wide range of capabilities and features, including advanced features designed to meet very specific patient health care needs. Blood glucose monitoring systems are not interchangeable, and clinicians need to determine and prescribe the features that best meet that patient's needs, considering comorbidities and other health factors.

For instance, some blood glucose monitoring systems are unsafe for use by individuals on dialysis because they provide falsely elevated glucose readings in patients receiving dialysis solutions containing maltose or galactose, or oral d-xylose. The FDA has warned that there have been serious injuries and even deaths from false glucose readings in these situations that have lead to overly aggressive insulin therapy.[8] In fact, the FDA has posted many safety alerts on this issue, as recently as November 2005. The agency requires the package insert for these types of glucose monitoring systems to include a warning such as "Peritoneal dialysis solutions containing icodextrin cause overestimation of glucose test results" or "Patient receiving peritoneal dialysis using solutions containing icodextrin (e.g., Extraneal®, Icodial) should not use [this product]." Because approximately 50 percent of patients on dialysis have diabetes, it is critical that patients using these dialysis solutions in each CBA have access to blood glucose monitoring systems that minimize or eliminate interference with these solutions, such as monitoring systems that use GDH-NAD or glucose oxidase. Other blood glucose monitoring systems prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen, each of which can distort blood glucose readings for patients with such conditions as arthritis or gout. Beneficiaries in each CBA need to be able to access blood glucose monitoring systems that are unaffected by these common agents.

If CMS includes blood glucose monitoring systems in competitive bidding, it could limit access to blood glucose monitoring equipment with a greater therapeutic advantage to individuals, which would compromise the beneficiary's ability to monitor and control his or her blood glucose levels, increase the risks of serious adverse impacts, and even jeopardize the patient's life. We therefore recommend that CMS exercise its statutory authority to not include blood glucose monitoring systems in competitive bidding.

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7 (ADA, 2005). See also the DCCT Trial and the United Kingdom Prospective Diabetes Study ("UKPDS").

8 See http://www.fda.gov/cber/safety/maltose110405.htm.

4. Interference with Coordinated Care/Chronic Care Demonstration

According to CMS itself, "Fragmentation of care is a serious problem, especially for Medicare beneficiaries," who on average see seven different physicians and have 20 prescriptions each year.[9] The difficulties of coordination of care for individuals with diabetes, and its impact on health care outcomes, also have been documented in a recent series in the *New York Times*. For instance, one recent article pointed out that "a study last year by Georgetown University found that insurance restrictions on strips and other services for diabetics were reducing the quality of care." The same article also quoted an 82-year old individual with diabetes who observed that "Controlling my condition isn't that hard. . . The hard part are the things outside my control, like getting the test strips and the medicines."[10]

The problems associated with fragmentation of care for diabetes patients and the need to carefully manage the diabetes and comorbidities of Medicare beneficiaries is the reason the federal government has included diabetes care in its major chronic care demonstration project. Specifically, the MMA authorized the development and testing of voluntary chronic care improvement programs, now called Medicare Health Support programs, to improve the quality of care and life for people living with multiple chronic illnesses. The programs are designed to help participants adhere to their physicians' plans of care and obtain the medical care they need to reduce their health risks, while providing savings to the Medicare program and beneficiaries. CMS selected beneficiaries with diabetes and/or congestive heart failure for inclusion in the Medicare Health Support program because they "have heavy self-care burdens and high risks of experiencing poor clinical and financial outcomes," and because of the prevalence of comorbidities. CMS notes that evidence indicates that "self-care support, education, and assistance in coordinating care for people with these conditions can be effective in improving clinical outcomes, reducing their healthcare costs, and improving participant and provider satisfaction."[11] The Medicare Health Support programs are operated by organizations that were chosen by CMS through a competitive selection process. CMS has not discussed in the proposed rule how restricting beneficiary choice of suppliers or pharmacists through DMEPOS competitive bidding would impact coordination of care for Medicare beneficiaries with diabetes who are participating in Medicare Health Support programs. Moreover, CMS does not discuss how DMEPOS competitive bidding would affect the pay-for-performance approach established through the Medicare Health Support program, under which fees to organizations are based on meeting standards for quality improvement, savings to Medicare, and increased satisfaction levels in their assigned beneficiary populations – outcomes that could be affected by the restrictions imposed by competitive bidding. Likewise, CMS does not address how competitive bidding could undermine CMS's ability to evaluate the effectiveness of the Medicare Health Support programs for beneficiaries who live in DMEPOS CBAs.

More broadly, CMS should consider the adverse impact of competitive bidding on coordination of care for patients with diabetes, both for beneficiaries enrolled in the Medicare Health

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9 See http://www.cms.hhs.gov/CCIP/02_Highlights.asp.

10 Urbina, Ian; "In the Treatment of Diabetes, Success Often Does Not Pay," New York Times, January 11, 2006.

11 See http://www.cms.hhs.gov/CCIP/downloads/MHSOverview012306.pdf.

Support program and for beneficiaries who coordinate their care through their clinicians, pharmacists, and other caregivers. For instance, Medicare beneficiaries who are enrolled in Medicare Part D may receive their oral medications, insulin, and syringes – along with pharmacist counseling -- through their pharmacy. Including blood glucose monitoring products in competitive bidding could further fragment care for this population.

5. Limited Potential for Cost Savings

According to the ADA, one out of every 10 health care dollars is spent on diabetes and its complications. Direct and indirect spending on diabetes care reached $132 billion in 2002, $40.3 billion of which was spent for inpatient hospital care and $13.8 billion for nursing home care for people with diabetes. Cardiovascular disease accounted for more than $17.6 billion of the direct medical costs for diabetes in 2002. Studies have shown that frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.[12]

Competitive bidding risks jeopardizing beneficiary access to the most appropriate blood glucose meters and strips, which could make it more difficult for beneficiaries to control their diabetes, leading to increased complications and costly hospital care.[13] In fact, in a June 2006 report to Congress, the Medicare Payment Advisory Commission ("MedPAC") points out that "longer term savings could come from improved management of conditions such as diabetes because poor glucose control in diabetics can lead to worse cardiovascular health in the longer term."[14] CMS clearly has the statutory authority to exclude from competitive bidding those products "for which the application of competitive acquisition is not likely to result in significant savings." Given the potential for increased Medicare costs – particularly Part A hospital costs – resulting from complications associated with inappropriate diabetes care, CMS should undertake an assessment of the potential financial impact on the Medicare program related to diabetes complications prior to including such products in competitive bidding.

B. Significant Clinical and Technological Distinctions of Blood Glucose Monitoring Products – Risk of Limiting Access to Medically-Necessary Features [Physician Authorization/ Treating Practitioner; Conditions for Awarding Contracts]

Abbott Recommendation: CMS should preserve access to products with medically-necessary features. If CMS includes blood glucose monitoring products in any future phase of competitive bidding, CMS should exercise its statutory authority to establish separate subcategories within codes for bidding purposes to recognize blood glucose

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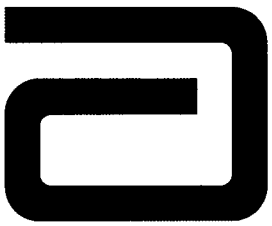
12 *See, e.g.*, Karter et al., "Self-Monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry," 111 Am. J. Med. 1 (2001).

13 Agency for Healthcare Research and Quality, Economic and Health Costs of Diabetes (2005).

14 MedPAC "Report to the Congress: Increasing the Value of Medicare" (June 2006).



monitors and strips with advanced features (e.g., those that prevent interference from such substances such as aspirin, uric acid, vitamin C, and acetaminophen; those that are safe for use by beneficiaries undergoing dialysis; those that have multiple body site testing capabilities, and those that require small blood sample size and therefore minimize pain associated with testing, increasing compliance and improving health outcomes). CMS should either exclude the advanced subcategories from bidding or require suppliers to bid on all subcategories. Moreover, bidding suppliers should only supply blood glucose monitoring systems that offer beneficiaries 24/7 manufacturer support.

There is only one HCPCS code for all blood glucose test strips (A4253 Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and one blood glucose meter HCPCS code (E0607 -- Home blood glucose monitor) that encompasses almost all of the meters currently on the market. These codes have been in place for over 15 years. During this time, meter and strip technologies have changed significantly, and now there are important features that improve accuracy and promote testing compliance. Particular features of products within these codes provide a greater therapeutic advantage to individuals, including preventing potentially life-threatening false readings in the presence of interfering substances.

The MMA provides CMS with the authority to establish separate subcategories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes. Specifically, the statute provides the following:

> CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

In a number of situations, there are blood glucose monitoring systems that provide a clear therapeutic advantage to individuals, such as by preventing false glucose level readings that could lead to ineffective or potentially harmful medical interventions. For instance, some blood glucose monitoring systems are unsafe for use by individuals on dialysis because they provide falsely elevated glucose readings in patients receiving dialysis solutions containing maltose or galactose, or oral d-xylose. There have been serious injuries and even deaths from false glucose readings in these situations that have lead to overly aggressive insulin therapy. In addition, beneficiaries using acetaminophen for arthritis or gout must use blood glucose monitoring systems with low or negligible interference from acetaminophen or they could receive inaccurate glucose level information and subsequently make inappropriate or harmful treatment decisions. Also, it is now well established that patients with diabetes have elevated uric acid levels; many systems using glucose oxidase are severely affected by elevated uric acid levels. Likewise, ascorbic acid (vitamin C) in elevated doses is widely used by many consumers, yet it can interfere with some glucose monitoring systems. Other systems provide therapeutic advantages because they have multiple body site testing capabilities or require smaller blood sample size, thereby minimizing pain associated with testing and enhancing beneficiary compliance with testing regimens.

Beneficiaries and their clinicians must have access to the most clinically-appropriate blood glucose monitoring system for their conditions. Given the proposed bidding structure, there is a real risk that suppliers seeking to submit a competitive bid may choose not to offer advanced equipment and supplies – unless compelled to do so – because of concerns that their bids will

not be low enough to be selected, which would jeopardize their opportunity to serve beneficiaries in the bidding area. Beneficiary access to these therapeutically and clinically necessary features could then be compromised.

Therefore, if blood glucose monitoring products are included in any future stage of competitive bidding, CMS should exercise its authority to protect patients by establishing subcategories within the blood glucose meter and test strip HCPCS codes to recognize these advanced features, and either: (1) exclude the advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Our recommendations for subcategories are presented below. We recommend that CMS establish a public review and comment period regarding any subcategories it develops.

Moreover, in recognition of the unique and critically-important role of manufacturer education and technical support for patients using blood glucose monitoring systems, we recommend that CMS require that suppliers may only submit bids for any category or subcategory of blood glucose monitors or test strips if the products offer 24-hour/7-day-a-week 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. As noted, 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). A single manufacturer can receive between *75,000 and 100,000 calls from patients, caregivers, and health care providers in a single month*. Manufacturers of high-quality blood glucose monitoring systems like Abbott have intensely-trained professionals that provide technical support and professional guidance on how to operate the equipment, including responding to questions and concerns in multiple languages. These staff members are trained to distinguish between user and technical errors, and to assist beneficiaries with their questions and concerns regarding effective management of their diabetes, and often encourage patient follow-up with their health care providers. Not every manufacturer offers these critical services, however. There is a danger that under the competitive bidding framework, there will be an incentive for suppliers to bid on the least expensive products within a code, even if the manufacturers of these products do not provide comprehensive patient support for their products. This would not promote quality of care for Medicare beneficiaries, a key goal of lawmakers in the MMA. Therefore, if CMS includes blood glucose monitoring products in any future phase of competitive bidding, it should specify in its request for bids that that suppliers may only submit bids for blood glucose monitors or test strips if the products offer 24-hour/7-day-a-week manufacturer support. CMS or its contractors should provide suppliers with a list of eligible equipment under this requirement.

Recommendations for Subcategories

We recommend that CMS establish the following subcategories within codes A4253 (Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips), and E0607 (Home Blood Glucose monitor) if these products are included in any future phase of competitive bidding:

HCPCS	Descriptor	Subcategory	Descriptor
A4253	**Blood Glucose Test or Reagent Strips for Home Blood Glucose Monitor, per 50 Strips**	A	Protection Against Interfering Substances
		B	Safe with Commonly-Used Dialysis Solutions
		C	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms
E0607	**Home Blood Glucose Monitor**	A	Protection Against Interfering Substances
		B	Safe with Commonly-Used Dialysis Solutions
		C	Small blood sample size – 1.0 microliter or less
		D	Blood samples accessed from multiple/alternative body sites
		E	Aids for Visual Impairments
		F	Testing Alarms

CMS should either: (1) exclude these advanced systems from competitive bidding, or (2) require suppliers to submit separate bids for each subcategory. Additional information regarding the clinical efficiency, value, and therapeutic advantages of these products follows.

1. Protection Against Interfering Substances

Blood glucose monitoring systems vary in their ability to minimize interference from certain common substances, such as aspirin, acetaminophen used for arthritis or gout treatment, elevated uric acid levels, or ascorbic acid (vitamin C) in elevated doses. Interference effects may result from relatively high voltages applied to the blood glucose test strips, interference from oxygen, or enzyme interactions. For instance, some strips, including the FreeStyle™ Blood Glucose Monitoring Strip, use glucose dehydrogenase -- rather than on glucose oxidase -- as an enzymatic catalyst during its reaction with glucose. Unlike glucose oxidase, oxygen is not involved in the reaction pathway of glucose dehydrogenase, and therefore interference by oxygen – a problem with older technology devices – is substantially reduced.

If test results are distorted by the inability of a blood glucose monitoring system to minimize interference from these common substances, it could lead to inappropriate treatment decisions that could have an adverse impact on beneficiary health. CMS therefore should establish a subcategory of meters and test strips that minimize interference and either exclude this subcategory from competitive bidding, or require suppliers to bid separately on the subcategory.

2. Safe with Commonly-Used Dialysis Solutions

Blood glucose monitoring and safety of patients undergoing dialysis is particularly important because approximately fifty percent of all dialysis patients have diabetes. The FDA has warned, however, that certain blood glucose monitoring systems provide falsely elevated glucose readings in patients receiving certain dialysis solutions. These falsely-elevated glucose readings can be life-threatening if they result in inappropriately aggressive insulin therapy. Serious injuries and deaths from such false glucose readings have occurred.

In November 2005, the FDA issued an alert entitled "Important Safety Information on Interference With Blood Glucose Measurement Following Use of Parenteral Maltose/Parenteral Galactose/Oral Xylose-Containing Products.[15] In light of the "potential for life-threatening falsely elevated glucose readings," the FDA warns that patients who receiving products containing the sugars maltose or sugars which are metabolized to maltose should "[u]se only test methods not affected by the presence of maltose, galactose, or d-xylose, such as glucose dehydrogenase nicotine adenine dinucleotide (GDH-NAD), glucose oxidase- or glucose hexokinase-based test methods."

Beneficiaries undergoing dialysis in every CBA must have available blood glucose monitoring systems that have been determined by the FDA to be safe for use by peritoneal dialysis patients. CMS should either exclude from competitive bidding blood glucose monitoring systems that are safe for use with commonly-used dialysis solutions, or establish a subcategory for these meters and strips and require suppliers to bid separately to supply meters and strips that are safe for this population.

3. Small Blood Sample Size – 1.0 Microliter or Less

Certain strips require a smaller sample size (for example the FreeStyle system requires approximately 0.3 microliter of blood, compared to as much as 4 to 5 microliters in older meters). The smaller volume is obtained by a less invasive blood draw mechanism that lowers pain, which is a major barrier to regular blood testing for people with diabetes. This improved technology encourages regular testing and good glucose monitoring and control. In addition, a smaller blood sample requirement can reduce the need for retests due to the meter registering "insufficient blood." The FDA reports[16] that users whose meters require less blood would have this insufficient blood retest problem less often – avoiding strip wastage. Likewise, some monitoring systems can measure the adequacy of the collected blood sample size, which ensures that the test starts only when enough blood has been collected, which again minimizes errors and retests and decreases costs associated with wasted strips. Beneficiaries in every CBA need access to blood glucose monitoring systems with this feature.

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15 See http://www.fda.gov/cber/safety/maltose110405.htm.

16 FDA, "Glucose Meters & Diabetes Management" (http://www.fda.gov/diabetes/glucose.html).

4. Blood Samples Accessed from Multiple/Alternative Body Sites

Some blood glucose monitoring systems, including the FreeStyle system, can effectively access samples from multiple body sites with fewer nerve endings per square inch than the fingertips. Therefore testing can be done using less painful sites like forearms, upper arms, thighs and calves. The greater flexibility in sites from which blood can be drawn, with lower pain thresholds, promotes patient compliance with testing. Studies have shown that frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.[17]

5. Aids for Visual Impairments

Some blood glucose monitors provide verbal instructions and results for safe and effective testing by individuals with vision impairment. Many users perform glucose tests in dim light condition. A monitor (such as the FreeStyle Flash) that has a backlit display and a test light illuminating the test strip area can help reduce test errors and decrease costs associated with wasted strips.

6. Testing Alarms

Adherence to blood glucose monitoring is a challenge for some patients. Certain monitors (such as the FreeStyle Flash and FreeStyle Freedom) allow the user to program up to four daily alarms to remind them to test. As previously noted, frequent testing and tighter control of blood glucose levels can dramatically reduce the adverse consequences of diabetes.

C. Conditions for Awarding Contracts/Market Demand and Supplier Capacity

Abbott Recommendation: CMS should ensure that beneficiaries have adequate access to retail suppliers. Mail order suppliers should not skew CMS's capacity calculations in a competitive bidding area. CMS should not overestimate the ability of blood glucose monitoring system suppliers to expand capacity. CMS should exclude bids from mail order suppliers in determining the pivotal bid and single payment amounts since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers.

CMS should preserve beneficiary access to retail suppliers and pharmacies. Indeed, blood glucose monitoring products are available at over 50,000 pharmacies nationwide. 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. Competitive bidding should not disrupt this important network for beneficiaries

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17 *See, e.g.*, Karter et al., "Self-Monitoring of Blood Glucose Levels and Glycemic Control: the Northern California Kaiser Permanente Diabetes Registry," 111 Am. J. Med. 1 (2001).

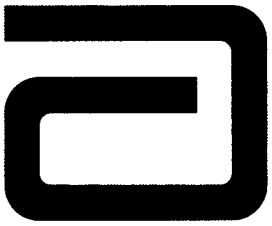
CMS is proposing that beneficiaries have a choice of at least two suppliers in a bidding area. We are concerned that two suppliers for a large CBA could be insufficient to provide beneficiaries with adequate access to a retail pharmacy. Instead, we propose that CMS apply its Part D retail pharmacy access standards to the DMEPOS competitive bidding program. These standards have been an important protection for beneficiaries enrolled in Part D, and offer a tested framework for the competitive bidding program to adopt. Specifically, under the Part D program, drug plans must establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

While a Part D plan's pharmacy network may be supplemented by non-retail pharmacies, including pharmacies offering home delivery via mail-order, these pharmacies do not count towards fulfilling the plan's pharmacy access requirements. We recommend adopting such a model under DMEPOS competitive bidding. Thus, If CMS decides to allow mail order suppliers to bid in DMEPOS competitive bidding, those mail order suppliers should not count towards the two-supplier minimum that CMS is establishing in each CBA.

CMS also should give greater weight to retail suppliers when determining supplier capacity to ensure that the presence of mail order suppliers does not reduce the number of retail suppliers available to a beneficiary. This is particularly important since the draft DMEPOS quality standards state that mail order services may not be used "for the initial delivery, set-up, and beneficiary education/training for certain DME equipment and supplies," and CMS must ensure that beneficiaries have adequate access to retail suppliers who can supply these critical services.

In the preamble to the Proposed Rule, CMS asserts that "most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor." We believe CMS is misinformed regarding the labor required to furnish appropriate blood glucose monitoring supplies, and we are concerned that this could lead CMS to approve fewer diabetes suppliers in a bidding area than is truly necessary to adequately meet beneficiary demand. Under the draft DMEPOS supplier standards, diabetes suppliers must provide extensive beneficiary services, including meeting detailed standards regarding product delivery, set-up, training, equipment usage and cleaning, and troubleshooting. The supplier also is responsible for follow-up services, including continuing communication with the treating physician or clinical team regarding outcomes of monitoring, maintenance, and operation of all equipment provided to the beneficiary; periodically reviewing the service plan with the treating physician or clinicians regarding the beneficiary's medical condition and the continued use and tolerance of the equipment and supplies; and communicating any clinically significant beneficiary concerns, needs, and condition changes that affect the beneficiary's use of equipment and supplies to the treating physician within 24 hours of determination. CMS



should recognize these important diabetes supplier responsibilities and ensure that there is sufficient supplier capacity to meet beneficiary needs.

CMS does not discuss how, if it contracts with mail order suppliers, it would consider mail order bids in determining the pivotal bid and single payment amounts. We believe it is obvious that CMS could not to consider mail order suppliers' bids in the same pool as retail supplier bids, since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers. In fact, mail order suppliers would be prohibited from providing these services under the draft DMEPOS supplier standards. Because mail order suppliers would not be providing the same level of beneficiary service, their bids would reflect lower costs than those of retail suppliers. Any comparison of the two types of bids (retail and mail order) would be particularly unfair to small retail suppliers, and could lead to inappropriate payment policies and capacity determinations. CMS should develop standards for the separate consideration of mail order bids before including mail order suppliers in competitive bidding.

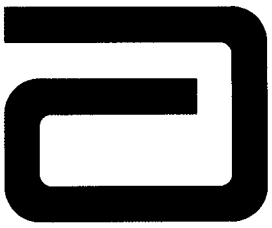
We also want to point out that CMS should consider the impact of its policies on supplier capacity beyond the Medicare population. CMS envisions dramatically fewer suppliers being able to provide services to Medicare patients since there will be relatively few winning bidders. Suppliers that are not successful bidders may no longer have the demand to support their ability to continue furnishing supplies in the competitive bidding area to Medicaid and private paying patients. This could reduce the availability of critical health care services to vulnerable patient populations, particularly individuals with diabetes.

D. Competitive Bidding Areas/Nationwide or Regional Mail Order Competitive Bidding

Abbott Recommendation: We support the voluntary, rather than mandatory, use of mail order suppliers.

Many beneficiaries with diabetes obtain their medical supplies and insulin through one of the 50,000 pharmacies that supply blood glucose monitoring products. Access to pharmacies is important for beneficiaries in managing their total diabetes care needs, including treatment for the comorbidities that so often accompany diabetes. Mandating the use of mail order suppliers for blood glucose monitoring supplies would prevent beneficiaries with diabetes from using one source to coordinate the pharmaceuticals, medical supplies, and equipment necessary to manage their complex medical conditions. Moreover, pharmacies and other retail suppliers can play an important role in continuing beneficiary education, training, and troubleshooting regarding their blood glucose monitoring equipment, a role that would be jeopardized by mandating mail-order replacement of supplies. Mail order suppliers would not be able to provide timely care if a beneficiary needs emergency refills. We therefore do not believe that "furnishing replacement test strips, lancets or other supplies can easily, effectively, and conveniently be performed by national mail order suppliers," as CMS stated in the preamble, and we urge CMS to reject this proposal.

If CMS decides to allow mail order suppliers to participate in competitive bidding, we recommend that it be voluntary for beneficiaries – just as CMS has provided under the Part D prescription drug benefit. Moreover, CMS should ensure that all appropriate DMEPOS quality



standards are met, including that the mail order suppliers furnish products and supplies that are consistent with the clinician's order, meet the product specifications as prescribed by the clinician, and that qualified staff are available to respond to beneficiary concerns and needs.

II. Comments Related to Enteral Nutrition Equipment and Supplies

A. Legal and Policy Rationale for Exclusion of Enteral Products [Criteria for Item Selection]

Abbott Recommendation: CMS should exercise the authority granted by Congress to select only those products for competitive bidding that will achieve Congressional goals of cost control and continued availability of high quality DMEPOS for Medicare beneficiaries. Moreover, CMS should include in the first phase of competitive bidding only those products that have been successfully tested in prior competitive bidding demonstrations. Because enteral products were found in Phase I of the Polk County demonstration to be "not as well-suited for competitive bidding" as other types of DMEPOS tested, and because inclusion of these products could compromise quality of care for beneficiaries who rely on enteral nutrition, CMS should not include enteral nutrition products in the first phase of the competitive bidding program.

1. Overview of Statutory Authority for Limitation of Products in Competitive Bidding

As previously noted, the MMA authorizes CMS to select products from within three statutory categories of DMEPOS to include in various CBAs. The MMA does not mandate that all products in these categories be included in competitive bidding. Instead, the MMA gives the Secretary considerable flexibility in establishing which products will be included in each area. Specifically, the MMA provides that competitive bidding areas "may differ for different items and services," recognizing that all products will not be included in bidding. CMS notes this authority in the Proposed Rule, stating that it "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding."[18]

The MMA also expressly excludes certain products from competitive bidding. In the related legislative history, Congress notes that it is excluding from competitive bidding certain products because they "sustain or support life . . . or present potential unreasonable risk . . . ."[19] While this legislative history pertains specifically to Class III devices, it also identifies a Congressional intent to exclude from competitive bidding certain products that raise significant patient safety concerns, and this intent should guide CMS in selecting products for competitive bidding. Abbott demonstrates in detail below that certain Medicare beneficiaries rely on enteral products to sustain or support life because they are the beneficiary's sole source of nutrition. If a patient does not have access to specific enteral products, it could compromise the patient's health, accelerate the disease process, and in serious cases lead to medical complications that could endanger the patient's life (i.e., aspiration resulting from incorrect feeding, inappropriate nutritional provided for a particular disease state). Competitive bidding for these products would present an unreasonable risk of adverse clinical impact. Using Congress' own standards for exclusion, enteral products should be excluded from competitive bidding.

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18 71 Fed. Reg. 25,670.

19 Conference Report to Accompany MMA Report, 108-391 at page 575.

Moreover, there apparently was confusion among the Congressional authors of the MMA's competitive bidding provision regarding the status of enteral products under competitive bidding. As CMS is aware, unlike most products in DMEPOS categories (e.g., orthotics, wheelchairs, hospital beds, etc.), enteral nutrition is covered as a prosthetic – a medical product that replaces all or part of a malfunctioning internal body organ.[20] A House Ways and Means Committee press release issued at the time of MMA passage states that the competitive bidding statute: "Exempts all prosthetics and implantable (Class III) devices" (emphasis added).[21] Lawmakers were mindful of the special safeguards needed to protect beneficiaries that rely on prosthetic devices that sustain and support life, and they concluded that the competitive bidding framework was inappropriate for these critical products. Thus, it is appropriate and consistent with Congressional intent for CMS not to include enteral products in competitive bidding.

In addition, under section 1847(b)(7), in a section entitled "Consideration in Determining Categories for Bids," Congress recognized the need to take into account clinical issues and the impact on patient care in determining products to be included in bidding. Specifically, the statute provides the following:

> (7) CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

As discussed below, certain enteral nutritionals have a greater therapeutic advantage to individuals with certain medical conditions. For instance, some specialized medical nutritional products are specially formulated to meet the unique nutritional and therapeutic needs of patients with chronic disease states, such as cancer, HIV/AIDS, kidney disease, pulmonary disease, Crohn's disease, and diabetes, and it would threaten a beneficiary's health and life if they did not have reasonable access to a supplier that could furnish their particular life-sustaining nutritional. Other enteral nutritionals are designed for patients with pressure ulcers, multiple fractures, wounds, burns, or surgery who have depressed immune mechanisms and rely on these products for wound healing and immune support. CMS should recognize the unique clinical nature of these products and their important role in comprehensive chronic disease care plans by excluding them from competitive bidding.

The MMA also provides statutory authority to phase in competitive bidding based on "items and services that the Secretary determines have the largest savings potential," and to

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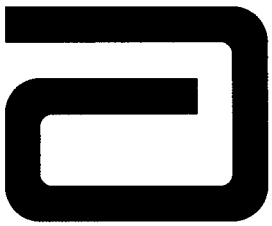
20 Medicare National Coverage Determinations Manual (CMS Pub. 100-03), §180.2 - Enteral and Parenteral Nutritional Therapy, "Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof."

21 Ways and Means Committee, "Medicare Prescription Drug, Improvement, and Modernization Act of 2003 -- Medicare DME Freeze And Competitive Bidding Saves Beneficiaries and Taxpayers Money," available at http://waysandmeans.house.gov/media/pdf/healthdocs/dmesummary.pdf.



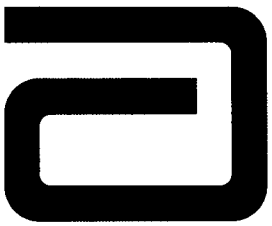
completely exclude products from competitive bidding if "the application of competitive acquisition is not likely to result in significant savings." Inclusion of enteral products would not achieve cost savings, since complications associated with inappropriate enteral care could result in higher overall health care costs for the Medicare program.
Research consistently shows that malnutrition – a state of inadequate or unbalanced nutrition – is a hidden cause of poor health outcomes and rising health care costs in the United States. There are also many studies that confirm the benefits of nutrition intervention including decreased morbidity and mortality, improved quality of life, and decreased length of stays and care costs. American Dietetic Association studies show that for every $1.00 spent on nutrition intervention, at least $3.25 is saved. Continuous monitoring and assessment of a patient's nutrition status is essential in the prevention of major complications like anemia, bone fusion failure, wound and joint infection, pressure ulcers, septicemia, pulmonary embolus, pneumonia, and others that add significant health care costs to the system. Competitive bidding risks jeopardizing beneficiary access to the most appropriate enteral nutrition products and services, which could interrupt care plans resulting in increased hospital admissions and increased home nursing services (covered under Medicare Part A). In addition, the prevalence of Medicare enteral use among nursing home patients and the strong case for excluding nursing homes from competitive bidding (detailed below) diminishes the potential for cost savings by including enteral products from competitive bidding, as the final DMEPOS demonstration project evaluation report concluded.

2. Complexity of Patient Care Needs

The proposed competitive bidding structure – which could result in dramatically fewer suppliers, diminished patient choice of suppliers, and decreased access to a range of medically-necessary items and services -- could have a particularly significant and negative impact on clinically-intensive patients who rely on enteral nutrition.

Unlike most products in DMEPOS categories (e.g., orthotics, wheelchairs, hospital beds, etc.), enteral nutrition is covered as a prosthetic – a medical product that replaces all or part of a malfunctioning internal body organ. Enteral nutrition is necessary for the Medicare beneficiary to survive. Thus, enteral products have both a distinct statutory Medicare benefit category and a unique clinical role as a beneficiary's sole source of nutrition.

Enteral nutrition is the delivery of necessary calories, nutrients, and other therapeutic ingredients through a tube placed into the gastrointestinal ("GI") tract (either directly into the stomach or through the small intestine), bypassing the mouth. Enteral nutrition is used by patients who have a disease or non-function of the structures that normally permit food to reach the small bowel, or a disease which impairs digestion and absorption of an oral diet. It is essential for patients who cannot swallow and/or digest and absorb adequate nutrition from traditional nutrient sources and for patients who are at risk of malnutrition. These patients include those patients with cancer, HIV/AIDS, stroke, multiple sclerosis, cerebral palsy, Parkinson's Disease, Amyotrophic Lateral Sclerosis, diabetes mellitus, liver failure, chronic renal failure, inflammatory bowel disease, among many others. Tube feeding is vital to sustain these patient's lives and to address their special medical needs. This is most often the individual's only form of nutrition, and choosing the specific enteral nutrition intervention strategy and integrating it with medical, surgical, and pharmacologic care is crucial to the overall health status of a beneficiary.

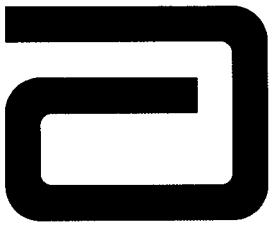


As recognized in the draft DMEPOS quality standards, beneficiaries using enteral products are subject to a wide range of complications from tube feeding, including constipation and nausea/vomiting, persistent or progressive abdominal pain, cramping, bloating, fullness or burning with feedings, infections, and leakage around the tube. Moreover, patients using enteral feeding often have comorbidities that complicate patient care, such as pressure sores, pneumonia, anemia, and infections. Serious metabolic complications like hypertonic or isotonic dehydration or overhydration can occur if the fluid and electrolyte status of a tube-fed patient is not monitored closely and correctly. Mechanical problems also are often associated with some aspect of the feeding tube itself: tube size, material, or location of the GI tract. For example, aspiration pneumonia, a potentially lethal mechanical complication, may occur from compromise of the lower esophageal sphincter by a large-caliber feeding tube or from dislodgment or misplacement of the feeding tube. Thus, the complex clinical nature of enteral nutrition is different than other conventional DME, orthotics, and commodity supplies.

When a beneficiary is placed on enteral nutrition, the clinician must determine the most appropriate site and access route for feeding based on patient-specific factors such as the physiology of the GI tract, risk of pulmonary aspiration of gastric contents (entry of gastric contents into the lungs during breathing), comorbidities, and the length of time enteral support will likely be needed. The clinician then must assess which products, including formula and in some cases nutrients, pumps, and tubes, are most effective for the individual patient's situation. Each patient has individualized nutrition needs, and there are several formula characteristics the clinician needs to consider, including complexity of nutrients (some formulas contain nutrients in their complex forms, while others have nutrients that are in a simpler form (predigested) for patients who have absorption problems), osmolality, caloric density (calorically dense formulas can be used for patients with fluid restrictions, fluid intolerance, or high energy requirements), micronutrient content (electrolytes, vitamins, minerals and trace elements), fiber, lactose, viscosity, and water content.

As discussed in greater detail below, there is a range of enteral products available within the same HCPCS code, but many of those products are designed for distinct patient needs and are not interchangeable. If a patient does not have access to specific enteral products, it could compromise the patient's health, and in serious cases could lead to a progressive decline in their condition and ultimately endanger the patient's life. Yet under the Proposed Rule, a supplier would only need to furnish one product within a HCPCS code. As a result, products designed for specific diseases could simply be unavailable through contract suppliers in a particular area, creating a gap in the availability of life-sustaining products. Before competitive bidding could be applied to enteral products, CMS would need to establish a mechanism to ensure that each product necessary for a patient's disease state, physiology, or other medical condition is available to the beneficiary in every locality.

A distribution system based on a competitive bidding methodology and low bid incentives also does not adequately recognize the intense supplier services required by the fragile patient population using enteral equipment. Compared to the provision of other DMEPOS products, enteral suppliers are responsible for detailed caregiver and beneficiary education, including steps to resolve common feeding problems, assembly, use, storage and maintenance of all equipment and supplies, cleaning the gastrostomy/jejunostomy site, setting up and cleaning equipment, and recognition and appropriate response to various types of complications, proper tube positioning; formula storage and safety; and problems associated with tube feedings. Because enteral formulas are rich media for promoting microbial growth, all enteral



feeding systems require meticulous care. Enteral nutrition patients often require other DMEPOS items and services associated with the patient's underlying medical condition and comorbidities; restricting access to suppliers based on the lowest cost would fragment patient care and could have a negative impact on medical outcomes.

Given that these products sustain and support life and have an extensive service component, we are concerned that competitive bidding could result in inadequate pricing for products. This would present an unreasonable risk that patients would not have access to needed enteral products and quality care. CMS therefore should use its statutory authority to exclude enteral products from competitive bidding.

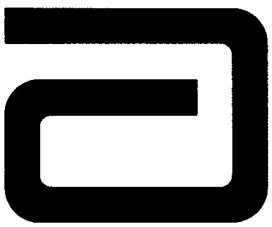
If CMS nevertheless does not exclude all enteral products from competitive bidding, CMS should: (1) limit inclusion initially to a single CBA to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care of beneficiaries using enteral nutrition products; (2) limit competitive bidding to enteral products in the home care setting (rather than in a SNF); (3) exclude specialized nutrients designed for disease-specific and patient-specific needs from competitive bidding; (4) ensure that product are included within certain HCPCS codes to reflect the clinical efficiency and value of certain features; and (5) and address certain other operational issues, as discussed below.

3. Enteral Products were Shown to be "Not Well Suited" for Competitive Bidding in Prior Demonstration

When Congress enacted the MMA, it appears lawmakers believed that the competitive bidding demonstrations were a complete success. For instance, according to the House Ways and Means Committee, "Competitive Bidding Demonstration Was Successful," and under the first round of contracts, "Access to quality equipment was maintained" and "beneficiary satisfaction remained high." Likewise, CMS states in the preamble to the proposed rule that "The competitive bidding demonstrations . . . were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program and offered beneficiaries sufficient access and a quality product."

However, these assessments fail to distinguish the results for enteral nutritional products from the other tested products. CMS included enteral nutrition products in phase one of the Polk County demonstration. The Final Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS prepared by the Center for Health Systems Research and Analysis and RTI International concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested. Moreover, under the first round of the competitive bidding demonstration, beneficiary satisfaction ratings for enteral nutrition and surgical dressings decreased the most, and unadjusted impacts were "fairly large and negative" for these products, according to the evaluation report. Indeed, because of the high volume of use of enteral products in the nursing home setting, rather than the home setting where other DMEPOS items are predominantly delivered, CMS did not include enteral products in subsequent rounds of competitive bidding demonstrations in order to concentrate on DME in non-institutional settings.

CMS states that one of the factors it will consider when determining whether a product is appropriate for competitive bidding is whether it has been successfully tested in a competitive bidding demonstration. In light of the negative evaluation enterals products received in the



Polk County demonstration, CMS should not include enteral products in competitive bidding unless the agency successfully tests it in a limited area (i.e., one CBA) and sufficient operational safeguards are in place to promote beneficiary satisfaction and ensure quality of care.

B. Limitation on Scope of Enteral Products [Criteria for Item Selection, Submission of Bids under the Competitive Bidding Program, & Physician Authorization/Treating Practitioner]

Abbott Recommendation: If CMS considers including enteral nutrition products in any phase of competitive bidding, we recommend that CMS:

(1) Do so only on a limited basis in a single competitive bidding area in order to monitor the impact and potential adverse impacts on beneficiary health, and only after adequate quality standards and other operational safeguards are in place;

(2) Add as a criteria for item selection those products used primarily in the home care setting (i.e., not in a skilled nursing facility setting), just as CMS adopted in two of the three rounds of the competitive bidding demonstration project;

(3) Exclude from competitive bidding those specially-formulated enteral nutritional products (B4153, B4154, and B4155) that are designed for beneficiaries with a particular medical condition, since there is a serious medical risk from inappropriate substitutions of formulas in this category; and

(4) Exercise its statutory authority to require suppliers to guarantee access to enteral products with specific medically-necessary features.

1. Single Competitive Bidding Area

If CMS includes enteral products in any phase of competitive bidding, there are unique, patient-critical operational issues that must be addressed, stemming from the complex therapeutic needs of the Medicare beneficiaries who rely on these products, the significant use of enteral product in the skilled nursing facility setting; the need to preserve access to specialized nutritional formulas; the patient-specific nature of selecting the appropriate specialized enteral nutrients, and the need to protect beneficiary access to certain enteral equipment and supplies with medically-necessary product features. Because enteral nutrition was not successfully tested in a previous demonstration, CMS needs to ensure that it develops a framework that adequately addresses the problems encountered in the demonstration and preserves access to specialized formulas and equipment. Thus if CMS decides to include enteral products in any phase of competitive bidding, it should do so first in a single competitive bidding area to ensure that CMS adequately addresses these operational issues in a way that protects the quality of care and safety of beneficiaries using enteral nutrition products.

2. Limit Competitive Bidding to Home Care Setting: Unique SNF Site-of-Care and Patient Severity of Illness Issues

As we discuss in greater detail below, unlike most other items of DME that may be subject to competitive bidding, enteral nutrition can be covered under Part B in the SNF setting in addition to the home care setting. Indeed, approximately 60 percent of Medicare enteral nutrition patients reside in SNFs.

CMS is proposing to require SNFs to participate in competitive bidding or contract with a winning supplier in order to furnish DMEPOS to their residents. However, competitive bidding has not been successfully tested in the nursing home setting, and the pilot failed to show significant savings. Moreover, the clinical needs of patients using enteral products in SNFs, the CMS quality standards, and the mechanism of distribution of products in the SNF are quite distinct from the home care setting. We therefore recommend that CMS not include SNFs initially in competitive bidding, and the agency should carefully consider the following issues before expanding competitive bidding to include SNFs.

a. Level of Care in a SNF Different than for Home Care Patients

Medicare patients in the SNF setting are often medically-complex with multiple comorbidities, particularly compared to beneficiaries in the home setting. Their need to be in a SNF is based on multiple clinical conditions and diagnoses, physical limitations, and need for assistance with activities of daily living. Beneficiaries receiving enteral nutrition rely heavily on the healthcare services that accompany the delivery of the enteral nutrition. In fact, the need for enteral nutrition is a qualifier for the "Clinically Complex" category under Medicare Part A prospective payment system rates. The services needed by SNF patients are considerably different than patients in the home care setting, and their treatment plans must be carefully managed and coordinated by their SNF. That is why the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") publishes separate Standards for Tube Feeding for different sites of care, including the home care setting and the SNF setting. Including enteral products for patients in the SNF setting could seriously interfere with established and functioning care plans, which could result in medical complications that increase overall costs of care to the Medicare program

b. CMS Has Not Successfully Tested Including Products Furnished to Institutional Patients in Competitive Acquisition

Although CMS included enteral products in the first round of the Polk County competitive bidding demonstration, beneficiaries living in SNFs could receive these products from nondemonstration suppliers that accepted the demonstration fee schedule. CMS did not include enteral products in subsequent rounds of competitive bidding demonstrations in order to concentrate on DME in non-institutional settings. The Final Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS prepared by the Center for Health Systems Research and Analysis and RTI International concluded that enteral nutrition "is not as well-suited for competitive bidding" as other products tested. Moreover, under the first round of the competitive bidding demonstration, beneficiary satisfaction ratings for enteral nutrition and surgical dressings decreased the most, and unadjusted impacts were "fairly large and negative" for these products, according to the evaluation report. We are concerned that in the

Proposed Rule, CMS characterizes the demonstrations as successful without noting that the negative evaluation of the inclusion of enteral products.

Under the Proposed Rule, CMS is proposing a different framework for including SNFs in competitive bidding than was tested in Polk County. SNFs would be mandated to use a winning supplier. This specific mechanism has not been tested before, so CMS has no data on its impact on beneficiary care. Before CMS considers extending competitive bidding to enteral products furnished in the institutional setting, the concept should be successfully tested in a more limited environment.

c. Competitive Bidding Could Jeopardize SNF Control over Beneficiary Care

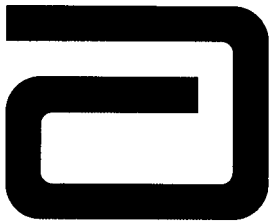
Due to the level of services SNFs provide, they operate with higher fixed costs than home medical equipment companies, which could compromise their ability to submit competitive bids to maintain care of their residents. If a SNF is not a winning bidder, it could force the SNF to contract with a third-party for services they handle themselves today, creating inefficiencies in nursing home care. In addition, SNFs would be restricted in contracting with the most appropriate suppliers to help manage the patient's total care needs, including DMEPOS, drugs, and medical and ancillary services – even though the SNF is ultimately responsible for the quality of care furnished to the resident. Including SNFs in competitive bidding also could complicate continuity of medical care for patients, especially if a patient must change suppliers when they move from Part A to Part B coverage. It also could disrupt current SNF contracts with third-party suppliers, since SNFs often contract with one supplier for all medical supply products for all patients. If a SNF's exclusive supplier is not a successful bidder, the entire contractual arrangement for all necessary supplies could be jeopardized. This could create inefficiencies and increase administrative burdens – contrary to the goals of competitive bidding.

d. The Draft DMEPOS Supplier Quality Standards Do Not Fully Apply to Institutional Settings

The draft DMEPOS supplier quality standards recognize the different service requirement expected for suppliers of enteral nutrition, equipment, and supplies depending on whether the supplier is furnishing products in the home setting, in an institutional setting, or under a home health agency ("HHA") plan of care. In fact, the draft standards exempt from the extensive enteral-specific quality standards those suppliers furnishing enterals in a SNF setting or to HHA patients. Specifically, the draft standards provide that:

> If the beneficiary does not receive home health services or does not reside in a SNF, the supplier shall provide qualified staff trained in enteral nutrition to implement beneficiary education, clinical monitoring, and follow-up.

Thus, SNF suppliers are not subject to the full range of quality standards. Yet, under the MMA, Congress mandates that any supplier participating in competitive acquisition must comply with the Medicare supplier quality standards – not just subsets of the standards. Specifically, Section 1847(b)(2) provides that:



(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1834(a)(20).

Likewise, in the explanation of the conference report, the conferees emphatically state that "the Secretary cannot award contracts in an area until the following conditions were met: (1) entities meet quality standards established by the Secretary. . . ." Because CMS does not apply the full range of supplier quality standards to enteral products furnished in the SNF setting, CMS likewise should not – and indeed is not authorized under the MMA – to apply competitive acquisition to enteral products furnished in the SNF setting.

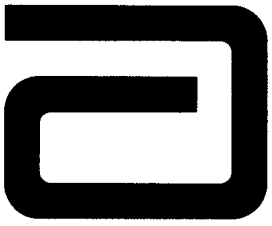
e. Different Service, Business Structures, and Operations Requirements in SNFs Versus Home Setting Could Compromise Bids

Under the Proposed Rule, enteral suppliers could be subject to one of three different sets of quality standards: (1) the draft DMEPOS general and enteral product-specific supplier standards (including a requirement that the supplier provide qualified staff trained in enteral nutrition for beneficiary education, clinical monitoring, and follow-up) would apply to home care suppliers; (2) the draft DMEPOS general supplier standards – but not the enteral product-specific supplier standards -- would apply to suppliers serving SNF patients under arrangement with the facility; and (3) the current stringent SNF conditions of participation would apply to SNFs that bid to provide enterals to their own patients. If enteral products furnished to SNF patients are included in competitive bidding but are subject to very different quality requirements, bidders would have widely different service-related costs. It is unclear how suppliers would be able to submit realistic bids under the competitive acquisition program, since supplier's mix of services provided to beneficiaries in institutional settings versus the home care setting could be difficult to forecast. Indeed, this situation could have the unintended effect of jeopardizing access to enterals for home care patients, since suppliers might be encouraged to seek out patients that are not subject to the extensive servicing requirements for home enteral products established under the Medicare supplier quality standards – even though the nursing home patients have higher overall acuity levels. A uniform payment rate may be inappropriate in this situation. CMS needs to develop a way to determine equitable bidding and payment policies before including SNFs in competitive bidding.

3. Specialized Enteral Nutrients (B4153, B4154, and B4155) are Inappropriate for Competitive Bidding Framework and Should Be Excluded

Although we believe that CMS should not include any enteral nutritional products in the first round of competitive bidding, it is critical for CMS to exclude specialized nutrient products from competitive bidding (HCPCS codes B4153, B4154, and B4155).

While nutritionally-complete standard medical nutritionals are appropriate for some patients, other patients have medical conditions that require the use of specialized medical nutritional products. Products in these categories are specially formulated to meet the unique nutritional and therapeutic needs of patients with chronic disease states, such as cancer, HIV/AIDS,



pressure ulcers, kidney disease, pulmonary disease, Crohn's disease, diabetes, and severe burns. Only three HCPCS codes encompass this wide and diverse array of nutrients. Products within these categories are clearly not interchangeable. Feeding an inappropriate product within this category to a patient can lead to a cascade of dangerous medical complications that worsen a patient's condition, accelerate the disease process, and in some cases result in death. It would threaten a beneficiary's health and life if they did not have reasonable access to a supplier that could furnish their particular life-sustaining nutritional.

Under the proposed competitive bidding framework, a supplier would only need to furnish one product within a HCPCS code. This would not work for codes B4153, B4154, and B4155, since suppliers could choose to offer a single product in each code that helps beneficiaries with one disease state, but is useless or even dangerous for other beneficiaries that depend on other nutritional in these categories. There could even be a situation where no contract suppliers bid to supply a particular nutritional that is critical for a beneficiary's health and life.

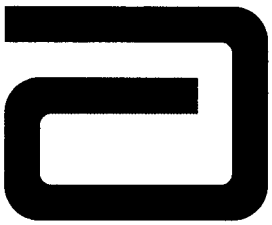
The unique patient benefits provided by the products in codes B4153, B4154, and B4155 are detailed below:

B4153 (Enteral Formula, Nutritionally Complete, Hydrolyzed Proteins (Amino Acids and Peptide Chain), Includes Fats, Carbohydrates, Vitamins and Minerals, May Include Fiber, Administered Through an Enteral Feeding Tube, 100 Calories = 1 Unit)

Hydrolyzed protein elemental formulas are nutritionally complete formulations that are made for patients with vastly different acute and chronic conditions, ranging from tolerance issues like malabsorption and maldigestion, to metabolically-stressed patients that are immunosuppressed and have elevated energy and protein needs. Some products in this category contain simpler nutrients, peptides, and free amino acids that use the dual protein absorption system of the gut for patients with chronically impaired gastrointestinal function. Many patients rely on these products as their sole source of nutrition, and they are the only thing the patients can digest. Other products in this category are designed for patients with pressure ulcers, multiple fractures, wounds, burns, or surgery who have depressed immune mechanisms and rely on these products for wound healing and immune support. Without these products, which not only contain the partially-hydrolyzed, peptide-based protein for easier absorption but are also calorically dense and high in protein, these patients would not be able to heal.

B4154 (Enteral Formula, Nutritionally Complete, For Special Metabolic Needs, Excludes Inherited Disease Of Metabolism, Includes Altered Composition of Proteins, Fats, Carbohydrates, Vitamins and/or Minerals, May Include Fiber, Administered Through an Enteral Feeding Tube, 100 Calories = 1 Unit)

The nutritionally-complete products in this category are as different as the metabolic conditions for which they are used. These products have customized caloric distribution formulated specially to meet the needs of patients with conditions such as kidney disease and chronic kidney failure; metabolic stress resultant from acute injury, surgery or chronic disease; pulmonary disease; diabetes; HIV/AIDS; and cancer. Products in this



category are not interchangeable; in fact, substituting different products within these codes designed for different diseases could be detrimental to the patient and the condition being treated. Lack of access to any of these products can compromise the health of a patient and will impact quality of care. For instance, feeding a patient with a chronic respiratory condition (i.e., COPD) a product that is designed for someone with kidney disease who is not yet being treated with dialysis would provide a protein level that is too low as well as a carbohydrate level that is too high, causing excess carbon dioxide. Due to their lack of lung function and inability to fully respirate, this could result in toxic levels of carbon dioxide in the blood stream, leading to hospitalization. On the other hand, another product in this category specially designed for pulmonary patients would provide such patients with the clinically-appropriate levels of carbohydrates to ensure controlled carbon dioxide production and concentrated calories and protein in order to maintain low volumes of fluid consumed, a major concern for the respiratory patient. Likewise there are products in this category that are specifically designed for individuals with kidney disease being managed without dialysis. Feeding a product designed for people with diabetes to this patient would provide excessive protein and an inappropriate renal solute load that might compromise their already-impaired renal function.

B4155 (Enteral Formula, Nutritionally Incomplete/Modular Nutrients, Includes Specific Nutrients, Carbohydrates (e.g., Glucose Polymers), Proteins/Amino Acids (e.g., Glutamine, Arginine), Fat (e.g., Medium Chain Triglycerides) or Combination, Administered Through an Enteral Feeding Tube, 100 calories = 1 unit)

Products within this category are nutritionally incomplete but contain specific nutrients that address very different patient needs. For instance, one product is designed to provide an easily-digested source of carbohydrate calories for patients with increased caloric needs that cannot be consumed in food but who are on a fat-restricted diet. Another product is a therapeutic nutritional that contains a patented blend of arginine, glutamine and HMB (beta-hydroxy-beta methylbutyrate) clinically proven to help build lean body mass, enhance immune response, and promote collagen synthesis in patients with advanced stages of pressure ulcers. This product also has been shown to replenish weight in the form of lean body mass or functional tissue, not fat mass, and supports immune function in patients with HIV/AIDS.

Because of the specialized nature of these products, Medicare currently requires the patient's medical record to adequately document the specific condition and the need for the specially formulated nutritional. Products in these categories represent those that are developed according to the most current nutritional recommendations, and they contain specialized formulations of ingredients as well as patented ingredients in some products. Excluding these product categories from competitive bidding would ensure beneficiary access to the appropriate specialized products.

In addition to the strong clinical reasons for excluding specialized nutritionals from competitive bidding, CMS also has authority to exclude these products under its statutory authority to exclude products that would not result in significant savings. Current Medicare spending on

products in these categories represent only 2% of total enteral nutrition spending in home setting and only 7% in all settings. (Based on 2004 CMS BESS Procedure Data). In view of the highly diversified needs of patients using these products, we do not expect competitive bidding to result in significant savings for this class of products. Since enteral nutrition sustains and supports life, and unreasonable risks could result from disruption in access, this class of products meets Congressional standards for exclusion and thus should be excluded from bidding.

If CMS nevertheless decides to include codes B4153, B4154, and B4155 at any stage of competitive bidding, CMS would need to ensure that beneficiaries in every CBA had access to products within each code that are appropriate for their distinct medical conditions or therapeutic needs. Because each product within these three codes is uniquely formulated and appropriate use is dependent on varying combinations of patient-specific factors, the development of subcategories within these codes is a complex task. We recommend that CMS work with clinical specialists to develop any such requirements and that there be an opportunity for public comment.

4. Significant Clinical and Technological Distinctions of Enteral Products – The Need to Protect Access to Medically-Necessary Features

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 as well as packaging to enhance safety, and particular features may be critical to a patient's medical care. Given the proposed bidding structure, there is a real risk that suppliers seeking to submit a competitive bid may choose not to offer enteral products with such advanced, medically-necessary features unless compelled to do so. Moreover, they may choose to substitute items and base their bids on other devices and supplies not designed for enteral feeding due to concerns that their bid will not be low enough to be selected and they will lose their opportunity to serve Medicare beneficiaries in the bidding area.

The MMA provides CMS with the authority to recognize during the bidding process those products within codes that have enhanced clinical efficiency and value. Specifically, the statute provides the following:

> CONSIDERATION IN DETERMINING CATEGORIES FOR BIDS.—The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

If enteral products are included in competitive bidding, CMS should exercise this authority to require that suppliers guarantee access to enteral products with certain important features that promote patient safety, as detailed below. Such features should be specified in the bidding instructions, and suppliers should indicate on the bid sheets the exact products they would supply with these features. Moreover, CMS should ensure during its bid review process that any bids for enteral products include only products designed specifically for enteral feeding, since we are aware of some suppliers substituting lower-cost products (such as urinary catheters used as feeding tubes or enema bags used as feeding sets) that are not specifically designed for enteral tube feedings and that can lead to allergic reactions, corrosion of tubing, and adverse patient outcomes.

The following is a discussion of the specific product features that should be available in every CBA.

a. HCPCS Code B4150 (General Purpose Formulas) & B4152 (Calorically Dense Formulas) – Access to Both Can and Pre-Mixed Packaging

Nutritional products within the HCPCS codes B4150 and B4152 are available either in premixed bottles (also called "ready to hang" or "ready to use") or in cans. Ready to hang products require no handling or pouring of the product. This delivery system is important for product safety (rather than just for beneficiary convenience). Product in cans must be decanted into a feeding set or alternate container, which significantly increases the chances of contamination. Contamination refers to the introduction of bacteria into the product, which increases the risk of spoilage and can cause symptoms of food poisoning (e.g., vomiting and diarrhea), or may introduce infection. These problems may lead to dehydration or sepsis, severely compromising an already debilitated patient. A Hazard Analysis Critical Control Point ("HACCP") analysis concludes that ready-to-use products that do not expose enterals to the air during assembly have lower contamination rates than open systems. HACCP's "Guidelines for preventing healthcare-associated infections during enteral feeding in primary and community care" therefore recommend that "Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution," and the "system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube."[22] Beneficiaries, their clinicians, and caregivers need access to ready to hang products as appropriate; in fact, some clinical care protocols require the use of such products. Accordingly, CMS should ensure beneficiary access to ready to hang product by requiring suppliers to guarantee access to and availability of ready to hang products within the B4150 and B4152 HCPCS codes.

To ensure patient access to ready to hang packaging, CMS should require suppliers to specify on the bidding sheet that they will supply both can and ready to hang packaging for products in codes B4150 and B4152, and provide such products to the beneficiary in the packaging specified by the patient's health care professional.

b. HCPCS Code B9002 (Enteral Feeding Pump w/Alarm) – Access to Pumps with Automatic Flush Feature, that are Ambulatory, have Anti-Free Flow Feature, and Lock-Out Option

CMS should require that suppliers guarantee access and availability of enteral pumps with essential features to meet their specific medical needs. The features include:

22 Final Guideline: Prevention of healthcare-associated infections in primary and community care, June 2003.

(1) Automatic Flush. This feature is necessary for patients who need small bore feeding tubes such as jejunostomy tubes and are prone to tube clogging (i.e., patients who use multiple medicines and patients who need to have residuals checked frequently).

(2) Ambulatory. This feature is necessary to allow patients who are not bed ridden to move around with their pump (i.e., get up to use the bathroom).

(3) Anti-free flow. This safety feature prevents inadvertent free flow of product that could result in overfeeding and other inadvertent adverse events.

(4) Lock-out option. This safety feature prevents tampering with pump settings to prevent overfeeding or underfeeding. This feature is necessary for patients with mental disabilities such as Alzheimer and patients with small children in the home.

CMS should specify in the bidding instructions that enteral suppliers must furnish a range of product options within HCPCS code B9002 that include an automatic flush feature, are ambulatory, have an anti-free flow feature, and a lock-out option, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features.

c. HCPCS Code B4086 (Gastrostomy/jejunostomy tube, any material, any type, standard or low profile) – Access to Safety Features, Designed for Enteral Use

Feeding tubes vary widely in terms of their dimensions, composition, ability to prevent clogging or contamination, among other important features. Beneficiaries need access to the tubing selected by their provider to be safe and medically-appropriate. CMS should ensure through the bidding process that any supplier bidding on enteral tubing agree to furnish tubing with the following features:

(1) Polyurethane and silicone. Tubes may be constructed of various materials, ranging from polyvinyl chloride ("PVC") and latex to polyurethane and silicone tubes. PVC and latex tubes are cheaper than polyurethane and silicone tubes, but they can stiffen and erode from contact with digestive juices, are associated with allergic reactions, and often are not designed specifically for enteral feeding (i.e., some suppliers substitute with foley catheters designed for bladder drainage) Polyurethane and silicone tubes, while more expensive, are the most biocompatible and appropriate for patient care

(2) Radiopaque material. This is necessary to help ensure proper placement of a tube into the stomach or small intestine and x-ray confirmation of tube placement.

(3) Weighted tips. This is necessary to lessen the risk of improper placement and backward migration of the tube, to which some patients may be prone.

(4) Eyelet design, flow-thru tips. This feature is necessary to reduce tube clogging that can result in a premature need for tube replacement.

(5) Y-port/Interlocking connectors. This is necessary to provide an additional port used for flushing the tube and for administering medications without the need to disconnect the feeding set and tube. This helps minimize the risk of touch contamination, which is essential to quality patient care and safety. Another important part of the Y-port connector is the cap that interlocks with the O-ring on the feeding set. An interlocking feature minimizes leakage and potential for inadvertent or accidental separation, which could result in a patient not getting fed appropriately.

(6) Skin disk or external retention hub at the surface of the skin. This is necessary to maintain tube position, decreasing the chance of tube migration inward and minimizing leakage of gastric contents around the tube.

(7) Internal bumper. This is a necessary feature that secures the tube up against the gastric wall to minimize unwanted changes in position and leakage of gastric contents.

CMS should specify in the bidding instructions that enteral suppliers must furnish products within HCPCS code B4086 that are composed of polyurethane and silicone; include radiopaque material; and/or have the following features: weighted tips; include eyelet design/flow-thru tips; Y-port/interlocking connectors; skin disk or external retention hub; and internal bumper. Suppliers must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. Moreover, CMS should review the items specified on the bid sheet to ensure that they are designed and manufactured specifically for enteral feeding.

d. HCPCS Code B4081 (Nasogastric tube with stylet) & B4082 (Nasogastric tube without stylet) – Access to Polyurethane Tubes, With or Without Stylet

CMS should require that suppliers guarantee access and availability of nasogastric tubes with specific features to ensure beneficiaries have access to tubes that will meet their specific medical needs. Such features within HCPCS code B4081 and B4082 include:

(1) Polyurethane tubes. Soft, flexible material necessary for both patient comfort and to decrease tube-related complications when placing a tube through the nasal passage for enteral feeding. Tubes made of any other substance (i.e., PVC) become brittle with repeated use, resulting in unnecessary discomfort and tube-related complications for the patient.

(2) Nasoenteric tube with stylet. This is necessary for placement of a soft and flexible small bore tube. The stylet provides the temporary stiffening of the tube during this invasive placement procedure.

CMS should specify in the bidding instructions that enteral suppliers must furnish nasogastric tubes (B4081 and B4082) comprised of polyurethane, and they must provide such products to the beneficiary as specified by the patient's health care professional. Suppliers should indicate on the bid sheets the exact products they would supply with these features. CMS should review the items specified on the bid sheet to ensure that they are designed and manufactured specifically for enteral feeding. Likewise, CMS should require suppliers to furnish nasogastric tubes with or without stylets as specified by the patient's health care professional.

e. HCPCS Code B4035 (Pump Supply Kit), B4034 (Syringe Supply Kit) and B4036, (Gravity Supply Kit) -- Access to Appropriate Feeding Supply Kits

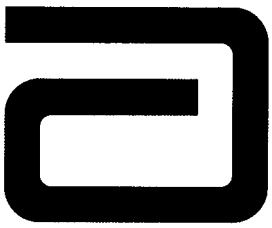
Manufacturers specifically design enteral feeding supply kits (pump, syringe and gravity) to connect to feeding pumps (HCPCS code B9002) and feeding tubes (HCPCS codes B4086, B4081 and B4082) as an integrated system for enteral nutrition delivery. These designs include special interlocking connectors that eliminate the need to tape connectors and decrease the likelihood of inadvertent or accidental separation from the feeding set, which can result in underfeeding and increased risk of leakage and contamination. Manufacturers research and test the use of these integrated systems to ensure both patient safety as well as ease of use, which is particularly important for patients and caregivers in the home setting.

CMS should specify in its bidding instructions that suppliers must use supply kits that are manufacturer-researched and tested to be appropriate for use in an integrated enteral feeding system. Moreover, if a supplier begins servicing a beneficiary that already owns or rents an enteral feeding pump, the supplier must provide the beneficiary with the appropriate supply kit for the beneficiary's specific equipment.

C. Conditions for Awarding Contracts/Market Demand and Supplier Capacity

Abbott Recommendation: CMS should protect beneficiary safety and choice by implementing, at a minimum, the Medicare Part D proximity measures when determining capacity needs for CBAs.

Section 1847(b)(4)(A) provides that in determining the number of suppliers necessary for a CBA, the Secretary shall:



> . . . take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

We are concerned that CMS's proposal to provide as few as two suppliers in a CBA would be insufficient to meet this statutory requirement and to protect beneficiaries who rely on enteral nutrients. Enteral nutrients are the sole source of a beneficiary's nutrients and they play a life-sustaining role in a beneficiary's health care regimen. Since enteral nutrients are the food supply for these beneficiaries, they simply cannot wait for days to receive service from a restricted number of winning suppliers. These beneficiaries also need to 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.

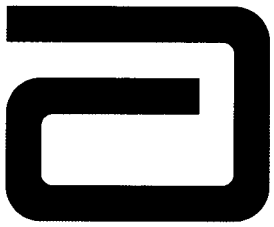
Likewise, the delivery of enteral nutrition involves intense supplier services for and consistent routine monitoring of patients using enteral equipment, as discussed above. Beneficiaries using enteral products are subject to a wide range of serious and even life-threatening complications from tube feeding. The complex clinical nature of enteral nutrition is different than other conventional DME, orthotics, and commodity supplies, and suppliers need to be in close proximity to their patients to immediately address complications.

In addition, CMS should respect the close nature of the relationship between the beneficiary and the supplier, and ensure beneficiaries have a choice in which supplier will enter their home to delivery enteral nutrition products. It is critical that these patients feel comfortable with the supplier that will enter their home and stand bedside to educate them on steps to resolve common feeding problems, use, storage, and maintenance of all equipment and supplies; including cleaning the gastrostomy/jejunostomy site and recognition and appropriate response to various types of complications.

Due to the critical nature of enteral nutrition and the need to have suppliers in close proximity to their patients, we recommend that CMS implement as a minimum standard the Medicare Part D proximity measures when selecting suppliers for a CBA. As noted above, the Medicare Part D proximity standards require drug plans to establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;
- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and
- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

Application of the Medicare Part D proximity standards to home care suppliers under the DMEPOS competitive bidding program would help ensure suppliers are close enough in proximity to their patients to service their enteral nutrition needs without an unreasonable travel delay. As in the Part D program where only retail suppliers count toward meeting this



proximity standard, under Part B only home medical equipment suppliers should count towards this minimum number. Likewise, if CMS decides to allow mail order suppliers to bid, those mail order suppliers should not count towards the minimum number of suppliers that CMS is establishing in each CBA, since the draft DMEPOS quality standards limits the services mail order suppliers may provide to beneficiaries.

It is also important for CMS to consider the impact of its policies on supplier capacity beyond the Medicare population. CMS envisions dramatically fewer suppliers being able to provide services to Medicare patients since there will be relatively few winning bidders. Suppliers that are not successful Medicare bidders may no longer have the demand to support their ability to continue furnishing supplies in the competitive bidding area to Medicaid and private paying patients. This could reduce the availability of critical health care services to vulnerable patient populations, particularly patients requiring enteral nutrition. In addition, suppliers that provide enteral products usually have a larger portion of non-Medicare patient populations (i.e., pediatric patients). If there is insufficient DME supplier interest in bidding to supply enteral items for the Medicare population, it could have a negative impact on non-Medicare beneficiary access to critical enteral nutritional items and services.

D. Bidding Requirements/Enteral Nutrition Equipment and Supplies

Abbott Recommendation: If enteral products are included in competitive bidding, CMS should establish separate single payment amounts for enteral nutrients and enteral supplies. CMS should not reduce rental payments for enteral equipment in months 4 through 15.

1. Single Payment Amounts

In the discussion of enteral nutrition equipment and supplies, CMS states that "Based on the bids submitted and accepted for new items, we would calculate a single payment amount for purchase of enteral nutrients and supplies." This language could be read to indicate CMS is contemplating a bundled payment for both nutrients and supplies, although the proposed regulatory text appears to indicate that CMS would establish a single payment amount for purchase of enteral nutrients and a separate single payment amount for supplies. We seek to confirm that if enteral products are included in competitive bidding, CMS intends to establish separate single payment amounts for each enteral nutrient and supply HCPCS code – rather than a bundled payment amount for enteral nutrients and related supplies.

2. Reduction in Rental Payments

We also are concerned about CMS's proposal to reduce rental payments for enteral equipment in months 4 – 15 from 10 percent of the purchase amount (as is the case under current Medicare fee-for-service rules) to 7.5 percent of the single payment. Due to the service-intensive nature of providing enteral nutrition and the possible increased costs that new quality standards requirements will impose on suppliers, reducing the rental payment formula in addition to reducing payment through the bidding process could further impede suppliers' ability to provide high-quality products and services to Medicare beneficiaries.

E. Grandfathering of Suppliers [Payment Basis]

Abbott Recommendation: If CMS includes enteral equipment in competitive bidding, CMS should include enteral equipment in the grandfathering process.

We support CMS's proposal to allow grandfathered suppliers to continue to furnish rental items under existing rental agreements and to allow accessories and supplies used in conjunction with grandfathered rental DME to be furnished by grandfathered supplier. However, it appears under the technical regulatory language that the provision would not apply to rented *enteral* feeding pumps. It appears that the omission of enteral pumps from the grandfathering provision is an oversight since enteral pumps technically fall under the orthotics and prosthetics benefit category, rather than the DME category. Moreover, CMS provides in the CMS Medicare Claims Processing Manual that "Payment policies for these pumps generally follow the rules for capped rental items."[23] Thus it would be consistent for CMS to apply the grandfathering process to enteral feeding pumps just as it does to capped rental DME items.

Beneficiaries using enteral equipment should have the benefit of this provision, particularly because of the importance of continuity of care for these clinically-complex patients and their intensive service needs. We therefore respectfully request that CMS specifically apply the grandfathering provision to suppliers of enteral nutritionals, equipment, and supplies in the final rule.

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23 Medicare Claims Processing Manual, Chapter 20, section 30.7.1.

III. Other Competitive Bidding/Payment Reform Comments

A. Physician Authorization/Treating Practitioner

Abbott Recommendation: We support CMS's proposed requirement that suppliers fill prescriptions with the brand or mode of delivery specified by the physician or prescribing clinician.

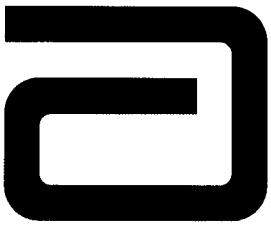
CMS proposes to allow a physician or treating practitioner to prescribe a particular brand of an item or mode of delivery of an item if he or she determines that it would avoid an adverse medical outcome for the beneficiary, and the supplier would be required to furnish the specified brand or mode of delivery. We strongly support this provision. As we have previously noted, blood glucose monitoring products and enteral products within a particular code are not interchangeable. In many cases, substitution of enteral nutrition or blood glucose monitoring products other than those specifically prescribed by the physician could lead to adverse medical outcomes. We therefore agree with CMS that physicians and practitioners need to be able to prescribe the most clinically-appropriate product for their patients, and that to prevent interference with the practice of medicine, suppliers should be prohibited from switching products without written physician authorization.

B. Conditions for Awarding Contracts/Quality Standards & Accreditation

Abbott Recommendation: We recommend that CMS establish final supplier quality standards and ensure that suppliers are accredited before implementing bidding in any region.

Quality standards are key to protecting beneficiaries in CBAs, particularly for beneficiaries with diabetes and those that rely on enteral nutrition because of the often complex clinical management of the beneficiaries' medical conditions and the critical need for ongoing beneficiary support. Quality standards are the main safeguard against suppliers submitting unreasonably low bids and then providing inferior items and/or poor beneficiary service. However, to date CMS has released only a draft contractor report on the quality standards.

CMS staff have indicated that the agency received more than 5000 comments on the draft standards, and that substantial revisions would be made in the final version. We are concerned that CMS has not provided sufficient detail regarding the proposed supplier quality standards to allow informed public comment, as is required under the Administrative Procedure Act. CMS's notice must describe the range of alternatives being considered with reasonable specificity; otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decision-making. See Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 549 (D.C. Cir 1983) (holding that the EPA did not give adequate notice that it might issue a strict interim lead-content limit for leaded gasoline produced by certain small refiners and this procedural error was reversible error). CMS therefore should keep open the comment period on the Proposed Rule until after the final quality standards are issued and the public has sufficient time to review those standards and their interaction with the competitive bidding framework.



Moreover, in light of the importance of the quality standards to the whole competitive bidding program, we recommend that CMS issue the revised quality standards in proposed form and allow another comment opportunity on the quality standards. Suppliers also will need time to develop systems and train personnel to comply with these standards and to become accredited. Given the delay in releasing final quality standards, it will be difficult for suppliers to come into compliance in time for competitive bidding to be implemented in 2007. CMS should not implement competitive bidding until appropriate quality standards are in place and a sufficient number of suppliers are accredited to provide adequate services to meet beneficiary demand.

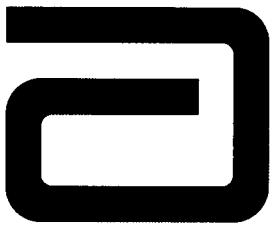
C. Conditions for Awarding Contracts/Determining the Pivotal Bid, & Determining Single Payment Amounts for Individual Items

Abbott Recommendation: We recommend that CMS establish payment amounts in the first phase of competitive bidding after excluding outlier bids, and test alternatives to the use of the median price (e.g., mean and weighted mean). CMS should exclude the bids of limited service DMEPOS suppliers (e.g., SNFs and physicians) and mail order suppliers when establishing pivotal bids and single payment amounts. CMS should only include bids of suppliers that have been accredited. CMS should establish safeguards to prevent suppliers from skewing pivotal bids and single payment amounts by bidding unrealistically low prices and then dropping out of the program.

1. Pivotal Bid and Payment Methodologies

It is critical that CMS establish a bid selection process that is equitable and that will result in payment amounts that are sustainable and compatible with access to quality care for Medicare beneficiaries. We are concerned that under the Proposed Rule, bid prices could be distorted by extremely low bids for a particular product (there is little incentive to bid very high prices since it is unlikely such a bidder would be selected as a contract supplier). CMS would achieve pricing that is more reflective of the marketplace if it did not include in its calculation of pivotal bids or single payment amounts outlier bids based on two standard deviations of all bids submitted. Likewise, CMS should weight bids by supplier capacity to prevent suppliers that expect to offer few items from having as much weight as major suppliers in an area and possibly distorting payment amounts.

Moreover, by using a median of winning bids to set the single payment amount, CMS is proposing an untested methodology under which half of "winning" bidders would actually be paid less than the amount they bid. It is doubtful that half of the winning suppliers will be willing or able to accept payment amounts below their bid price, particularly since there is such a strong incentive under the bidding framework to bid as low as possible to have the best chance of continuing to serve Medicare beneficiaries. This could have a dramatic impact on the number of suppliers that actually decide to participate in the program once the single payment amounts are announced, and subsequently could adversely impact convenient beneficiary access to suppliers. It also appears that setting payment rates at a fairly arbitrary level does not comport with the free-market dynamics that Congress envisioned when establishing competitive bidding. We therefore recommend that CMS use the first phase of competitive bidding to test alternative payment methodologies, such as using the mean or a



weighted mean, in various CBAs. This would provide important information to CMS on which to build when the program is expanded in 2009.

2. Inclusion of Limited Service, Mail Order, or Unaccredited Bidders

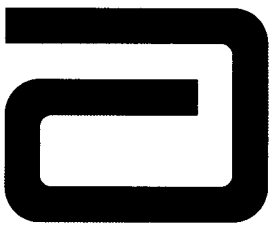
There also is a danger that the pivotal bids and single payment amounts could be distorted by the inclusion of bidders providing a restricted set of services, by bidders who are not accredited, or by "low-ball" bidders who can simply leave the program if not satisfied with the ultimate reimbursement rates. This in turn could deny legitimate suppliers the ability to participate in the program, render it difficult to establish sufficient supplier capacity, and ultimately diminish the availability of DMEPOS items and services for beneficiaries.

CMS contemplates including all bids submitted by all suppliers when determining the pivotal bid. CMS then would consider all supplier bids that are at or below the pivotal bid when determining the single payment amount for an item. However, CMS is proposing separate requirements for some bidding suppliers that would impact their cost of doing business and could distort bidding amounts.

For instance, CMS proposes that physicians who are also DMEPOS suppliers would not be required to furnish DMEPOS items to beneficiaries in competitive bidding areas who are not their patients if they choose not to function as commercial suppliers. Likewise, CMS states that a SNF would not be required to furnish competitively bid items to beneficiaries outside of the SNF if it elects not to furnish as a commercial supplier. On the other hand, non-physician and non-SNF suppliers must agree to furnish competitively bid items to all beneficiaries who maintain a permanent residence or who visit the competitive bidding area and request those items from the contract supplier. Because commercial suppliers would not be permitted to select or restrict their customers, as a SNF or physician could, they would have very different costs of doing business. Moreover, SNFs would not be responsible for complying with the full set of DMEPOS quality standards, as previously discussed, which again would widen the differences in their costs compared to commercial suppliers. SNF and physician bid prices thus should not be directly compared to the bids of retail suppliers. The most equitable policy would be to exclude SNF and physician bids from consideration when determining the pivotal bid and the single payment amount.

Similarly, as noted previously, CMS should not to consider mail order suppliers' bids in the same pool as retail supplier bids, since mail order suppliers would not be subject to the same initial delivery, set-up, and beneficiary education/training requirements as other suppliers. Indeed, mail order suppliers would be prohibited from providing these services under the draft DMEPOS supplier standards. Because CMS is imposing narrower service-related costs on mail order suppliers, it would be unreasonable and unfair to include their bids in the determination of pivotal amounts or single payment amounts. Including mail order suppliers – with their reduced responsibilities and therefore reduced costs -- in the same bidding pool as retail suppliers also would distort the median bids and make it more likely that small retail suppliers would have to accept a single payment amount that is below the amount that they bid.

In addition, compliance with quality standards – promoted through supplier accreditation – is a significant factor in determining bid amounts. The costs associated with such compliance are unknown since CMS has not yet released final quality standards. CMS states that it will not award a contract to an entity unless the entity meets applicable quality standards, but CMS



may grant a grace period for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. If a supplier does not then successfully attain accreditation, CMS would suspend or terminate the supplier contract. CMS also states that it would ensure that suppliers meet quality and financial standards prior to arraying the bids for determination of the pivotal bid. However, CMS is silent on whether suppliers benefiting from a grace period would be included in the pivotal bid determination or single payment amounts. Because such suppliers have not demonstrated their compliance with supplier quality standards, and because they ultimately may not be accredited or participate in the bidding program, CMS should not consider their bids when setting the pivotal bid or single payment amounts.

Moreover, the proposed rule is silent on whether each individual retail location of a chain supplier will be allowed to submit a bid for the same product category in a particular CBA if each location has its own supplier number. We are concerned that allowing one parent company to essentially bid multiple times – either at the same or different bid prices -- would distort the bidding process by overly weighting one company's bids and result in skewed payment amounts. Moreover, due to the parent company's contracting arrangements, it could potentially limit the range of items available to beneficiaries and clinicians within a particular HCPCS code. CMS therefore should clarify in the final rule that even if a corporate entity has multiple supplier numbers, it may submit only one bid for a product category in a CBA.

3. Impact of Winning Bidders Dropping Out of Program

Finally, we are concerned that suppliers may bid prices below which they actually can afford to supply covered items in the hopes of being a winning bidder and in the expectation that prices will be brought up by other, higher bidders. If the single price ends up insufficient for such suppliers, they may simply leave the program. Yet the unrealistic, unsustainable prices they submitted would continue to have an impact on other suppliers through the artificially low payments for the three years of the contract. Such unrealistically low prices could make it difficult to attract new suppliers to fill the capacity resulting from the low-ball bidder leaving the program. Under the Proposed Rule, there is little drawback to a supplier adopting such a low-ball strategy, despite the impact it has on payment levels, capacity calculations, and beneficiary service. CMS should consider more effective ways to prevent such manipulation of the system.

We also recommend that CMS monitor reductions in the number of suppliers for a particular item, which could indicate an unrealistic and unsupportable payment amount (notwithstanding CMS's plans to try to recruit more suppliers to replace those that leave the program). If reductions in supplier capacity reaches a certain threshold, such as a 10 percent difference in the original winning suppliers, CMS should rebid the products rather than continue to attempt to find suppliers willing to accept a price that clearly does not reflect what the market as a whole can support.

D. Payment Basis: Authority to Adjust Payments in Other Areas

Abbott Recommendation: We recommend that CMS not extend pricing developed in competitive bidding to any other areas until a complete impact analysis can be performed and mandated reports have been submitted. After such analysis has been completed, CMS should issue a proposed rule which would offer the public an

opportunity to comment on standards for any extension of pricing from competitive bidding in other areas.

CMS proposes to exercise its authority to use payment information determined under competitive bidding to adjust fee schedule payments for items that are not in CBAs. However, the agency has not yet announced a detailed methodology for such a process.

Given that the scope of this provision would extend far beyond the limited number of competitive bidding areas, CMS should establish this policy through a separate rulemaking that spells out the criteria for making fee schedule adjustments. We recommend that CMS adopt as a minimum standard the procedural safeguards included in the final inherent reasonableness rule,[24] which provides among other things that:

- Payments may not be reduced by more than 15 percent in a given year (except in extraordinary situations and after additional procedural safeguards are observed);
- CMS must publish in the Federal Register proposed and final notices announcing the new payment limits prior to adoption;
- If the dollar impact of an adjustment exceeds $100 million in any one year, CMS must publish in the Federal Register an impact statement, including an analysis of the effect of quality of care, access issues, and the financial viability of suppliers in the marketplace;
- If CMS makes adjustments that have a significant effect on a substantial number of small entities, it must publish an analysis in compliance with the Regulatory Flexibility Act;
- In no case may the effective date of an adjustment be sooner than 60 days after publication of the final notice; and
- CMS must ensure the use of valid and reliable data.

Moreover, we recommend that CMS not apply competitive bidding prices in other areas until the results of the first phase of competitive bidding are fully assessed. Specifically, CMS should not extend competitive bidding prices beyond CBAs until: (1) the Government Accountability Office ("GAO") issues its report on the impact of competitive acquisition on DME on patients, suppliers, and manufacturers of medical equipment, and (2) the Secretary submits its report to Congress on program savings, access to and quality of items and services, and beneficiary satisfaction. It would be imprudent to extend the reach of competitive bidding prices without the benefit of the Congressionally-mandated analyses, which will assess how competitive acquisition affects beneficiary access to DMEPOS along with product quality and services related to DMEPOS.

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24 67 Fed. Reg. 76,684 (December 13, 2002).

E. Other Competitive Bidding Issues

1. Education and Outreach

We commend CMS for proposing extensive supplier and beneficiary outreach and education initiatives as part of the competitive bidding program. Such efforts will be an important component in ensuring the smooth implementation of the new distribution and payment structure. We also urge CMS to include physicians and other clinicians in these outreach and education efforts, given their important role in prescribing the most appropriate products for their patients.

2. Monitoring and Complaint Services for the Competitive Bidding Program

We support CMS's plans to establish a formal complaint monitoring system to address complaints in each CBA. We believe that the information collected will be particularly helpful to CMS as it prepares to expand competitive bidding to additional areas in subsequent phases of the program.

We recommend that CMS include in its complaint monitoring system the collection of brand-specific information on medical complications related to competitively-bid equipment, especially for blood glucose monitoring products and enteral products if they are included in competitive bidding because of the potential for complications with these items. Moreover, CMS should collect data on suppliers that do not successfully furnish particular brands of equipment specified by practitioners. We recommend that CMS release timely reports on the results of its complaint monitoring system to inform public dialogue and analysis regarding the competitive bidding program and to ensure adequate data is available to guide development of subsequent phases of the program.

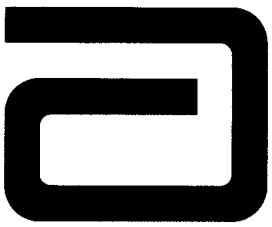
3. Miscellaneous Codes

CMS does not discuss how it would consider miscellaneous equipment and supply codes in competitive bidding. Because miscellaneous codes can encompass a wide range of products at a wide range of prices, and because suppliers would not be able to predict which brands of miscellaneous products they would need to supply during a three-year bidding cycle, we recommend that CMS exclude miscellaneous codes from competitive bidding.

F. Gap Filling Payment Methodology

Abbott Recommendation: CMS should issue a separate rulemaking to clarify and refine the gap fill pricing methodology, and should not adopt "functional technology assessments" as currently proposed. The new rulemaking should set forth the possible criteria, evidentiary standards, and procedural safeguards CMS proposes to use in performing functional technology assessments.

CMS is proposing significant revisions to its pricing policy for DMEPOS fee schedule amounts. Instead of a "gap fill" process that has been used since 1989, CMS is proposing to base payment for new items in part on a new "functional technology assessment" process, which takes into account one or more of the following factors: (1) functional assessment; (2) price

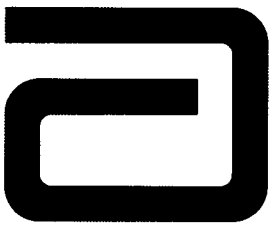


comparison analysis; and/or (3) medical benefit assessment. CMS also is proposing to use the new technology assessment process to adjust prices already established using the gap-filling methodology. Further, CMS indicates that these analyses also will be used in the HCPCS coding process and potentially the Medicare coverage process.

We are concerned about CMS raising this major pricing reform (and potentially coding and coverage policy changes) in the context of the DMEPOS competitive bidding rule, since the scope of this proposed policy goes far beyond the statutory competitive bidding authority. Gap-filling is an important and complex process with an impact on thousands of medical products, and it deserves appropriate attention apart from the competitive bidding rule. Given the impact the proposed pricing policy would have on new and established technologies and the significant changes already planned in 2007 as a result of competitive bidding, CMS should not adopt any changes in the gap filling methodology until at least 2008.

If CMS decides to pursue this policy, a separate, detailed proposed rule should be issued with an opportunity for public comment. CMS would need to provide much greater specificity than it has in the context of the proposed competitive bidding rule, since CMS has failed to define key concepts and left important questions unanswered, such as:

- What CMS means by "significantly improved clinical outcomes";
- What clinical data CMS would review;
- How the agency would determine what products are "similar" for price comparison purposes;
- What timelines of data would be utilized in such analyses;
- How CMS would define and determine "effectiveness";
- What procedural safeguards CMS would employ in making functional assessment determinations, such as how the agency would notify manufacturers and beneficiaries regarding pending decisions and what opportunities would be made available for submitting evidence and comments;
- What procedural and evidentiary standards *carriers* would be required to follow in making such functional assessments;
- What the relationship would be regarding the functional assessment process and CMS's current coverage process, as it appears the proposed policy would duplicate a number of functions of the CMS coverage group;
- How the process would interact with the current HCPCS coding process, including the potential impact on transparency of coding decisions (e.g., public meetings and notification of pending decisions); and
- How CMS would ensure that its new policies would not further extend the timelines for coding, coverage, and reimbursement decisions.



Moreover, if CMS considers changes to the gap-filling policy in the future, CMS should ensure, through Open Door Forums and other means, that suppliers, clinicians, the medical technology community, and beneficiaries are fully consulted on potentially dramatic changes in Medicare coverage, coding, and reimbursement policies.

We recommend that CMS proceed cautiously in this area, given its potentially significant impact on coding, coverage, and payment policy, and ultimately is effect on beneficiary access to innovative medical technologies.

G. Regulatory Impact Analysis

We are concerned that CMS may underestimate the impact on of the Proposed Rule on beneficiary access to their choice of supplier. While CMS acknowledges that "competitive bidding may result in some beneficiaries needing to switch from their current supplier if their current supplier is not selected for competitive bidding," CMS states that it expects this need for switching to be "minimal." We believe this severely underestimates the impact of the reduced choice of supplier. CMS expects only half of bidding suppliers to be selected, which undoubtedly will result in restricted beneficiary choice of suppliers. Moreover, only limited types of DMEPOS are eligible for the grandfathering provision. We believe CMS should reassess its estimates on beneficiary access and ensure that the final rule promotes the widest beneficiary choice of suppliers.

We also seek to ensure that CMS provide realistic estimates of the administrative costs associated with the competitive bidding program, since it will be essential to determine the extent to which administrative costs offset the savings to the program resulting from reduced Medicare reimbursement rates. CMS expects bidding-related costs to suppliers to reach over $36 million in just the first round of bidding, and that CMS and its contractors will have approximately $1 million in immediate fixed costs for startup and system changes. CMS also will incur maintenance costs and bid solicitation and evaluation costs, but the agency does not quantify those costs because those costs "will ultimately depend on number of suppliers that chose to submit bids." We believe that CMS should provide more constructive information on these expected costs.

Moreover, we believe that any evaluation or estimates of Medicare program savings should include an analysis of offsetting increases in hospital and other Part A costs associated with adverse clinical outcomes related to competitive bidding. Specifically, CMS should compare Part A 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. Such findings should be made publicly available.

Likewise, 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.

* * * *

In conclusion, we believe that enteral and diabetes products are poor candidates for the first round of the competitive bidding program, as detailed above, and should qualify for exclusion. If, however, CMS seeks to subject enteral and diabetes products to competitive bidding in any later phases, then we urge CMS to adopt the protections and qualifications as described in our comments above.

We appreciate your commitment to developing the competitive bidding program in a way that protects beneficiaries and promotes efficiency in the Medicare program. We trust that our comments provide constructive information for CMS to consider in adopting the final competitive bidding rule. Given the importance of this issue to beneficiaries with diabetes and those that rely on enteral equipment, we would appreciate the opportunity to meet with your staff to discuss the impact on these two specific patient groups and the special operational issues that would need to be adopted to safeguard their medical care. I will be in touch with your office to arrange a meeting. In the meantime, please feel free to call on me if you would have any questions.

Sincerely,

Virginia Tobiason

Virginia Tobiason
Senior Director
Corporate Reimbursement

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100 Years of Leadership
1905–2005

Tara A. Cortes, RN, PhD
President and CEO

June 30, 2006

Mark McClellan, MD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att: CMS-1270-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8013

Re: Low Vision Aid Exclusion

Dear Dr. McClellan,

On behalf of millions of Americans who are visually impaired, Lighthouse International is requesting reconsideration of the Centers for Medicare and Medicaid (CMS) proposed rule to exclude coverage for low vision aids/assistive technology devices that that are critical to maintaining independence for people with impaired vision, particularly older adults.

Lighthouse International was founded over 100 years ago, and is a leading low vision/vision rehabilitation resource for people who are at risk for, or experiencing, uncorrectable vision loss due to age-related eye diseases such as macular degeneration, diabetic retinopathy, glaucoma and cataracts.

There are 16.5 million Americans age 45+ who self-report vision impairment. This number is rising dramatically with our aging population, and is expected to balloon to 20 million by 2010. The incidence of self-reported vision impairment, which is among the most disabling conditions for older adults, rises dramatically with age, from approximately 1 in 6 age 45+ to 1 in 4 age 75+. In addition to the millions of aging baby boomers who will be facing vision impairment in record numbers, Americans over 85 comprise the largest growing segment of our population, making vision impairment and its disabling consequences one of the leading public health concerns of our day.

Low vision aids are prescribed by low vision doctors as part of the comprehensive vision rehabilitation process designed to restore functioning for people who are visually impaired. Low vision care is a treatment modality and devices are part of the complete continuum of care. Ranging from strong reading lenses and magnifiers to electronic magnification systems (closed-circuit television systems known as CCTVs) and other low vision technologies, these

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are critically important tools that enable people who are visually impaired to read, write, cook, and remain safe and independent. For example, without a low vision device, people with impaired vision would not be able to read medication labels, which would have untold disastrous consequences. These aids are essential to ensuring function, health and quality of life for older Americans living with impaired vision and, oftentimes, an increasing number of co-morbid conditions.

The cost of some low vision devices is prohibitive, especially for older Americans on fixed incomes. Without CMS coverage, an alarming number of people will be at risk for medical complications, accidents and injuries, further straining our overtapped healthcare system. It is striking to note that today, vision impairment is one of the four leading causes of loss of independence among older adults; lost independence due to all causes costs the US over $26 billion in medical and long-term care each year.

We can not stress strongly enough the need to distinguish between routine eyeglasses that correct refractive errors, which are not covered, and low vision devices that do not correct refractive errors, but enlarge or redirect images for people with uncorrectable vision loss, as part of a comprehensive vision rehabilitation program. This issue has been delineated so effectively by the American Academy of Ophthalmology: "These devices do not correct the visual acuity through the correction of refractive errors; they are prosthetics that replace part of the function of a non-functioning organ."

Lighthouse International joins the Academy and other leading organizations like the American Foundation for the Blind in urging that CMS reconsider its proposed rule to bar coverage of low vision devices that would have a devastating effect on the lives of millions of Americans.

We welcome the opportunity to contribute to the development of policy that would distinguish between conventional eyeglasses and low vision devices/assistive technologies, and appreciate the opportunity to comment on the CMS proposed rule.

Sincerely,

Tara A. Cortes, PhD, RN
President and CEO

NOTE- attempted to e-mail on 6/30 but CMS system down.
RBK - Lighthouse Int'l.

Error Executing Database Query.

[Macromedia][Oracle JDBC Driver][Oracle]ORA-01704: string literal too long

Please try the following:

- Enable Robust Exception Information to provide greater detail about the source of errors. In the Administrator, click Debugging & Logging > Debugging Settings, and select the Robust Exception Information option.
- Check the ColdFusion documentation to verify that you are using the correct syntax.
- Search the Knowledge Base to find a solution to your problem.

Browser	Mozilla/5.0 (Windows; U; Windows NT 5.1; en-US; rv:1.8.0.4) Gecko/20060508 Firefox/1.5.0.4
Remote Address	72.246.36.11
Referrer	http://www.accessdata.fda.gov/
Date/Time	30-Jun-06 02:33 PM

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Ann-Marie Lynch
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June 30, 2006

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

File Code CMS-1270-P: Comments Related to Proposed Rulemaking re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006).

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide this comment letter to the "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Proposed Rule). AdvaMed is the largest medical technology trade association in the world. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed shares CMS's goals of assuring beneficiary access to services, and continues to take a keen interest in ensuring access to high quality DMEPOS related items and services. As noted in both our April 4, 2006 and May 12, 2006 letters to CMS, AdvaMed and its members are deeply concerned regarding the process for implementing competitive acquisition (competitive bidding) and the development of new quality

standards for DEMPOS suppliers. The Proposed Rule would implement competitive acquisition for certain covered items of DMEPOS in accordance with sections 1847(a) and (b) of the Social Security Act. CMS notes that "The DMEPOS supplier industry is expected to be significantly impacted by this rule when finalized," and estimates that about 50 percent (approximately 8,500 small suppliers in the ten competitive bidding areas) would lose all of their Medicare DMEPOS business. As outlined later in this letter, AdvaMed believes that CMS should take steps to relieve the negative impact on small suppliers.

We appreciate the enormity of CMS's task in implementing competitive bidding, and we know that CMS staff are fully dedicated to the task at hand. However, AdvaMed believes that there are a number of key issues that need to be addressed before any aspect of competitive bidding can be implemented. As noted in our previous letters of April 4 and May 12, a key component of CMS's implementation of competitive bidding under the Proposed Rule involves the application of 'quality standards' for all DMEPOS suppliers, including DMEPOS suppliers that participate in the DMEPOS competitive bidding program. The Proposed Rule also contains requirements for CMS approved accreditation organizations that will be applying quality standards for all DMEPOS suppliers, including DMEPOS suppliers participating in the competitive bidding program

AdvaMed has noted in previous correspondence with CMS that CMS has not finalized its quality standards, having to date released only draft standards on September 23, 2005. While CMS accepted public comments on those standards, there has been no publication of final standards notwithstanding that the quality standards are an integral part of the Proposed Rule.

As we noted in our previous letters, stakeholders are currently in the untenable position of having to make substantive analysis and comment on the incomplete parameters contained in the Proposed Rule. The proposed quality standards are exhaustive and may include performance management requirements to ensure development, implementation, monitoring, and evaluation of policies, procedures, and products to enable suppliers to maintain compliance with regulatory requirements and CMS policy instructions. We do not believe that CMS should proceed with the implementation of competitive bidding (as described in the Proposed Rule) until there has been a formal notice and comment process sufficient to allow stakeholder assessment of the quality standards within the context of competitive bidding

As we have stated in previous correspondence, we believe CMS should hold the comment period in abeyance until it issues the supplier quality standards. Stakeholders would then have the opportunity to evaluate the quality standards, a critical part of competitive bidding, in the appropriate context with competitive bidding in a proposed rule prior to CMS's issuance of a final rule. If CMS does issue a Final Rule absent the release of quality standards, we believe that the rule should be issued only as an interim final rule, and that a new proposed rule should be issued at the time the quality standards are released. The new proposed rule would allow stakeholders to comment on

competitive bidding within the appropriate context of supplier quality standards and definitive parameters for implementation.

Before proceeding with our specific comments below, we would like to emphasize that any competitive bidding program developed by CMS should include the following:

- Beneficiaries should be guaranteed access to the most appropriate technology.
- Competitive acquisition should support technology innovation and ensure that beneficiaries are the recipients of the latest technological advances.
- The entire competitive bidding process should be transparent to all stakeholders.
- To the extent that CMS wishes to assess costs or savings within the context of competitive bidding, such assessment should take into account all costs, and not just the short-term cost that may be reduced through competitive acquisition. Any assessment of costs or savings should include examination of long-term impact, such as improved patient quality of life, and impact on necessity for follow-up treatment, including hospital inpatient admissions and emergency room and physician office visits, as well as costs to administer the program, that may accrue.

It is only through appropriate guarantees for beneficiary access to innovative technology that competitive bidding will have a chance to successfully address the health care needs of beneficiaries.

An overarching concern we have with the Proposed Rule is that it is a significant expansion beyond the CMS competitive bidding demonstrations. At least for this first round of competitive bidding, we urge CMS to consider only those DMEPOS products that were successfully tested during either of the two Medicare competitive bidding demonstration projects. As you are aware, those two demonstrations were conducted in relatively small geographic areas, and involved considerable "hand holding" by CMS and its contractors, a degree of oversight that is not likely to be possible when competitive bidding is applied simultaneously to ten very large MSAs. As a result, we believe it would be advisable for CMS not to attempt to add product categories early in the life of the new competitive bidding program. This would give the Agency time to assess whether fine tuning is needed in the competitive bidding methodology and related policies (for example, with respect to physician authorization, beneficiary travel and transition issues) before deciding whether the program is ready to be expanded to include additional DMEPOS products.

Should CMS contemplate expansion of products beyond those successfully tested in the demonstrations, AdvaMed would encourage CMS to "test" or phase in a new product or product category in only a single competitive bidding area, and then build on this experience in subsequent rounds of bidding, rather than choosing the far riskier strategy of subjecting such products to competitive bidding in multiple areas from the outset.

There are considerable differences among the range of DMEPOS projects eligible for competitive bidding (for example, with respect to distribution channels, technological sophistication, the role played by manufacturers as opposed to suppliers, the role of ordering physicians, and the impact on beneficiary health and well-being). It would, therefore, be best for CMS to gain real-world experience with each product and product category in a reasonably limited area to minimize risks to beneficiary access, quality of care, and the DMEPOS market itself.

"Education and Outreach"

In the 'Education and Outreach" section, CMS states "[W]e believe that it is important for beneficiaries to learn about the benefits of the Medicare DMEPOS Competitive Bidding Program, such as lower out-of-pocket expenses and increased quality of products from suppliers that have completed the detailed selection process that CMS will require under the program."

This statement assumes that competitive bidding will lead to increased quality, and strongly implies that the suppliers who are successful in competitive bidding will provide higher quality products than suppliers who either choose not to become suppliers or who do not submit winning bids. We do not believe that is necessarily the case, and there is certainly nothing to support that winning bidders will provide higher quality products. We do not believe that it is appropriate for CMS to attempt to 'market' the competitive bidding program as a means to increase quality when there is no evidence to support that this will occur. We also believe that CMS should be very careful regarding any statement that would imply that winning bidders provide better quality items and services. As CMS is aware, suppliers who do not submit winning bids in one MSA can win bids to be suppliers in another MSA. CMS should be aware that overarching and unsupported claims of increased quality can be detrimental to products and suppliers that are not selected for competitive bidding. There will be a myriad of reasons that a particular supplier may not become a supplier in a given MSA -- such as the inability to provide an item in sufficient quantities -- that are completely independent of quality.

"Competitive Bidding Areas"--Proposed § 414.410

The Proposed Rule provides a number of criteria that CMS intends to use to select Metropolitan Statistical Areas (MSAs). However, CMS does not provide any guidance as to which MSAs will be selected. AdvaMed believes it would have been appropriate for CMS to name specific areas to which competitive bidding will be applied. As it currently stands in the Proposed Rule, CMS does not name specific areas, and even proposes expanding competitive bidding outside of MSA boundaries. We do not believe that an expansion of competitive bidding beyond MSA boundaries would be appropriate. CMS made clear in the Proposed Rule that ten of the largest MSAs are scheduled to receive competitive bidding in 2007. Given the enormity of the administrative task of implementing competitive bidding in ten of the largest MSAs, we do not believe it would be feasible to attempt to expand the scope of competitive bidding beyond the boundaries of these areas.

AdvaMed urges CMS to adopt competitive bidding in areas that are somewhat smaller than the MSA to help minimize the risk of a competitive bidding area crossing state lines or areas shared by more than one DMERC. We believe that doing this will make the areas more manageable administratively, and lessen the confusion for suppliers in bidding and for beneficiaries obtaining DMEPOS items.

Additionally, the proposed formula for selecting competitive bidding areas would rely heavily on two measures: (1) DMEPOS allowed charges per beneficiary; and (2) suppliers per beneficiary. We are concerned that neither measure may be completely accurate, which could lead to inequities in the selection of competitive bidding areas.

For example loss or gain of large numbers of beneficiaries during certain portions of the year (the "snowbird" phenomenon) could alter significantly the apparent satisfaction of criteria for selection as a competitive bidding area. DMEPOS allowed charges are credited to the MSA housing a beneficiary's legal residence. If many beneficiaries spend half the year in different MSAs, the estimated demand for DMEPOS in the "legal residence" MSA could be too high and the estimated demand in the "non-legal residence" MSA could be too low. In this case, the number of suppliers in the "legal residence" MSA could appear to be relatively low, while the number of suppliers in the "non-legal residence" MSA could appear to be relatively high. **To the extent that Medicare beneficiaries move between identifiable MSAs for extended periods of time, CMS should adjust data on DMEPOS allowed charges and on numbers of beneficiaries and suppliers before selection of competitive bidding areas.**

"Nationwide or Regional Mail Order Competitive Bidding Program"--Proposed § 414.410(d)(2)

AdvaMed strongly opposes the proposed provision to implement a national or regional mail order competitive bidding program for DMEPOS equipment and supplies. One of the basic tenets of competitive bidding is to allow the market forces to shape the cost of goods and accessibility to providers and products. Implementing a national or regional mail order DMEPOS competitive biding program—or the proposed mail order alternative requiring Medicare beneficiaries to obtain certain DMEPOS items via mail order suppliers—would manipulate the market rather than promote competition. Mail order suppliers who meet the quality, financial and other Medicare standards are already included under the proposed provisions. There is no need to create a distinct or separate DMEPOS competitive bidding program for mail order.

Additionally, rather than a mandatory requirement for provision of DMEPOS items via mail order, CMS should continue to allow Medicare beneficiaries to obtain their DMEPOS products via their preferred access channel. While some Medicare beneficiaries may choose to obtain certain DMEPOS items via mail order, many Medicare beneficiaries prefer to obtain necessary DMEPOS items from local community suppliers. AdvaMed strongly believes that beneficiary choice must be maintained to ensure that beneficiary adherence to prescribed treatment regimens is not jeopardized.

"Criteria for Item Selection"

CMS proposes to use HCPCS codes individually or grouped together in "product categories" as the basis for competitive bidding. Because there are significant inconsistencies in the specificity of existing codes included in the product groups listed in the Proposed Rule, we are concerned that use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

We note the importance of very specific, detailed data/information collection and analysis for each product category under consideration for competitive bidding. Every product category has its own unique issues relating to how the products are provided, related services, patient characteristics, distribution channels, and manufacturer's role. Furthermore, such characteristics should be taken into consideration in creating product bundles for bidding. We continue to urge CMS to recognize product-specific variables in all facets of the implementation of the competitive bidding program. In order to ensure that product categories are appropriately defined, we also recommend that CMS seek stakeholder input and publish for comment all proposed product category subdivisions prior to bidding.

We commend CMS for determining that surgical dressings are excluded from competitive bidding due to the lack of savings attributed to these products during two rounds of demonstration projects in Polk County, Florida and San Antonio, Texas. Surgical dressings were did not offer savings through competitive bidding in the demonstrations.

"Establishing Payment Amounts for New DMEPOS Items: 'Gap-Filling'"-- Proposed § 414.210(g)

Establishing payment amounts for new DMEPOS items is an extremely important process that is unrelated to the implementation of the DMEPOS competitive bidding program. Because of this, AdvaMed believes that it is inappropriate to include this provision within the DMEPOS competitive bidding Proposed Rule and requests that any proposals related to payment for new DMEPOS items be made under a separate rulemaking process. Doing so will ensure that all appropriate stakeholders have an opportunity to properly evaluate and provide comment on the proposed provisions. We also note that CMS is combining coding, coverage, and payment decisions for new DMEPOS technology into a single, newly-created decision-making process. AdvaMed believes that coverage and payment determinations should be separate and distinct processes.

AdvaMed accordingly recommends that CMS deal with the technology assessment issues in a separately published Proposed Rule containing specific procedural

criteria. AdvaMed also recommends that all references to the technology assessment as a part of gap filling be removed from the Final Rule.

"Fee Schedules for Home Dialysis Supplies and Equipment"-- Proposed § 414.107

CMS proposes to implement nationwide fee schedule amounts for home dialysis supplies and equipment currently reimbursed on a reasonable charge basis, effective January 1, 2007. These rates would be based on the average allowed charges for services furnished from January 1, 2005 through December 31, 2005, increased by the percentage change in the Consumer Price Index-Urban (CPI-U) for the 24-month period ending June 2006. In future years, the rates would be updated by the CPI-U for the 12-month period ending in June of the previous year.

AdvaMed agrees that home dialysis reimbursement is an important issue, but does not believe that this issue is related to competitive acquisition of DMEPOS. **As such, we recommend that CMS issue a separate Proposed Rule on this payment issue, inviting comments from all stakeholders.** This new Proposed Rule should describe how CMS will ensure a smooth transition to the new fee schedule. When CMS introduces a new reimbursement methodology, suppliers are likely to experience additional costs and delayed payment of claims. For example, suppliers of home dialysis supplies and equipment have experienced several changes to the claims process over the past few years. These changes have increased the cost burden of the supplier in the development of line-item claims and in the posting of the reimbursement received. Any further changes should include input from the small number of DME suppliers who currently offer home dialysis supplies and equipment.

CMS notes that it expects the total payments made under the fee schedule will be approximately equal to the total payments that would have been made under the reasonable charge payment methodology. Home dialysis modalities can give patients a better quality of life, allow many patients to remain employed, and can provide considerable savings to the total Medicare program. We ask the Agency to carefully ensure that the fee schedule rates are appropriate to protect beneficiary access to home dialysis treatment.

"The Effect of Competitive Acquisition on Small Suppliers"

AdvaMed believes that competitive acquisition will have a larger negative impact on small suppliers and result in more business consolidation than is currently anticipated by CMS. There are significant variations in DMEPOS suppliers and AdvaMed requests that CMS take into account these differences in its definition of "small" suppliers. Revenue and payer mix are valid measures of supplier "size". However, the types of DMEPOS sold should also be taken into account and separate provisions should be allowed for small suppliers of technologies that require a degree of personal and on-going customer service, such as ostomy supplies. We believe that competitive acquisition may result in negative impacts on beneficiaries that rely on small suppliers.

CMS estimates that 50 percent of bidders will be winners based on the experience with the demonstration projects. Approximately 8,500 small suppliers in the ten competitive bidding areas would lose all Medicare DMEPOS business. We believe that the following are compelling reasons that demonstrate that a much smaller proportion of small suppliers will be successful under the process outlined in the Proposed Rule:

- The methodology used to arrive at a pivotal bid by accumulating capacities in ascending order of bid level is different from what was used in the demonstrations and will likely lead to fewer and larger winners.

- Higher acquisition costs due to new supplier standards and accreditation requirements and the need to bid on every HCPCS code within a product category will inevitably put small suppliers at a disadvantage.

- The contract price will be below the bid price for some successful bidders which introduces a significant financial risk that will be more difficult for smaller suppliers to tolerate.

AdvaMed believes that the Proposed Rule contains inadequate protection for small suppliers. Formation of supplier networks (proposed section 414.418) is an unrealistic option for many small suppliers as this would require a high degree of collaboration with competitors under stressful and unique circumstances, and potentially without knowing the quality standards that they would be required to meet. Small suppliers also may not possess the business resources or experience necessary to form these networks, and will be hard pressed to do so under such short notice. In addition, formation of a network arrangement will likely require costly and lengthy legal arrangements beyond the financial reach of many small suppliers. Lastly, allowing suppliers to bid on only one or a few categories is not a significant benefit to small suppliers because in many cases, they are already specialized and able to bid only a few categories.

To mitigate the impact that competitive acquisition will have on small suppliers, **AdvaMed recommends that for small suppliers, CMS relax the rule requiring winning suppliers to cover an entire MSA.** While this would impact CMS's determination of supplier capacity and number of winning bids per MSA, it would allow winning small suppliers to service their existing geographic area without the burden of expanding capacity or forming networks. **In addition, AdvaMed recommends that the grandfathering provisions in the NPRM be expanded to include all DMEPOS product categories that are subject to competitive bidding and not be limited to rental DME and oxygen supplies.** This would allow small suppliers that are willing to accept the contract prices for their MSA and meet the accreditation and quality standards, the opportunity to continue servicing their existing Medicare customers and potentially stay in business until the next bid period. **Finally, AdvaMed recommends that if CMS decides to allow mail order suppliers to participate in DMEPOS competitive bidding prior to 2010, those mail order suppliers should not count towards the two-supplier minimum that CMS is establishing in each competitive bidding area.**

"DMEPOS Manufacturers as Suppliers"--Proposed §414.412

The Proposed Rule does not propose specific product categories, but it does list policy groups and assumes that interested bidders would be required to submit bids on all items included in a product category. However, in the case of DMEPOS products for which manufacturers now serve as suppliers, the requirement to bid on all HCPCS codes in a product category could be a major problem, especially if the product categories are very broad. In fact, this policy could impact beneficiary access and significantly disrupt the existing marketplace for some DMEPOS products.

CMS could simply exclude from competitive bidding those DMEPOS products now commonly provided directly by manufacturers, perhaps on the grounds that these products are available from relatively few suppliers and would not produce Medicare savings. Alternatively, the Agency could also adopt special rules for manufacturers wishing to bid, permitting them to bid only on the products they manufacture. If CMS chooses this last option, it would also need to modify its proposed method for calculating composite bids and selecting contract suppliers. In sum, we wish to highlight the fact that CMS could inadvertently end up precluding manufacturers from continuing to serve as suppliers in competitive bidding areas to the detriment of the Medicare beneficiaries living in these locales.

"Physician Authorization/Treating Practitioner"--Proposed §414.420

The Proposed Rule would keep intact the provision that permits a physician to prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome (section §414.440). However, the Proposed Rule defines physicians as doctors of medicine or osteopathy in accordance with section 1861(r)(1)) of the Social Security Act), a definition that excludes dentists, podiatrists, and optometrists, who may order DMEPOS. At the same time, the Proposed Rule would expand the provision by allowing certain treating practitioners, including physician assistants, nurse practitioners, and clinical nurse specialists to order a particular brand or mode of delivery. **AdvaMed recommends that CMS expand the definition of physician to allow podiatrists, optometrists, and dentists to prescribe a particular brand or mode of delivery of DMEPOS, along with physician assistants, nurse practitioners, and clinical nurse specialists.**

As CMS correctly notes in the Proposed Rule, suppliers under competitive bidding may only offer certain brands within a HCPCS code. AdvaMed supports CMS's decision to permit a variety of qualified practitioners, in addition to physicians, to prescribe particular brands or modes of delivery where appropriate. We believe this will help to ensure that patients have access to the most appropriate treatments and technologies, leading to enhanced quality of care. While the expansion of this provision is highly positive, AdvaMed urges CMS to build in sufficient flexibility so that the physician authorization process will rarely be used.

When there is a need for a physician authorization, AdvaMed urges CMS to:

1) Implement a simple authorization process, especially in the early rounds of the competitive bidding program. While the standard suggested by CMS in the Proposed Rule would allow a qualified practitioner to prescribe specifically to avoid an adverse outcome, we believe that CMS should recognize that certain products, such as blood glucose monitors, may not fit neatly within what may traditionally have been considered in the context of avoiding an adverse outcome. However, there are multiple features in the many blood glucose monitoring systems currently available such that a physician may specify a particular brand to meet the beneficiary's needs at that time. A prescription for the most appropriate product can be determinative regarding whether a patient will follow a treatment regimen; and

2) Keep this authorization process very simple. For example, having the physician or other practitioner document in the patient's record and on the prescription form the specific product brand or mode of delivery required for the beneficiary. CMS has a similar documentation policy for beneficiaries receiving additional glucose test strips per month. This process helps to ensure that the right products are received by the beneficiary based on the qualified provider's decision, and also allows CMS, if necessary, to review the reason for the use of the particular product or supply.

"Skilled Nursing Providers"--Proposed §414.404, §414.422

AdvaMed believes that beneficiaries in skilled nursing and long-term care facilities are substantially different from much of the Medicare home care populations, and that including Skilled Nursing Facilities (SNFs) and Long-Term Care Facilities (LTCFs) patients/residents within the competitive bidding process that is essentially designed for home care patients will potentially create problems that should be addressed by CMS. We refer here to the 'long-term care facilities' that serve dually eligible beneficiaries, with Medicare paying for Part B covered services and Medicaid covering custodial care. We ask that CMS consider the following:

- **The Proposed Rule permits a SNF/LTCF to submit a bid to care for their own patients/residents.** SNF/LTCF patients are more dependent, frail, and vulnerable than patients cared for at home. More than 80 percent of all enteral patients residing in SNFs/ LTCFs, for example, require an enteral pump for safe delivery of nutrition, while less than half of all enteral patients residing in their homes have such a requirement. The difference in the severity of illness of patients in these two care settings should be recognized in the bid process.

- The proposed quality standards are explicitly designed to govern home care. Care provided in SNFs and LTCFs is covered by existing facility care standards. The proposed standards are unclear about the application of product-specific standards in situations where products are provided by a

supplier that shares responsibility for patient care with a SNF, LTCF or a home health agency. Quality standards need to be explicit about supplier patient care responsibility in these shared-responsibility situations.

- If a SNF or LTCF is unsuccessful in winning a contract, the facility will be required to recruit an outside supplier to provide inpatient care. The outside supplier would be unfamiliar with the facility's operational procedures and patient care requirements. In some situations, the transition could replace an effective internal patient care system with an unknown guest firm. We are concerned that this could cause disruption to quality, as various providers would be responsible for different facets of the supplies provided to patients, resulting in fragmented accountability for quality and greater difficulty in the ability to coordinate the receipt of supplies with overall residents' needs.

AdvaMed recommends that CMS consider modifying the Proposed Rule to exclude patients that are in institutional settings, or, alternatively, exempt DMEPOS products that are primarily used in SNFs/LTCFs pending further examination. We believe that these issues need further examination, including potentially a separate set of quality standards for SNF/LTCF suppliers, published through notice and comment rulemaking, to ensure quality DMEPOS for SNF/LTCF residents should the SNF/LTCF not be the supplier under a competitive bidding arrangement. Postponement of applicability of this Proposed Rule to institutionalized patients would allow CMS to conduct the kind of in-depth analysis and examination that is necessary to address these issues. **We recommend that CMS consider the ongoing difficulties SNFs and LTCFs are currently experiencing with the transition of their residents to the new Medicare Part D drug benefit. We recommend that CMS postpone DMEPOS competitive bidding in these settings until CMS can convene a working group of key stakeholders to examine the requirements for a competitive bidding program in these facilities.**

"Determining Single Payment Amounts for Individual Items"--Proposed 414.416(b)

The Proposed Rule shifts the calculation of the single payment rate from the pivotal bid (the highest winning composite bid, the price that all bidders have accepted) to the median of all winning bids. This change in the calculation methodology will decrease provider payment rates dramatically. AdvaMed believes that the use of a median statistic is flawed for the following reasons:

- The demonstration projects employed an Adjustment Factor Method (AFM), evidently without confusion or obstacle. The Medicare Modernization Act provision expanding competitive bidding was based on the AFM's proven methodology.

- Calculations of an unweighted median could be vulnerable to a variety of gaming strategies, as providers serving a few Part B beneficiaries have the same impact on the calculation of the median value as providers responsible

for a large number of beneficiaries. Bidders with a small percentage of their total business through Part B could submit low bids, driving down the median rates. If CMS insists on using a median rate, bids should be weighted by proposed capacity, so payment rates will more accurately represent the market of successful bidders.

AdvaMed requests that the median of supplier bids not be used by CMS, but that CMS instead use the same "Adjustment Factor Method" used in the competitive bidding demonstrations. Given that the scope of the Proposed Rule is significantly greater than that of the demonstrations, we do not believe now is the appropriate time for CMS to deviate from the statistical basis that was used in the demonstrations to determine successful bids.

Also, we believe quite strongly that only the bids of fully accredited suppliers should be used to determine the single payment amounts under the DMEPOS competitive bidding program. From the information available to us, we presume that CMS agrees. If so, then the Agency should take steps to assure that any bids submitted prior to accreditation are not used in payment calculations unless the submitting bidder has subsequently been accredited. Otherwise, there is simply too great a risk that the bids of unaccredited suppliers could bias the payment calculation.

"Review of Financial Standards"--Proposed 414.414(d)

Financial standards are a significant component in the approval process for candidate bidders. The authorizing legislation states that the Secretary may not award a contract to an entity that does not meet applicable financial standards. The Proposed Rule invites comments on financial standards, while describing the documents that might be required from bidders. Proposing data collection instruments is not the same as proposing financial eligibility standards. CMS should first consider the difficult question of which financial standards are appropriate, then determine the documentation needed to implement those standards.

The establishment of financial standards for Part B providers is an unprecedented task. While financial standards exist for managed care organizations, hospitals and other cost reporting providers, such standards will not easily or automatically translate to the diverse DMEPOS markets. These financial standards must be flexible enough to regulate mail order companies, small local DME dealers, skilled nursing facilities, departments of hospitals, retail pharmacies, publicly-traded national corporations and privately-held family firms.

Development of these standards will require careful thought and insightful help from well-informed consultants. **We encourage CMS to assign a priority to this program linchpin, and to bring this issue to the PAOC at the next available meeting.** Given the obligation of the PAOC to advise the Secretary on an issue which can, by itself, determine whether a company continues within Medicare or not, this important issue needs full and candid examination. The opportunities for serious inadvertent errors

should not be underestimated. If financial standards are too restrictive, then qualified suppliers and new companies without a financial history will be eliminated from the Medicare Part B program. On the other hand, if financial standards are too lax, then suppliers may be unable to meet the challenges of a competitive acquisition market with potentially dramatic implications for patients under their care.

"Payment Basis"--Proposed §414.408

The Proposed Rule describes a potential grandfathering process for certain rental agreements. However, we believe that a comprehensive transition policy will be essential to a successful roll-out of the new DMEPOS competitive bidding program.

- **We urge CMS to allow beneficiaries in a new competitive bidding area to continue to obtain DMEPOS products that are subject to competitive bidding from non-contract suppliers during a transition period.**

- **We also recommend that, for DMEPOS products that require regular replacement supplies, CMS assure that Medicare beneficiaries can continue to obtain needed replacement supplies for their current equipment through careful consideration of options for transitioning to suppliers under competitive bidding.**

For beneficiaries in a new competitive bidding area, **we propose that non-contract suppliers could continue to be paid at the established fee schedule amounts. We propose this would occur over a relatively short period of time, during which beneficiary educational materials would be made available to non-contract suppliers for distribution to beneficiaries at the time of a DMEPOS transaction.** The materials would explain the new competitive bidding program, list the DMEPOS products subject to competitive bidding in the area, identify the contract suppliers selected by CMS, and provide other important information, such as contact information for Medicare contractors, ombudsmen, and CMS personnel.

For DMEPOS products that require regular replacement supplies, CMS could simply require contract suppliers to provide the replacement supplies in question during a transition period even if they did not plan to offer that specific brand of replacement supplies for the full contract period.

The Proposed Rule addresses various beneficiary travel scenarios. AdvaMed believes that CMS should ensure that beneficiaries who may travel outside their competitive bidding area (CBA) would be able to obtain their DMEPOS items. For example, a beneficiary could lose or damage her blood glucose test strips and need to purchase replacement test strips that day. It is not realistic for a beneficiary whose residence is in a particular CBA to know what DMEPOS items are being competitively bid in a different CBA that the beneficiary may be visiting for medical or personal reasons, locate contracted suppliers in that area, and identify what contracted supplier has the brand of DMEPOS they are using. In fact, it is a distinct possibility that none of the contract suppliers in the area that

a beneficiary may be visiting would be offering the specific brand of replacement supplies that the beneficiary needs for their current brand of DMEPOS product. **We therefore urge CMS to take all of these practical considerations into account in adopting a reasonable travel policy that would ensure beneficiary access to replacement supplies during travel.**

AdvaMed accordingly recommends CMS take these practical considerations into account and adopt a reasonable travel policy that would ensure beneficiary access to supplies, including replacement supplies, during times when beneficiaries travel outside of their CBA. AdvaMed supports allowing beneficiaries to purchase their DMEPOS products (especially replacement supplies) from any community Medicare supplier who is either a Medicare participating supplier or a nonparticipating supplier who will agree to accept assignment for the DMEPOS equipment and supplies.

While we can understand CMS's desire to start a new competitive bidding program on a date certain with no transition, we believe that there could be considerable confusion and beneficiary dissatisfaction if some type of short-term transition period is not adopted. The transition period that we recommend CMS consider would give beneficiaries time to consult with their doctor or other health professional about the appropriateness of switching to one of the brands of DMEPOS available under competitive bidding or, if need be, execute a physician authorization to assure continued access to their current brand if required to prevent an adverse medical outcome.

"Conditions for Awarding Contracts"--Proposed §414.414

CMS expects bidding suppliers to meet its quality standards and be accredited by a CMS-approved organization. However, the Proposed Rule notes that a grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. The length of this grace period (which would be specified in the request for bid) would be determined "by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area." The Proposed Rule also notes that suppliers that received "a valid accreditation before CMS-approved accreditation organizations are designated" will be considered to be grandfathered if the accreditation was granted by an organization that CMS ultimately designates.

We are concerned that CMS is making unrealistic assumptions about how quickly the accreditation process can be implemented and assess large numbers of suppliers, even if the immediate focus is only on suppliers in ten large MSAs. As we understand it, CMS plans to issue a solicitation for accrediting bodies only after publication of a final rule. The selection of accrediting bodies itself would presumably take a fair amount of time. Selected organizations would also likely require time to gear up, hire additional staff, adopt new policies and procedures and otherwise prepare to take on the new workload. We urge CMS to pay very careful attention to the timeline and not attempt to rush the accreditation process. Moreover, as we emphasize elsewhere in these comments, it would be completely inappropriate to use bids submitted by suppliers that have not been

accredited in calculating the single payment amounts. It would also be inappropriate to consider such bids in determining the pivotal bid or in selecting contract suppliers.

In the Proposed Rule, CMS clearly indicates that it wishes to match supply and demand in selecting the number of winning suppliers. However, the geographic distribution of winning suppliers is never mentioned, and there is no indication in the Proposed Rule that CMS was planning to take this into account. While the geographic distribution of contract suppliers will be important for all DMEPOS, it will be especially important for products typically obtained by the beneficiary through local type of outlets, such as a nearby pharmacy or other retail outlet. Of course, assuring a reasonable geographic distribution of contract suppliers will not be easy and will require an in-depth understanding of each competitive bidding area (for example, natural boundaries, road conditions, travel times, the availability of public transportation, and the distribution of beneficiaries across the area). However, if competitive bidding produces a serious mismatch between the location of contract suppliers and the location of Medicare beneficiaries, certain segments of the beneficiary population could be seriously disadvantaged.

Given this risk, we believe that the bid-evaluation process should incorporate a mechanism for assuring beneficiary access throughout the. The determination of supplier capacity should assure that all residents within an MSA can receive products from successful bidders. After an initial determination of capacity, CMS could analyze capacity by zip code, to assure that patients within each zip code would be served by several winning bidders. Appropriate adjustments to the list of winning suppliers may need to be implemented if convenient access is lacking. Policies regarding these adjustments and disclosure of these decisions should be announced in the Final Rule.

Congress addressed the issue of geographic distribution in the context of Medicare Part D by specifying that each prescription drug plan must have a network of pharmacies that ensures "convenient access." TRICARE standards are being used as a model for assessing the network. Specifically, under the Part D program, drug plans must establish retail pharmacy networks as follows (with certain limited exceptions):

- Urban areas -- At least 90 percent of the Medicare enrollees in the drug plan's service area must, on average, live within two miles of a network retail pharmacy;

- Suburban areas -- At least 90 percent of the Medicare enrollees in the plan's service area must, on average, live within five miles of a network retail pharmacy; and

- Rural areas -- At least 70 percent of the Medicare enrollees in the plan's service area must, on average, live within 15 miles of a network retail pharmacy.

We believe that Medicare's DMEPOS competitive bidding program should provide a similar level of "convenient access" for DMEPOS products, especially those typically obtained by beneficiaries from retail outlets, such as a local pharmacy.

The Final Rule needs to discuss the issue of geographic distribution of contract suppliers and indicate how CMS plans to address it.

"Assurance of Savings" -- Proposed §414.414(f)

To assure savings from competitive bidding, CMS proposes to require that single payment amounts for each item in a product category may not exceed the current fee schedule amount for that item. Furthermore, CMS proposes not to accept any bid for an item that is higher than the current fee schedule amount for that item.

AdvaMed believes that limiting bids for all items in a product category is overly restrictive, and could lessen savings from competitive bidding. Instead, CMS should permit potential suppliers to bid based on their costs of providing each item. For some items, costs could be lower than the fee schedule amount, while for other items, costs could be higher.

AdvaMed supports the alternative CMS interpretation of "less than the total amounts that would otherwise be paid" which is based on product category instead of each item within the category. CMS could still meet its requirement--to award contracts only if savings are anticipated--by accepting bids where payment amounts for the product category are below fee schedule amounts for items in that product category. If CMS requires bids for all items to be below fee schedule amounts, and suppliers can provide only some items below the fee schedule amount, the suppliers will be: 1) prohibited from participating; or 2) forced to cross-subsidize within the product category.

In the Proposed Rule, CMS notes that during the demonstrations, several product categories received overall savings but payment amounts increased for a few individual items within those product categories. CMS notes that "this may not result in adequate savings." We disagree with this conclusion from the demonstrations. Instead, we would argue that these results indicate inaccuracies in the fee schedule amount for both items with competitive bids below the fee schedule amount (which would produce savings to Medicare) and items with competitive bids above the fee schedule amount (which would produce costs to the program). The goal of a competitive bidding program should be to assure that Medicare payments align with the costs of providing high quality services, while continuing to encourage access to advances in medical technologies.

"Fee Schedule Updates for Class III Devices"

The background section of the Proposed Rule requests solicitation of comments on the appropriate Medicare fee schedule percentage change for Class III durable medical equipment for 2007 and 2008. CMS noted that they will consider these comments in conjunction with recommendations made in a March 2006 Government Accountability Office (GAO) report. The Food and Drug Administration (FDA) regulation at 21 C.F.R. section 860.3(c)(3), notes that Class III devices usually support or sustain life, are of substantial importance in preventing impairment of human health, or present a potential, unreasonable risk of illness or injury. Under the DME fee schedule, Class III devices

include osteogenesis stimulators, infusion pumps and their related supplies, neuromuscular stimulators, certain ultraviolet light therapy systems, and automatic external defibrillators and related supplies.

In the Proposed Rule, CMS alludes to recommendations made by the GAO in a March 2006 report. In that report, GAO recommended that the Secretary of Health and Human Services establish "a uniform payment update" for 2007 for both Class II and Class III devices, and that the Congress consider establishing such a uniform update for 2008. AdvaMed finds this GAO report disappointing. Instead of providing a full assessment of changes over time in the costs of producing, supplying and servicing Class III devices, the GAO report focuses only on selected issues, mainly pre-marketing costs. Further, in saying that the updates for Class II and Class III devices should be "uniform" or "the same," the GAO report never actually specifies what the specific percentage update for 2007 or 2008 should be. The GAO report does assert that Class III devices do not warrant a distinct annual payment update. However, in addition to its shortcoming with regard to a lack of a specific payment update, the report fails to include a rigorous assessment of payment adequacy, and does not review the many factors contributing to manufacturer costs and changes in these costs over time. In addition, the report examines Class III devices in relation to only a very limited number of higher-technology Class II items that may not be reflective of Class II items more generally. The report acknowledges that an earlier draft was criticized for failing to recommend a specific percentage update.

We recognize that the Medicare Modernization Act specified that the update for Class II devices for 2007 and 2008 should be zero, but we note that the GAO report never explicitly says that its analysis supports a zero update for Class III—or even Class II—devices. Given changes in prices in the economy at large, we believe it would be unreasonable to assume that Class III device manufacturers and suppliers are somehow immune from the cost pressures being felt elsewhere in the economy.

We recommend that CMS continue using the CPI-U to adjust Medicare fee schedule amounts for Class III devices. We note that CMS stated that the Agency will use this same adjustment factor to update the single payment amounts in years 2 and 3 of a DMEPOS competitive bidding cycle. We presume this means that CMS considers CPI-U to be a reasonable estimate of changes in supplier costs over time. Of course, under DMEPOS competitive bidding, these changes in supplier costs would relate to Class II devices, and not the more sophisticated Class III devices, which Congress chose to exclude from the new competitive bidding program.

"Rebate Program" – (Proposed 414.416(c))

CMS proposes to allow contract suppliers to provide beneficiaries with rebates. The rebate would occur in instances when the supplier submitted bids for an individual item in an amount below the single payment amount. The rebate would be equal to the difference between the provider's actual bid and the single payment amount.

The Proposed Rule suggests that rebates would be voluntary but that contract suppliers would not be able to implement them on a case-by-case basis. If a contract supplier submits a bid below the single payment amount and chooses to offer a rebate, the supplier would have to offer the rebate to all Medicare beneficiaries receiving the competitively bid item to which the rebate applies. According to CMS, if a supplier chooses to provide a rebate, the rebate would become a binding contractual commitment for that particular supplier to all beneficiaries receiving the item from that supplier. Once agreed to, contract suppliers would be prohibited from altering the provision of a rebate during the term of the contract. Contract suppliers would be prohibited from "directly or indirectly" advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals. However, this would not preclude CMS from providing to beneficiaries comparative information about contract suppliers that offer rebates. Only contract suppliers that submitted bids below the single payment amount would be allowed to issue rebates. CMS believes that allowing suppliers to offer rebates will give beneficiaries the ability to realize additional savings and the full benefits of the Medicare DEMPOS Competitive Bidding Program.

AdvaMed does not believe that the rebate provision should be included in competitive bidding. Such payments could be considered inducements to beneficiaries and potentially violate the Federal Anti-Kickback Statute (Statute). It is fairly certain that rebates provided directly to beneficiaries would fall under the Statute's purview as a form of inducement to beneficiaries in exchange for referrals. The Statute prohibits the knowing and willful offering or giving of remuneration either in return for referrals or with the intent to induce referrals for items and services reimbursed by Medicare.

In order to ensure that they would not run afoul of the Statute's prohibitions, suppliers would thus have to ensure that their provision of discounts would fall within one of the safe harbor provisions, such as the discount safe harbor. This is an additional layer of legal complexity that is being added in an ad hoc fashion to competitive bidding, in addition to an already large number of potential changes. AdvaMed believes that it would be difficult for suppliers to provide any form of rebate without assuming the uncertainty of additional risk under the Statute.

The rebate proposal also creates a tension with the Federal Anti-Kickback Statute's safe harbor for discount arrangements. To qualify for the discount safe harbor, a rebate must be disclosed in writing to the buyer at the time of the initial purchase to which the discount applies. However, the Proposed Rule contains an express prohibition on the supplier from advertising either directly or indirectly to beneficiaries, referral sources, or prescribing health care professionals. It is difficult to envision a sufficient window of time during which suppliers could meet both the discount safe harbor (requiring disclosure in advance of the arrangement) and the regulation's prohibition on advertising of the rebate (which would appear to apply to the supplier informing the beneficiary directly about the rebate after it is official).

It thus appears unlikely that a supplier could offer a rebate and gain the safe harbor's protections. At a minimum, these limitations greatly limit the circumstances under which

suppliers can be assured of protections against prosecution under the Statute. At a maximum, there could be no way to meet the regulatory requirements and the safe harbor criteria. **If CMS provides for rebates in the Final Rule, AdvaMed believes that CMS should address this issue completely and provide very clear details before implementing any rebate provision in competitive bidding.**

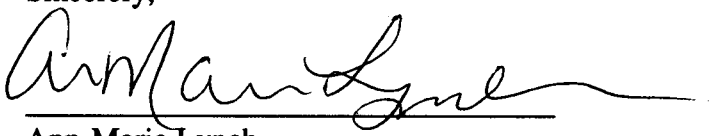
AdvaMed believes that it would be inappropriate for suppliers to be exposed as potential test cases for the limits of this regulatory authority. AdvaMed believes it would be appropriate to offer a safe harbor to suppliers to enable full disclosure of discounts to beneficiaries pursuant to competitive bidding. AdvaMed also questions whether CMS should take the position that rebates, once offered, should become a 'binding contractual commitment' when an express contractual provision would not exist. AdvaMed also believes that CMS's implementation of competitive bidding should allow suppliers to supply products at the standard payment amount, and not at arbitrary prices that would vary based upon supplier willingness to offer rebates after the fact. Allowing a supplier to provide a rebate would create such a discrepancy. Additionally, while CMS believes that this could potentially drive down prices, there is no evidence that this would occur. Any enhancement of future price-cutting based on offering a rebate is uncertain. What is more certain is that confusion will likely be caused by some suppliers offering rebates and others not doing so, and difficulty beneficiaries will have keeping fully apprised regarding which suppliers are offering rebates. The problems will be aggravated by situations in which beneficiaries are traveling outside of their home MSA. AdvaMed does not believe it would be appropriate for CMS to be permitted to disclose these rebates when the regulation would prohibit suppliers from doing so. Absent explicit safe harbor protections and complete reworking of the advertising prohibition, AdvaMed does not believe rebates should be included in competitive bidding.

CONCLUSION

The Proposed Rule provides a framework for competitive bidding but leaves unanswered many critical questions and issues. We have highlighted a number of these in our letter. Our central points are: 1) the Proposed Rule lacks both parameters and an important degree of specificity that we view as absolutely critical to allowing manufacturers and suppliers to participate fully, conform to the program's structure, and provide the highest quality DMEPOS items and services to Medicare beneficiaries; 2) the Proposed Rule contains several items, such as a technology assessment and commentary on the pricing of Class III devices, that are unrelated to competitive bidding and should not be included in the Proposed or Final Rules; 3) the Proposed Rule is simply too encompassing and potentially too problematic to administer, and leaves many parameters of such central importance unspecified in the Proposed Rule which would have to be addressed before the start of the program; and 4) to the extent that CMS wishes to assess costs within the context of competitive bidding, such assessment should take into account all costs, including long-term cost impact, improved quality of life, costs to administer the program and impact on necessity for follow-up treatment.

We welcome the opportunity to work with CMS on these issues to ensure that beneficiaries continue to receive appropriate care and full benefit from advances in medical technology.

Sincerely,



Ann-Marie Lynch
Executive Vice President

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Comments on Medicare Competitive Bidding draft proposal
CMS file code CMS–1270–P

Submitted by: Patrick Naeger

Rebates (§414.416(c))

This is a notion that took everyone by surprise and with good reason. It appears contrary to decades of healthcare law and rules that prohibit Medicare providers from offering beneficiaries rebates on healthcare items and services (remember the beneficiary inducement statute?). The rebate concept is structured to encourage providers to submit the lowest bid possible--so they can increase their chances of winning the bid and gain an advantage over other winning providers. The greater the difference between the provider's low bid and the winning bid amount, the greater the cash rebate the beneficiary will be able to pocket if he chooses you. For the consumer, that's a pretty attractive proposition. Think about it: When the rebate amount is greater than the beneficiary's co-payment amount, you could be paying patients to use your services! In an attempt to address the obvious legal issues, CMS proposes that providers not be able to advertise rebates. Presumably, the government will advertise the respective rebates of various winning providers. Interesting. This section is extremely flawed and should be reconsidered.

Grandfathering (§414.408)

If a provider loses the bid and no longer wishes to serve his existing Medicare beneficiaries, winning HMEs must take over that business. That means winners will have to provide ongoing rentals for beneficiaries with medical needs for cap rental items or oxygen. For example, a winning provider may be required to take on 100 hospital bed rentals that have been occurring for 11 months or oxygen rentals that have been occurring for 30 months. As CMS states in the proposed rule, providers should be accounting for these additional costs when determining the bid to submit for particular items. While CMS will have estimated projected utilization for each HCPCS code it intends to bid, CMS will not be able to provide information regarding how many beneficiaries have been renting a hospital bed or have been on home oxygen therapy by the time the contract will begin. How then can any provider begin to intelligently calculate these additional costs into their bids? This becomes a huge liability to the providers where as in many cases by inheriting the Medicare beneficiary at a debt and the provider suffers significant losses in this types of scenario.

Quality Standards (§414.414)

One of the largest and yet to be resolved issues is the Quality Standards. While the proposed rule was officially published May 1, and CMS scheduled a meeting of the Program Advisory and Oversight Committee (PAOC) in late May, the final Quality Standards were not scheduled to be issued until sometime in June. Quality Standards are so integral to the implementation of competitive bidding that it is difficult to provide meaningful comments to the proposed rule while we are unaware of the content and requirements of the Quality Standards. Perhaps the one positive statement in the entire competitive bidding proposed rule is CMS's apparent attempt to make sure that Quality Standards are implemented at the same time as competitive bidding, and that providers in the initial bid geographic areas will be required to be accredited by an organization whose standards are determined by CMS to meet the CMS Quality Standards. But at another point in the proposed rule, CMS states that the accreditation organizations will be able to grant providers in a bid area a grace period to become accredited within some unstated period of time. Now that's clarity.

Getting It Right Is More Important than Rushing Implementation

CMS should stagger the bidding in MSAs in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Also, the initial MSAs and products selected should be identified in the final rule. And under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

Have Accreditation and Standards in Place before Starting

Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies *now*. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

Make Competitive Bidding Competitive, and Sustainable

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either. This portion of the rule is predicated on the illusion that some how the current fee schedules are adequate to sustain providers. In fact there are provisions in the rule that essentially require the provider to provide equipment to

a patient that is brand specific if the physician so orders. If the CB providers bid was based on a relationship they have with a manufacturer for a specific brand then there will be a substantial burden on the provider to bear the cost of a specific brand. This will adversely impact the provider.

What is CMS proposing if a doctor writes a prescription for a brand name product that. a provider is contractually unable to provide:

> Examples:
> A. A physician writes a prescription for a Hoverround power wheelchair. Hoverround is a manufacturer that follows a direct to consumer business model. The winning provider will not be able to supply a Hoverround product because Hoverround will not sell the product to the winning provider. What will be CMS's solution to this problem?
> B. A physician writes a prescription for a portable concentrator. The manufacturer of the portable concentrator has a distribution contract with a non winning provider. In this case the winning provider will not be able to provide that equipment due to the contract. What will be CMS's solution to this problem?

If the physician writes a prescription for a product that the acquisition cost for the product is below the reimbursement for the product - what options does the provider have to substitute for the brand name?

Don't Make it Harder for Providers to Sell their Businesses

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Consider the Impact on the Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Impact Analysis

In this section, a number of statements appear to directly contradict other statements in this section and throughout the rule, particularly regarding the ability of smaller providers to successfully bid in the programs. While CMS continually alludes to the demonstration programs in Polk County and San Antonio, stating that small providers were able to successfully participate in those bids, CMS's impact statement says that this rule "will have a significant impact on a substantial number of small providers." Two pages later, CMS continues: "We

anticipate that the bidding process will be designed to neither reward nor penalize small providers." In a similar vein, CMS states that "since providers can choose whether to submit a bid for the competitive bid program, the regulation imposes no direct cost." Sure, if you don't submit a bid you don't incur the costs of submitting a bid; but if you don't submit a bid you have eliminated all chances for becoming a winning provider. Furthermore CMS proposes to put into place a whole new bureaucracy in order to formulate, analyze and evaluate all the bids. What additional cost will this mean. Will there be any savings after that bill is paid?

CMS has published that they are expecting competitive bidding to provide a 20% cost savings based on the demonstration projects and that CMS feels that 20% cost savings is achievable. In this projection CMS has failed to consider the following:

A. Increase operational costs that have occurred since 2002:
    1. Gas
    2. Insurance- Liability, Auto, workers compensation, and Health insurance
    3. Personnel costs- Raises
    4. 2003 and 2004 CPI freezes
    5. The FEBHP allowable cuts that occurred Jan 1, 2005
    6. The general and administrative costs to administer the program

With the above mentioned increases and cuts, how is CMS calculating a 20% cost savings? We would like to see the projected cost savings example to verify the accuracy of CMS's prediction. CMS should be more concerned about providing an accurate savings prediction rather than a politically sensitive savings prediction.

Bullet Point Comments Regarding MSA Selection Criteria
Background Information
Section 1847(a)(3) of the Act allows CMS to exempt from the Medicare DMEPOS Competitive Bidding Program rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item. CMS proposes to use this authority to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on a combination of the following indicators:

- Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas.
- Low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas; and/or
- Low number of Medicare FFS beneficiaries in the area relative to other similar geographic areas.

CMS proposes to make decisions regarding what constitutes low (non-competitive) levels of utilization, suppliers, and beneficiaries on the basis of our analysis of the data for allowed charges, allowed services for items that may be subject to competitive bidding, and the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, CMS proposes to use the definitions currently in §412.64(b)(1)(ii) of the regulations. CMS invites comments on the methodologies proposed for determining whether an area within an urban area that has a low population density is not competitive. CMS will be reviewing the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding. In addition, CMS also invites comments on standards for exempting particular rural areas from competitive bidding.

Comments:

1. Rural areas tend to be underserved under the present system. Providers routinely travel hundreds of miles to provide services in various areas of the country. Travel costs have never been covered by Medicare.

2. In certain areas of the country complex Rehab Technology services are available from only one or two providers for several hundred miles in any direction. Access is already compromised in many areas as a result.

3. CMS has no published criteria outlining the optimal number of providers serving a geographic area. Furthermore there is nothing to indicate once the winners are picked what time frame would be used to establish whether or not there are adequate providers to serve the CB area. The greatest fallacy in this is that once some of these suppliers are not the successful bidder it won't be long and they will be out of business. Then who would be called on to fill the void. There are no network adequacies standards what-so-ever for CMS to follow.

4. The proposed criteria to use a review of the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding is subjective at best.

5. The analysis of the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas may not reflect reality. This is due to the great distance that patients must travel to receive services in rural areas of the country. In addition discrimination is a problematic area, especially in remote areas with significant lower income populations where beneficiaries already have limited access to services due to significant transportation issues. Rural areas tend to have a greater percentage of elderly population compared to urban areas, and these areas already suffer from a primary care physician shortage.

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MELROSE PHARMACY INCORPORATED
611 West Main Street
Melrose, Minnesota 56352

June 16, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for considering the following comments and suggestions regarding the proposed competitive bidding program for DMEPOS.

- **Competitive Bidding Areas**
- We strongly oppose CMS' proposal that would eliminate beneficiaries freedom to choose where to obtain their replacement supplies of certain DMEPOS. Beneficiaries access to DMEPOS will be severely restricted which may lead to a decline in patient compliance and positive therapeutic outcomes.
- Exceptions must be made for those suppliers who provide DMEPOS to beneficiaries that reside in rural communities. Competitive bidding areas should exclude rural suppliers even if to some the commute may seem feasible. Many beneficiaries will not have access or transportation in order to obtain DMEPOS from a selected competitive bidding area outside of their rural community.
- Therapeutic relationships may be hindered if beneficiaries are required to obtain DMEPOS supplies from a designated supplier. Small suppliers have the ability to build therapeutic relationships with their beneficiaries due to the smaller market. Positive therapeutic outcomes rely on beneficiaries receiving their medications, DMEPOS, and education from the same supplier.

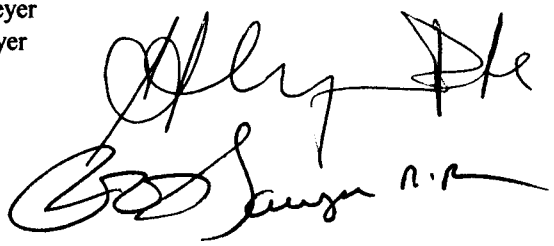
- **Criteria for Item Selection**
- The competitive bidding program should not include DMEPOS supplies that require convenient and frequent access such as diabetic testing supplies. Managing patients with diabetes requires frequent changes in therapy and testing supplies need to be easily accessible whenever changes are necessary.
- The competitive bidding program should also exclude items such as walkers, canes, and respiratory medications. Beneficiaries often need these items immediately. Obtaining these supplies may be delayed for many beneficiaries due to the need to travel to a designated area.

- **Opportunity for Participation by Small Suppliers**
- Small suppliers in rural communities should be allowed a separate competitive bidding area or be exempt from the proposal. Rural suppliers are unique in that they provide services and DMEPOS supplies to a small market. It is imperative that small suppliers are able to continue to provide these services/supplies for their beneficiaries. Many rural suppliers would not be able to compete with larger suppliers in metropolitan areas. Small suppliers that offer a lower bid in order to be contracted will likely lose money on every sale due to the proposal of the single payment for each item of DMEPOS.
- We currently provide the following types of DMEPOS in our practice: diabetic testing supplies, walkers, canes, orthotics, and respiratory medications. If revisions are not made to the final regulation we will not be able to provide these services to members of our rural community.

- In conclusion, We urge CMS to revise the regulation to allow beneficiaries to continue to choose where to obtain their DMEPOS supplies. Especially for beneficiaries in rural communities where commuting to obtain DMEPOS is not convenient or possible. Small rural suppliers must be given special consideration in order to continue providing DMEPOS supplies for beneficiaries in rural communities. Certain supplies such as diabetic testing supplies, walkers, canes, orthotics, and

respiratory medications should not be included in the competitive bidding program due to the need for convenient and frequent access.

Thank you for considering our views and concerns.
Sincerely,
Melrose Pharmacy Inc.
Stacy Meyer
Jeff Sawyer



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Paul McWilliams
Plaza Discount Pharmacy
451 West Bankhead Hwy
Villa Rica, Ga 30180

6/19/06

To Whom It May Concern:

After reading the recent proposals for certain segments of the DME program I am extremely upset that a mandatory mail order would even be considered. Taking away the patients ability to have personal contact with the provider is a huge mistake. Patients should have the ability to choose a provider and most will not choose mail order unless they are coerced. In the past I have had patients switch to us from the mail order services seen on television. Many times they had been sent supplies without requesting them and in some instances had large stockpiles of products. Patients only receive supplies when requested from our Pharmacy.

I am willing to accept a competitive bidding process as long as the small supplier is not left out. Our health care system needs some reform but destroying the ability of local DME providers to stay in business is not a good idea. Our pharmacy is a one stop shop for patients who want medications and supplies or equipment. Many times people need help immediately and want to deal with someone they trust and know.

Our nation's pharmacies have had to shoulder the burden of Medicare part D. Many had to borrow money just to make up for delayed payments. Now for those of us who supply DME items we are potentially being dealt another blow. Mandatory mail order and blocking small legitimate suppliers is not the way to save money in the long term. It certainly is not the way to take care of patients either.

Sincerely,

Paul McWilliams,R.Ph

JoAnn Shropshire, OTR/CHT
Karen L. Sipp, OTR/CHT
Connie L.S. Simon, OTR/CHT
Holly W. Renard, OTR/CHT
Laurie Petrie-Kampa, OTR/CHT
Nicole A. Salm, OTR/CHT
Maureen McGrath-Doran, OTR/CHT
Ann Porretto-Loehrke, PT/CHT/COMT
Julie A. Ver Straate, OTR/CHT

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Laurie Field, OTR/CHT
Donna Nennig, OTR
J. Michelle Mueller, PT

June 19, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to express my concern regarding Medicare's consideration to implement a competitive acquisition program for suppliers of durable medical equipment. I work in at a hand center, which supplies a number of pre-fabricated splints to Medicare beneficiaries. The implementation of this type of program would not allow trained professionals, such as occupational and physical therapists, to supply these types of splints. These elderly patients may result in the risk of skin break down or other potentially adverse effects. For example, when providing a prefab wrist-hand-orthosis for the conservative treatment of carpal tunnel, the metal stay should be placed in a straight (or neutral) position to minimize stress on the median nerve. Pre-fabricated splints typically position the wrist at 30 degrees of extension. Having this type of splint provided by a non-therapy provider may cause harm to the median nerve and exacerbation the patients symptoms. This may result in more health care dollars spent to address potential problems created by not allowing rehabilitation professions to provide pre-fabricated splints.

Please consider allowing occupational and physical therapists to provide pre-fabricated splints to Medicare patients. Many of these patients need training and instruction on splint care and precautions that may not be provided with a centralized DME provider.

Thank you for your time and consideration.

Sincerely,

Ann Porretto-Loehrke

Ann Porretto-Loehrke, PT/CHT/COMT
Physical therapist/Certified Hand Therapist

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ALVARADO ORTHOPEDIC MEDICAL GROUP, INC.

5555 Reservoir Drive, Suite 104, San Diego, CA 92120-5198
Medical Office: 619-286-9480 Facsimile: 619-286-4568 Business Office: 619-286-6930

June 19, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other issues; Proposed Rule (CMS-1270-P)

To Whom It May Concern:

I write in regard to the above-captioned proposed rule ("Proposed Rule") and on behalf of Alvarado Orthopedic Medical Group, Inc. This is a multi-physician practice located in San Diego, CA. In June 2005, the Group obtained a Medicare DMEPOS supplier number. The sole purpose for doing so was for the Group to be able to furnish off-the-shelf (OTS) orthotics and braces, to our patients. Being able to offer these products and supplies directly to our patients is a significant benefit for our patients. Unfortunately, the Proposed Rule may undermine the ability of the Group to be able to continue to supply OTS orthotics, and braces to its Medicare beneficiary patients. I write to express my opposition to this possibility and to explain why I believe that this would be ill advised.

1. To begin with, physicians being direct suppliers of OTS orthotics and braces, is consistent with other Medicare policy on the issue. In January of 2001, the Centers for Medicare and Medicaid Services ("CMS") published final regulations implementing the Ethics in Patient Referrals Act (commonly known as the Stark Act). As you know, the Stark Act generally prohibits physicians from referring patients to entities with which the referring physician has a financial relationship for the provision of "designated health services," including orthotics and supplies. There are, however, several significant exceptions to this prohibition,

including an exception for certain designated health services provided by a physician to the physician's patients in the physician's office (i.e., the In-Office Ancillary Services Exception). 42 C.F.R. & 411.355(b). The In-Office Ancillary Services Exception evidences the federal government's recognition of the importance of providing continuous, high-quality health care services to patients directly from medical practices. In January of 2001, CMS confirmed that the In-Office Ancillary Services Exception was available for orthotics and related supplies furnished to Medicare beneficiaries and Medicaid beneficiaries and Medicaid recipients by there treating physician. In other words, a treating physician may provide and bill Medicare and Medicaid for orthotics and related supplies, so long as those services are ancillary to the underlying professional services and are provided in the same building where the physician provides substantially all of his/her professional services or in a centralized building where the physician provides ancilliary services. See Fed. Reg. 856,932 (Jan. 4, 2001) ("Prosthetics, prosthetic devices, and orthotics may be provided to a patient by a physician under the in-office ancillary services exception....")

CMS's position regarding the provision of orthotics pursuant to the In-Office Ancillary Services Exception is consistent with sound public policy. A physician should not be prohibited from providing his/her patients with medically necessary orthotics and related supplies at the time and place of service. To the contrary, I want to be absolutely certain that patients receive the correct items and proper fittings. Additionally, it is inconvenient for patients to be forced to travel to a "designated supplier" in order to receive ancillary products which are readily available from this office, at the same price as offered by a "designated supplier."

2. While I understand that Congress has mandated that the Secretary of Health and Human Services ("Secretary") must develop a competitive acquisition program for certain DMEPOS items and services, I also note that Congress afforded the Secretary exception authority for, among other things, "items or services for which the application of competitive acquisition is not likely to result in significant savings. 42 U.S.C. & 1395w-3(a)(3)(B). Similarly, the statute,42 U.S.C. & 1395w-3(b)(6)(D), requires the Secretary to "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section." Based upon the foregoing, to ensure patient convenience, I would encourage the Secretary to: (a) carve-out OTS orthotics, braces and casts from the competitive bidding program; or (b) if that is not an option, continue to allow physician suppliers, such as the Group, that are willing to supply OTS orthotics, braces and related supplies to their Medicare beneficiary patients at the rates determined through the competitive bidding program.

As a threshold manner, OTS orthotics should be carved-out of the competitive bidding program. CMS' own empirical evidence establishes that OTS orthotics account for a negligible percentage of eligible DMEPOS charges. See 71 Red. Reg. 25654, 25691 (Table 10)(May 1, 2006). Indeed, when combined, lower limb, spinal and upper limb orthoses accounted for only 2% of DMEPOS allowable charges in 2003. 71 Fed. Reg. at 25691 (table 10). Accordingly, competitive bidding for OTS orthotics is not likely to result in significant savings for the Medicare program and will lead to more inconvenience for Medicare beneficiaries.

If the Secretary is unable or unwilling to carve-out OTS orthotic from the competitive bidding program then, in an effort to accommodate small suppliers, the Secretary should afford physicians that only furnish DMEPOS to their patients in accordance with the In-Office Ancillary Services Exception (like the Group) the opportunity to continue to furnish such items in accordance with the prices determined by the competitive bidding program. Effectively, the Secretary would establish an "any willing provider" program for the physicians seeking to furnish DMEPOS to their Medicare beneficiary patients. The Secretary's alternative for accommodating small suppliers – i.e., through the establishment of networks for bidding purposes – is untenable for physician suppliers. The Stark Act would effectively preclude the formation of such networks by physician suppliers who refer their Medicare beneficiary patients to those network suppliers for DMEPOS as those networks could not operate within the parameters of the In-Office Ancillary Services Exception. Physician suppliers that otherwise provide quality items and services to their patients should not be unfairly excluded from continued participation in the Medicare program as DMEPOS suppliers.

We appreciate you careful consideration of our position.

Sincerely,

Tracy L. Maghato
Administrator

LA CASA DEL CONVALECIENTE, INC.

PO Box 9066366, San Juan, P.R. 00906-6366
Ave. De Diego #759, Caparra Terrace, San Juan, P.R. 00921 • Tel. (787) 774-0800 • Fax (787) 774-0814
Compañía Acreditada por: " Joint Commission " Estandarte de Oro por Calidad en Cuidado de Salud

211-0

(4)

June 20, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
P. O. Box 8013
Baltimore, MD 21244-8013

Dear Sirs:

I'm writing this letter to express one of the reasons why we should not considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another relevant aspect to consider is that the Allowed Charges used to consider Puerto Rico in the implementation of this initial phase corresponds to the 2004 fee schedule. During 2003 to 2004 CMS allowed charges to Puerto Rico witch were higher than in the States due to the recognition of the added cost involved importing. DME suppliers now have to absorb these previous added costs, therefore the use of allowed Charges of 2004 does not reflect the current reality of Allowed Charges in Puerto Rico, with the PAPC is using to select the MSA's that are to be included in the initial phase of the program in 2007.

Thank you for attention.

Sincerely,

Carlos Iglesias

Carlos Iglesias
Gereral Manager

PERTH AMBOY
Medical Equipment Corp.
VENTA Y ALQUILER
DE EQUIPOS MEDICOS

CALLE ANDRES MENDEZ LICIAGA # 6
SAN SEBASTIAN
PUERTO RICO, 00685

212-D
(38)

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

The I am writing this letter to express one of the reasons why we should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

Another important factor that needs to be addressed is the language barrier that currently exists between Puerto Rico and the United States, given the majority of the islanders are native Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

CIV Pharmacy

213-0
(37)

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express one of the reasons why Puerto Rico should not be considered in the competitive bidding process or a least not considered in the first 10 MSA's (Metropolitan Statistic Area).

In addition, long-standing relationships between beneficiaries and familiar supplier will be interrupted causing disruptions in services and dissatisfaction for patients. Given Puerto Rico's location in the heart of the Caribbean Sea the island is impacted yearly by hurricanes and tropical storms that makes is impossible for distant suppliers to provide the service needed because of sudden flooding in many of the small, rural roads in the cast region of the island, theses common events impacts the beneficiaries access to DME supplies, such as oxygen tanks that are needed on a regular basis. In summary, the result of the implementation of the Competitive Bidding Program would be that small, community-based suppliers would be displaced by larger chain suppliers that can take advantage of economies of scale, but which may not be in the interests of beneficiaries. The Competitive Bidding Program will make it impossible for the beneficiary that decides to continue with Traditional Medicare to do so, because although is essence the beneficiary would be entitled to continue under the label of "Traditional Medicare", they would not have the actual benefits of selecting from an array of suppliers since only one or two suppliers would be available to provide services. It is this freedom of selections that is currently provided by Traditional Medicare that must be vigilantly safeguarded.

Sincerely,

Juan A Roman
Manager

CIV Pharmacy
Calle Muñoz Rivera # 9
San Sebastián, PR 00685

(214)

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

6/16/06

Dear Sirs,

We are glad to hear you are thinking about including "LOW VISION AIDS" in the approved "medical equipment" rulings. We were glad to see wheelchairs, crutches and bathroom aids approved. Having CCTV's, magnifiers and other aids will help keep more of us in our homes, especially those who cannot afford them on their own.

I belong to a "vision loss support group". Some of the members couldn't be as independent as they are without their magnifiers, CCTV's and special glasses.

Please consider this request.

Natalie S. Riecks
121 Dakota Dr
Loda, IL 60948

215

Independent Medical Co-op, Inc.
129 Executive Circle
Daytona Beach, FL 32114

386.258.1530 Fax 386.258.1525
www.imcoinc.com info@imcoinc.com

DATE: June 26, 2006

TO: Centers For Medicare & Medical Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

FROM: Deb Bullock
IMCO
Vice President of Acute Care & LTC Markets

REFERENCE: Competitive Acquisition Program for Certain DMEPOS and other Issues. (42 CFR Parts 411, 414 and 424)

IMCO is a healthcare distribution association representing approximately 70 DMEPOS distributors nationally. Their customer base includes over 500 skilled nursing facility providers.

IMCO and our membership is opposed to the inclusion of "any willing provider" environment to include skilled nursing facilities. Requiring SNF's to competively bid is fraught with concerns:

1. The competitive bidding demonstration has not been successfully conducted in skilled nursing facilities.
2. Nursing facility patients require a higher level of care than non-residents:
   - Care plans could be interrupted as a result of competitive bidding putting patients at risk.
   - Patient access to quality products could be compromised resulting in serious or life threatening complications and increased cost of care.
3. "Cost in Use" analysis is not considered
   - Many products appear to be less expensive however, in use they require either additional or replacement products.

Englewood Health Care Center

Amber McDonald, Administrator

216

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Englewood Health Care Center, LLC. Englewood is located in Monroeville, Alabama. Englewood is licensed for 87 Medicare/Medicaid beds providing services such as skilled nursing care including physical therapy, occupational therapy, and speech therapy. Englewood also offers Restorative programs, an activity program and Social Services. Englewood employs on average 120 employees.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

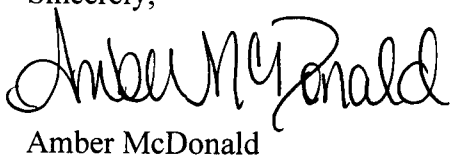
At Englewood we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

2046 South Alabama Avenue • Monroeville, Alabama 36460 • Telephone (251) 575-3285 • Fax (251) 743-9736

I appreciate your attention to this matter.

Sincerely,



Amber McDonald
Administrator

217

BARR PHARMACY
BLAIR MEDICAL SUPPLY
1651 WASHINGTON STREET
BLAIR, NE 68008
6-27-06

CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTENTION CMS-1270-0
P.O. BOX 8013
BALTIMORE, MD 21244-8013

RE: CMS-1270-P

DEAR SIR OR MADAM:

I appreciate the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments.

Competitive Bidding
The proposal that would require beneficiaries to obtain replacement supplies through designated providers I feel restricts the beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

Opportunity for Participation by Small Supplies
CMS needs to take steps to ensure that small suppliers can participate in the program. We need to be allowed to designate a smaller market in which to provide DMEPOS.

I feel that any small supplier willing to accept the single payment amount that CMS has established should be allowed to join the program as a contracted supplier.

Beneficiaries should have convenient access to the DMEPOS supplies they need. Not every beneficiary lives in or close to a metropolitan or large city.

We currently provide oxygen, wheelchairs, beds, walkers, ostomy supplies, medication and diabetic supplies in our pharmacy and without these revisions to the final regulation, I will be unable to continue providing these valuable services to our patients.

I strongly urge you to revise the regulation so that small suppliers can continue to meet the needs of the patients in our smaller and rural communities. Each beneficiary should have the right to chose where they go as long as the supplier is a willing provider.

Thank you for considering my view.

Sincerely,
Dr. Charles C Barr R.P.

Dr. Charles C Barr, R.P.

Patient Support Services

218

June 26, 2006

Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop *C4-26-05*
7500 Security Boulevard
Baltimore, MD 21244-1850

Via Overnight Delivery

Re: Comments to Proposed Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS"), File Code CMS-1270-P

Dear Sir or Madam:

These comments are submitted on behalf of Patient Support Services, Inc. ("PSSI"). PSSI is an accredited small business located in Texarkana, Texas that provides enteral nutrition to patients in Texas, Arkansas, and Oklahoma. PSSI is a niche provider of enteral nutrition and related supplies. The provision of enteral nutrition products makes up ninety-five percent of the company's business. PSSI submits these comments in response to the proposed rule related to competitive acquisition of DMEPOS products published in the Federal Register 011 May 1, 2006.

I. Criteria for Item Selection

Enteral nutrition is an area in which poor service by the DMEPOS supplier can seriously affect patient care. There are no fewer than 100 different types of enteral nutrition products on the market. Although the products vary in the number of calories provided to the patient, the differences do not stop there. Enteral nutrition products contain different concentrations of nutrients and vitamins and the supplier of enteral nutrition must be knowledgeable about and able to provide the formula as prescribed. On more than one occasion, PSSI has been contacted by a discharge planner to take over the provision of enteral products for a patient who had been receiving services from a provider that represented itself as knowledgeable and capable of providing enteral nutrition. Oftentimes, companies that have the experience to provide other types or DME represent themselves as enteral nutrition providers when in reality they have insufficient expertise to provide enteral nutrition products. When the enteral nutrition provider does not have the requisite knowledge about enteral nutrition, the caregivers to the patient are unable to get the guidance and product they need. PSSI's small business structure and emphasis on quality has made it the enteral supplier of choice for a number of discharge planners who have worked with larger companies.

Many patients and residents of Skilled Nursing Facilities (SNFs), long term care facilities, and nursing homes require enteral nutrition. Oftentimes, the supplier of enteral nutrition for the residents of these facilities is selected by the facility. Many enteral nutrition

companies have agreements with SNFs; long-term care facilities and nursing homes to act as their supplier for enteral nutrition products. In choosing a supplier, the facilities look for the best quality of service. As written, the proposed regulations require that all SNFs either become contract suppliers or utilize contract suppliers for the provision of DMEPOS. The regulations further require that residents of long term care facilities and nursing homes obtain supplies only from contract suppliers, unless the grandfathering provision applies. PSSI believes that this approach will prove to be problematic, especially in the area of enteral nutrition and recommends that enteral nutrition be excluded from competitive bidding altogether as was the case in the San Antonio demonstration project and the second and final round of bidding in the Polk County demonstration project

Under the grandfathering provisions, it appears that a SNF, long term care facility, or nursing home may be able to continue to use its former enteral nutrition supplier if it chooses to do so. What is unclear, however, is whether a SNF, long term care facility, or nursing home may continue to use that same supplier for all of *its* patients, including new residents who arrive at the facility after the contract suppliers are determined.

SNF patients as well as long term care patients who require daily attention and care should have the opportunity to use the services of a DMEPOS company that has proven itself to be effective, reliable and responsive to the needs of patients in fragile health. Because of the uniqueness of enteral nutrition services as well as the potential impact competitive bidding can have on the quality of enteral nutrition services available to patients, PSSI further recommends that, at a minimum, a demonstration project which reviews the effect of competitive bidding on the provision of enteral supplies be completed prior to widespread implementation.

II. Regulatory Impact Analysis

Under the new competitive bidding regulations, *it* is likely that small businesses such as PSSI that have built their companies on quality care will be unable to compete against large companies and small businesses that claim to provide enteral nutrition but do not have the resources to do so. Although many companies may claim that they are capable of providing enteral nutrition, few have invested in the knowledge and expertise required to supply enteral nutrition properly. The physicians and nurses at each SNF, long term care facility, and nursing home are the best persons to determine and recommend those suppliers that provide the best quality service.

One way to reduce the impact of competitive bidding on small business suppliers and to protect patient choice is to allow any supplier who submits a bid, and who is willing and able to provide the product for the competitive bidding price, to participate as a contract supplier

In the preamble to the proposed regulations; it is explained that the regulation specifically does not allow any willing supplier to provide a competitively bid product, even if that provider is wilting to accept the contract price. The reason provided in the Regulatory Impact Analysis *is*

that the statute requires a company to have submitted a bid in order to be a supplier. This rationale does not take into consideration those companies that submit good faith bids but are not awarded contracts. The statute does not prevent the Secretary from naming any bidding supplier willing to provide product at the competitive bid price as a contract supplier. Allowing small businesses to participate in this manner after submitting a good faith bid will allow for the participation of more small businesses as mandated by the statute, and will allow for more patient choice. The presence of more businesses competing to serve patients at the competitive bidding price will ensure that the patients receive better quality care from their DMEPOS supplier.

III. Opportunity for Participation By Small Suppliers

At the present time, at least 90% of the suppliers of DMEPOS are small businesses. Under the program outlined in the proposed regulation, large corporations will have an enormous advantage. If the regulation is implemented as proposed, small businesses will very likely cease to be the norm in the DMEPOS industry. *It* should be anticipated that in an effort to compete with the big companies, some small businesses will submit bids below the prices they can afford. This will at a minimum affect the quality of the small companies' services, and will most likely cause a large number of small businesses to fall into financial ruin. While the regulation does provide small companies with a networking option, it is unlikely that such an option will be enough to assure that small businesses will survive under competitive bidding. If anything, it is more likely that the networked small companies, if successful, will eventually become a single large company. Creating a single large company will not assure the participation and protection of small suppliers as required by the Medicare Modernization Act.

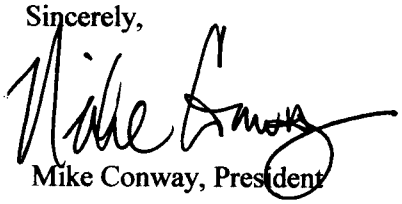
In order to provide small businesses with the opportunity to compete in a competitive bidding area, PSSI proposes that the Secretary implement procedures which have been in existence in the federal government for many years. The government should set aside a certain portion of competitive bidding slots solely for small business. Small business set-asides have been used under the Federal Acquisition Regulation procedures for many years and have helped to provide small business opportunities within the government contracting realm.

Small businesses face even greater threats if they do not receive special consideration under the competitive bidding regulations than they face in typical government contracting. In most industries, there is a market for the services rendered by the small businessperson outside of the competitive bidding arena. Unfortunately, for many DMEPOS products, Medicare represents by far the largest portion of the market. If a small business does not win the opportunity to serve as a contract supplier during the initial competitive bidding process, then it is likely that the company will cease to exist. Thus, during the second round of competitive bidding, there will be no new companies to join the ranks of competition. With no new competition, the government will be forced to accept higher bids from the remaining large companies during the second competitive bidding cycle three years later. Because many small

DMEPOS suppliers will not be able to survive without Medicare business, the cost savings achieved through competitive bidding will be short-lived.

Thank you for taking the time to review my comments.

Sincerely,



Mike Conway, President

PSK/sk

219

CHRIS ALBRITTON, D.P.M.
Podiatrist -- Foot Specialist

2501 South Willis
Suite A
Abilene, Texas 79605
325-695-8990

wingfoot@affcpodiatry.com
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Fax: 325-695-0901

Diplomate, American Board of Podiatric Surgery
Board Certified in Foot Surgery

Fellow of the American College of Foot and Ankle Surgeons

Chief of Staff, Hendrick Center for Extended Care

June 27, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required instead to bid to supply my entire Metropolitan Statistical Area (MSA), my patients will be negatively impacted.

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only, and the right to execute a physician authorization.

In my practice, I use a variety of DMEPOS items, and the most frequent item I use is a Cast Walker (walking boot). Mrs. JH is a delightful, spry, 78 year old female who loves to walk for exercise. She presented to me with pain and swelling in her left foot, and stated she could no longer walk for exercise. This was extremely distressful to her, because she has coronary artery disease, as well as Peripheral Arterial Disease, and continuing her walking program is vitally important to her health. After examination and x-rays, I diagnosed her with a fracture of her 2nd metatarsal bone in her left foot, associated with osteoporosis. I placed her into a Cast Walker (a DMEPOS item dispensed from my office), increased her calcium intake, and in 4 weeks, she was able to resume her walking program at 50%.

If I no longer function as a supplier, these patients will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. Being unable to bear full weight on the injured extremity places these patients at high risk of falls, which so often results in other additional injuries, such as hip fractures, forearm fractures, and shoulder injuries. If I am not a supplier in the new program, my patients will suffer.

Please change the physician definition from 1861(r)(1) to 1861(r) so that my patients will continue to be able to receive from me the medical care and medical products that they need.

Sincerely,

Chris Albritton, DPM

The Foot & Ankle Center

Mitchell R. Waskin,
D.P.M., FACFAS

(804) 320-FOOT (3668)
(804) 320-2600 (Fax)

1465 Johnston-Willis Drive
Richmond, VA 23235

www.320FOOT.com

220

June 26, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) **FROM** 1861(r)(1) **TO** 1861(r)(3).

Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items ***to my patients only*** and the right to execute a physician authorization. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive acquisition program.

Sincerely,

Mitchell R. Waskin, D.P.M., FACFAS
Foot & Ankle Center, L.L.C.
1465 Johnston-Willis Drive
Richmond, Virginia 23235

(221)

1/2

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

6-26-06

Bryan Wodaski
Occupational Therapist
1005 Brown Ave
Cumberland MD 21502
301-724-9114

Dear Sir or Madam,

I am an occupational therapist who is a certified hand therapist. I see dozens of patients each day in my outpatient clinic. Many have acute conditions of wrist, hand, elbow and shoulder as well as neck & back problems. As a result of these injuries, changes can be rather rapid. A case of tendonitis suddenly worsens. A cut tendon is repaired but accidently ruptured by the patient. Or perhaps a nerve is inflamed and requires a different splint to reduce pressure on the area. All take flexibility in treatment by me the therapist as well as the doctor.

A rapid response is required. The changes proposed would not allow me to make this adaptation to a changing injury or problem. Problems which can lead to

disability or prolong treatment and increase overall costs. All Othosis are provided based on needs which change. Our clinical skills allow us to make informed decisions for the correct orthosis.

This proposal may place us in a position where I need to do the right thing ethically but my hands will be tied. The savings of bidding off the shelf orthoses will be small as medicare itself has stated but the costs to the patients will be significant and to medicare as well. I have seen inappropriate splints given that can limit motion and create finges that refuse to move. This takes more time in therapy to get them moving and costing more in time & money. It can also result in permanent disability.

I hope to continue to have the freedom to make decisions for my patients that are in their best interest for rehabilitation. Please consider the best outcomes for the patients. This means the person who places the off the shelf orthotic device on that persons injured hand can best judge based on their ability to assess the needs of the patient & their injury. Perhaps most importantly the environment the orthotic device will be used in based on a thorough history, evaluation and patient therapist relationship help keep that relationship at its highest professional level. Reconsider this proposal

Sincerely

Susan J. Hodek, MS, OTR/L, CHT

222

Clarkesville Drug, Inc.
P.O. Box 1659
596 West Louise Street
Suite D
Clarkesville, Ga 30523
(706) 754-3763

May 26, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

The opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS is greatly appreciated. The following comments are those of Clarkesville Drug, Inc. and its representatives.

On the issue of competitive bidding areas, I greatly disagree with the CMS proposal that would require beneficiaries to get replacement supplies of certain items from designated providers. This would limit beneficiaries ability to get needed supplies and greatly affect my patient's healthcare.

The criteria for item solutions should never include common DMEPOS supplies like diabetes testing products. The bidding process should only apply to unique products that could be provided by a control supplier.

I strongly urge CMS to include and ensure that there is a process to include smaller supplies like my pharmacy. Please allow us to be a smaller supplier to provide for DMEPOS. We cannot compete in a large metropolitan area. If we are willing to accept the payment amount allowed, we should be allowed to be in the competitive billing program.

Please take steps to continue to allow beneficiaries access to our pharmacy and continue our provider to patient relationships. I currently provide the following types of DMEPOS in my practice, Diabetic Testing Supplies, Pulmonary Products, Influenza Vaccine, Pneumovax Vaccine.

In concluding, I hope CMS will look at the total picture and make the best decisions for the patient's welfare and care. We enjoy our jobs and take our patients healthcare very seriously. Please do not allow us to be left out.

Sincerely,

David Ledbetter

David Ledbetter, Rph
Clarkesville Drug, Inc.

223

June 23, 2006

CMS – 1270 – P
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS – 1270 – P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Gentlemen:

I am writing in reference to the Competitive Bidding Proposal that will be voted on this year. There are several points that I feel very strongly about and I firmly believe that you are venturing into very dangerous territory. You will be limiting the quality of equipment that is available. Additionally, you will cause the "most needy" portion of the population to be at the mercy of suppliers who you have been chosen based on price. This is not the way I wish to end my years. I do not wish to have to settle because the government is trying to save money. This means, as always, those with expendable income will be able to purchase a better grade of equipment. Anyone who has to depend on Medicare will have to make do. This is patently unfair and you, as a governing body are about to foist this upon an unsuspecting public.

Please take a few minutes to consider what I propose.

1. Allow time for all bidders to be considered and the price(s) they quote, along with their explanation for same. (By this I mean that they need to be able to factor in the time to assemble and explain the use of the item/equipment they are delivering). Please be very aware that DME Providers spend a great deal of time "holding the hands" of clients in terms of reassuring them that a piece of equipment is functioning correctly. In addition, it is sometimes necessary to go their home and reassure them that there is not a problem, or if there is, make the necessary repairs. Please be aware that some of these clients are in such condition that they cannot leave their home readily and one of our representatives is like having "company" and they will talk and talk (on the phone or in person). This is a service that does not come with a price tag, and we do it willingly.

2. Do not cater to the large DME providers to the exclusion of the small dealers (who are to be found in small, sometimes out-of-the-way locations). If you only rely on the larger providers, the clients who live in the fringe communities or in out-of-the-way locations will not be served because they require a great deal of time to get to and return. Of course they could become like the "Scooter Store" and drop ship the needed items. However, if it is incorrect or does not work, then what does a client do, especially if they are in real need? Most suppliers have provisions in place to handle emergencies, 24/7. We have had personnel that went out of the way on their drive home to drop off, pick up or swap out a piece of equipment. Again, this is not a service that has a price tag attached. We "know and value" our clients. Some have been with us for a long period of time and we, in effect, become like family.

Someone who is in this business strictly for the money, or who is trying to conserve "every penny" because he won the **low bid** for an item, is not going to go out of his way. Every trip out and back will cost extra money, money he will not be reimbursed for. There is no incentive to do anything extra, in fact there is more incentive to "cut corners". Then the consumer is the loser, as I suggested earlier.

3. Do not split categories. What I mean is if a provider "wins" the bid for hospital beds, then they should also be allowed to carry the related items. This holds true for wheelchairs and other such equipment that has necessary and related accessories.

These are just a few of my thought. I definitely do not like the idea of competitive bidding, as you can tell. I sincerely believe that it will become rife with problems and abuses. Then we will have to come up with more costly methods to repair it. My feeling is, it really is not broken, why do you feel the need to fix it? Most certainly, the current system can be improved upon, but not to such an extent that it will be so totally changed.

Thank you for taking the time to read and consider my suggestions. I look forward to your response.

Respectfully,

Joan B. Curcio

Joan B Curcio
19 Barn Owl Drive
Hackettstown, N J 07840

Cc: Congressmen

June 28, 2006

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Roche

Diagnostics

Hon. Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services,
Department of Health and Human Services
7500 Security Boulevard
Attention: CMS – 1270-P
Mail Stop C4-26-05
Baltimore, MD 21244-1850

Re: Comments on Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule (Docket Number CMS-1270-P)

Dear Dr. McClellan:

Roche Diagnostics is pleased to submit comments on the Proposed Rule on the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. We have manufactured diabetes care test systems for almost 30 years and have an insulin pump business.

Roche Diagnostics believes that CMS should either delay competitive bidding for diabetes care self-test systems or at minimum, severely limit the size of the competitive bidding area for these products. We do not make this recommendation lightly and are well aware of the need for CMS to demonstrate cost savings. To support our position, Roche Diagnostics makes the following observations:

Diabetes Self-Test Care Systems are Different from Other Types of DME

- They are interactive - not passive - devices.

- Diabetes care systems are a cornerstone of primary care in the management of diabetes and are used by beneficiaries to run tests – sometimes many times daily – on which treatment regimens are based and continually adjusted. The Agency for Healthcare Research and Quality reported that Medicare could save $1.3B annually if beneficiaries with diabetes received appropriate primary care.

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- Compliance with diabetes care testing is difficult to achieve for many reasons – it may be painful, embarrassing, inconvenient, hard to perform, or not recognized as a priority because like high blood pressure, diabetes is often a silent disease.

- Ultimately, failure to test results in devastating complications. It is these complications, not testing, that account for the burden of costs in diabetes care.

- Health care providers – physicians, diabetes educators and pharmacists – work with the beneficiary in selecting the best test system that will meet his or her needs, thereby increasing testing compliance.

- Most first time users of diabetes care systems must be trained to operate the new system and manage their care based on the results.

- Health care providers educate and train the patient in the use of blood glucose test systems.

- Many beneficiaries need continuing assistance with blood glucose monitoring.

Diabetes Affects America's Sickest and Most Vulnerable Seniors

- Nearly 1/3 of Medicare costs support beneficiaries with diabetes. A significant number of these individuals have other comorbidities, reduced cognition, poor literacy, or are low income dual eligibles.

- Diabetes affects a disproportionate share of minority beneficiaries. Behaviors and communications toward managing the disease can differ significantly among these populations.

Changes in Distribution and Products Could Adversely Impact Thousands of Beneficiaries

- Distribution systems for diabetes care products are significantly different than other types of DME. Sixty percent of beneficiaries acquire supplies

at their local pharmacy often at the same time their prescriptions are being filled. The remaining obtain their supplies via mail order.

- The number of beneficiaries in a large MSA who would require any singular item of DME will pale in comparison to the number of beneficiaries with diabetes who will need to switch out their blood glucose test systems.

- Health care providers will be responsible for carrying the burden of educating and retraining beneficiaries who must switch systems in competitive bidding areas.

Neither of the two competitive bidding demonstration projects tested diabetes care self test systems or similar kinds of devices. It is unknown, therefore, the impact that competitive bidding will have on the parameters listed above or how the resultant changes to some of these parameters will be accommodated. Due to the thousands of beneficiaries and health care providers who will be significantly impacted by a large competitive bidding program, we urge CMS to give serious consideration to our request to delay or to restrict a competitive bidding program for diabetes test systems. This will allow the Agency time to gain experience.

Roche Diagnostics believes that CMS should consider exempting insulin pump systems from the competitive bidding program. If the Agency decides not to exempt these products, we recommend that a competitive bidding program for insulin pump systems be delayed or limited to a small area in order for CMS to gain experience with these items. To support these recommendations, we would like CMS to consider the following:

Insulin Pump Systems are Low Volume Complex Devices

- Like diabetes care self test systems, insulin pump systems are interactive – not passive devices.

- Many beneficiaries need continuing assistance with insulin pump maintenance and operation and must play a direct role by calibrating insulin administration to blood glucose levels.

- Insulin pump systems are a low volume product in the Medicare system – only 10% of beneficiaries with Type I diabetes use these products. As CMS is aware, Type I diabetes represents only 5-10 percent of the cases overall and the number of Type I cases is growing much more slowly than Type II cases.

- We do not expect that Medicare costs for insulin pump systems will grow significantly any time soon due to CMS' recent national coverage decision which would preclude the use of these products for beneficiaries with Type II diabetes. In addition, these are relatively complex products and cannot be used by all beneficiaries with diabetes. As CMS has noted in its national coverage decision, insulin pumps –

  > "do not measure blood glucose levels or automatically adjust insulin delivery rates. For proper effect, the...user must measure blood glucose several times per day and program the pump to deliver an appropriate basal rate and pre-meal boluses of insulin. Because of this, not all patients are candidates for [pump-based therapy].

Compared to Typical DME Products, the Supplier Market is Different and Significantly Limited

- In its Proposed Rule, CMS has proposed as a criterion a high ratio of suppliers to beneficiaries. The insulin pump market is supplied primarily by four manufacturers. For the most part, the manufacturers distribute these products directly to the beneficiaries; thus, the ratio of suppliers to beneficiaries is low.

- Excluding any of the four suppliers from the market through competitive bidding could reduce competition.

Neither of the two competitive bidding demonstration projects included insulin pump systems or similar kinds of devices. It is unknown, therefore, the impact that competitive bidding will have on the parameters listed above or how the resultant changes to some of these parameters will be accommodated. In addition, these are low volume complex devices obtained from a very limited number of suppliers. Because of this, Roche Diagnostics recommends that insulin pump systems be excluded from the competitive

bidding program. If CMS does decide to seek competitive bids for these products, we recommend that the competitive bid area be limited in order to give the Agency experience in this area.

Below are Roche Diagnostics' comments on specific provisions of the Proposed Rule.

I. Background

D. Medicare Competitive Bidding Demonstrations

Competitive Bidding of Blood Glucose Systems Should Be Delayed or Limited Until CMS Gains Further Knowledge of the Impact of the Program

CMS states that the competitive bidding demonstration programs in Polk County, Florida and San Antonio, Texas achieved "mostly successful results" and that "statistical and qualitative data" indicate that beneficiary access and quality of services were essentially unchanged." We are aware however, of the many problems that CMS encountered, particularly with urological supplies. We are also not aware of any CMS issuances to the public on the detailed statistical, quantitative and qualitative methodologies that were used by the Agency in analyzing the degree to which beneficiary access and quality of products and services was determined. We acknowledge that the purpose of a demonstration project is to ferret out problematic areas such as those identified with urological supplies, but are very concerned that the Agency did not grasp the nature of these items at a very fundamental level prior to incorporating them into the program. We make these observations in light of the unique issues that are presented by blood glucose systems. We believe that the Agency must be able to accurately measure not only the savings achieved by the competitive program but also overall affect on beneficiaries in terms of the quality of care and reduction of clinical costs.

As CMS is aware from our November 23, 2005 comments to the Agency on the Quality Standards (included with these comments), diabetes test systems are entirely different from other types of DME. They are mostly acquired at retail outlets when other prescriptions are being filled, can require significant support in terms of education and compliance, and are a diagnostic tool that must be used on a daily basis to prevent extremely devastating and costly clinical complications. We firmly believe that changing these systems on a mass scale

will be an extremely unsettling process for the tens of thousands of beneficiaries affected and could result in unintended and costly consequences – most notably an increase in physician office and emergency room visits, inpatient admissions and an increase in complications such as retinopathy, blindness, kidney disease and failure, cardiovascular disease and amputations.

We strongly recommend that CMS give serious consideration to delaying competitive bidding for diabetes care products or to limiting competitive bidding to a very small area until the Agency gains sufficient experience with products that are less complex. In addition, we believe that CMS should be able to detect and measure untoward clinical events in a statistically valid manner. The Agency should state the methodologies that will be used to accomplish this in its next issuance of the competitive bidding rule.

F. Deficit Reduction Act of 2005

As CMS acknowledges in its Proposed Rule, section 5101(a) of the Deficit Reduction Act of 2005 (DRA) amends the Social Security Act to effect changes in the way Medicare pays for certain capped rental items. What CMS does not acknowledge is the greater level of complexity that beneficiaries will face as they attempt to manage their diabetes amid the combined effects of the new competitive bidding and DRA changes.

DRA provides for transfer of title of capped rental items from suppliers to beneficiaries for those items for which the first month of rental occurs on or after January 1, 2006. Such transfer is required to occur after 13 continuous months of rental. These DRA-required changes, even standing alone, raise serious questions about how beneficiaries will ensure adequate maintenance and service for their pumps. If combined with the new competitive bidding program, beneficiaries will encounter even greater uncertainty about maintenance and service.

As CMS notes in the Proposed Rule, the implementation of the DRA's capped-rental changes will be the subject of a future rulemaking. We therefore suggest, at a minimum, that CMS defer considering application of competitive bidding to insulin pump systems until these DRA changes are implemented in final regulations.

To illustrate the importance of such a deferral, consider the fact that one issue the DRA regulations will address is the basis upon which Medicare will make

statutorily mandated payments for the maintenance and servicing of capped rental equipment after title to that equipment has passed to a beneficiary. Until CMS has deliberated on stakeholder comments and finalized its approach to these payments, the Agency's competitive bidding structure for insulin pump systems is necessarily clouded and ambiguous, adding another layer of uncertainty for beneficiaries.

In all, CMS should at a minimum defer competitive bidding of insulin pumps systems at least until the DRA changes are finalized. Such a deferral would allow CMS to structure payments for insulin pump systems coherently and holistically, thereby allowing suppliers and beneficiaries to understand the full reimbursement parameters before bidding begins.

G. Program Oversight and Advisory Committee

CMS Should Fulfill the MMA Mandate to Develop Proposals on the Efficient Interaction among Manufacturers, Providers, Suppliers and Individuals

Due to the unique circumstances surrounding diabetes care and access to supplies, Roche Diagnostics believes that the PAOC meetings did not adequately address the "efficient interactions among manufacturers, providers of services, suppliers and individuals." In the diabetes disease management continuum, all of these entities work closely with each other and the beneficiary to train, provide support services and monitor the patient with the objective of maintaining an optimal clinical status. We are aware of only one PAOC panel that was devoted to diabetes. This panel primarily focused on supplier issues and not the relationship between the key entities in the diabetes care continuum. We are also not aware of any meetings between CMS or RTI with national supplier, provider and manufacturer organizations to discuss the impact that competitive bidding will have on the interaction of these groups and the effect on the day to day management of beneficiaries with diabetes. Roche Diagnostics notes that failure to meet with these stakeholders to specifically discuss what we consider to be a fairly complex chain of interactions has resulted in Quality Standards that do not reflect the current standards of care for diabetes. The Proposed Rule raises these same issues and concerns. We recommend that these interactions be addressed prior to the second issuance of the Quality Standards and the competitive bidding rule.

H. Quality Standards for Suppliers

CMS Should Work with National Supplier and Provider Organizations and Beneficiaries with Diabetes to Develop Standards that will Result in Quality Products and Care

Roche Diagnostics agrees that CMS should only award competitive bidding contracts to those suppliers who are in compliance with the Quality Standards. Due to the significant shortcomings in the first draft of the standards with regard to diabetes care systems, however, we question whether CMS can realistically issue a final version that will meet its stated competitive bidding implementation timeline. As noted earlier in these comments, we submitted extensive comments to the Agency on the Quality Standards. In general, we believe that the standards need to be modified significantly in order to ensure that minimal disruptions occur in care. Beneficiary access to quality diabetes products should be guaranteed and adequate safeguards should be in place to prevent the use of counterfeit or substitute products. There should not be undue encouragement or pressure on beneficiaries to obtain additional products if they are not needed. In developing the Quality Standards - and as recommended to the Agency in our comments on the Quality Standards - we strongly recommend that CMS adhere to its statement in the Proposed Rule that says "We are using contractor support and input from industry suppliers and national organizations to develop the quality standards. Additionally, the contractors will meet with beneficiaries who use the specific products to solicit their input..."

The Quality Standards Should be Treated as a Rule

Roche Diagnostics believes that due to the impact the Quality Standards will have on tens of thousands of suppliers (many of whom are small), CMS should perform an economic impact analysis and comply with the Regulatory Flexibility Act. Because CMS did not apply formal notice and comment to the Quality Standards, we also believe that CMS should comply with the Congressional Review Act. Additionally, because compliance with the Quality Standards will result in the generation of new forms, the burden and necessity of these should be analyzed by CMS and submitted to the OMB Office of Information and Regulatory Affairs as per the requirements of the Paperwork Reduction Act.

I. Accreditation for Suppliers of DMEPOS and Other Items

Roche Diagnostics agrees that CMS should follow the Administrative Procedure Act with an opportunity for comment when issuing the procedure for designating and supervising accreditation agencies. We also support CMS' proposal that those suppliers who are currently accredited be grandfathered in.

K. Establishing Fee Schedule Amounts for New DMEPOS Items
This is an extremely important proposal that is not related to competitive bidding. Roche Diagnostics does not believe that this should be included in the Proposed Rule. To ensure that stakeholders are given the time to properly evaluate this provision, we strongly urge CMS to issue this under a separate rulemaking procedure.

M. Covered Item Updates for Class III DME for Class III DME for CYs 2007 and 2008
This is an extremely important proposal that is not related to competitive bidding. Roche Diagnostics does not believe that this should be included in the proposed rule. To ensure that stakeholders are given the time to properly evaluate this provision, we strongly urge CMS to issue this under a separate rulemaking procedure.

II. Provisions of the Proposed Regulation

B. Implementation Contractor
Roche Diagnostics supports the CMS decision to use Competitive Bidding Contractors to implement the competitive bidding program.

C. Payment Basis

3. Special Rules for Certain Rented Items of DME and Oxygen (Grandfathering of Suppliers)

a. Process for Grandfathering Suppliers
Roche Diagnostics supports the CMS proposal to allow continuation of rental agreements by suppliers who have furnished supplies prior to the start of the competitive bidding program in an area (or prior to the start of a subsequent round of a competitive bidding program in an area), but disagrees with making completion of the rental agreement for grandfathered items optional. Making completion of an established rental agreement optional has no benefit to the beneficiary. This would result in abrupt transitions from grandfathered suppliers to other suppliers, causing increased short-term costs to the Medicare program that would be incurred through the clinical disruption to diabetes care.

These disruptions can be substantial. Roche Diagnostics, for example, provides 70 percent of its pumps directly to beneficiaries and provides beneficiaries extensive training – often conducted face-to-face, complemented by 24-hour support-line assistance. Beneficiaries removed from this training and support network would therefore find it difficult to maintain quality care on a continuing and seamless basis.

Thus, transitioning to new suppliers before expiration of the rental period could lead to delayed care. It might also require retraining on new products if the new suppliers do not offer the same products on which beneficiaries had previously relied. Complicating any such transition is the fact that it is not the insulin pump alone on which a beneficiary is trained and supported, but also associated insulin cartridges (to be inserted into the pump) and infusion sets (tubes and needles to facilitate infusion of insulin into the beneficiary). Thus, an "infusion pump" is actually an interrelated system of technology and supplies. A beneficiary cannot easily transition from one system to another.

In addition to increased training costs, there could be considerable financial loss associated with the technology itself. Specifically, FDA regulations discourage the reuse of a pump removed before expiration of the rental period by another beneficiary, despite the fact that the product retains useful life. These additional accelerated costs would need to be offset against any savings competitive bidding would purportedly yield.

b. Payment Amounts to Grandfathered Suppliers

(1) Grandfathering of Suppliers Furnishing Items Prior to the First Competitive Bidding Program in an Area

Roche Diagnostics supports CMS' proposal to allow grandfathered suppliers to complete the terms of capped-rental rental agreements for DMEPOS supplied prior to implementation of the first competitive bidding program in an area at the fee schedule amount and not at the amount produced by competitive bidding. For additional comments, please refer to II.C.3.a regarding avoiding acceleration of costs associated with transition of beneficiaries and the resulting increase in costs to the Medicare program.

(2) Suppliers That Lose Their Contract Status in a Subsequent Competitive Bidding Program

Roche Diagnostics believes that suppliers that lose their contract status in a subsequent competitive bidding should be allowed to complete the terms of rental agreements at the single payment amount that was effective at the time the rental agreement began, and not be required to accept payments at the subsequent competitive bidding program single payment amount rate in order to continue to supply the capped-rental item. For additional comments, please refer to section II.C.3.a regarding avoiding acceleration of costs associated with transition of beneficiaries and the resulting increase in costs to the Medicare program.

c. Payment for Accessories for Items Subject to Grandfathering

Roche Diagnostics supports the proposal to allow grandfathered suppliers to continue to supply the accessories to the grandfathered DME items at the fee schedule amount in effect prior to the start of a competitive bidding program in an area. For additional comments, please refer to II.C.3.a regarding avoiding acceleration of costs associated with transition of beneficiaries and the resulting increase in costs to the Medicare program.

4. Payment Adjustment to Account for Inflation

Suppliers Should Consider Inflation When Determining Bids

Roche Diagnostics appreciates the intent behind CMS' willingness to adjust competitive bidding payment amounts for inflation. We note, however, that the Agency may not be able to control this process. We wonder, therefore, if it is wise to advise suppliers not to consider inflation when determining bids unless CMS can guarantee that it will be taken into account as part of its competitive bidding contracts.

5. Authority to Adjust Payment in Other Areas

Payment Adjustment Should Not Be Considered Until the Full Program has Been Established and Should Be Implemented Through Rulemaking

Roche Diagnostics believes that there are numerous factors that must be considered before a process can be established that allows competitively bid prices to be applied to other areas. Virtually all businesses – including payers - recognize the distinct differences in the cost of providing items and services in various areas of the U.S. Some of these include overhead, wage index, disproportionate share, malpractice, cost of living, service, and demographic mixes. From a diabetes care perspective, many of these elements will be

significantly different between small independent pharmacies, pharmacies that operate as part of a large retail chain and mail order. Roche Diagnostics recommends that until the competitive bidding program has been fully implemented and evaluated, this approach should not be considered. The potential for negatively impacting beneficiary access to quality products and harming thousands of suppliers is too great. If CMS does consider this approach, we believe that the process should be proposed through notice and comment rulemaking.

6. Requirement to Obtain Competitively Bid Items from a Contract Supplier

CMS Must Ensure Against Barriers to Access

The majority of Medicare beneficiaries with diabetes receive their supplies from local retail pharmacies. CMS will need to implement a very aggressive educational program that explains all of the circumstances that may limit beneficiary access to products though familiar distribution channels. Of particular importance will be an explanation as to why a beneficiary who obtains supplies from a national retail chain in their area of residence cannot receive those supplies from that same retailer when in another area – whether or not it is close to home. This may be especially difficult when the beneficiary can receive his or her prescription drugs covered under Part D Medicare (or by another payer) from that retailer – either at home or when in another location. CMS must also make available a complete listing of competitive bidding suppliers for beneficiaries who travel. To ensure that access is not compromised, Roche Diagnostics strongly recommends that CMS adopt the TriCare Pharmacy Access Standards, as was done with Medicare Part D. Last, we recommend that CMS address the situation concerning beneficiaries who have Medicare as a secondary payer and their primary payer requires them to obtain supplies from its contracted supplier. We recommend that in instances where this occurs, there should be an exclusion to competitive bidding rules since a relatively small population is affected.

D. Competitive Bidding Areas

1. Proposed Methodology for MSA Selection for 2007 and 2009 Competitive Bidding Programs

The Special Needs of Minority Populations should be considered in MSA Selection

Diabetes affects minority populations in disproportionate numbers. Theses populations are in many respects entirely different from one another, not only in their behavior toward their disease but also in the need for differentiated communications. CMS should be cognizant of these differences as it monitors and evaluates any competitive bidding areas containing minority populations.

2007 MSA Selection Criteria should be applied in 2009

The initial criteria used to select MSAs in 2007 should be applied to the 2009 selection. CMS must build in adequate time to measure and assess beneficiary access and quality of care under the 2007 program before considering any changes to MSA selection criteria. Roche Diagnostics believes that a proper analysis for diabetes – especially the effects on access and quality of care - cannot be performed prior to the 2009 MSA selection.

2. Establishing Competitive Bidding Areas

CMS Should Not Require Mail Order for Beneficiaries in Areas within Urban Areas Having Low Population Density

In applying the provision in the MMA whereby CMS can exempt from competitive bidding areas with low population density within urban areas that are not competitive unless there is a significant national market through mail order, the Agency must be cognizant of the number of minorities and low income or dually enrolled beneficiaries in that area and their unique needs. In this instance, we believe that requiring mail order as a sole source for obtaining diabetes supplies will have negative consequences.

a. Authority to Exempt Rural Areas and Areas with Low Population Density within Urban Areas

CMS Must Better Define a Noncompetitive Market

CMS needs to better define the criteria it will use in determining a noncompetitive area – low utilization, population density, and a low number of suppliers does not mean that a market is noncompetitive.

b. Establishing the Competitive Bidding Areas for 2007 and 2009

Roche Diagnostics believes that including or excluding specific counties, zip codes, etc. will be extremely confusing to beneficiaries who are accustomed to obtaining their diabetes supplies at their local pharmacies.

c. Nationwide or Regional Mail Order Competitive Bidding

Competitive Bidding Must Ensure Competitiveness, Access to Quality Products, and Reasonable Utilization

Roche Diagnostics has a number of concerns surrounding the implementation of a national or regional mail order program for diabetes supplies. Today, 60% of Medicare beneficiaries obtain their supplies at retail outlets. There are a number of reasons for this which we have described in detail to CMS in our comments on the Quality Standards. They include convenience and the training and support that beneficiaries can receive during face to face meetings with the pharmacist. These services are important in managing diabetes and are especially needed by the increased numbers of beneficiaries in the Medicare population who have cognitive disorders, are poorly educated, speak English as a second language, or have low incomes.

In section E. Criteria for Item Selection in its Proposed Rule, CMS recognizes that "...a relatively large number of suppliers...would likely increase the degree of competition...and increase the probability that suppliers would compete on quality for business and market share." We agree with this statement. Forcing beneficiaries into national mail order will create a noncompetitive market unless another viable competitive market exists. We strongly believe for the many reasons given throughout our comments on the Proposed Rule that this alternative market is retail. CMS should support a retail market by establishing pricing strategies similar to the Agency initiative that recognizes the inherent differences in the acquisition costs of drugs between retail pharmacies and national mail order suppliers. In this regard, retail pricing information would be extremely helpful. Preservation of competition will ensure that Medicare beneficiaries can choose which product delivery system is best for them and with which they are the most comfortable. Ultimately, this choice will directly impact the testing compliance regimen of many beneficiaries, the first line of defense in preventing costly and devastating complications.

Before proceeding with a mail order strategy of any significant scale for diabetes supplies, CMS must thoroughly understand this market and the types of products and services that would be available under competitive bidding.

E. Criteria for Item and Service Selection

CMS Should Exclude or Limit Competitive Bidding for Diabetes Supplies and Seek Retail Pricing Information

Because the number of beneficiaries affected, distribution chains, and training and support services associated with diabetes care systems are so radically different from other types of DME and because diabetes products were not competitively bid via a demonstration project, we recommend that they be excluded from the 2007 program until the Agency gains further experience with more standard types of DME. If the Agency does decide to competitively bid diabetes products in 2007, the affected area should be reasonably small in terms of the number of beneficiaries affected. This will minimize disruption due to product switching and retraining needs.

We agree with the methodology that CMS proposes for product categories. As mentioned earlier and from our own experience, we also agree with CMS' position that a large number of suppliers is usually indicative of a robust market that competes on quality and market share. With this in mind, we recommend that CMS actively seek retail pricing information for diabetes care supplies to determine if payment adjustments are warranted.

F. Submission of Bids under the Competitive Bidding Program

4. Bidding Requirements

d. Capped Rental Items

Roche Diagnostics supports the CMS proposal that would require the bid price of DMEPOS items to be calculated as a monthly rental single payment amount. Allowing suppliers to submit bids in this manner simplifies the bid calculation process, reducing costs to suppliers and therefore reducing bid amounts. This reduction in bid amount obviously will increase savings to Medicare.

Nonetheless, Roche Diagnostics is concerned by the specified percentages of the purchase price proposed by CMS to serve as rental payments. Roche Diagnostics believes these dramatic reductions will drive suppliers from the market, and create shortages for the products. As noted previously, there are only four major suppliers of insulin pump systems – too few to derive the level of savings that warrant competitive bidding. Moreover, with so small a universe

of suppliers, CMS will be unable to implement a competitive bidding program that ensures an adequate supply for beneficiaries, as the statute requires. In all, CMS' approach is not market bidding, but price setting, and that approach does not guarantee an adequate supply for beneficiaries.

G. Conditions for Awarding Contracts

1. Quality Standards and Accreditation

Competitive Bidding Participants Must Comply with the Quality Standards and Be Accredited

A competitive bidding program involving diabetes care supplies should not be initiated until the Quality Standards are in place and there is a mechanism through the accrediting organizations to actively enforce these standards. In our comments to the Agency on the Quality Standards, we emphasized the need to protect beneficiaries from counterfeit, adulterated or substitute products, ensure the continuation of reliable 24-hour support services, properly educate and train, minimize disruption, and supply the beneficiary with a quality product that meets his or her needs. In the case of diabetes, tens of thousands of beneficiaries could be negatively impacted by only one unscrupulous supplier. There should be no grace period for accreditation of diabetes care suppliers. Instead, sufficient time should be given for suppliers to comply with the standards and receive accreditation before they are eligible to participate in a competitive bidding program.

3. Financial Standards

The Instructions for the Financial Standards Should be Explicit and the Paperwork Burden Minimized

CMS should give attention to the reducing the paperwork burden associated with the financial standards to the extent possible because they can be particularly onerous for small mail order and independent pharmacies as well as independent pharmacies within large chains. With regard to the latter, CMS should issue explicit instructions on the information that will be needed from both the parent company and its subsidiaries.

4. Evaluation of Bids

a. Market Demands and Supplier Capacity

The Unique Factors Surrounding Diabetes Care Should be Addressed in Determining Supplier Capacity

CMS should ensure that the rising prevalence of diabetes is taken into account when determining supplier capacity. An increase in utilization may also potentially be found with mail order and we recommend that the Agency study this phenomenon prior to implementing mail order on a large scale. As CMS is aware, the service demands for blood glucose test systems are relatively small when compared to other DME, although the need for 24/7 support services is high. The need for beneficiary retraining and education will be quite significant and will have a large impact on pharmacies and mail order firms. The issue of switching out product, retraining and education for beneficiaries with diabetes in determining supplier capacity in addition to enhanced support services should be added as a major provision in the next issuance of the regulation.

b. Composite Bids

CMS Should Use the Polk County Methodology for Determining Composite Bids

Roche Diagnostics believes that the use of composite bids will create the incentive to provide aberrant pricing in order to produce a good composite score. CMS should use the approach taken in Polk County to determine the composite bid because this approach has been successfully demonstrated. The Agency always has the opportunity to modify the methodology in the future.

c. Determine the Pivotal Bid

To Prevent Disruption, CMS Should Use the Median Bid for Diabetes Supplies

Beneficiary access to quality products with minimal disruption should be of primary concern to CMS in selecting a methodology for determining the pivotal bid for diabetes supplies. While achieving targeted savings, the Agency should focus on maximizing the number of suppliers available. CMS should use the median bid for diabetes supplies because this will ensure that a greater number of suppliers are selected. This will lessen the burden of switching out product, retraining and education. It will ensure that convenient access for beneficiaries is maintained. Because the need to supply high quality products that meet the unique needs of the beneficiary are so great in addition to the capacity needed to provide education and assistance, Roche Diagnostics believes that CMS should

evaluate the compliance of all eligible bidders with the Quality and Financial Standards in conjunction with bid submissions.

d. Assurance of Savings

CMS Should Use the Total Cost of the Product Category
CMS should use the approach taken in Polk County to achieve savings because this method has been successfully demonstrated. It allows suppliers some flexibility which may be important in establishing a new business model and as long as overall cost savings for the entire product category are achieved, it should not matter if the cost of one item increases. The Agency has the opportunity to modify this approach in the future.

H. Determining Single Payment Amounts for Individual Items

1. Setting Payment Amounts for Individual Items

CMS Should Use an Adjustment Factor
In determining the payment amount for individual diabetes supplies, we recommend that CMS use an adjustment factor in order to discount low bids. This methodology was used successfully in Polk County and will be of benefit to small pharmacies and mail order companies.

2. Rebate Program

A Rebate Program Raises Serious Legal Concerns
The proposal of suppliers offering rebates to beneficiaries raises a number of serious issues that CMS should consider in its next issuance of the competitive bidding rule. We believe that the Agency must address the following questions:

- Is this inducement?
- How can contract suppliers take advantage of a rebate program if they cannot advertise either directly or indirectly to beneficiaries?
- Does CMS have the resources to implement the very aggressive oversight that will be needed to audit a rebate program and to address the enormous potential for fraud and abuse?

I. Terms of Contracts

5. Furnishing Items and Services to Beneficiaries who's Permanent Residence is Within a CBA

CMS Must Ensure that Beneficiaries Can Easily Obtain Diabetes Testing Supplies

Beneficiaries with diabetes from a noncompetitively bid area must be assured of having a complete and updated list of all Medicare contract suppliers and their exact location in order to ensure access to needed supplies when in a competitively bid area. It is also important that this information include those suppliers who can provide items in an emergency situation. A complete list of the individual products offered by each contract supplier should be provided in order for beneficiaries to determine if that supplier carries the items that match the blood glucose test system that he or she is using.

K. Opportunity for Participation by Small Suppliers

The Impact of the Competitive Bidding on Small Suppliers of Diabetes Care Products Needs to be Further Investigated

In this section as well as throughout this Proposed Rule, it is clear that CMS is thinking primarily of typical DME suppliers and not suppliers of diabetes care items. It also does not appear that CMS has directed RTI to conduct a focus group with small suppliers of diabetes care products. We believe that most of these small suppliers will be at an extreme disadvantage in complying with many aspects of the Quality Standards and with this rule as presently proposed and as noted in our comments to the Agency. If RTI has not convened a focus group of small diabetes care suppliers, we recommend that it do so prior to issuance of the next rule and the Quality Standards.

L. Opportunity for Networks

Roche Diagnostics does not support the formation of networks due to the anticompetitive nature of this type of business model. We do not understand how this is not considered collusion as stated in the Proposed Rule in section N., Monitoring and Complaint Services.

M. Education and Outreach

Detailed Guidance Must be Given to Beneficiaries and Providers on Product Switching, Education and Retraining

We are extremely pleased that CMS will be establishing a competitive bidding education and outreach program. As the Agency is well aware, there will most likely be tens of thousands of beneficiaries with diabetes in the selected MSAs who will need to understand the changes that will be made. Just as important will be much needed guidance on the process for product switching and the intended plans for beneficiary education and retraining. CMS may want to consider a phased-in approach to switching and retraining so that providers and suppliers are not overly burdened with these duties. Special attention may have to be given to inner city, minorities and low income populations who are often in walking distance or a short bus ride to their customary supplier and who may be more difficult to contact than the population at large. We also think that providers – physicians, pharmacists and diabetes nurse educators - who have patients in the competitive bidding area will need education. Many providers prescribe diabetes care systems based on advanced features including IT connectivity and the ability to load patient results into a clinical evaluation program that is housed in the physician's office. Under competitive bidding, it is likely that these features will not be available on the products that will be selected. Pharmacists, if they can no longer provide diabetes supplies to their customers, should have information in order to guide the beneficiary to a new supplier.

Selection of a Product or Supplier in a Competitive Bidding Area Does not Confer Lower Quality to Non Selected Products and Suppliers

In this section, CMS states that one of the benefits conferred by competitive bidding is that beneficiaries will be told that they are receiving higher quality products. We strongly disagree with this statement and firmly believe that the opposite will be true. This type of inference will be extremely detrimental to products and suppliers of products that are not selected for competitive bidding solely based on price or ability to provide the item in sufficient quantities - not on the quality of the products or the ability to comply with the Quality Standards. This statement should not be considered as a strategy to promote the competitive bidding program to Medicare beneficiaries.

N. Monitoring and Complaint Services for the Competitive Bidding Program

CMS Must Aggressively Monitor the CB Program

We strongly support all CMS efforts to detect any abuses that occur under competitive bidding. Due to the serious medical outcomes resulting from failure

to appropriately monitor blood glucose levels, we urge the Agency to be especially aggressive and timely in its oversight. As mentioned previously in these comments, there is the potential for only one supplier to harm thousands of beneficiaries. We also recommend that in instances where a breach of quality has been identified, that the affected beneficiaries be notified immediately so corrective action can be taken.

O. Physician Education and Outreach

Supplying all Brands within a HCPCS Code will Lessen the Burden of Mass Switching

In our comments to the Agency on the Quality Standards, Roche Diagnostics included a list of blood glucose system features beyond what was recommended in the standards. These features, listed below, should be made available by suppliers who are selected to participate in the competitive bidding area.

- Diabetes information management capabilities such as connectivity/downloading, memory, averaging, user prompts, etc.

- Ability to compensate for reduced cognition or physical impairments such as vision loss, poor dexterity, compromised motor skills, thinning of the skin at lancing sites, etc., and

- Products that provide more accurate results by accounting for anomalies caused by hematocrit, medications, humidity, temperature, etc.

We recommend that CMS require these features as a basis for product selection because they will cover the vast majority of clinical needs and desired characteristics. We also wonder if information from the Polk County and San Antonio demonstration projects could be used to inform CMS in a timelier manner as to whether all brands within a HCPCS code should be supplied. We believe that this may be a much more preferable option in that it will resolve many access issues and prevent the need to switch out products and educate and retrain the thousands of beneficiaries with diabetes.

R. Establishing Payment Amounts for New DMEPOS Items

Payment Amounts for New DMEPOS Should be Issued as a Separate Regulation

This is an extremely important proposal that is not related to the implementation of the competitive bidding program. Roche Diagnostics does not believe that it should be included in the Proposed Rule. To ensure that stakeholders are given the time to properly evaluate this provision, we strongly urge CMS to issue this under a separate rulemaking procedure.

CMS Should not Combine Coverage, Coding and Payment Decisions

In this provision CMS appears to be combining coverage, coding and payment decisions. This is not appropriate. In addition, we find that not enough information has been given regarding the specific methodologies that will be used to perform the functional and the medical benefits assessments. These should be made available for public comment. For some new products, a medical benefits assessment can be difficult if not impossible to perform if there is not enough scientific literature available. We also note that the Food and Drug Administration is charged with determining the safety and effectiveness of medical products. Thus, CMS' proposal to evaluate these criteria is in conflict with regulatory simplification measures.

V. Regulatory Impact Analysis

B. Anticipated Effects

CMS Should Establish a More Realistic Timeline for Program Implementation

CMS proposes to conduct the first round of competitive bidding in 2006 with the program taking effect in 2007. We think that this timeline cannot accommodate the finalization of the Quality Standards, issuance of the Proposed Rule on accrediting agencies, selection of accrediting agencies, finalization of the competitive bidding regulations, issuance of an RFB and holding a bidder's conference. We are very concerned about this aggressive approach because to date, we do not believe that the Agency has adequately addressed the issues associated with diabetes care in the draft Quality Standards or in this Proposed Rule.

UMRA Applies to the Competitive Bidding Rule

Roche Diagnostics disagrees with the Agency's assertion that the Unfunded Mandates Reform Act does not apply to competitive bidding rule. In order to participate in the Medicare program at all, suppliers are forced to bid in the program.

D. Program Savings

The Medicare Advantage Plans are modeled after the commercial plan market. Many of these plans utilize various cost controls for diabetes supplies similar to the Part D benefit, including formularies and co-pays. As a result, we do not think that CMS should assume additional savings from these programs.

E. Effect on Beneficiaries

The Effect of Competitive Bidding on Beneficiaries with Diabetes Has Not Been Adequately Assessed

Diabetes care supplies are obtained in an entirely different manner than other DME products. Thousands of beneficiaries – a significantly higher population with respect to the number of beneficiaries receiving an individual DME product - will be affected by competitive bidding implementation. Many will have to change suppliers. It is likely that tens of thousands will have to switch products and be retrained. Diabetes care supplies do not meet the criteria for grandfathering. They were not included in either of the two demonstration projects. For all of these reasons, we believe that CMS has failed to demonstrate the impact that competitive bidding will have on beneficiaries with diabetes.

F. Effect on Suppliers

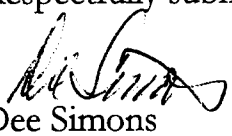
1. Affected Suppliers
2. Small Suppliers

CMS Should Not Base Assumptions on the Demonstration Projects

In the Proposed Rule, CMS has indicated that it would like to change the methodologies that were used in the demonstration projects. We question, therefore, the assumption that 50% of suppliers will be awarded contracts. It is also incorrect to assume that a diabetes supplier such as a retail pharmacy receives 50% of its revenue from Medicare.

Thank you for considering our comments. Should you have any questions or require additional information, please contact me.

Respectfully submitted,



Dee Simons
Director Public Health Policy
Roche Diagnostics

November 23, 2005

Roche

Diagnostics

Mr. Herb Kuhn
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C5-08-27
Baltimore, MD 21244-1850

Re: Comments on Draft of Proposed Recommendations on Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services

Dear Mr. Kuhn:

Roche Diagnostics is pleased to submit comments on the draft Quality Standards for DMEPOS and Other Items and Services. Our company is proud to be one of the leading manufacturers of diabetes care systems. We have been developing these technologies for almost thirty years. During that time, diabetes care systems, consisting of the meter, strip, lancet device, lancet and control solutions have been vastly improved. The initial large, cumbersome, inaccurate and painful systems from 30 years ago have evolved into user friendly ones that are compact, light, accurate and less painful. Data downloads from these systems identify trends for a number of blood glucose parameters. Providers and patients use this information to adjust treatment plans involving diet, exercise, insulin and other medications, as well as to evaluate the efficacy of treatment and educational programs. These connectivity features are becoming increasingly important as we foster disease management programs and move toward a national heath information technology infrastructure.

Many of the technological improvements such as not having to handle individual strips or lancets, simpler maintenance, alternate site testing, easier blood collection, smaller sample sizes, ability to adjust puncture depth and larger readout displays can make a vast improvement in the health and quality of life for a Medicare beneficiaries. These technological advances result in increased testing compliance with an accompanying decrease in the devastating and costly complications of diabetes. The development of each one of these features has required years of research and work, involving many consumers, scientists and other experts in the fields of clinical and market research, software development, engineering, biochemistry, and ergonomics.

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In reviewing the draft of the Quality Standards, our first impression is that the document, for the most part, appears to be written for the "standard" DME supplier, not for retail pharmacy chains or firms that supply diabetes care systems via mail order. We also note that the standards do not reflect – or perhaps more importantly – do not take advantage of current standard practices in diabetes care that are more efficient, safer and of higher quality than those proposed in this draft document.

Last, we wish to point out that the operation, features and differences in the components of diabetes care systems can be quite significant - not only between brands but within the same product line. This is not acknowledged in the standards and is, in fact, marginalized. Roche believes that this is dangerously misleading considering the vulnerability of the affected population.

One example in the document that encapsulates many of the above observations is the requirement that the supplier – in this case most likely a retail pharmacist – train beneficiaries on diabetes care systems and provide a 24-hour assistance program. It is Roche's view that this is not practical, feasible, safe or efficient. We elaborate on these points further in the body of our comments.

General Recommendations

Consult with diabetes care providers.

The list of contributors for first draft of the Quality Standards did not include individuals or organizations that provide health care services to beneficiaries with diabetes. The proposed standards suffer because of this oversight by attempting to create a new system that will be at best extremely disruptive, if not detrimental, to beneficiary well being. Due to the unique interactive nature of diabetes care systems with the patient, we believe that CMS should seek input from the American Diabetes Association, American Association of Clinical Endocrinologists, American Association of Diabetes Educators, National Association of Chain Drug Stores and National Association of Community Pharmacies as it revises the Quality Standards. By obtaining this counsel, CMS can build and improve upon current practices.

Consult with suppliers of diabetes care products.

Roche has also observed that the contributors to the draft Quality Standards included Internet and mail order pharmacies, but not retail suppliers, the predominant choice for seniors when obtaining their diabetes care products. It

is worth noting that these retail suppliers not only include drugstores such as CVS® and Rite Aid® but pharmacies in large chain grocery stores and large retail chains such as WalMart®. Thus, these standards have considerable potential to affect thousands of retail suppliers throughout the U.S and millions of Medicare beneficiaries.

We believe that it is critical that CMS seek input from The National Association of Chain Drug Stores and the National Association of Community Pharmacies. These groups can inform CMS about the demographics and needs of its purchasers in addition to the role that the pharmacist plays in the day-to-day management of beneficiaries with diabetes and how this role is significantly different from "standard" DME suppliers. We are particularly concerned that some of the requirements in the draft Quality Standards may prove to be overly burdensome for small suppliers – both independent pharmacies and mail order providers. Other requirements, however, may prove very costly if applied to a large supplier base.

Incorporate the "Standards of Medical Care in Diabetes."

The American Diabetes Association's "Standards of Medical Care in Diabetes" is an excellent resource on information about diabetes care with specific sections addressing the team of health care providers needed to properly educate, manage and treat a patient with diabetes, self-monitoring of blood glucose, and diabetes care for the elderly. We recommend that CMS refer to these and incorporate the ADA standards into the Quality Standards for diabetes care systems where appropriate. We are including a copy of these standards with our comments for your reference.

Harmonize the Draft Quality Supplier Standards with the Diabetes Education and Training Quality Standards.

The Balanced Budget Act of 1997 expanded Medicare coverage for diabetes outpatient self-management training. This resulted in the issuance of 42 CFR Parts 410, 414, 424, 480, effective February 27, 2001, which delineate the standards that should be met for this training in order for the provider to receive Medicare payment. The proposed Quality Standards for Suppliers fails to address how compliance with the 2001 regulation would alter supplier compliance as stated in the proposed Quality Standards. For instance, if a beneficiary receives training on the operation and use of a diabetes care system administered through an entity that meets the requirements under 42 CFR Part 410, it would not be necessary for the supplier to repeat this training.

Beneficiary health outcomes must be measured.
CMS has stated that one of the goals of the Quality Standards is to improve beneficiary outcomes. Roche agrees and recommends that CMS issue its plan for how it will demonstrate the effect that the competitive bidding Quality Standards will have on the health of beneficiaries with diabetes. We believe that these measures should be of appropriate scientific rigor to demonstrate accurately whether the quality of care has been diminished or enhanced through evaluation of endpoints such as outpatient, inpatient and long term care costs and an increase or decrease in diabetes comorbidities such as vision loss, amputation, and renal disease.

Develop separate administrative standards for diabetes care systems.
Due to the extreme differences between "standard" DME suppliers and their distribution chains and those that exist for diabetes care systems, we recommend that separate administrative standards be drafted for suppliers of diabetes care systems.

Specific Comments

Section 1: Supplier Business Quality Standards

Administration

3. Procurement and testing of quality DME, first bullet. Diabetes care products are cleared or approved for marketing by the Food and Drug Administration. Most large manufacturers are ISO certified. As such, the manufacturer supplies the FDA with substantial documentation regarding product quality and safety. Some of this information is proprietary in nature and thus protected. It is unclear to Roche as to why a retail supplier would need this same information, or for that matter, be able to make sense of it. Moreover, the proprietary nature of this information would make manufacturers exceedingly reluctant to submit it to a supplier unless appropriate legal safeguards were in place. We suggest that for diabetes care systems, CMS defer to FDA cleared or approved products.

Roche strongly recommends that due to the significant problems with the sale of counterfeit, diverted or otherwise misbranded diabetes products, CMS require suppliers to provide only FDA approved products and packaging that are either

directly procured from the manufacturer or a distributor whose sole source of product is directly from the manufacturer.

4. ***Delivery of quality services to beneficiaries, first bullet.*** Roche recommends that CMS further clarify the policies and procedures that define the scope and provision of supplier standards, beneficiary eligibility requirements, how services are coordinated with the treating physician and health care team, and business and emergency operating hours with regard to retail outlets and mail order firms. Because suppliers of diabetes care systems differ significantly from other DME suppliers, we believe that CMS should consider developing separate standards for the former. Moreover, these provisions, when applied to retail and mail order firms have strong potential to be overly burdensome. We suggest that CMS learn more about the interactions of the diabetes health care team with the supplier and the interactions the supplier has with the diabetes care system manufacturer by consulting with the appropriate organizations.

4. ***Delivery of quality services to beneficiaries, second bullet.*** Again, we must underscore the unique differences between the supply of diabetes care systems and other types of DME and emphasize the need for standards that are more applicable to the former... The requirement *"Ensures that mail order services are not used for the initial delivery, set-up and beneficiary education/ training for certain DME equipment and supplies"* establishes a clear inconsistency in the way that the standards are applied to mail order suppliers and pharmacies. One is required to train beneficiaries and one is not. Moreover, the proposed standards are silent as to how the training will be accomplished in the latter instance.

Roche notes that under 42 CFR Part 410, the beneficiary is entitled to training in the management of diabetes, including the use diabetes care systems. The choice of who performs this training is left to the discretion of the provider. The Quality Standards, however, state that the supplier must perform training. In order to avoid significant confusion in the provider and supplier communities concerning these requirements, the Quality Standards must clarify in what instances training should be performed by a supplier.

We recommend that face-to-face training be required for the initial use of a new diabetes care system and that the training be performed by an appropriately credentialed individual. Training should include the witnessing of the beneficiary's ability to correctly operate the meter, strip and lancet – all of which may differ significantly from the beneficiary's previous system. The beneficiary

must also be able to properly interpret the results particularly with regard to pre and post prandial fluctuations which occur due to diet, exercise and stress. (Bergenstal 2005). Most suppliers cannot be held responsible for performing this type of training for reasons given later in our comments.

5. ***The supplier shall:, third bullet, item c).*** Roche agrees that each supplier location should meet the quality standards and be accredited. We note, however, that accrediting agencies will face a formidable task in accrediting and monitoring large retail suppliers having hundreds of locations in many MSAs. In addition, the overall burden of compliance with the standards will be enormous for national retailers with thousands of outlets. Roche recommends that CMS consult with large retail suppliers and potential accrediting agencies to see if there is a way to streamline compliance procedures.

6. ***The supplier shall develop and implement a compliance plan...*** Roche notes that it is likely that small independent pharmacies, some regional pharmacies and small mail order firms will not have enough resources to meet these standards. We recommend that CMS consult with the appropriate organizations to determine the effect that these requirements will have on small businesses.

Financial Management

1. ***A financial management plan...*** *and,* ***2. Financial statements...*** Small independent pharmacies and small mail order companies may have difficulty meeting these requirements. CMS should consult with these suppliers. We also recommend that CMS seek guidance regarding how individual pharmacies within a large chain and foreign owned subsidiaries can meet these standards most effectively. Perhaps the financial information from the parent company would be most suitable in these instances.

3. ***Notification to CMS and the accreditation organization...*** CMS needs to state the criteria that define "potential adverse financial conditions." We suggest that the Agency work with diabetes care suppliers to clarify how this would apply to large chains and small independents.

Human Resource Management

1. ***The supplier shall obtain criminal background checks...*** When considering all of the types of retail outlets that could receive a competitive bidding award, Roche notes that the number of criminal checks necessary could number in the many thousands. The resource burden is enormous. We recommend that CMS solicit input from retail and mail order suppliers to determine the necessity of this requirement.

2. ***The supplier shall have sufficient full-time and part-time personnel to provide the services...,*** *and* ***4. The supplier shall have and implement an assessment program...*** Roche believes that the overall burden for implementing these requirements in the current retail distribution chain is enormous. Small independent pharmacies and mail order firms may not be able to comply with these standards. It is also unclear if the competency requirements for the supplier – in this case a retail pharmacist or a lay person in a mail order firm - would need to meet the qualifications of a certified diabetes educator. We recommend that CMS consider developing a standard that is specific to diabetes care systems and consult with the appropriate pharmacy and mail order organizations.

Beneficiary Services

1. ***The supplier shall process...***Roche recommends that the supplier be required to document and inform both the provider and beneficiary of the reason for a change or deviation from the original item ordered to what was actually dispensed. This may help to reduce product switching.

2. ***The supplier shall ensure..., first bullet.*** Roche believes that suppliers should clearly designate in any advertising or outreach to providers and patients which products are available to Medicare beneficiaries and which products are not available.

3. ***The supplier shall ensure..., third bullet.*** Roche does not believe that most of this information is critical to obtaining diabetes care systems. It will unnecessarily result in a massive recordkeeping burden on both the providers and the suppliers. In addition, we question whether privacy laws and regulations would allow for the sharing of superfluous patient information. Last, we wonder if the supplier will be able to determine from this information whether the

correct diabetes care system has been selected by the provider. We recommend that CMS consult with provider and supplier groups to determine the standards that are needed specific to diabetes systems and to determine the state of current practice in this area.

Performance Management

1. ***The supplier shall provide evidence...*** We believe that much more detail is needed here and that it be made more applicable to the suppliers of diabetes care systems. Roche strongly recommends that CMS confer with the appropriate supplier groups to determine how this can be implemented for small retail/mail order suppliers and individual pharmacies within a chain.

2. ***The supplier shall identify...*** Roche is extremely concerned about this provision. FDA regulations mandate that the manufacturer evaluate product complaints and inform the Agency via the Medical Device Reporting regulations (21 CFR 820.198 and CFR 803) in cases where problems are considered to be "reportable" events. These regulations are in place to protect the public health. The CMS requirement for suppliers to investigate root causes makes little sense because the supplier cannot possibly perform this function. Of equal importance is that in this proposed scenario the manufacturer may never even know about the event and be able to address it, report to FDA, or take corrective action if needed. Thus, this provision has the potential to endanger the public health. Roche strongly recommends that CMS require suppliers to report problems including any adverse effects of the equipment and supplies, to the manufacturer of those products.

3., 4., 5., 6. ***The supplier's performance management system...*** In many instances, these requirements do not appear to be easily adapted or applicable to retail situations. Due to the enormous resource burden that this will place on the suppliers in addition to the apparent lack of applicability, Roche recommends that CMS, after consultation with the appropriate supplier groups, issue a revised standard for diabetes care products that is more appropriate for the retail environment.

Equipment and Safety

1. ***The supplier shall maintain...*** To the best of our knowledge, the supplier does not track the batch numbers for diabetes care supplies. The manufacturer maintains batch numbers.

2., 3., 6. ***The DME supplier shall implement...*** These do not pertain to diabetes care suppliers; therefore, they should be specifically excluded from this requirement.

Beneficiary Right and Ethics

1. ***Suggested additions.***

- For diabetes care equipment, the specific brand and model numbers offered by the supplier.
- Explanation as to why a product is no longer offered or not available.
- Availability of diabetes care systems not offered under competitive bidding and how they can be obtained if desired.

1. ***Policies for after-hour and emergency coverage, fifth bullet.*** This is an extremely important requirement for Medicare beneficiaries with diabetes. As a manufacturer of diabetes care equipment and supplies, Roche operates a multilingual (186 languages) assistance service dedicated to our ACCU-CHEK® product line. This live service is manned around the clock 365 days per year. We average almost 1.4 million calls annually. About half of these are from individuals who are 65 years of age or older. It is very likely that other leading manufacturers have similar services and numbers of inquiries. We believe that for diabetes care systems, a standard based on anything less than an in-depth knowledge of the diabetes care system and live 24/7/365 support is not adequate. These elements are critical to the care of a population known to have significant comorbidities, increased cognitive problems and limited literacy.

Information Management

8. ***The supplier's marketing materials...*** We recommend that CMS adopt a marketing approval process for suppliers similar to the Agency's Medicare Part D approval process. Without such an approach, we do not see how this can be enforced.

8. ***Forms for beneficiaries..., last bullet.*** Since many seniors do not have access to the Internet, Roche recommends that the Quality Standards require suppliers to make forms available by additional means.

Section 2: Appendices for Supplier Product-Specific Service Requirements

Appendix A: Supplier Product-Specific Service Requirements

Inspection and Preparation

Diabetes care supplies are received by the supplier prepackaged, making it impossible for the pharmacy or mail order firm to ensure the safety or functionality of the product. Were suppliers to actually open the packaging for purposes of ensuring safety and functionality, this would have significant implications under the Food, Drug and Cosmetic Act and related regulations. Indeed, it could have a tremendous impact on patient safety. Proper storage (temperature and light), tampering and counterfeiting should be addressed in the standards. We are not aware of instances where the supplier would actually attempt to adjust or replace parts.

It is usually the physician or the diabetes educator who recommends which product is appropriate for the patient, not the supplier. Roche agrees that it is important for the pharmacist to be aware of changes in patient status. The proposed Service Plan, however, can only be applied to typical DME suppliers. It cannot be applied to retail pharmacies who may see hundreds of patients in a year or to mail order suppliers who do not see patients at all. We recommend that the appropriate provider and supplier groups be consulted to determine what the requirements, if any, should be established for diabetes care suppliers.

Delivery and Setup

This section is not applicable to diabetes care supplies and should be so stated.

Training/Instruction to Beneficiary and Caregiver

Training in the use of diabetes care supplies is a cornerstone to the successful management of diabetes. The ability to effectively use diabetes care systems is directly related to the quality of training received and the capabilities of the individual beneficiary. Because of this, a blanket requirement that the pharmacist/supplier perform all training is ill conceived. Roche also notes that requiring a pharmacy to provide instructions for use could have implications under the FDCA. The package insert for blood glucose meters, which is governed as labeling under the auspices of FDA, contains the instructions for use. These are provided by the manufacturer, not the supplier.

Training for those who are newly diagnosed and training on new systems for beneficiaries with reduced cognition, limited literacy or certain physical impairments should be given face-to-face by a diabetes educator or similarly qualified health care professional. Mail order suppliers will not be able to perform this type of training. For those beneficiaries who are well experienced in the management of diabetes, training may not be necessary at all, while others may only need an overview of the basic operations of the diabetes care system. In the former instance, required supplier training would squander significant resources. Instruction sheets/videos and manuals may be appropriate for beneficiaries experienced in diabetes management but should not be considered as a replacement for appropriate training and education of Medicare beneficiaries who are newly diagnosed, learning impaired or who are otherwise unable to benefit with these learning tools. In all cases the supplier should require attestation that the beneficiary/caregiver has successfully completed training via a Medicare-approved diabetes self-management training course or during the course of, or incident to, a physician or other qualified health care provider service.

CMS must ensure that beneficiaries receive the training that is necessary to meet their individual needs. Patients are often unaware of actions they should take in response to their blood glucose results (Bergenstal 2005). While most pharmacists are an excellent resource to reinforce the basic operations of the equipment, they cannot be expected to possess an in depth knowledge of multiple product lines and differing features to the extent needed to properly perform the training of hundreds of beneficiaries a year, many of whom have

reduced cognition and limited literacy. Pharmacists also cannot be expected to be able to integrate that training into the complex management necessary to achieve glycemic control.

In its Standards of Medical Care for Diabetes, the American Diabetes Association states:

> "Because the accuracy of SMBG [self-monitoring blood glucose] is instrument- and user-dependent, it is important for health care providers to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. In addition, proper use of SMBG requires proper interpretation of the data. Patients should be taught how to use the data to adjust food intake, exercise, or pharmacological therapy to achieve specific glycemic goals. Health professionals should evaluate at regular intervals the patient's ability to use SMBG data to guide treatment." (Diabetes Care, 2005).

Roche believes that many in the Medicare population will require more than a basic tutorial on how to operate a diabetes care system. As CMS is well aware, Medicare beneficiaries include a high share of individuals with functional and cognitive impairments. (Kaiser Foundation 2005). Further, reduced cognitive function is linked to diabetes. (Brands, 2005; Cox, 2005; Ferguson 2005; ADA Standards – Diabetes Care, 2005). Limited literacy is also characteristic of the Medicare population. Approximately 44% of adults age 65 or over have limited reading skills, 38% of Medicare beneficiaries have not completed high school and 23% have less than 9 years of education. (Goldstein, 2001). The following are identified risk factors pertinent to the Medicare population that are associated with limited literacy (IOM 2004; Weiss, 2003):

- Advanced age (≥ 65 years)
- Limited formal education (less than high school)
- Poverty or limited income
- Presence of chronic disease
- Medicare/Medicaid beneficiary
- Ethnic or minority group

The impact of limited literacy on health is well documented. Limited literacy results in:

- Higher hospitalizations (Baker, Gazmararian, Williams, Scott, Parker, Green, Ren & Peel, 2002)
- Greater annual health care costs (Weiss & Palmer, 2004)
- Poorer management and knowledge of chronic disease (Schillinger, Grumbach, Piette, Wang, Osmond, Daher, et. Al., 2002; Williams, Baker, Honig, Lee, Nowlan, 1998; Williams, Baker, Parker, Nurss, 1998))
- Underuse of preventive health services (Scott, Gazmararian, Williams, Baker, 2002)

Roche believes that it is imperative that the Quality Standards take the above findings and their implications into account when considering education and training for Medicare beneficiaries with diabetes. If the physical, cognitive and literacy limitations of this population are ignored, beneficiaries will suffer harm and the costs associated with the treatment of diabetes complications will rise.

We recommend that in lieu of a blanket requirement for supplier training, CMS build upon the education and training systems already in place by seeking advice from the appropriate professional and supplier organizations, reviewing 42 CFR Parts 410-498 and the ADA Standards.

Roche also notes that presently, after hours support is most often performed by the product manufacturer. While a 24-hour pharmacy could offer such a service, it is likely that it will not be able to field most questions and will not have the in depth experience needed in order to be effective with the Medicare population.

Follow-up

Roche recommends that this section not be applied to diabetes care suppliers and to consult with provider and supplier organizations to determine appropriate standards, if any.

Appendix H: Diabetic Equipment and Supplies

Inspection and Preparation

General Product-Specific Service Requirements section.
Please refer to our previous comments. In addition, we recommend that the following be added:

"Suppliers must provide products that meet individual beneficiary needs. The range of products should include the following features:

- Diabetes management capabilities such as connectivity/downloading, memory, averaging, user prompts, etc.;
- Ability to compensate for reduced cognition or physical impairments such as vision loss, poor dexterity, compromised motor skills, thinning of the skin at lancing sites, etc.; and
- Products that provide more accurate results by accounting for anomalies caused by hematocrit, medications, humidity, temperature range, etc."

Equipment Management

General Product-Specific Service Requirements section. Please refer to our previous comments.

Amend the bulleted sentence as follows: "Furnish a home blood glucose monitor that is appropriate for any physical limitations such as visual impairment, thinning of the skin in lancing site areas, impaired cognition or dementia, limited dexterity or other factors such as pharmacologic interferences."

Delivery/Setup

General Product-Specific Service Requirements section. Please refer to our previous comments.

Add a second bullet: "Mail order suppliers shall not overly dispense products and will maintain recorded telephone logs of supply orders in addition to maintaining documentation of such orders."

Training/Instruction to Beneficiary and Caregiver(s)

General comment on this section. Again, Roche notes that suppliers cannot be expected to perform primary training on diabetes care systems for all Medicare beneficiaries. The observations for the following sections are made to provide additional information only.

Laser skin-piercing device and disposable film cartridge

Equipment Usage

How to select..., first bullet. Delete "glucometer" in this section and in all other sections. Glucometer® is a brand name for a blood glucose monitoring system.

Home Blood Glucose Monitor
Equipment Usage

Usage is likely to vary slightly...first bullet. Roche knows that system operation and use can vary substantially - not only among products manufactured by different companies, but within an individual product line.
The American Diabetes Association also recognizes that diabetes care systems are unique and are prescribed based on the patient profile. In its "Standards of Medical Care in Diabetes," the ADA states that:

> "It is recognized that the use of formularies, prior authorization, and related provisions, such as competitive bidding, can manage provider practices as well as costs to the potential benefit of payors and patients. However, any controls should ensure that all classes of antidiabetic agents with unique mechanisms of action and all classes of equipment and supplies designed for use with such equipment are available to facilitate achieving glycemic control and to reduce the risk of complications. To reach diabetes treatment goals, practitioners should have all classes of antidiabetic medications, equipment, and supplies without undue controls. Without appropriate safeguards, these controls could constitute an obstruction of effective care. (Diabetes Care 2005).

We suggest that the statement be revised to "Usage will vary among brands and brand models."

Add the following bullet: If the blood glucose monitoring system includes memory, pattern management, connectivity features, beneficiary instruction in the appropriate and successful use of these features is required.

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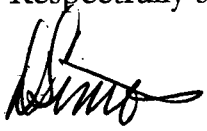
In conclusion, Roche recognizes that developing Quality Standards for diabetes care is a difficult task made even more so because they will potentially impact the practices of thousands of suppliers and providers and the lives of millions of beneficiaries. We trust that our comments have been helpful and look forward to working with CMS to design standards that promote the health and quality of life for beneficiaries who have diabetes. Please contact us if you require additional information.

Respectfully submitted,



Dee Simons
Director Public Health Policy
Roche Diagnostics

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COALITIONS OF

Enteral Nutrition Manufacturers
Respiratory Care Manufacturers
Wheelchair Seating Manufacturers
Wound Care Manufacturers

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June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

The Coalitions of Enteral Nutrition Manufacturers, Respiratory Care Manufacturers, Wheelchair Seating Manufacturers and Wound Care Manufacturers ("Coalitions")submit the following comments in response to the proposed rule on *Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues*, 71 F.R. 25654 (May 1, 2006) (the "Proposed Rule").

The Coalitions would like to comment on the following issues:

- CMS should issue the final rule as an interim final rule with comment period
- Gap-Filling Proposal
- Criteria for Item Selection
- Exclusion of Surgical Dressings entirely from the competitive acquisition program (CAP)
- Exclusion of Enteral Nutrition from the first phase of the CAP
- Rebate Program

CMS Should Issue the Final Rule as an Interim Final Rule with Comment Period

The Coalitions have been on the record at both the PAOC meetings and the open door meeting to address the proposed rule in complimenting the CMS staff for its hard work that it has devoted to this effort. However, it occurs not only to us but also to other associations that CMS has laid out a number of unanswered questions without the Agency committing to a concrete proposal on particular topics. The product selection section of the regulation, which simply sets out general criteria for subsequent product selection, and the section regarding the application of competitively bid rates in other areas of the country, are two examples of this practice.

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In addition, the quality standards that are extremely relevant to the competitive bidding program have not been released yet, even though both stakeholders and CMS would benefit from comments that reflect the application of the final quality standards to this program. At the PAOC meeting, CMS staff noted that the Agency had received over 5.000 comments on the quality standards and that they had been modified. It is imperative for stakeholders to see the final quality standards since they interrelate with key elements of the proposed rule due to their impact on the type and number of suppliers who may be able to submit, bids, the size of the suppliers, the construction of product categories and the appropriateness of the approach of the proposed rule's method for determining a single payment amount.

At this juncture, it is difficult to project what the final rule will look like on a number of important issues where CMS did not propose a specific course of action. For that reason, we suggest that CMS issue the final rule as an interim final rule with comment period, so that the public will see, for the first time, CMS' decisions on an array of issues and thus will have an opportunity to comment on concrete proposals.

This would be more than good and fair policy. It also would be consistent with applicable law. Section 1871(a)(4) of the Social Security Act provides that a final rule will be treated as a proposed rule if it includes provisions that are not "logical outgrowth(s) of a previously published notice of proposed rulemaking." Congress clearly was concerned about the type of situation where a proposed rule does not flesh out CMS' intent with enough specificity so that the final rule's provisions surprise the public that commented on the proposed rule. The success of the CAP resides with defining and administering the details of the program. It is very difficult to comment if we do not know CMS' thinking on various issues which are integral to the implementation of the program.

Gap-Filling Proposal

The Coalitions commend CMS' recognition of the inadequacies of the gap-filling methodology. The gap-filling formula in antiquated and has become more problematic due to fee schedule freezes mandated by Congress. Moreover, the problem is intensified by the growing trend toward testing requirements and the SADMERC code verification of products.

CMS proposes to amend its current gap filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. The proposed new procedure would include a technology assessment based on a comparison of three areas: function, price and medical benefit. CMS states that the Council on Technology and Innovation has endorsed this initiative in order to coordinate the activities of coverage, coding and payment and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

While we agree that it is important to coordinate communication of technology information among different sections of CMS and between CMS and its contractors, the administration and review of a comparative technology assessment is a comprehensive effort that raises many important procedural questions, such as:

- What would trigger such an assessment?
- Which of the three areas of the assessment would be the first area of comparison?
- Which criteria would be used for assessment in each of the three areas?
- Which entities within CMS would participate and at what level?
- What is the role of the FDA?
- When and how would outside contractors be used?
- When and how would outside stakeholder opinions be solicited?

Because of the complexity, comprehensive nature and serious implication for this type of initiative, CMS's use of the comparative technology assessment should be held to at least the same level of procedural predictability and transparency as the process for development of a National Coverage Determination, which has recently been defined in a guidance document published by the CMS Coverage and Analysis Group.

CMS also proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. The Coalitions strongly oppose this aspect of the proposal.

Since this new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA, the Coalitions recommend:

- All references to the technology assessment as a part of gap filling should be removed from the final rule
- CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support their opinion.
- CMS should publish this provision for comment as a separate proposed rule, with specific procedural requirements.

Criteria for Item Selection

CMS should not combine medical policies together in competitive bidding categories

The Coalitions recommend that HCPCS codes from multiple medical policies not be combined together into one competitive bidding category. We also have concerns that the proposed rule does not provide a sufficient method to evaluate whether specific medical policies and/or HCPCS codes should be included in a competitive bid.

Medical policies are created as much to categorize medical conditions and coverage as they are to categorize products and codes. For example, if competitive bidding is considered from the standpoint of managing specific conditions, it would be unreasonable to consider combining a wound care patient group together with a patient group requiring a hospital bed or a wheelchair. Yet, from a simplistic approach it may seem appropriate to combine the medical policy for "wheelchair seating" with "wheelchairs" and "support surfaces" with "hospital beds" in forming competitive bidding product category.

However, there are stark contrasts among the medical policies that apply to these items. In order to insure quality and access in a competitive bidding environment CMS must insure that the best providers have the opportunity to bid. Many providers structure their business around addressing specific disease states and conditions. It cannot be assumed that providers with a wound care expertise and focus are also wheelchair or hospital bed providers, nor can the reverse be assumed.

The goal of competitive acquisition must be to reasonably reduce program and beneficiary costs while maintaining or enhancing quality and access. Any combination of HCPCS codes from multiple medical policies together into one competitive bidding product category will reduce the number of providers capable of bidding for specific goods and services. Those providers that carry the broadest product offering will benefit to the detriment of the specialty providers, and the level of competition will be reduced. Ultimately, the very providers most adept at providing quality goods and services for a specific medical policy may be prohibited from bidding due to medical policies being combined that extend beyond their expertise and product offering.

The Sufficiency of Current HCPCS Codes for Competitive Bidding

CMS proposes to use HCPCS codes individually or grouped together in "Product Categories" as the basis for competitive bidding. Because there are significant inconsistencies in the specificity of existing codes included in the product groups listed in the proposed rule, as the Coalitions have stated previously in our October 19, 2004 CMS comments and in our November 28, 2005 quality standards comments, use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

Inappropriate code specificity exists when products with a limited set of basic features and benefits are assigned to the same code with related products that have advanced features. Some examples are:

E0277 – Powered Air Mattress
E0601- CPAP
E2402- Negative Pressure Wound Therapy Pump

In each of these codes, the advanced products have different technological features that provide greater therapeutic benefits and/or support the special needs of some beneficiaries. Market utilization data from a variety of sources shows that both clinicians

and beneficiaries prefer the advanced products because of these improved patient benefits. For each of the codes listed above, the advanced products account for a majority of the Medicare Part B claims.

Because of the additional costs associated with these features, the advanced products are also at the higher end of the price range for each of these codes. Current fee schedules allow for adequate payment of the advanced products. Given the proposed bid methodology, there is a real risk that suppliers may choose to provide only the less-advanced, less-costly products classified in the code in order that they may be selected as a contracted supplier. If this occurs, there could be such significant reductions in payment that the advanced products, those preferred and used most often, will no longer be available to Medicare beneficiaries. Competitive bidding should not restrict or reduce beneficiary and/or clinician access to the most appropriate, medically necessary products.

In addition, certain current HCPCS codes are not appropriate for competitive bidding by code. These are codes that include within one code items of widely varying cost, technology and clinical application. Examples of these codes include support surfaces and wheelchair seating, which include within single HCPCS codes items of varying cost and complexity which are prescribed based on the patient's specific clinical condition. In the case of HCPCS codes containing items of widely varying cost, competitive bidding will not maximize program savings and will diminish beneficiary access and quality of care.

In the case of support surfaces, since the Support Surface Standards Initiative is currently devising testing for these devices, the Coalitions recommend that support surfaces cannot be effectively bid under the current HCPCS codes (which is why the Coalition of Wound Care Manufacturers is working to recommend new coding to the SADMERC) and medical policy and would request that they be excluded from competitive bidding until such time as a new coding structure and a new medical policy is implemented.

Competitive bidding of items in such codes will fail to maximize program savings because suppliers will have to include in their bids an amount reflecting the anticipated cost of the higher priced items in the code. The mix of higher and lower cost items within the code will be difficult for suppliers to accurately estimate because they do not have access to data regarding the mix in the competitive bid area; instead they only have their own mix data.

In addition, the mix may be affected in amounts that are not possible to predict due to the SSA's provision that physicians may prescribe a specific brand or mode of delivery of product within a competitively bid code. *See* SSA § 1847(a)(5)(a). Suppliers necessarily will be forced to add some amount of risk premium over the amounts that they would be able to bid for only the lower cost items, or for a known mix of lower and higher priced items. Program savings will be greater if higher and lower priced items currently in a single HCPCS code are separated into different HCPCS codes because these uncertainties and unknowns will be eliminated and suppliers will be able to bid their best prices for each of the lower and higher priced items.

Both of these effects can be avoided if competitive bidding is initially limited to codes that contain only homogenous, generic and clinically equivalent items. Many such codes offer significant opportunity for savings precisely because the included items are similar to each other in cost and technology. While competitive acquisition in product categories including such codes is implemented, a critical review of other codes can be conducted so that more appropriate codes can be established that do not include items of widely differing costs, technologies and clinical applications. With some of the current codes, any supplier wishing to win a competitive bid may be forced into a situation where it disregards quality and efficacy for price.

Historically, ethical providers have strived to differentiate themselves by their level of quality and service. If an under-defined HCPCS code, which includes a wide variety of technologies, is bid then such a provider will either have to reduce its standards or lose business. By more finely dividing the items selected for bidding, and increasing the HCPCS codes, CMS may achieve the benefit of competitive bidding without jeopardizing access where medically appropriate to higher cost, higher technology items.

Exclusion of Surgical Dressings Entirely From the Competitive Acquisition Program (CAP)

The Coalition of Wound Care Manufacturers concurs with CMS in the Agency's exclusion of surgical dressings in the competitive acquisition program (CAP). It is our understanding that surgical dressings are not included for several reasons. First, the plain meaning of section 302(b) supports exclusion of surgical dressings from the CAP. The statute does not reference the section of the Social Security Act pertaining to the surgical dressing benefit [section 1861(s)(5)], nor did it reference surgical dressings by name.

Had Congress intended to include surgical dressings within the items covered under the CAP, it would have done so with clear and unambiguous language referencing these items by name, and/or by referencing section 1861(s)(5) of the SSA. Interpretation according to the plain meaning of section 302(b) fails to demonstrate any intent by Congress to include surgical dressings in the CAP.

Moreover, none of the three categories of items covered by the CAP (which are covered under a separate statutory section 1861(s)(6) of the SSA).- DME and medical supplies, other equipment and supplies, and off-the-shelf orthotics -- include surgical dressings.

Exclusion of Enteral Nutrition From the First Phase of the CAP

The Coalition of Enteral Nutrition Manufacturers agree with two other associations (National Alliance for Infusion Therapy [NAIT] and the National Association for the Support of Long Term Care) that we do not believe enteral nutrition's inclusion in the *first* phase of the competitive bidding program in 2007 would make significant progress towards the two goals of competitive bidding: (1) improve the level of care for Medicare beneficiaries requiring Part B items and services, and (2) reduce Medicare expenditures,

including the amount of beneficiary co-payments. Instead, it would present costly and complicated administrative challenges for CMS and its contractors. As explained below, enteral nutrition presents some of the most challenging obstacles for inclusion in the competitive bidding program, and we believe it would be an difficult selection for the competitive bidding program to begin with in light of CMS' objective of getting off to a successful start of this enormously complex program.

It is clear that CMS has the discretion under the MMA to (a) exclude products and product categories from the 2007 phase of the competitive bidding program, which CMS acknowledges in the preamble to the proposed rule, and equally importantly, (b) exclude products and product categories in particular settings, such as nursing homes, from the 2007 phase of the competitive bidding program.

Section 302 of the MMA expressly distinguishes between where Congress intended the Secretary to exercise significant discretion and those where it did not. The statute provides that the Secretary "**shall** establish and implement programs under which competitive acquisition areas are established" and that the programs "**shall**" be phased in so that competition occurs in a certain number of the largest MSAs by certain times. However, the statute also provides that the program "**may**" be phased in first among the highest cost and highest volume items and services or those with the greatest savings potential, and that the Secretary "**may**" exempt certain rural and low population density areas and items and services for which competitive acquisition is not likely to achieve significant savings. The statutory language specifically directs the Secretary to establish competitive acquisition areas on a certain schedule, but permits flexibility in design and implementation to encourage efficient operation. By stipulating that the competitive acquisition areas "**may** differ for different items and services," Congress gave the Secretary wide discretion to choose those products and services that are most amenable to competitive bidding (and to exclude products and product categories that are not) and to first implement the program in the metropolitan statistical areas of his choosing.

These grants of discretion gave the Secretary sufficient flexibility to implement the program in the most effective way possible. It also is clear, then, that if there is evidence that it would be in the interests of a successful competitive bidding program to exclude nursing homes from the first implementation phase, the Secretary has the discretion to do so.

Factors Determining Product Selection

CMS lists these factors as some which determine the products to be selected in competitive bidding in the 2007 phase:

- Level of Medicare expenditures
- Rate of growth in expenditures
- Demonstration project experience

I will address each of the these factors' application to enteral nutrition.

I. Level of Medicare Expenditures

Enteral nutrition is listed in the proposed rule as fourth in total Medicare expenditures for Part B items for 2003. That number, however, is seriously misleading, since enteral nutrition is not a monolithic therapy provided in one setting. Rather, enteral nutrition, for policy purposes, should be divided into three parts:

(1) Enteral nutrition provided to residents in long term care facilities ;
(2) Enteral nutrition provided in the home to patients who also qualify for the home health benefit; and
(3) Enteral nutrition provided in the home to patients who do not qualify for the home health benefit.

Historically, a clear majority of Medicare Part B enteral patients are residents of long term care facilities. The percentage of enteral patients who are in long term care facilities increased from 2003 to 2004 to approximately 56%, based on BESS data. This fact is extremely relevant to CMS' ultimate decision of whether to include enteral nutrition in the 2007 phase of competitive bidding. We understand, based on our involvement with CMS in the development of the new Part B quality standards, that the new standards apparently will not apply to these enteral patients, and thus will not apply to the majority of Part B enteral patients. Enteral patients in long term care facilities are and will continue to be treated pursuant to the nursing home conditions of participation, not the Part B standards.

Similarly, those enteral patients qualifying for the home health benefit are and will continue to be treated pursuant to the home health conditions of participation, not the Part B standards. Thus, the only segment of the enteral patient population who will be subject to the Part B quality standards are the home care patients who do not quality for the home health benefit, a distinct minority of the Medicare enteral patient population. That small segment of the population does not involve Medicare expenditures anywhere near the top ten items of Part B expenditures.

II. Rate of Growth

In its comments, NAIT analyzed enteral claims data from the years 2002-2004 indicates that Medicare payments for enteral nutrition do not have any dramatic increases; if fact, the opposite is true. The rate of growth of Medicare allowed charges increased by 1.7% from 2002 to 2003, and actually decreased by approximately 5% from 2003 to 2004. Thus, Medicare allowed charges for enteral nutrition in 2004 were $20,624,897 less than they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS' product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

III. Demonstration Project Experience

Enteral nutrition was not tested successfully during the two demonstration projects and was categorized as not well suited for competitive acquisition by CMS. Enteral nutrition originally was included in CMS' Polk County, Florida demonstration project that tested competitive bidding for certain Part B items. Importantly, enteral nutrition was removed from that demonstration after the first phase of the project. We believe it was removed primarily because most enteral patients reside in long term care facilities, where the application of the competitive bidding regimen would be difficult and confusing. Thus, use of competitive acquisition to set prices and pay for enteral nutrition in Medicare has not been tested sufficiently or successfully.

In addition, based on its own analysis of the data from the DMEPOS competitive bidding demonstration projects, CMS concluded in its final report to Congress that enteral nutrition was not well suited for competitive acquisition. Recently, CMS staff echoed this perspective, indicating that certain products may not be suitable for competitive acquisition because Medicare will not realize sufficient savings to justify the administrative expense of the competitive acquisition program.

Importantly, enteral nutrition was the only therapy in the demonstrations where the majority of patients are in a setting other than the home. Competitive bidding clearly was designed by Congress with the home care patient in mind, a concept that the long term care component of enteral nutrition would greatly complicate. We address this issue in greater detail in the section below about long term care facilities.

The reasons for excluding enteral nutrition from the first phase of the competitive bidding program are not limited to the criteria set out above. There are important other bases for omitting enteral from the 2007 portion of competitive bidding, including the following:

Enteral Patients in Long Term Care Facilities

As indicated above, most enteral nutrition is provided in nursing facilities, which presents issues that go far beyond the scope of the competitive acquisition program. It is apparent that CMS and its contractors will be burdened with numerous complex issues to implement the competitive acquisition program even in the most basic manner possible. Attempting to use competitive acquisition for products used in long term care facilities raise a whole host of issues involving access and choice that are not easily resolvable, especially in the immediate timeframe.

Nursing facilities have a special relationship with their residents. In most instances, the facility is the resident's home. The nursing facilities are responsible for coordinating the work of an array of clinicians, providers and suppliers to meet patient health care needs, and they are held accountable for the quality of these services. Nursing homes must meet detailed conditions of participation to participate in the Medicare and Medicaid programs

as well as a wide array of additional quality standards. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, trust and respect for their level of professionalism.

For these reasons, most nursing facilities will be extremely concerned if they are forced to admit unfamiliar suppliers into their facilities to provide services, supplies, and equipment to their residents. Nursing facilities must be able to select the suppliers the facilities believe can best enable them to meet resident needs and comply with applicable standards. The competitive acquisition program would interfere with their ability to make these decisions, and potentially interrupt ongoing relationships that have worked to the benefit of their residents.

CMS' demonstration projects did not test a model of competitive acquisition that involved long-term care facilities. This is extremely important, because the proposed rule reflects an overly simplistic view of how long term care facilities operate and how they could fit into the competitive bidding program. We are concerned that the proposed rule appears to reflect a view that a nursing home is simply a supplier that does not have to travel to treat its patients. The only recognition that a nursing home is different in any respect is the provision that a nursing home can limit its participation in the competitive bidding program to treating its own residents. What is surprising is the clear implication that a nursing home actually has to be a winning bidder just to treat its own residents. Residents in nursing homes usually are more impaired than home care patients and require a different regimen of care. Primarily for that reason, it would not be a fair or accurate process to combine nursing home bids with home care bids for a particular products category.

The proposed rule also does not account for Part B suppliers whose entire business is treating beneficiaries who are residents of nursing homes. Nursing home suppliers have very different businesses than home care suppliers. They are not interchangeable, and definitely should not be combined into a single grouping to demonstrate that an area has a certain number of suppliers.

The Coalition of Enteral Nutrition Manufacturers do not understand how there can be fair and responsible competitive bidding when there are at play different quality standards, different settings of care, and different patient needs. As explained below in the section on competitive pricing principles, competitive bidding requires bidders to have to meet the same requirements in the same context. The nursing home component flies in the face of this principle. With all respect, we do not believe CMS has considered the differences and particular problems the nursing home setting brings to the competitive bidding program. We urge CMS to refrain from selecting products for inclusion in competitive bidding if, as with enteral nutrition, most of the Medicare market for those products is in the long term care setting.

Application of Quality Standards

The competitive bidding program is predicated in large part on the application of the Part B quality standards and the requirement that every participating supplier be accredited in accordance with the accreditation provisions of the proposed rule. This is an important component of the overall scheme of the competitive bidding program, wherein bidders will have similar costs and will benefit from a generally level playing field. That makes perfect sense – again, except with regard to enteral nutrition.

For the enteral patient population, there will not be one set of quality standards – there will be **three** sets of standards: the conditions of participation for long term care facilities; the conditions of participation for home health agencies; and the quality standards under development in connection with the competitive bidding program. This creates a unique problem for enteral nutrition.

As described above, most of the enteral patients are in long term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long term care market. The proposed rule would require these enteral nutrition suppliers to be accredited for compliance with the Part B standards, even though those standards do not apply to the patients they serve. The absurdity of that result is evident.

Likewise, the provision of enteral nutrition to patients who qualify for the home health benefit would not be subject to the new Part B standards.

It would be highly illogical to subject all of enteral nutrition to the competitive bidding program at this point, because of the involvement of the three different sets of quality standards. The costs of compliance with the standards differ, due in large part to the fact that the settings of care differ. Further, we do not believe it is a feasible option to simply limit the competitive bidding program to homecare enteral patients, since those patients make up less than half of the enteral patient population and thus CMS would not achieve the savings envisioned by the MMA. Regardless, the administrative costs of sorting out the various enteral patient populations and standards within the context of the competitive bidding program would be disproportionate to any value derived from applying competitive bidding to this area.

Enteral HCPCS Codes

The enteral formulas within particular billing codes are not interchangeable, which would thwart one an objective of the competitive acquisition program to achieve cost savings by forcing competition not only among Part B suppliers but also among medical manufacturers as well. One of the basic tenets of the competitive acquisition program appears to be an assumption that the program can generate additional savings by limiting coverage to particular products within billing codes that may be cheaper than other products within those codes. For this approach to work, the products within a billing code must be interchangeable. That is not the case for several of the enteral formula billing codes, which were updated within the past few months.

Two codes, B4153 and B4154, are among the two growing codes among the enteral formula codes. As enteral nutrition becomes even more accepted as a viable and cost-effective substitute for parenteral nutrition, we can expect more new enteral formulas for specific diseases and conditions added to these codes. As these codes will contain a growing number of the enteral formulas used in the care for Medicare beneficiaries, this is additional evidence that enteral nutrition is not as suitable for the competitive acquisition program as would be other products that: (1) are clinically interchangeable within their HCPCS codes, (2) do not involve the nursing home resident population, and, (3) do not involve services and other functions that the Medicare program has yet to cover explicitly.

Rebate Program

The Coalitions do not believe that the rebate provision should be included in competitive bidding. Such payments could be considered inducements to beneficiaries and potentially violate the Federal Anti-Kickback Statute. ("Statute") It is fairly certain that rebates provided directly to beneficiaries would fall under the Statute's purview as a form of inducement to beneficiaries in exchange for referrals. The Statute prohibits the knowing and willful offering or giving of remuneration either in return for referrals or with the intent to induce referrals for items and services reimbursed by Medicare.

We appreciate the opportunity to comment on this proposed rule and would happy to discuss any provision with you at your convenience.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director
Coalition of Enteral Nutrition Manufacturers
Coalition of Respiratory Care Manufacturers
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ALLINA.
Hospitals & Clinics

June 28, 2006

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Baltimore, Maryland 21244-1850

RE: Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule Published in the Federal register on Monday, May 1, 2006.

Dear Dr. McClellan:

I appreciate the opportunity to comment on the proposed competitive acquisition structure on behalf of Allina Hospitals & Clinics (Allina). Allina is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. Allina businesses cover the continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, medical transportation, home (or durable) medical equipment and oxygen, pharmacy, home care and hospice services. Allina serves communities throughout Minnesota and western Wisconsin.

I am writing today specific to the needs of Allina Home Oxygen and Medical Equipment (HOME) and the patients we serve through this important part of our business. Allina HOME has provided oxygen, medical equipment and supplies in our community for over 20 years. We are a full service provider carrying a wide array of medical equipment. We serve patients from pediatrics to geriatrics with varying needs, providing oxygen and respiratory equipment, rehabilitation and mobility equipment, specialty beds as well as other medical equipment and supplies. We serve approximately 55,000 patients annually.

Please review our comments below.

General Comments

The lack of finalized quality standards, no identified accrediting body/bodies, identified bidding areas or identified supplies to bid, and the need for updated data on the population and volume statistics in order to determine what metropolitan sites are include in the Phase I, make it extremely difficult for us to begin to plan for the changes that may result from finalization of any of the changes of the proposed rule.

We understand the requirements for change that come from the MMA and the Deficit Reduction Act, however, we are quite concerned about the significant payment reductions our industry continues to have to swallow. We have already been significantly impacted due to rate reductions to the FEHBP levels and the MMA rate freezes. Further reductions that CMS hopes to gain through competitive acquisition on top of the current reductions and freezes will force a number of suppliers out of business. CMS is already experiencing the positive impacts of the reductions to date.

We are concerned that the additional administrative expense that will be incurred through the implementation of the competitive bidding model may not lead to the real savings that CMS is seeking. We ask that CMS seriously consider the implications this may have on access to supplies and services for beneficiaries in great need.

Access to Services

In Minnesota, 607,125 people are eligible for Medicare. Currently, these individuals receive products, supplies and services from over 450 durable medical equipment (DME) companies. Today, that is one DME provider for every 1350 potential beneficiaries. For the years 2010, 2020 and 2030, respectively, it is projected there will be approximately 671,787; 910,080 and 1,173,339 Medicare-eligible citizens residing in Minnesota. Using existing DME provider statistics, this would mean one provider for every 2,608 potential beneficiaries. We expect that a large number of the smaller providers in rural Minnesota and western Wisconsin may not pursue competitive bidding or not be selected as a CMS supplier and may go out of business without a Medicare contract. CMS must consider the significance of reduced providers on the long-term growth in the Medicare population and their access to services in the rural areas. We are greatly concerned that access to services may be jeopardized in rural Minnesota and western Wisconsin as a result of the competitive bidding model proposed. Under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

Implementation Contractor

We support the development of a separate structure and designation of the Competitive Bidding Implementation Contractor. The complexity of this process and the phasing in of implementation requires a contractor that is focused solely on this work and committed to maintaining the highest level of integrity.

Payment Basis

MSA Selection

CMS has made the decision to exclude New York City, Chicago and Los Angeles from Phase I implementation. We would suggest that at least one of these large metro areas be included in the first phase to allow for rigorous testing of all systems and processes and to show the financial savings that CMS projects to gain from the competitive bidding process.

CMS has provided a list of potential MSA's to be included in Phase I but indicates that these could change with updated census and volumes data. It is challenging to know how to respond to this rule without knowing for sure whether the Minneapolis/St. Paul MSA would be included with updated data.

Allina supports the proposed methodology of combined population and charge data as the basis for MSA selection. In order to achieve the savings that CMS seeks, it is imperative to include charge data an essential component in the MSA selection criteria. We recommend that CMS stagger the bidding in MSA's in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread.

Submission of Bids Under the Competitive Bidding Program

Conditions for Awarding Contracts

We are deeply concerned that the quality standards and the process for accreditation have not been finalized. CMS must allow additional time for providers to analyze the quality standards in conjunction with the proposed rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process. If only accredited providers should be eligible to submit bids, CMS should not proceed with competitive bidding until it is certain that the accreditation work can be accomplished on a timely basis. CMS must identify the criteria it will use to select the accrediting bodies as soon as possible and should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

With only 20-40% of DMEPOS companies currently accredited, we are very concerned about the selected accrediting body's ability to do what needs to be done to assure that all bidding companies are eligible to bid. We are not clear how the grace period will be viewed when it comes to making decisions on awarding the contracts. Will it be viewed as a weakness of the bid if up against other suppliers who are already certified? This should not be the case. In order to have a fair and equitable process, the accrediting body selected must have the resources to meet the volume demands for accreditation prior to the submission of initial bids.

How can CMS legitimately establish whether a supplier actually has the capacity to meet the demand in a CBA? We are concerned about the potentially subjective nature of this assessment. If CMS is only looking at a two-year history of claims data, how does CMS know the ability of the supplier to grow their business? A supplier with a firm financial foundation alone does not necessarily have the other resources required to meet the demand in terms of equipment, service, and customer relationships. We ask that CMS develop specific objective criteria upon which to base this decision. Simply "evaluating capacity to meet demand" is not enough.

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Bidding Requirements

We have issues with the single payment amount determination for capped rental. The implications of reducing the percent down to 7.5% for months 4-13 does not account for the suppliers need to finance the equipment for that period. We ask that you consider maintaining the 10% for the full 13 months or pay an additional fee to the supplier to account for the time value of money related to financing.

We feel very strongly that the service of equipment after the sale is vital to the beneficiary. We support requiring the supplier to maintain and service the equipment after the sale. We ask that CMS develop a clear mandate for suppliers to provide follow up service on all equipment sales and provide appropriate reimbursement for any services provided. We want to be sure that beneficiaries are not left with equipment they have no idea how to maintain and where to go if service is required. We do not want suppliers that may sell equipment without providing the ongoing service required after the sale to end up being selected as a competitive bidder.

CMS proposes to separate out bids for oxygen and oxygen equipment. We strongly urge CMS to keep these products combined under the same contractor. Separating the service and supplies will create confusion for the beneficiaries. They will struggle with which supplier to call for equipment problems versus oxygen supply. There will also be issues related to equipment problems that result from oxygen fills. Oxygen and oxygen equipment and supplies are best provided through the same supplier. This will assure that the equipment is handled appropriately and the beneficiary only needs to deal with one supplier coming to their home and managing their oxygen needs.

Bid Amounts

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item; otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either rational or sustainable.

Rebate Programs

We do not support a rebate program being part of the competitive bidding model. From a compliance perspective, we have significant concerns about the potential for kickbacks and inducements. In addition, rebates will create significant administrative complexity, particularly when the rebate amount may end up exceeding the Medicare co-payment amount. The opportunity to offer rebates also sets up the potential for low bidding versus competitive bidding. If CMS finds it necessary to offer a rebate program, we would suggest that the rebates are not voluntary. If the bids put a supplier in a position to offer a rebate they should be required to do so in order to assure that they are not bidding low just to be selected and then have their reimbursements raised to the median level automatically. This would stop those who would set up deliberate low-ball bidding.

Change in Ownership

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent upon the need to preserve capacity within the MSA.

Suspension or Termination of a Contract

We would like to see greater clarification on the provision for termination of a contract for "convenience." At a minimum, there should be an explicit notice period required prior to termination.

Administrative/Judicial Reviews

We recommend that CMS establish some type of expedited review process specific to contract award decisions. In order to support the highest level of integrity in this process, we seek full transparency of factors influencing contract award decisions.

Final Comments

In closing, we ask CMS to recognize the difficulty of responding to proposed changes without having the fundamental components of the competitive bidding process spelled out explicitly in the rule. With no quality standards, no decisions on accrediting bodies, MSA's that could change, the lack of defined competitive bidding areas, and the absence of a defined set of products to be included in the bidding process, we have tremendous concerns about the promulgation of a final rule of which we have no opportunity to challenge and a very short timeline to implement.

CMS has major work to do prior to this rule going forward and we have much trepidation about the ability of CMS to establish the solid foundation that is essential to support this massive change.

On behalf of our Home Oxygen and Medical Equipment business, Allina Hospital & Clinics sincerely appreciates the opportunity to provide feedback on these proposed changes. We ask that CMS seriously reconsider the aggressive timelines and delay implementation until we can be assured that the fundamental components of a reliable and sustainable competitive bidding process are in place. Please feel free to contact me if you have questions. I can be reached at 612-262-4912.

Sincerely,

Nancy G. Payne, R.N., M.A.
Director Regulatory Affairs

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Eric P. Milledge
Company Group Chairman

June 28, 2006

The Honorable Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule for Medicare Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues – CMS-1270-P

Dear Dr. McClellan:

On behalf of LifeScan Inc., a Johnson & Johnson company, I am writing in response to the Centers for Medicare & Medicaid Services (CMS) Proposed Rule published in the May 1, 2006 *Federal Register* for Medicare Competitive Acquisition for Certain DMEPOS and Other Issues. We appreciate the opportunity to submit comments in the spirit of assisting in the successful implementation of a very complex program mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). LifeScan is a leading manufacturer of blood glucose monitoring products and other diabetes management systems. LifeScan is committed to improving the lives of all patients with diabetes today and with continued innovation in the future.

LifeScan commends CMS as it faces the challenge of requiring DMEPOS suppliers to meet consistent, strong quality standards, achieve cost savings in the DMEPOS benefit category, and at the same time, make sure that Medicare beneficiaries get the care and treatment necessary to meet their medical needs. This is an overwhelmingly complex process to implement based on the outcomes of two relatively small demonstration projects that focused on a limited range of products. We urge CMS to be thorough, careful, and conservative in the implementation of Medicare Competitive Bidding for the least disruption for the beneficiaries and to consider program savings for the long term with full consideration of the administrative costs and costs possibly shifted into other benefit areas such as Part A.

Before turning to our comments on specific sections of the proposed rule, we would like to make a few key points that need to be kept in mind when considering DMEPOS used by Medicare beneficiaries to help manage their diabetes.

Diabetes is a life-threatening condition that is affecting a growing number of Americans. A four-part series published in the January 9-12, 2006 issues of the *New York Times* recently catalogued the growing problem of diabetes in the United States, labeling it a "crisis" and calling attention to its "awful toll." A subsequent editorial concluded that this is "the time to develop a

coordinated plan with a long view to take control of diabetes." As of 2005, the Centers for Disease Control and Prevention reported 20.8 million Americans with diabetes, of which over 6 million remain undiagnosed. According to a report released on March 1, 2005 by the Agency for Healthcare Research and Quality (AHRQ), the agency found that "*Medicare could save $1.3 billion annually, and Medicaid $386 million a year by reducing hospital admissions for diabetes complications. Up to $2.5 billion—roughly two thirds of the total—might have been averted with appropriate primary care for individuals with complications.*" The proposed rule listed Medicare allowed charges for diabetes supplies and equipment in 2003 at about $1.1 billion. However, CMS has also acknowledged that the care of beneficiaries with diabetes consumes roughly 32 percent of total Medicare expenditures. In 2003, Medicare Part A and B benefit payments totaled $275.9 billion dollars. Thus, in that year, Medicare allowed charges for diabetes supplies and equipment represented only about 1.2 percent of all Medicare expenditures for the care of patients with diabetes, that is $1.1 billion ÷ $88.3 billion ($275.9 billion × 0.32).

Devastating and costly diabetes complications due to lack of appropriate glucose control may include: kidney failure, heart attack, stroke, diabetic retinopathy and other vision problems, neuropathy, and amputation. Regimented self-testing is a critical component to tight glucose management. While it is difficult for any patient to effectively manage a chronic condition, even more challenges exist when older Americans are faced with the daily struggles of proper glucose control often managed by multiple therapies (oral agents, insulin, behavior modification including diet and exercise) and possibly the added burden of treating co-morbidities. If Medicare beneficiary access or continued access to the most appropriate glucose-monitoring device is disrupted, patient compliance with their treatment regimen may be jeopardized and health outcomes could be adversely impacted.

Blood glucose meters and their supplies are an integrated system. Patients must use the unique blood glucose test strips made for their brand of blood glucose monitor, not just any brand of test strips. Blood glucose monitoring is an integrated technology where the test strips are designed specifically and uniquely to work with a specific meter. A glucose meter without the right test strips is worthless. Any required change in manufacturer of glucose meter or test strips would require the beneficiary to change to a different monitoring system. A change in system will require re-education of the patient, which has associated costs.
There are significant differences between blood glucose systems and many other DMEPOS products, including the following:

- Patients with diabetes typically go to a supplier, such as a local pharmacy, to obtain their blood glucose monitoring equipment and related supplies; unlike other DMEPOS products, such as oxygen and oxygen equipment, that supplier does not usually deliver the products to the patient's home.
- Patients purchase their diabetes supplies on a regular basis, often monthly; this is a fundamental difference from the typical one-time acquisition of other DMEPOS products, such as a hospital bed or wheelchair.
- Patients now can and do routinely obtain their diabetes supplies from a wide range of sources, including pharmacies, food and drug stores, mass merchandisers, small DME shops, and even mail order companies; they are not restricted to just a few options. In fact, there are more than 56,000 retail outlets now offering diabetes equipment and supplies. Close-to-home access helps minimize the risk that patients will fail to test their blood as indicated if their procurement of diabetes supplies is disrupted or confusing. Also, regular contact with a pharmacist, often an important member of the diabetes management team, can reinforce proper diabetes care. Neglecting to test and manage blood glucose levels can lead to the many costly and devastating issues mentioned previously.
- Variation and fluctuation in patient condition may require product, testing frequency and other adjustments in blood glucose monitoring in order to continue to meet the current needs of the individual. Manufacturers of blood glucose monitoring systems continue to provide innovative products designed to better meet the needs of patients with diabetes.

Unimpeded access to the most appropriate products, including the latest innovations, is very important to a successful diabetes treatment program.

We believe that CMS should approach the topic of diabetes equipment and supplies very carefully, thoughtfully and perhaps incrementally. If these products are subjected to competitive bidding, we recommend that CMS consider these products under its proposal to "phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding". In fact, **since diabetes equipment and supplies were not included in the two Medicare competitive bidding demonstration projects, we recommend that any competitive bidding for diabetes supplies and equipment be limited to no more than one competitive bidding area, at least during the first round of bidding.** We note, too, that in selecting suppliers to contract with Medicare, CMS would need to take special care to ensure that beneficiaries throughout a competitive bidding area would continue to have convenient geographical access to the many distribution channels available for diabetes supplies today.

KEY COMMENTS AND RECOMMENDATIONS

With the above background in mind, below is our list of key comments and recommendations on the various elements of the proposed rule.

- We strongly support phasing in "some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding" (as discussed in the proposed rule). If CMS decides to subject diabetes equipment and supplies to competitive bidding, it should begin by doing so in no more than one MSA due to the fact that these products were not included in the demonstration projects.
- CMS must assure a reasonable geographic distribution of contract suppliers for DMEPOS products typically obtained by beneficiaries at a nearby retail outlet rather than delivered to their home.
- CMS must assure beneficiaries have reasonable access to a sufficient range of products within a HCPCS code to ensure individual requirements are met.
- CMS must recognize that blood glucose meters and test strips are an integrated system; if subjected to competitive bidding, these products must be included in the same product category.
- We strongly oppose basing the single payment amount on the median of winning bids. No contract supplier should be paid less than their bid amount.
- We strongly oppose requiring beneficiaries to use mail order for replacement supplies and also question a separate national or regional mail order program.
- CMS must adopt special policies in order to allow a manufacturer to serve as a contract supplier.
- CMS policies should require suppliers to inform the relevant DMEPOS manufacturer of any problem with the equipment or supplies so that the manufacturer can make the FDA-required reports and take any other appropriate action.
- CMS must assure that the physician authorization process is as simple as possible, especially during the first few rounds of competitive bidding.

SPECIFIC COMMENTS & RECOMMENDATIONS TO THE PROPOSED RULE

Following is our detailed comments and recommendations to the proposed rule labeled with the captions recommended by CMS.

Payment Basis (proposed §414.408)

CMS is proposing to update the single payment amount set under the competitive bidding process in subsequent years of the contract cycle by the percentage increase in the CPI-U for the 12 month period ending with June of the preceding calendar year. We strongly support this approach. We believe that it will help facilitate the bidding process and provide a reasonable and efficient means for adjusting Medicare payment amounts during each contract cycle.

The proposed rule describes a potential grandfathering process for certain rental agreements. However, we believe that other important transition policies would be needed if certain diabetes supplies and equipment are subjected to competitive bidding in one or more areas. A large number of Medicare beneficiaries are already using glucose monitoring systems (that is, blood glucose meters and compatible test strips), and they may well have been using these items for a long period of time. Unfortunately, it seems quite possible that competitive bidding could force some, many or even most beneficiaries in an area to switch to a glucose monitoring system other than the one they are currently using. This would occur, for example, if contract suppliers offered only one brand of glucose monitoring system—or even several brands—not now commonly used by Medicare beneficiaries. Remember, too, that a beneficiary must have access to both a particular meter and the test strips designed for that specific meter; being allowed access to one without the other would be meaningless.

A sudden forced switching of glucose monitoring systems by large numbers of Medicare beneficiaries in an MSA could have a very disruptive effect not only on beneficiaries, but also on the physicians and diabetes educators who care for them. It could reduce beneficiary compliance with the testing regimen recommended by their physician and lead to a wide range of adverse outcomes. Such forced switching could also have cost implications for the Medicare program if it resulted in substantial numbers of claims for new glucose monitoring systems, a problem that could repeat itself in subsequent rounds of competitive bidding in a given area. **Note, for example, that Medicare now generally covers a new glucose meter only once every 5 years, but could find itself paying for new meters every three years under competitive bidding (the presumed length of supplier contracts), if contract suppliers elected to offer different brands of glucose monitoring systems during different contract cycles.**

Later in these comments, we offer several suggestions for minimizing the risk of such forced switching. However, even if all our suggestions were accepted, it might still not guarantee that some beneficiaries would not be forced to switch at some point. **We, therefore, urge CMS to adopt a transition policy under which beneficiaries now using a specific brand of DMEPOS could continue to have access to the supplies that are compatible with that specific brand for a period of six months following the start of a DMEPOS competitive bidding program in an area.** In the case of diabetic equipment and supplies, this would mean allowing beneficiary access to the test strips that are compatible with their current brand of glucose meter. Among other things, this transition policy would provide time for beneficiaries to consult with their physician or diabetes educator to assess the appropriateness of switching to another brand of glucose meter or the need for executing a physician authorization providing for more permanent access to a specific brand of DMEPOS. This transition policy could be implemented in a variety of ways. One option would be simply to require contract suppliers to comply with such a transition policy. In other words, they would agree to provide glucose test strips for the brands of meters now used by Medicare beneficiaries (and even a replacement meter, if necessary), even if such suppliers did not plan to offer that brand of test strips (and compatible meter) on a longer-term basis. Another option would be to give beneficiaries a six-month "grace period" during which they could continue to obtain replacement items from any qualified supplier.

In fact, given the potential disruptive effect if competitive bidding is implemented on a date certain in a large metropolitan area, **we would encourage CMS to provide a "grace or transition period" of at least 90 days during which beneficiaries could obtain DMEPOS subject to competitive bidding from non-contract suppliers with these suppliers paid under the applicable fee schedule (or perhaps the single payment amount).** When beneficiaries obtain DMEPOS in this way, they could be given educational materials explaining the new program, listing the contract suppliers available in their area and other important information. Expecting a sudden transformation in the DMEPOS marketplace to go smoothly is simply unrealistic, and recent experience with Medicare Part D shows us how difficult it is for beneficiaries to adjust to a new program without some kind of transition. We see nothing in the MMA that would preclude CMS from providing such a "grace or transition period."

The proposed rule also addresses various beneficiary travel scenarios. However, we believe it is unrealistic for CMS to expect a beneficiary traveling into a competitive bidding area to be able to know which DMEPOS items are subject to competitive bidding in that area, identify and locate contract suppliers for that item, and determine which contract suppliers in the area might be offering the specific brand used by the beneficiary (since contract suppliers may well offer different brands). For example, a beneficiary might require replacement test strips that are compatible with their specific brand of glucose meter (which could even be a meter obtained from a contract supplier in the area where the beneficiary maintains a permanent residence). Perhaps they forgot to pack their test strips, or the test strips they brought were misplaced or damaged during the trip. How could CMS possibly assure that such a beneficiary would not have significant difficulties in obtaining the replacement items they need? We do not believe that it could. **We, therefore, conclude that CMS should allow beneficiaries who travel to obtain replacement supplies from any supplier, not just contract suppliers in a competitive bidding area.**

In the proposed rule, CMS also announces its intent to use its statutory authority to adjust DMEPOS payments in areas not subject to competitive bidding based on its experience under competitive bidding. CMS notes that it has "not yet developed a detailed methodology" for using this authority, and invites comments on this issue. To begin with, we strongly believe that before deciding whether and how it will apply the competitive bidding experience to DMEPOS payments in other areas of the country, CMS should fully assess the impact of competitive bidding on beneficiary access and quality within the designated MSA. Then, once CMS is in a position to develop a detailed methodology for applying the special authority, the agency should publish its proposed methodology for public comment as part of a future rule-making exercise. Since the authority in question is not effective until January 1, 2009 at the earliest, there is plenty of time for CMS to do this. This is an extremely important issue with potentially far-reaching consequences for all stakeholders, including beneficiaries, suppliers, and DMEPOS manufacturers, and it would not be appropriate to implement this special authority merely through manual instructions, especially since the policy in question is likely to easily satisfy the definition of a major rule.

Competitive Bidding Areas (proposed §414.410)

We strongly disagree with CMS' proposal to adopt competitive bidding areas in 2007 and 2009 that go beyond MSA boundaries. We do not believe this would be compatible with the plain meaning of in an MSA. On the other hand, we do agree with CMS' view that it could adopt competitive bidding areas smaller than an MSA. In fact, we would encourage the agency to take advantage of this option to minimize the risk of adverse outcomes from DMEPOS competitive bidding, especially for products not included in the two Medicare demonstration projects, by limiting the area subject to competitive bidding. This approach might also provide a way for minimizing the complications when a selected MSA crosses state (or even DMERC) lines by restricting competitive bidding to the portion of the MSA that lies within a single state or the service area of a single DMERC. It would also have the added advantage of facilitating implementation of the new program, especially in 2007. Moreover, we believe that it would help increase the likelihood of a successful roll-out of the new competitive bidding program.

In terms of the proposed mail order competitive bidding program, **we strongly oppose the idea of requiring beneficiaries to use mail order for replacement supplies.** We believe this would be anticompetitive, effectively precluding other suppliers, such as retailers and independent pharmacies, from continuing to provide these products to Medicare beneficiaries, and would, therefore, have very serious business implications for the affected suppliers. We note, too, that during the May 22-23, 2006, meeting of the Program Advisory and Oversight Committee (PAOC), CMS staff did not mention that this was one of the options under consideration, and instead emphasized that the agency was not planning to require beneficiaries to use mail order. In addition, we do not see how beneficiaries could be required to use mail order for replacement supplies unless the contract mail order suppliers were at the same time required to offer all brands of such replacement supplies that beneficiaries around the country might need.

Otherwise, a beneficiary might obtain a glucose meter from a supplier, even a contract supplier in one of the many competitive bidding areas scattered across the country, and then be unable to obtain compatible replacement test strips from the contract mail order supplier. Finally, while some beneficiaries may consider mail order the best option for them, other beneficiaries may do better with the kind of support that can only be provided by a face-to-face encounter with a pharmacist or other supplier. In sum, we urge CMS to preserve beneficiary access to mail-order and all other current distribution outlets, instead of forcing all beneficiaries to use only mail order (or any other single type of distribution outlet) for certain products or under certain circumstances.

Beginning in 2010, CMS is proposing to phase in a national or regional mail order competitive bidding program for certain items. We urge CMS to proceed cautiously in this regard. Since CMS will also have implemented competitive bidding in 80 MSAs by that point with more MSAs expected to be added after 2009, we believe there is a serious risk of confusion if a regional or national mail order competitive bidding program is overlaid on top of the regular competitive bidding program. In addition, since mail order firms will be permitted to bid during the early rounds of the competitive bidding program, it is not clear how a separate mail order program be made compatible with what has already occurred. For example, some mail order firms may have been selected as contract suppliers during the early rounds of the competitive bidding program, while other mail order firms were not selected or chose not to bid. Mail order firms selected during Rounds 1 and 2 for specific MSAs could end up being supplanted by other mail order firms choosing to bid on a regional or national basis. To the extent that CMS is planning to extend the competitive bidding program beyond the 100 MSAs already envisioned, the agency should simply continue to allow mail order firms to compete on the same basis as other suppliers. In short, **we question the whole notion of a separate competitive bidding program for mail order firms as opposed to a program under which mail order firms are allowed to compete fairly against other suppliers.**

Criteria for Item Selection

The proposed rule notes that CMS "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." As noted earlier, we strongly support this approach, especially with respect to DMEPOS products and supplies, such as glucose monitoring equipment, not included in the two Medicare demonstration projects. In fact, as we understand it, CMS expressly decided not to include glucose monitoring equipment in the Medicare demonstration projects, and we believe those demonstrations provide relatively limited information about how competitive bidding would work for products typically obtained at a wide range of retail outlets (as opposed to products delivered to the patient's home).

Among other things, the concept of phasing in some product categories would allow CMS to gain experience with different product distribution channels (for example, DMEPOS typically obtained by a beneficiary at a local retail outlet compared to products typically delivered to the patient's home). This approach would also simplify implementation during the early rounds of competitive bidding and minimize the risk of adverse beneficiary outcomes. We cannot emphasize enough how important we believe it is for CMS to avail itself of every possible means for proceeding cautiously as it implements the new competitive bidding program. Phasing in certain product categories will help CMS identify issues and make refinements prior to subjecting a large number of Medicare beneficiaries to a new system. As noted earlier, we recommend that any competitive bidding for diabetes equipment and supplies be restricted to a single competitive bidding area, at least during the first round of the bidding process.

As acknowledged in the proposed rule, the MMA gives CMS the authority to "exempt items for which the application of competitive bidding is not likely to result in significant savings." In terms of diabetes equipment and supplies, we believe that the history of Medicare DME fee schedule changes for these products since 1998 (described in more detail below) raises serious questions about whether competitive acquisition could achieve such "significant savings" because the Medicare program has already implemented a number of cost saving methods in this area.

To begin with, the MMA froze payments for glucose meters, test strips and lancets for 2004. It also mandated payment reductions for test strips and lancets for 2005 of 4.1 percent and up to 5.3 percent, respectively. The MMA also specifies a continuing payment freeze for glucose meters, test strips and lancets for the years 2006, 2007 and 2008. Payments for glucose meters, test strips and lancets were previously frozen in 1998, 1999, and 2000, and again in 2002. In sum, for the period 1998 to 2006, payments for glucose monitors, test strips and lancets were either frozen or reduced in 7 of these 9 years, while from January 1998 to May 2006, the consumer price index for all urban consumers (U.S. urban average) rose by almost 25 percent. This history causes us to question the feasibility of achieving significant additional Medicare savings through competitive acquisition without compromising Medicare beneficiary access or quality.

Submission of Bids Under the Competitive Bidding Program (proposed §414.412)

We are concerned that CMS may not allow a sufficient amount of lead time for DMEPOS suppliers to submit bids. We believe that considerable advance notice will be required to permit suppliers in designated competitive bidding areas to negotiate with DMEPOS manufacturers, and fully assess the cost implications of new DMEPOS supplier quality standards and the related accreditation process (including the specific fees that the accrediting bodies yet to be selected by CMS will be charging for their accreditation services). We believe, for example, that it would be unrealistic for CMS to issue requests for bid (RFBs) immediately following publication of the final rule and then give suppliers only a short period of time to develop and submit their bids. Even DMEPOS manufacturers not planning to serve as direct suppliers will need some time to adjust once CMS has actually announced the 10 MSAs selected for Round 1 of competitive bidding and the specific product categories that will be used in each of these MSAs. **We, therefore, recommend that RFBs not be issued until 60 to 90 days following publication of the final rule in order to give suppliers and other stakeholders time to review the rule and understand its implications without also having to simultaneously deal with the RFBs. We also urge CMS to give suppliers in designated competitive bidding areas at least 90 days to submit their bids following release of the RFBs for Round 1.**

Moreover, ideally, suppliers would not have to submit bids until they have been accredited as meeting the new supplier quality standards and can therefore be certain they have built into their bids all the costs of complying with those standards. As we understand it, during the recent PAOC meeting, a representative of one of the major accrediting organizations in the country said that it would take 3 to 6 months for suppliers in the designated competitive bidding areas to be accredited once CMS has selected the accrediting organization(s). In any case, as we will emphasize again later in our comments on the single payment amount, **if supplier bidding ends up preceding supplier accreditation, then CMS must ensure that only the bids of accredited suppliers end up being used in calculating the single payment amounts for DMEPOS items under the competitive bidding program.**

The proposed rule does not propose specific product categories but assumes that interested bidders would be required to submit bids on all items included in a product category. However, for some DMEPOS, manufacturers are now serving as direct suppliers. In fact, for some products (for example, insulin pumps), manufacturers may now be the principal source of the product. Medicare supplier and claims data should help CMS assess this. For other DMEPOS products, manufacturers might wish to begin serving as direct suppliers under competitive bidding. However, manufacturers of specialized equipment might obviously not be in a position to bid on every item included in a product category, especially if CMS decides to create very large categories. This creates a problem. CMS could attempt to carefully design product categories to avoid shutting out manufacturers or it could adopt special rules for manufacturers wishing to bid. Of course, the latter would also require adjustments to the methodology for calculating composite bids (or their equivalent) if a manufacturer were not required to bid on every item in a product category. We have no definitive solution to suggest at this time but **we do believe it would be a mistake for CMS to exclude manufacturers from competitive bidding**—and even seriously

disrupt the existing marketplace for certain products. In this regard, we also wish to note that a bidding manufacturer would obviously only be in a position to offer their own brands of DMEPOS, but we again do not believe that this should automatically exclude them from the opportunity to bid and serve Medicare beneficiaries.

If CMS elects to subject elements of the diabetes supplies and equipment policy group to competitive bidding, we urge the agency to recognize that blood glucose monitors and test strips function as a system (a specific brand of test strip is only compatible with a specific brand or very closely related brands of glucose monitors). This means that both components of the system should either be excluded from competitive bidding in an area or both components included in the same product category. In fact, if CMS decides to implement competitive bidding for blood glucose monitoring equipment, we believe that a reasonable product category would include the basic code for blood glucose monitors (E0607), the code for test strips (A4253), the code for control solutions (A4256), the code for lancets (A4259), and the code for lancing devices (A4258).

Conditions for Awarding Contracts (proposed §414.414)

The proposed rule notes that individual products subject to competitive bidding will be identified by HCPCS codes and "will be further described in the RFB." However, no details are provided to explain what such further description might entail. Such further description of products in the RFBs would provide a means for assuring continued beneficiary access to a range of products now reported by a single HCPCS code. For example, for any single HCPCS code, CMS could specify product features that would need to be included among the brands offered by a contract supplier, or specify a minimum number of different brands that would need to be available to Medicare beneficiaries. In the context of blood glucose meters, this is important because nearly all meters are reported by the same HCPCS code (E0607), although they have different handling properties, different display readabilities (e.g., Spanish displays), and different data managing capabilities (which may, in some cases, provide clinical advantages), and any one of these differences can be extremely important to the individual patient. A "least common denominator" meter is not likely to meet everyone's needs. Failing to recognize differences between products could also have the unintended consequence of stifling innovation aimed at improving this category of products.

As part of its "further description" of products, CMS could also specify the need to offer those that carry adequate warranties (which are typically offered by manufacturers, not suppliers). For some DMEPOS products, it could specify the need to offer products that are backed up by manufacturer-run patient support systems (for example 24-7 toll-free lines that accommodate the principal languages spoken by Medicare beneficiaries living in a competitive bidding area), especially for products where this is the common (but not necessarily universal) practice today.

Companies such as LifeScan provide such patient support systems, but CMS should not assume that all manufacturers of diabetes equipment and supplies do so or will continue to do so. In fact, it seems quite possible that contract suppliers could end up offering DMEPOS products lacking the most advanced features or the current level of patient support in order to bid low (or to maximize their profits after they are selected as contract suppliers). We realize that the supplier quality standards may address some of these concerns. However, we urge CMS to recognize that not all products reported with a single HCPCS code today are equivalent in quality, and so a competitive bidding system that does not further specify the expected quality of deliverables risks creating a two-tiered system, under which Medicare beneficiaries in competitive bidding areas have access to only a small subset of the products available to beneficiaries in areas not subject to competitive bidding, and those products may lack important features as compared to the other products in the marketplace.

To the extent that supplier decisions about product offerings would force beneficiaries to switch from the DMEPOS products they now use to other brands, bidding suppliers should be required

to include a plan for educating patients about the use of the new product so that the potentially negative consequences of a forced switch are minimized.

CMS proposes to have bidding suppliers indicate how many units of each product they would be able to offer in a competitive bidding area. However, it is not clear how CMS plans to verify whether these supply estimates are reasonable. For example, the ability to offer a product must specifically include the ability to support the volume of product offered (for example, patient counseling, training, handling patient calls in a timely fashion, working with prescribing physicians, etc.). CMS also needs to understand that, at least for some DMEPOS products, the supply might not be completely within the control of the bidder. For example, if a supplier's promised capacity and bid price assumes that a store brand or a product that now comprises a tiny share of the marketplace will be the only one offered under one of the HCPCS codes in a product category, how will CMS assess whether the manufacturer of that particular product will be capable of increasing supply fast enough to meet beneficiary needs for that item?

In the proposed rule, CMS promises to match supply and demand in selecting the number of winning suppliers. However, **no mention is made anywhere of the need to assure that winning suppliers will be geographically distributed across the entire competitive bidding area**, rather than concentrated in one portion of the area. While this may be less of a concern in the case of DMEPOS products typically delivered to a beneficiary's home, it is a major issue when the products are typically obtained by the beneficiary from a retail outlet. Today, beneficiaries most likely obtain such products from a retailer near their home. Although the proposed rule generally requires contract suppliers to serve an entire competitive bidding area, in the case of retail outlets, a beneficiary must first travel to a specific retailer to request service. We acknowledge that it will be very difficult to assure a reasonable geographic distribution of contract suppliers, since this will require an intimate knowledge of the marketplace in each competitive bidding area. However, without great care, the competitive bidding program could end up disadvantaging lower-income beneficiaries living in rural or inner city areas, minorities, or other vulnerable subsets of beneficiaries. And in the case of diabetes equipment and supplies, these might be the very population subsets with high rates of diabetes and most in need of unimpeded access to blood glucose monitoring equipment. In fact, CMS might find it necessary to select suppliers with bids above the pivotal bid (or its equivalent) in order to assure full coverage of an area.

We note Congressional sensitivity to this very issue in Medicare Part D, where prescription drug plans are expected to have a network of pharmacies that ensures "convenient access" and TRICARE standards are used as a model for assessing this. For example, under Medicare Part D, at least 90 percent of Medicare beneficiaries living in urban areas and served by a particular Part D plan, on average, must live within 2 miles of a network pharmacy. We recommend that Medicare's DMEPOS competitive bidding program be designed to assure a similar level of "convenient access," at least for diabetes supplies.

Other negative outcomes are also possible in selecting contract suppliers under the proposed methodology. We believe it would be anti-competitive, for example, for CMS to select a single chain of drug stores (with multiple locations) to serve a competitive bidding area. While this would technically satisfy the requirement to select at least two suppliers for an area, this "two" would in reality represent a single corporate entity. CMS has shown sensitivity to the notion of market concentration by proposing to restrict the size of the marketplace that a supplier network could represent, but this same issue could arise outside of the network context.

Determining Single Payment Amounts for Individual Items (proposed §414.416)

CMS is leaning in favor of setting the single payment amount for a HCPCS code at the median of the bids at or below the pivotal bid for the code. **We strongly oppose this**. To begin with, the proposed methodology does not propose to "weight" the bids by the amount of product being promised by the bidding supplier. Thus, the bid from a supplier proposing to provide 100 units would be treated the same as a bid from a supplier proposing to provide 100,000 units. This

could end up meaning that the single payment amount would be below—perhaps substantially below—the amount bid by the suppliers with the capacity to serve the bulk of the competitive bidding area.

Second, as noted earlier in these comments, CMS must only use the bids of accredited suppliers in calculating the single payment amount, and so if supplier bidding precedes supplier accreditation, then CMS will have to determine whether presumptive "winning" bidders have subsequently been accredited and thereby qualify to have their bid used in the payment calculation. Otherwise, the bid of an unaccredited supplier could inappropriately bias the calculation of the single payment amount (for example, that bid might be unduly low simply because the supplier had not taken into account all the costs involved in meeting quality standards).

Third, as CMS acknowledges, the Medicare DMEPOS competitive bidding demonstration projects did not base payment on the median of winning bids, but an adjustment factor was applied in order to minimize having the payments set below the prices bid by winning suppliers. As a result, CMS does not have experience using the median of winning bids in a competitive bidding program, and it is hard to predict what impact this approach would have. We believe that the same kind of payment adjustment used in the demonstration projects or another equivalent approach should be used to help assure that winning bidders actually win. For example, perhaps CMS could set the single payment amount at the 90th percentile of winning bids or no lower than 5 percent below the highest winning bid. If the median is used as proposed, some winning bidders may be forced to reduce beneficiary access, product quality and beneficiary service in order to live within the single payment amount.

CMS is proposing to allow contract suppliers with bids below the single payment amount to offer rebates to beneficiaries equal to the difference between their actual bid and the single payment amount. We join the members of the PAOC in believing that such rebates could lead to fraudulent and abusive practices by both contract and non-contract suppliers. We urge CMS to reconsider this proposal.

Terms of Contracts (proposed §414.422)

The proposed rule mentions a non-discrimination contract provision, which is intended to assure "that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers." Unfortunately, the proposed rule provides very little detail about what would be expected or how CMS would assure that the provision was being met. It is not clear, for example, whether this contract provision relates to the range of products reported by a single HCPCS code. However, contract suppliers may be inclined to offer fewer choices of product within a particular HCPCS code under the Medicare competitive bidding program than they offer to other customers. The final rule needs to discuss this issue in more detail so that suppliers and beneficiaries will be able to understand what CMS has in mind, and know what protections are being afforded to beneficiaries by the non-discrimination provision.

We note, too, that the draft bidding sheet (Form B) asks bidding suppliers to list the models of DMEPOS products for each HCPCS code, but there appears to be considerable uncertainty, both inside and outside of CMS, about what this information is intended to imply and how it will be used by CMS in evaluating bids. For example, by listing a specific brand, would the bidding supplier be making a commitment to offer that brand throughout the contract period? Will CMS be using the information to determine whether a bidding supplier is planning to offer an adequate range of brands or choices for each HCPCS code? If so, how does CMS propose to do this? Would the model information submitted by bidding suppliers serve as a means for making an "up front" assessment of whether a supplier would be likely to satisfy the proposed non-discrimination contract term? Would a bidder later be able to add new brands (for example, new products on the market) or would Medicare beneficiaries be denied access to products brought to market after bids were submitted or awarded (for the full period of the Medicare supplier contract)? We doubt

this is what CMS intends and urge CMS to explain the purpose of requesting such brand information.

The proposed rule also proposes to place the burden of repairing or replacing patient-owned items subject to competitive bidding on contract suppliers. In doing so, however, we believe that CMS may misunderstand what happens today and the respective roles of suppliers and product manufacturers in the process. For products such as glucose monitors, for example, it is a manufacturer warranty that applies, not a guarantee on the part of the supplier. More importantly, FDA regulations require manufacturers, not suppliers, to evaluate product complaints and inform the agency, as required under the Medical Device Reporting regulations (21 CFR 820.198 and CFR 803), in cases where problems are considered to be "reportable" events. CMS policies on item repair (and/or supplier quality standards) could, therefore, become an obstacle to manufacturer discharge of these regulatory obligations. **CMS policies should instead require suppliers to inform the relevant DMEPOS manufacturer of any problem with the equipment or supplies, including any adverse effects involving Medicare beneficiaries, so that the manufacturer will be in a position to address the problem, report to the FDA, or take other corrective action if needed**. In addition, CMS policies should in no way imply that a product warranty is the supplier's legal obligation as opposed to that of the product manufacturer.

Opportunity for Participation by Small Suppliers

The MMA requires the Secretary to take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS competitive bidding program. In our view, the proposed rule has not gone far enough in this regard. CMS has proposed a definition of "smallness" that includes roughly 90 percent of all suppliers. We doubt that Congress intended to mandate special procedures for nearly all suppliers, as opposed to a smaller subset of suppliers. In addition, while nearly all suppliers may meet the Small Business Administration's definition of a small business, this masks a wide range of "smallness."

We urge CMS to provide a fairer and more balanced commercial climate for small suppliers. One option would be to permit truly small suppliers (perhaps defined by the number of full time equivalent employees in the firm, or by total revenues substantially below the SBA cut-off for a small business) to serve less than the full competitive bidding area. Another option would be to permit truly small suppliers to send in a modified "bid" that simply promises to accept the single payment amount or even to be deemed as having submitted such a bid, rather than requiring them to submit a complete bid. This approach would have the added advantage of preventing the bids of very small suppliers from having an undue (and inappropriate) impact on the calculation of the single payment amount in a competitive bidding area. In addition, special treatment for truly small suppliers is likely to have a positive impact on beneficiary access, since smaller suppliers are more likely to be serving less populated areas of a competitive bidding area and located closer to the homes of beneficiaries living in these less populated areas than other contract suppliers.

Opportunity for Networks (proposed §414.418)

CMS is proposing to allow suppliers to form networks for bidding purposes, and sees this as one of its special accommodations for small suppliers. However, a very similar option offered to suppliers during the Medicare demonstration projects went unclaimed. We anticipate a similar outcome here. The proposed network option appears to be very complicated in design and it seems rather unlikely that a group of interested suppliers would be able to create a network in time to submit bids.

Education and Outreach

The proposed rule provides relatively little information about CMS' plans to educate beneficiaries about the competitive bidding program. We believe that this issue should be discussed in more detail in the final rule. **We believe that CMS may underestimate the difficulty of such an education program, given the range of products that might be subjected to competitive bidding, the large number of suppliers now serving Medicare beneficiaries (including**

essentially every local pharmacy), the range of items (and brands) covered by many HCPCS codes for DMEPOS and the diversity of features offered by these products. In addition, there are the further complications that arise when beneficiaries travel. According to the proposed rule, traveling beneficiaries will have to determine whether the area they are visiting is a competitive bidding area, which DMEPOS are subject to competitive bidding in that area, where the contract suppliers are located, and which brands each of these contract suppliers has chosen to offer for purposes of the competitive bidding program. In effect, a beneficiary coming from a non-competitive bidding area and using a specific brand of glucose meter could either find it extremely difficult—or even impossible—to locate replacement test strips for that brand if glucose testing equipment were subject to competitive bidding in the area they were visiting.

Moreover, since the beneficiary would be visiting and perhaps far from their usual source of medical care, even a physician authorization might be difficult to execute. We again urge CMS to consider allowing beneficiaries who travel to a competitive bidding area to obtain replacement supplies from any supplier, not just contract suppliers, in that area. This would greatly simplify the beneficiary education process.

Monitoring and Complaint Services for the Competitive Bidding Program

The proposed rule provides no specifics about the proposed complaint monitoring system (for example, how the system will work or where it will be housed). The final rule needs to provide more information about this system. In addition, we urge CMS to assure that ombudsmen are designated for each competitive bidding area and that they play an important role in addressing and resolving beneficiary complaints. The proposed rule appears to suggest that CMS has not yet firmly decided whether to create an ombudsman program for the DMEPOS competitive bidding program. We believe that ombudsmen are absolutely essential to protect Medicare beneficiaries and that experience during the Medicare competitive bidding demonstration projects confirms this.

Physician Authorization/Treating Practitioner (proposed §414.420)

CMS is proposing to implement a physician authorization mechanism under which a physician or treating practitioner would be able to indicate that a specific brand of DMEPOS is necessary to avoid an adverse medical outcome (that is, when a range of products are described by a single HCPCS code and the specific brand in question is not otherwise available from contract suppliers).

We urge CMS to keep the physician authorization process as simple as possible, especially during the early rounds of the competitive bidding program. A "dispense as written" approach or simply documentation in the medical record should suffice. In addition, the issue or definition of adverse outcome will vary from one category of DMEPOS to another and may not be amenable to a "one size fits all" policy. For example, in the case of glucose monitoring equipment, specific features of a glucose meter and/or the test strips compatible with that meter may be essential in facilitating patient compliance with the physician-recommended testing regimen. Thus, different patients may require different products (all currently reported under the same HCPCS code) to meet their needs. A beneficiary forced to switch to another brand of meter or to use a meter with limited functionality might simply choose to test less frequently or not to test at all, which could adversely affect his or her glucose control. In this case, while the adverse outcome might not be immediate, it is well understood that poorly managed diabetes may ultimately lead to adverse outcomes that could have been prevented or ameliorated.

In sum, to the extent that CMS attempts to define the term "adverse outcome," we urge the agency to recognize that the term has different implications for different categories of DMEPOS. For example, since blood glucose monitoring is not a treatment per se, the concept of adverse outcomes in the case of such equipment is far different from that for other DMEPOS used for treatment purposes, such as TENS devices, infusion pumps, and nebulizers. Given all of this, we

believe that Medicare beneficiaries would be better served if CMS did not attempt to "second guess" physicians on the issue of adverse outcome, especially during the early rounds of the competitive bidding program.

We recommend, instead, that CMS monitor the use of physician authorizations, determine the reasons for their use (for example, perhaps because contract suppliers are only offering products with less advanced features that will not adequately meet their patients' needs), and assess the need for potential changes in the competitive bidding program, not solely in the physician authorization process, based on this experience. Ideally, the competitive bidding program will be designed and implemented in a way that minimizes the need for physician authorizations, especially since such authorizations are a very inefficient means for assuring beneficiary access and quality.

In implementing the physician authorization process, CMS also needs to be mindful of the fact that certain DMEPOS products, such as replacement test strips for a particular brand of glucose meter, will be needed on a regular basis. To the extent that a physician determines that a patient should use (or continue to use) a specific brand of glucose meter, CMS should not require a physician authorization each time a beneficiary must obtain replacement test strips for such meter. Instead, if a physician authorization is required for replacement test strips, one such authorization no more frequently than every six months should be all that is required. Otherwise, the physician authorization process would become extremely burdensome for products requiring frequent replacement supplies and thereby impose a significant barrier to beneficiary access. Under not too dissimilar circumstances now, when a particular beneficiary requires, for example, more than 100 glucose test strips per month, the ordering physician must document in the patient's medical record the need for a frequency of testing that exceeds the utilization guidelines, and new documentation must be present at least every six months, not every time the patient requires a new supply of test strips. A similar documentation requirement could be used to implement the physician authorization mechanism under DMEPOS competitive bidding.

Gap-filling (proposed §414.210(g))

LifeScan is extremely concerned about the proposed new functional technology assessment methodology for gap-filling. While CMS notes that this new methodology would involve a functional assessment, a price comparison analysis, and a medical benefit assessment, the proposed rule does not provide much detail about exactly how this would be done, what data would be used, what role product manufacturers and other stakeholders would have in the process, and how the process would be made reasonably transparent. As it stands, we view the proposed functional assessment as a kind of "black box" and this makes it difficult for us to offer thoughtful comments. **We urge CMS to eliminate this provision from the final rule and use a separate rule-making process to request comments on a more fully-developed proposal, one that includes specific examples of how this kind of assessment would be done with appropriate input from stakeholders.**

Regulatory Impact Analysis

The proposed rule does not provide estimates of the full costs of administering the competitive bidding program. We believe these costs will be quite significant, especially if the program is managed in a way designed to minimize adverse outcomes for beneficiaries, such as those that would arise from access barriers and reductions in quality.

We also urge CMS to take into account the potential impact of the competitive bidding program on other Medicare expenditures. We fear, for example, that savings from competitive bidding could simply translate into increased Medicare expenditures for other services, such as emergency department visits and hospital admissions, especially if competitive bidding ends up reducing beneficiary access to high quality DMEPOS. Although not directly addressing DMEPOS competitive bidding, a report published in the June 1, 2006 issue of the *New England Journal of Medicine* by Hsu et al. indicates how a cost-savings intervention (a cap on annual drug benefits)

can increase Medicare expenditures for services such as emergency department visits and non-elective hospitalizations, and even increase beneficiary deaths.

Fee Schedule Updates for Class III Devices

The background section of the proposed rule requests comments on the appropriate Medicare fee schedule percentage change for Class III durable medical equipment for 2007 and 2008. CMS plans to consider these comments along with recommendations made by the Government Accountability Office (GAO) in a March 2006 report.

We believe that the GAO report has some serious flaws and is misleading. Rather than recommend a specific update factor for Class III devices, the report simply says that future updates should be "the same" or "uniform" for both Class III and Class II devices. In addition, the report compares unfavorably to the standard payment adequacy assessments and payment update recommendations found each year in the March report of the Medicare Payment Advisory Commission (MedPAC). For example, in its March 2006 report, MedPAC assesses the adequacy of Medicare payments for hospital inpatient and outpatient services, physician services, outpatient dialysis services, skilled nursing facility services, home health services, long-term care hospital services and inpatient rehabilitation facility services. Following each detailed assessment, MedPAC then recommends an update policy for each provider category for the coming year. The GAO report never justifies its alternative assessment methodology or its failure to take into account changes over time in manufacturer costs for Class III devices.

In short, we urge CMS not to rely on the GAO report in reaching a decision about the appropriate update factor for Class III devices for 2007. Until a more thorough assessment of the issue can be completed, **we recommend that the update for Class III devices continue to be based on changes in CPI-U.**

We welcome the opportunity to comment on the proposed rule and we hope these comments will help CMS craft a final rule that will assure continued beneficiary access and quality.

Sincerely,

Eric P. Milledge
Company Group Chairman

228-0

(14)

Crowne

June 28, 2006

Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To whom it may concern:

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS").

I am the Administrator at Crowne Health Care of Mobile, LLC located in Mobile, Alabama. We are a 174-bed facility employing 220 staff. Our services include Physical, Speech and Occupational therapy, which greatly enhance the quality of life of our residents.

The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to residents/patients.

Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.

At Crowne Health Care we have numerous residents whose care could be interrupted as a result of this implementation – jeopardizing their health and safety. The proposed rule has the potential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,

Stephen Davis, Administrator
Crowne Health Care of Mobile, LLC

Manatee County Rural Health
June 27, 2006

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Centers for Medicaid, Medicare Services
Department of Health and Human Services
P. O. Box 8013
Baltimore, MD 21244-8013

Attn: CMS-1270-P

Re: CMS-1270-P

Dear Sir or Madame:

This letter is in regards to commenting on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation. Imperatively, I strongly object to CMS's alternative proposal that would require beneficiaries to obtain replacement supplies of certain items to (designated providers). This would restrict the beneficiaries choice of where to obtain items. This proposal would severely restrict the beneficiaries ***access*** to needed items and supplies. It may also compromise patient health outcomes.

My situation is unique. I work for the Manatee County Rural Health Services, which provides needed medical care to the poor and to the underserved. From my point of view, if beneficiaries are designated to go elsewhere to obtain needed items (DME items), this would severely limit their access to obtain these items. My patients, for the most part are poor and without such amenities such as cars and affordable transportation. Sometimes their only transportation would be on foot, bicycle or bus routes. They have difficulty in getting to the health center to obtain needed medical attention, even when they are critical, i.e. blood pressure out of control, blood glucose 400-500 or ulceration and gangrenous digits. They would have an even greater hardship if they were forced to go elsewhere to obtain needed supplies that could avert some of these medical complications. Our health centers are usually a last resort for those patients that are rejected from the established medical community because of lack of ability to pay. We do not turn anyone away and we provide the needed medical care that they deserve. This proposal would severely compromise my ability to treat my patients in the best possible manner and to avoid unnecessary complications of their condition. This proposal, in my opinion would penalize those that are in most need.

I urge CMS to take steps to insure that small suppliers, which include the majority of pharmacy based suppliers, can participate in the competitive bidding program. As stated above, our health centers do in fact possess their own pharmacies, in which we distribute diabetic supplies, DME items, etc. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible for small suppliers to participate in competitive bidding in large metropolitan areas.

Through our pharmacy and through my particular part of the health care practice at Manatee County Rural Health Systems, we provide diabetic supplies, braces, diabetic shoes, padding, orthotics, wheelchairs, walkers, crutches, etc. These items are most needed in the treatment of the types of patients that come to me in my practice. I have example after example of patients that have been treated in the emergency room, told to follow up with an orthopedic surgeon, that have fractures and dislocations, etc. that have been turned away or that refuse to go to the orthopedic surgeon because that practice requires $150 up front before they would even be considered to be seen as a patient. These patients do not have the ability to pay. They wind up at Manatee County Rural Health Services so that we can provide the care that they need and deserve. Without these revisions to the final regulation, I will be unable to continue providing valuable services to my patients.

In conclusion, I urge CMS to allow smaller suppliers, such as what I have outlined above with Manatee County Rural Health Systems and other providers that provide needed care to the poor and under served to supply those needed pharmacy based DME items.

Thank you for considering my point of view. I hope to be able to continue to treat my patients in a standard that is not any less of a standard that exists for the rest of the population.

Sincerely,

Melvin B. Price, DPM, PT FACFAS

Manatee County Rural Health Services, Inc.

"Taking Care of All Your Healthcare Needs"

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21 June 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for allowing me to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments.

I object to the CMS' proposal that would limit the availability of DMEPOS supplies to only those suppliers selected through competitive bidding. The use of designated suppliers limits the beneficiaries ability to obtain supplies. This restricted access may compromise patient health outcomes.

Common DMEPOS supplies such as diabetic testing supplies should not be included in the competitive bidding program. The program should be limited to unique supplies that could be provided by a central supplier.

Small suppliers including pharmacy-based suppliers should be allowed to participate in the competitive bidding program. In addition after a single payment amount for each item has been established, any small supplier willing to accept that payment amount should be allowed to be a contracted supplier.

The proposed regulation needs to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

In conclusion, I urge CMS to revise the regulation to allow Manatee County Rural Health Services, Inc and other small suppliers to participate in the competitive bidding program or to contract to supply these services at the prices established by competitive bidding.

Thank you for your consideration.

Sincerely,

Brian Martin R. Ph. M.S., MBA, M.Ed., C.Ph.
Pharmacy Director

PARRISH HEALTH CENTER
P.O. Box 499 * Parrish, Florida 34219 * (941) 776-4000 (941) 776-4010

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We're on the Web!
www.DenverFoot.com

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

We're on the Web!
www.DenverDiabeticFoot.net

Dear Dr. McClellan:
In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician in finalizing its regulations.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

The Medicare/Medicaid patients in this community, especially the diabetic and indigent, rely significantly on the podiatric physician for preventive and management services. Creating another logistical barrier to necessary and timely care is not the pathway to cost effective health care services.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

G. Stephen Gill, DPM, MHS, MBA
Denver, CO 80110

Review this website for a little understanding of the issue!

Denver Diabetic Foot and Wound Center

"Healing and Preventing Foot Wounds Is Our Specialty"

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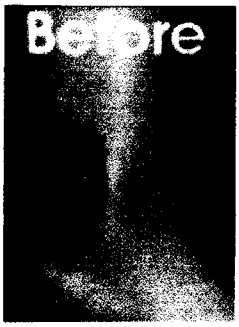
Click to select desired language



PURPOSE

PREVENTION THROUGH EDUCATION

This website is dedicated to the education - and prevention of foo and ankle complications associated with diabetes mellitus.

Information, illustrations and suggestions will be presented in a manner which avoids complicated medical explanations and recommendations.

Short paragraphs and brief explanations will be used to increase understanding and memory of important foot health information and available treatment options.

When possible, the material will be accompanied by photos illustration or examples that will visually inform and educate.

Links to other diabetic and educational websites will be suggested.

website sponsored by:

Denver Foot and Ankle Clinic, PC
Hampden Place Medical Center
Rocky Mountain Surgery Center

401 West Hampden, Suite 260
Englewood, CO 80110

tel. 303 761-5454
fax 303 761-5458
info@denverfoot.com

Please visit and share these websites:

Name: Jennifer DiMatteo

Institution: VNA of Boston

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

I work w Neighborhood Diabetes & small companies everyday referring patients for home teaching with new meters & supplies. Most of my patients speak Spanish & NDS has Spanish speaking educators who will spend time w my patients teach them how to use glucometers & test. When I refer to NDS I feel confident that they assist my patients & follow on reordering - if the glucometer fails NDS will troubleshoot or repair. They also are a valuable resource to us & healthcare professionals. Please DO NOT move to Competitive Bidding

Written comments must be received by June 30th, not just postmarked!

J. DiMatteo

Visiting Nurse Association of Boston
Southwest Office
130 Bradlee Street
Hyde Park, MA 02136

Centers for Medicare & Medicaid Services
Dept of Health & Human Services
Attn: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

21244+9013 B900

Name: Dana S Mennemi RN

Institution: Home Health VNA-Lawrence

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

Dear Sirs - Neighborhood Diabetes is just as the name implies! Because they don't pinch pennies today and take the long view. They give great service and vital service. Spending more time in the beginning and making it easy for pts. reduces fear and increases compliance! Increased compliance reduces big bills in the long run. Please don't limit us to the cheapest, shoddiest care possible. Thankyou

Written comments must be received by June 30th, not just postmarked!

233

Home Health VNA

360 Merrimack Street, Building 9, Lawrence, MA 01843

Ask for us by name

MIDDLESEX-ESSEX
MA 018 3 T
26 JUN 2006 PM

US POSTAGE

Centers for Medicare & Medicaid Services
Dept of Health & Human Services.
attn CSM-1270-P
PO Box 8013
Baltimore MD 21244-8013

21244+8013 B300

Name: Wendy Drew RN CDE

Institution: HealthReach Diabetes

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

We educate patients over a wide geographically diverse area. Without the individual service that small DME companies provide outside just filling Rx's our patients would be at a loss. Sending the meter alone is not enough help if it comes via the mail & only the directions on the box. The smaller DME providers take the time to listen and help patients in their own homes & the. The magic Choice is vital to finding a provider

Wendy Drew RN CDE

Written comments must be received by June 30th, not just postmarked!

171

5 ALUMNI DRIVE • EXETER, NH 03833

EXETER HOSPITAL
HealthReach Diabetes

PORTSMOUTH NH 038
26 JUN 2006 PM 1 L

Centers for Medicare & Medicaid Servs
Dept of Health & Human Servs
Attn CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Name: Jessica Kilgore RD

Institution: GMVNA

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

Having supplies i.e. diabetes supplies ~~(is a bad idea since)~~ distributed by the lowest bidder is a bad idea because there are small, reputable companies that not only supply the brand name meters but do training with the meters, community outreach and other services to keep the pts "on track." If poor teaching and poor meters are given to patients you will see more costly problems down the road. These small companies should be respected and given awards for "making a difference" in patients' lives.

Written comments must be received by June 30th, not just postmarked!

135

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Greater Medford VNA & Additional Care
278 Mystic Avenue, Suite 204
Medford, Massachusetts 02155

Centers for Medicare & Medicaid Services
Department of Health & Human Services
attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

21244B9013 B900

Name: Mae Powers

Institution: VNA of Boston

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

We need Neighborhood Diabetes it's close and provides compliancy. Competitive Bidding is too complicated in this world right now. It's nice to know that people will be there promptly. Medicare itself is complicated for the Seniors

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Written comments must be received by June 30th, not just postmarked!

Visiting Nurse Association of Boston
Southwest Office
130 Bradlee Street
Hyde Park, MA 02136

Center for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

21244+8013 B900

Pine Creek Podiatry

WILLIAM J. SCHLORFF, DPM, F.A.C.F.A.S.
PODIATRIC MEDICINE & FOOT SURGERY

BOARD CERTIFIED
AMERICAN BOARD OF PODIATRIC SURGERY
MEMBER OF
AMERICAN COLLEGE OF FOOT AND ANKLE SURGEONS

345 EAST CENTRAL AVENUE
JERSEY SHORE, PA 17740
TELEPHONE (570) 753-4335

237

Monday, June 26, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attn. CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am writing to urge the CMS to revise the physician definition from 1861(r)(1) to 1861(r)(3) in the proposed rule that would establish a competitive acquisition program for durable medical equipment, prosthetics, orthotics and supplies(DMEPOS).

As a podiatric physician, I both prescribe and dispense DMEPOS items to Medicare patients as an important adjunct to my patients care. As their provider of foot care I feel that I am the physician most qualified to both prescribe and dispense the appropriate device to suit my patient's conditions. Years earlier, prior to obtaining a DME license, I had to use several different DME suppliers. This proved to be a fiasco for my patients as they would obtain either the wrong device or a much poorer quality device which did address their condition properly.

If the physician definition 1861(r)(1) is implemented it will have a negative impact on my patients and my ability to offer them quality care. Therefore I strongly urge you to modify the physician definition to 1861(r)(3)

Sincerely,

William J. Schlorff, DPM

(238) 6-27-06

To: Centers for Medicare / Medicaid Serv

Re: Proposal in Section 414.15 -
Low Vision Aid Exclusion

Please do NOT bar Medicare coverage for devices such as CCTV System, magnifiers, or other Low Vision Aids or technologies!

My mother is legally blind due to macular degeneration. These aids are vital to her quality of life!

Sarah Shipley,
for Hallie Randolph

Item # 2071000

239

Docket Management Comment Form

Docket: CMS-1270-P - Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Temporary Comment Number: 85477

Submitter: Dr. Joseph Grillo **Date:** 06/28/06

Organization: American Podiatric Medical Association

Category: Physician

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Dr McClellan, Podiatrists ARE physicians and to classify them as otherwise is ridiculous.We admit patients,perform surgery and DAILY prescribe shoes,orthotics and other durable medical equipment and to exclude as physicians is predjudicial and an insult to myself and my patients. All this is is another assault on patient rights. Imagine if you walked into your doctors office,had a fracture or Charcot joint and had to go to another provider to get what you need to get better. I firmly oppose CMS attempt to put this up for contractual bidding and predjudicial exclusion of podiatrists from taking care of patients as we know best how to do. Sincerely,Joseph Grillo DPM-Ft. Myers,FL

Attachments

No Attachments

Print | Comment on Another Docket | Exit

Print - Print the comment
Exit - Leave the application

(240)

THUNDERBIRD
FOOTCARE
Podiatric Medicine & Surgery

Kathleen M. Stone, D.P.M.
Teisha L. Chiarelli, D.P.M.

June 29, 2006

Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P O Box 8013
Baltimore, Maryland 21244-8013

Attention: CMS-1270-P
Electronic Comments

Dear Doctor McClellan:

I am writing to you regarding the Centers for Medicare and Medicaid Services' (CMS) proposal with respect to the new competitive acquisition program for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). I believe this would be extremely detrimental to my Medicare population of patients if approved as currently proposed to provide the best quality and medically necessary care. I am requesting you consider excluding all physicians, including podiatric physicians, from this proposal.

I see Medicare patients on a regular basis in my 10-year old podiatric practice in the Phoenix metropolitan area. I am currently able to provide these patients with the best possible care in an efficient manner with respect to DME supplies, such as Cam walkers and braces, for various acute injuries and fractures. I understand CMS is still in its decision making process with respect to this proposal but do believe this could be detrimental and even harmful to my Medicare population should I no longer be able to provide this care.

In closing, I do hope that you and CMS as a whole are willing to reconsider excluding all physicians including podiatric physicians, from this competitive acquisition program. It is my hope that we as physicians are allowed to continue being DMEPO suppliers within our offices to provide the best possible care for our Medicare population.

Thank you for your consideration.

Sincerely,

Teisha L. Chiarelli, D.P.M.
tlc@thunderbirdfootcare.com

TLC:hw:61306

WS&S
MEDICAL

241

June 30, 2006

RE: Competitive Bidding Comments
Submittal: www.cms.hhs.gov/eRulemaking

Centers for Medicare & Medicaid Services,
Department of Health & Human Services
ATTN: CMS-1270-P
PO Box 8013
Baltimore, MD. 21244-8013

To Whom It May Concern:

As a DME provider, we are aware that the process of competitive bidding is inevitable. However, there is not enough clarity on the entire process in order for us to move forward in such a short period of time with such drastic changes that may effect not only a small business such as ours, but clients and patients who are dependant upon medical equipment and supplies. It is to our understanding that CMS intends on selecting items for the competitive bidding process that contain the highest cost and highest volume. We believe that this proposal poses a problem for those patients in urgent need of wheelchairs, hospital beds, patient lifts, oxygen supplies, diabetic testing supplies, etc. These supplies are vital to the physical condition of our clients.

Although we are already accredited by the Exemplary Provider Accreditation Program and remain in good standing with Medicare and are in respectable financial standing with our creditors; we are concerned about the jeopardy of our "small business". The fact, that Medicare proposes the idea of examining two years of past claims for each item on a monthly basis to determine the expected demand vs. how many suppliers are needed to meet the projected demand, is a major concern as a determining factor. To explain, we have been in business for almost 10 years and we are a growing company. The suppliers and clients that we have today are not comparable to what we had even in the past two years. If these determining factors abide, it seems as though the bigger corporations will "knock us out of the box", altogether.

According to the demographics described by CMS, New York, Los Angelos, & Chicago will be excluded from competitive bidding. Our office is located in New Lenox, IL approximately 30 miles outside of Chicago and we are unclear how this will affect our

company. Thus, a more thorough scrutiny and explanation of what "Competitive Bidding" entails is considered necessary in keeping us abreast as a small business.

Conclusively, in addressing the power mobility rule... physicians will have 45 days instead of 30 to provide us with a prescription and supporting documentation after a face-to-face exam with the patient. This rule affects the patient significantly because, in most cases, doctors hardly ever submit this information to us in a timely matter. We call repeatedly and these physicians "drag their feet". Our primary concern, must meet the needs of our patients/clients first and foremost. We must **NOT** cut corners with our client's health. It is our fiduciary duty to provide them with the best quality care possible. How are DME providers, such as our organization, able uphold our duty if we cannot afford to compete with the mass corporations? On behalf of our company, we trust that our concerns will be taken into careful consideration. Please do not hesitate to contact us, if you have any questions or concerns.

Respectfully submitted,

Sheba L. Wilburn, Admin. Asst.
Accounting Department

(242)

MARK A. ALDRICH, D.P.M., F.A.C.F.A.S.
CERTIFIED BY THE AMERICAN BOARD OF PODIATRIC SURGERY

June 27, 2006

Mr. Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services.
Department of Health and Human Services
Attn: CMS-1270-P
P. O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan and Those Concerned:

I am writing to you to express my opposition to the proposed rule establishing a competitive bidding program for certain durable medical equipment including prosthetics, orthotics and supplies including diabetic shoes (DMEPOS).

Competitive bidding would only allow provision of durable medical equipment by the largest suppliers and providers, who of course could make the lowest bids. Those like myself, who practice in rural areas would not be able to compete on a cost-bidding basis and therefore would not be able to supply such services including diabetic shoes to our patients.

Not only would my many diabetic patients be affected, but any of those individuals who need immobilization for sprains, fractures and the like, as I would again not be able to provide bracing or AFO's for them, because I could not compete with the larger suppliers.

This bidding proposal would affect all small practices including podiatrists and all physicians in a small practice situation. If I am no longer able to supply these services to my patients, they are the ones who ultimately suffer having to travel to get such services.

Therefore, I request that the centers for Medicare and Medicaid services exclude physicians including podiatric physicians from the new competitive acquisition program for durable medical equipment including prosthetics, orthotics and supplies.

As a podiatric physician practicing for more than 22 years, I have a clear understanding of what the recent competitive acquisition will do and the detrimental effect it will have on patient care provided through my office.

Thank you for your time and consideration in this matter.

Respectively Submitted,

Mark A. Aldrich, D.P.M.

MAA/la

737 Dorr Street • Antigo, WI 54409-1472 • Phone (715) 623-4710 • Fax (715) 627-2737

(243)

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RIVER WALK
SURGICAL ASSOCIATES
9300 Stockdale Highway, Suite 300,
Bakersfield, CA 93311

Re: Competitive Bidding

To Whom It May Concern:

Recently, there have been some changes to CMS guidelines and formulations regarding certain MSAs. Herein, NPWT will most likely be considered as an entity up for competitive bidding. As a plastic and reconstructive surgeon, I feel that this is a crucial issue and fear that if a "bidding war" comes about there will be a sacrifice in quality and result in a compromise in patient care. Negative pressure wound therapy is at the heart of my practice and is a mainstay for the thousands of wounds I treat every year. There are certain scientific elements that exist with negative pressure wound therapy (VAC therapy from KCI) and if the use of a device goes to the "cheaper" product (Versatile 1 from Blue Sky) based on price we may compromise patient care and subsequent outcomes (i.e. osteomyelitis, amputations, sepsis and major reconstructive surgical procedures). The Versatile 1 equates to longer hospitalizations, longer use of the cheaper product, multiplication of ancillary services and increased use of antibiotics which will lead to increase in bacterial resistance thus repeating the cycle.

My argument is not to promote "expensive" care, rather quality care that has proven the test of time. In my extensive experience I have yet to encounter a device that is comparable to the original VAC system and towards that end others may imitate but will never equal the original negative pressure wound therapy product.

I have worked with negative pressure wound therapy devices for approximately ten years and through the years it has changed my thought process and further changed the way thousands of plastic and reconstructive surgeons practice their art. We perform far less major reconstructive procedures because negative pressure wound therapy promotes healing with a decreased need for hospitalization thereby reducing costs.

In conclusion, I request that you consider a no competitive bidding effort toward negative pressure wound therapy and suggest that you inquire about the use of negative pressure wound therapy and ALL its applications before pursuing this matter further. I would like to thank you for giving me the opportunity to provide this important information for your review.

Respectfully submitted;

Vipul R. Dev, M.D.

Lancaster County Podiatry L.L.P.

Dr. Charles S. Yeager
Dr. Thomas M. Herrmann
Dr. Steven W. Kreamer
Dr. Peter J. Fodor
Dr. Melissa A. Cavallaro

Podiatric Medicine, Sports Medicine, Foot & Ankle Surgery

244

June 15, 2006

Centers for Medicare and Medicaid Services

RE: Proposed Rule Regarding Establishment of Competitive Acquisition Program For Durable Medical Equipment (DMEPOS)

To Whom It May Concern:

I am writing this letter in behalf of our practice regarding the proposed rule by which physicians' offices, as well as other suppliers of durable medical equipment, would need to compete for the ability to provide these materials to patients at our practice. It is my understanding that we would need to compete with all suppliers and that it is possible, if our bid was not accepted, that we would not be able to provide these services for our patients.

I have a significant concern about this as with the current setup we are able to customize our shoes to patients' needs. It has been my experience in the past with some other non-Medicare insurances that when we provided these services outside the office it was difficult to coordinate both fabrication and adjustment of these shoes and other devices. As a result, there were times when patients had irritation of certain areas and even ulcerations which required further treatment and cost, both to the patient and to the insurance company.

In reviewing research I understand that there are approxiamtely 7,300 podiatric physicians who have DMEPOS supplier numbers across the country. Of this number of physicians, they are responsible for only 3.1% of the DMEPOS allowed charges. This would seem to indicate that a very small percentage of the actual monies which are spent on these devices go to physician offices. Although I have no hard data, I would also suspect from what we have seen in our area in Lancaster, Pennsylvania that the shoes and other devices provided through the office are actually cheaper than those provided by the larger suppliers.

I also believe that with the small monetary percentage of payment to physicians that this would more than offset the potential additional treatments that may be required through inappropriate or inadequate shoes or modifications. I find that it is always easier for one person to deal with both the modification of orthotic devices and shoes and treating the patient as this can be coordinated in a much more streamlined manner.

912 W. Main St. Suite 401
New Holland, PA 17557
717-656-0344

804 Grandview Dr., Ste 1
Ephrata, Pa 17522
717-733-2251

104 E. Main St.
Lititz, PA 17543
717-626-1516

If you have any questions, please feel free to forward any additional concerns to me, but I would greatly appreciate it if you would consider this opinion prior to passing your proposed rule which I believe would be a concern for many patients, as well as physicians.

Sincerely,

Thomas M. Herrmann, DPM FACFAS

TMH/lb

Richmond Apothecaries

2002 Staples Mill Road, Richmond, VA 23230
PH (804)285-8055 FAX (804)285-8059

245

June 22, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Areas

Mail Order Competitive Acquisition Program

I strongly object to the proposal that would require beneficiaries to receive refills by mail order. Patients come to rely on their local pharmacist for questions and assistance. Loss of human contact would mean losing the opportunity for counseling. A bulk mail order program would never notice if a patient was not properly using their medication, or recommend another doctor visit if the patient's health declines. Often a pharmacy is the one place where the patient's care from multiple doctors comes together. Losing this would mean diminishing patient care.
Additionally, patient flexibility would be lost. There will be a reduction in available suppliers, particularly small providers, following the accreditation requirements. Further reducing the available suppliers by competitive bidding for items such as diabetic supplies would make it more difficult for diabetic patients to obtain their testing supplies. This is certainly not an area where we would want to make supplies hard to obtain. Monitoring blood sugar levels is key to diabetic patients maintaining a healthy lifestyle. Mailing a product takes days, local pharmacies can provide same day product delivery. As stated, losing flexibility could cause a decline in compliance to the doctor's orders. Creating a mail order program that would automatically replace items would not only increase the cost but would also violate the supplier standards established by Medicare. Patients should be given the option to go where they want to purchase their supplies when they are needed and not be forced to use what could be a confusing and long process.

Richmond Apothecaries

2002 Staples Mill Road, Richmond, VA 23230
PH (804)285-8055 FAX (804)285-8059

Criteria for item selection

The competitive bidding program should not select diabetic supplies for bidding. Diabetes is a complicated and dangerous disease to have. It should be monitored by professionals who will take the time to educate their patients and not by the location willing to sell for the least. Quality of care should play a factor in this process.

Determining single payment amounts

Determining cost by bids may give an unfair advantage to larger companies who are able to purchase in bulk. The average wholesale price for the item should be considered as well as the amount bid. If the bid is for less than what the average wholesaler can afford to sell a product line, again the number of available locations would be severely limited and small suppliers would be unable to participate. Inclusion of small suppliers should be considered when establishing the process.
Setting the rate as the median bid, then increasing by the consumer product index during the second and third years does not account for increases in acquisition rates. If the reimbursement rate becomes less than the cost of purchase for the item, suppliers will not be able to continue providing this product and stay in business. Ongoing availability should be considered when establishing the process.

Rebates offered by suppliers who could offer the product for less would give an unfair advantage to larger suppliers who can purchase items in bulk. If suppliers are permitted to advertise their rebate offers small suppliers may lose business to larger companies based on price and again be left out of this process.

Opportunity For Participation by Small Suppliers

Small suppliers, which include the majority of pharmacy-based suppliers, will not have the ability to participate if the only distinguishing factor is the product line. Many larger suppliers participating in the DMEPOS program carry all types of products. Independent pharmacies would be forced to compete with larger chains that are able to purchase items at a discounted rate.
Small suppliers should be given the opportunity to accept the single payment amount and join the competitive bidding program as a contracted supplier. I believe this should be done to preserve a population of small suppliers available to the Medicare DMEPOS community. If small suppliers could be pooled in a separate bidding process than the larger companies, the difference in rates could be evaluated to determine a fair reimbursement amount.

Richmond Apothecaries

2002 Staples Mill Road, Richmond, VA 23230
PH (804)285-8055 FAX (804)285-8059

Our company owns three independent pharmacies. We carry ostomy supplies, diabetic, supplies, supports and braces, immunosuppressive drugs, and nebulizer medications. Without these revisions and considerations, we will be unable to continue to provide these services for our patients, many of who have been our patient's for the last 30 years.

In conclusion, I urge CMS to abandon the mail order concept and leave the products with the local suppliers, to eliminate items such as diabetic supplies from the competitive bidding process, to ensure there is an even playing field by considering more than product type as a way to include small suppliers, to allow the average wholesale price of a product line play a factor in the approved amount for bid, to review and update the reimbursement rate yearly based on the acquisition cost, and perhaps give small suppliers the opportunity to bid in a separate grouping to even the playing field.

Thank you for considering my view.

Sincerely,

Wendy Herbert
Richmond Apothecaries
Program Manager
2002 Staples Mill Road
Richmond, VA 23230
(804)285-8055 ext 114

246

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June 30, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244

Re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

We are Joint Active Systems, Inc. (JAS). We are an Illinois corporation and currently employ about 70 workers. In addition, more than 160 individuals in other States work for JAS throughout the country. We manufacture clinically-proven, patented, static progressive stretch devices/orthosis used to treat restricted range of motion in the shoulder, elbow, wrist, forearm pronation/supination, knee, ankle, and finger joints secondary to trauma, surgery, immobilization, burns, or neurologic injury. More importantly, we have enrolled in the Medicare Program for the sole purpose of supplying and billing only the devices that we manufacture. JAS requested and obtained the following Healthcare Common Procedure Coding System (HCPCS) codes for its devices: E1801, E1806, E1811, E1816, E1818, and E1841. We respectfully submit our comments to the proposed rule regarding the Competitive Acquisition for Certain DMEPOS and Other Issues (CMS-1270-P), which was released on May 1, 2006 (71 Fed. Reg. 25654).

1. General Comments

We strongly urge the Centers for Medicare and Medicaid Services (CMS) to delay the implementation of the competitive acquisition program (CAP) for DMEPOS items until the Supplier Quality Standards (Quality Standards) are finalized and released by CMS. CMS must not require suppliers to make a competitive bid on any DMEPOS item without affording them the opportunity to be informed about the additional cost that they must incur in order to comply with the new Quality Standards. The benefits of true competition as Congress intended can only be realized if the suppliers have all of the facts that are necessary to make informed bids.

As you know, even the Program Advisory and Oversight Committee (PAOC) recommended that CMS delay the CAP until the Quality Standards are made available to the suppliers, especially given that, according to CMS, significant revisions have been made to the draft Quality Standards that were introduced on September 26, 2005. Furthermore, CMS has stated that it would release the final version of the Quality Standards in June of 2006. To date, CMS has not done so. Therefore, JAS requests that CMS accept the recommendation of the PAOC.

2. Criteria for Item Selection

If an entity that is the sole manufacturer and supplier of a particular DMEPOS item is unable to bid or participate in CAP, then the Medicare Program has effectively eliminated access to this DMEPOS item by the beneficiaries. This clearly is not the intent of Congress. Therefore, CMS must exempt such manufacturer-suppliers from the proposed requirement that all suppliers bid for all items in a particular product category to be finalized and announced by CMS. Instead, in order to protect each beneficiary's access to such single-source DMEPOS items, manufacturers like JAS that supply only those DMEPOS items that they manufacture should be afforded the same exemption proposed for skilled nursing facilities (SNFs) and physicians. Like SNFs and physicians providing DMEPOS items only to their patients, manufacturer-suppliers are not "commercial suppliers" because they do not supply every DMEPOS item reimbursable by the Medicare Program.

Alternatively, CMS should phase in such single-source DMEPOS items and manufacturer-suppliers after 2009. Delaying the inclusion of such items and suppliers will allow CMS to not only learn about the effects of CAP in general but also address the unique issues of single-source DMEPOS items and manufacturer-suppliers *in* particular. Likewise, CMS must designate the product categories narrowly. CMS must permit suppliers to bid for those DMEPOS items that only they can supply. By requiring suppliers to bid for every DMEPOS item in a product category, CMS would hinder true competition and fail to assure the most savings because the one manufacturer-supplier that could provide the lowest bid would actually not be able to bid because it only supplies those DMEPOS items that it manufactures.

In addition, CMS must comply with the Congressional mandate of Section 1847(b)(7) of the Social Security Act and actually "consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals." CMS must seriously consider excluding from CAP those DMEPOS items that are supplied only by the manufacturer. Congress did not intend CAP to prevent Medicare beneficiaries from accessing DMEPOS items that CMS has coded and has been reimbursing prior to either the enactment of the Medicare Modernization Act of 2003, which mandated the CAP, or the implementation of CAP itself.

3. Submission of Bids under the Competitive Bidding Program

CMS must only apply CAP to "commercial suppliers." Just as CMS realized that SNFs and physicians are not "commercial suppliers," CMS must understand and acknowledge that manufacturers that only supply the DMEPOS items that they manufacturer are not "commercial suppliers." While SNFs and physicians supply the full range of DMEPOS items only to their patients, manufacturer-suppliers supply only those DMEPOS items that they manufacture. Therefore, because of the limited type of DMEPOS items that such manufacturer-suppliers provide

to Medicare beneficiaries, they are less of "commercial suppliers" than even the SNFs and physicians supplying every type and quantity of DMEPOS items.

Again, CMS must designate the product categories narrowly. CMS simply must permit suppliers to bid for those DMEPOS items that only they can supply. It is not only logical but also beneficial to the Medicare beneficiaries. For JAS, it would be particularly ironic if it could not bid or participate in CAP. In 2005, JAS met with CMS (Joel Kaiser and a few DME Regional Carrier medical directors) to discuss the pricing of the codes for its devices that JAS has requested and obtained through the HCPCS coding process. CMS has not yet responded to the request to increase the reimbursement rates. Now, JAS is struggling with the painful requirement that all bids must be lower than the current Medicare rates. It would indeed be a slap in the face if CMS were to deny JAS, the sole supplier of the devices that it manufacturers, the opportunity to even bid because CMS defined the product categories broadly. Most importantly, the Medicare beneficiaries would be denied access to these clinically effective and cost efficient devices, which require 3 months of wear-time on average and not the 15 (now 13) months permitted by CMS.

4. Conditions for Awarding Contracts

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

5. Opportunity for Participation by Small Suppliers

CMS must consider the small manufacturers like JAS that have enrolled in the Medicare program only to be able to supply the DMEPOS items that they manufacture. These manufacturers have accepted this course, despite the risk of being subject to various additional Medicare restrictions (e.g., Stark self-referral prohibitions), because they have experienced problems merely selling their DMEPOS items to Medicare "commercial suppliers." They want to ensure that their DMEPOS items are properly delivered to, fitted by, and used by the Medicare beneficiaries. CMS must not penalize such manufacturer-suppliers.

Section 1847(b)(6)(D) addresses the "protection" of small suppliers and not just the identification of such suppliers. Therefore, CMS must treat small suppliers differently. Manufacturers that only supply the DMEPOS items that they manufacture are not "commercial suppliers" that supply the full and complete list of DMEPOS items. CMS must actively help small suppliers, including manufacturer-suppliers, so that they may participate in CAP and provide the Medicare beneficiaries access to such single-source DMEPOS items.

6. Opportunity for Networks

CMS must provide sufficient time for suppliers to establish and work collaborative in the networks permitted by CMS under the proposed rule if CMS truly wishes to allow suppliers to form networks in order to bid competitively. CMS must not erroneously believe that the potential for volume is the motivating factor for the suppliers. Instead, CMS must realize and accept the fact that suppliers want to and need to bid and participate in CAP to merely stay in the Medicare program.

7. Quality Standards and Accreditation

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

* * * * *

On behalf of over 230 hard-working families of JAS, we thank you for the opportunity to comment on the proposed CAP for DMEPOS items. We hope that CMS will truly consider each of our comments.

Sincerely,

Dean Kremer
President

cc: Sandra Bastinelli (via e-mail)
Carol Blackford (via e-mail)
Stacy Coggeshall (via e-mail)
Joel Kaiser (via e-mail)
Martha Kuespert (via e-mail)
Herb Kuhn (via e-mail)
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Mark B. McClellon, MD PhD.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellon:

We are writing to provide comments on Competitive Acquisition for Durable Medical Equipment proposed rule CMS-1270-P and its impact to patients and providers.

In way of background, Northeast Home Medical Equipment is a not for profit oxygen and durable medical equipment provider in Upstate New York. We are part of Northeast Health, a not for profit integrated network employing over 4,000 people and serving a 15-county area. Services include acute care, supportive housing and community services, skilled nursing care, home health care and independent retirement living.

Comments Regarding the Notice of Proposed Rule Making (NPRM):

1.) "General"- Getting It Right Is More Important Than Rushing Implementation. CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. In addition, CMS should stagger the bidding in MSAs over a twelve month period to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Additionally under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates the option for small providers to participate.

2.) "General"-CMS Must Publish An Updated Implementation Timeline. CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulations; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. We believe that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

3.) "General"- The Program Advisory And Oversight Committee (PAOC) Must Be Included By CMS In The Review Of Public Comments And The Development Of The Final Rule.

CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of establishing the PAOC.

4.) "Quality Standards and Accreditation for Suppliers of DMEPOS"- Only Companies That Are Accredited Should Be Eligible To Bid. Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should also allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

5.) "Conditions for Awarding Contracts"- An Appropriate Screening Process Must Be Developed To Determine Which Submitted Bids Will Qualify For Consideration. (proposed §414.414) CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid be processed for further review and consideration as to pricing.

6.) "Conditions for Awarding Contracts"- Competitive Bidding Must Be Competitive And Sustainable. CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either.

7.) "Competitive Bidding Areas"- Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries. The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done.

8.) "Criteria for Item Selection"- Product Selection Must Be Conducted With Beneficiary Welfare In Mind. (Criteria for Item Selection) How will "savings" be calculated; exempt items and services unless savings of at least 10 percent can be demonstrated as compared to the fee schedule in effect January 1, 2006; recognize problems with beneficiaries having to deal with multiple suppliers; recognition of items that are custom and service oriented that should not be competitively bid.

9.) "Criteria for Item Selection"- Consider The Impact On The Patient. CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

10.) "Determining Single Payment Amounts for Individual Items"- Rebate Provisions Must Be Eliminated. (proposed §414.416(c)) The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

11.) "Submission of Bids Under the Competitive Bidding Program"- Only Companies Currently Delivering Service To Medicare Beneficiaries In An MSA Should Be Allowed To Submit A Bid For That MSA. Any company that submits a bid should have a track record of serving the targeted geography to validate its capabilities and service record.

12.) "Conditions for Awarding Contracts"- Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts. (proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.

13.) "Conditions for Awarding Contracts"- Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid. (proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required.

14.) "Conditions for Awarding Contracts"- A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "compilation", "review", or "audit" report from an independent Certified Public Accountant. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from a recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Debt to Equity Ratio" and "Current Assets to Current Liabilities".

15.) "Conditions for Awarding Contracts"- Use A Factor Of 130% In Calculating Supplier Capacity Needed In An MSA. (proposed §414.414(e)) In determining the number of suppliers needed, CMS should apply a factor of 130% to the identified Market Demand. This would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payers, and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

16.) "Conditions for Awarding Contracts"- Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies. (proposed §414.414(e)) Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of units provided to Medicare beneficiaries the previous year.

17.) "Conditions for Awarding Contracts"- A Company Should Be Able To Bid For Only A Portion Of An MSA. The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.

18.) "Conditions for Awarding Contracts"- Do Not Restrict Submitted Bid Amounts. (proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical needs.

19.) "Terms of Contract"- Eliminate Requirement That Winning Supplier Must Repair Patient-Owned Equipment. (proposed §414.422(c)) The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these costs into their bids.

20.) "Terms of Contract"- Restrictions On What Products Can Be Supplied To Individuals Outside The Medicare Program Must Be Eliminated. (proposed §414.422) The terms and conditions section states "non-discrimination- meaning that beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier provides to other customers". This is unrealistic. In order for suppliers to bid lower prices they must either provide lower cost products or reduced services. Competitive bidding should be more like a contract with managed care where formularies are used. Medicare will be fully aware of what Medicare beneficiaries will receive, but it should not limit what customers outside of the competitive biding program receive.

21.) "Terms of Contract"- Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier. (proposed §414.422(c)) Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

22.) "Opportunity for Participation by Small Suppliers"- Require That A Minimum Number Of Small Suppliers Be Included In The Wining Contract Suppliers. ("Opportunity for Participation by Small Suppliers) At a minimum, small business suppliers in an amount equal to the number of winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount.

23.) "Opportunity for Networks"- Clarify Network Regulations. (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?

24.) "Opportunity for Networks"- Do Not Place Unreasonable Limitations On Formation Of Networks. (proposed §414.418) The 20% market share limitation should be removed. This is unnecessarily restrictive and does not apply to single entities that bid separately. Network members should be able to also bid as an individual entity.

25.) "Payment Basis"- Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowables. (proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in non-bid area, CMS should pay the traditional Medicare

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June 26, 2006

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Post Office Box 8013
Baltimore, MD 21244-8013

ATTN: (CMS-1270-P) Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

ZLB Behring is a leading researcher and manufacturer of life-saving biotherapeutics which include intravenous immune globulin (IVIG), used for treating conditions such as immune deficiencies; blood clotting factors to treat bleeding disorders, including hemophilia and von Willebrand disease; and alpha$_1$-proteinase inhibitor, used to treat alpha$_1$-antitrypsin deficiency, which is commonly referred to as genetic emphysema. These therapies are created through the pooling and manufacturing of donated human blood plasma or through the development of recombinant DNA technology.

Most recently, ZLB Behring launched a new therapy, a subcutaneous immune globulin (SCIG) under the brand name Vivaglobin, used specifically for the treatment of primary immune deficiency. Vivaglobin, which was approved by the Food and Drug Administration in late 2005, represents an advance in treatment and quality of life for patients. Infusions can now take place in the home, instead of a hospital setting; infusions will no longer last several hours in duration; and the response rate is greater with far less adverse reaction potential.

Vivaglobin will be administered through an infusion pump, qualifying the therapy for reimbursement under the Part B durable medical equipment (DME) provisions. In April of 2006, CMS preliminarily approved a HCPCS code for SCIG and there was no public opposition at the May 11, 2006 HCPCS public meeting where this application was discussed.

ZLB Behring requests that CMS exclude this innovative new therapy from the proposed competitive bidding regime applicable to certain durable medical equipment, prosthetics, orthotics and supplies. We believe that prior agency history with respect to IVIG can and should serve as a precedent for the treatment of SCIG in the future.

In particular we believe that CMS should exclude SCIG from the DMEPOS competitive bidding program in the same manner in which it excluded its predecessor therapy, IVIG, from the Part B drug competitive acquisition program (CAP). Excluding SCIG from the DMEPOS competitive bidding program is consistent with previous CMS precedent and the Congressional intent to exclude immune globulin in its intravenous method from the CAP.

Precedent set by Congress and CMS for a Broad Immune Globulin Exception

When Congress passed the Medicare Modernization Act (MMA) of 2003 creating the CAP it specifically excluded IVIG from the program (Public Law 108-173, Section 303, (b)(1)(E)(ii)). For its part, CMS recognized the uniqueness of immune globulin by acknowledging in the final rule implementing the CAP that IVIG, in addition to other forms of immune globulins, such as those administered intramuscularly would also not be excluded from the CAP. Moreover, other blood-plasma therapies such as blood clotting factors and $alpha_1$-proteinase inhibitor were also deliberately excluded from CAP.

SCIG was not yet approved at the time of MMA's consideration and was not available to patients, thus exclusion from the DMEPOS competitive bidding portion of the MMA legislation was not addressed. However, we believe Congress' action in excluding IVIG from CAP should apply to *all* forms of immune globulin from *all* varieties of competitive acquisition programs and should not be limited by the methods of administration. The precedent and intent is for the exclusion of immune globulin from the program and not the specific form of administration.

SCIG will treat Medicare beneficiaries with Primary Immune Deficiency, just as IVIG

SCIG is a treatment for a subset of patients who currently use IVIG. SCIG is indicated solely for the treatment of patients with Primary Immune Deficiency whereas IVIG is indicated for Primary Immune Deficiency in addition to other conditions, depending on the individual brand. SCIG may be particularly appropriate to treat those individuals with poor venous access (a detriment to intravenous use of immune globulin), and those who have developed adverse reactions to IVIG. For those reasons and others, we anticipate that many patients with primary immune deficiency may wish to migrate over time to SCIG.

Access to therapy is greater when excluded from CAP

Excluding most immune globulins from CAP but including the subcutaneous form of therapy in the competitive bidding program for DMEPOS would disadvantage and discourage access to a new and improved approach in treatment that will benefit segments of the immune deficient population. As more SCIG brands are approved and placed into the HCPCS code, the DMEPOS competitive bidding program could result in some therapies in the class not being covered. Such a situation could exacerbate ongoing patient access issues with immune globulin.

Vivaglobin specifically will provide some relief to the pressing IVIG access situation, as it is a new source of therapy manufactured from a different facility than ZLB Behring's existing brand of IVIG. However, if SCIG is incorporated into the competitive bidding program for DMEPOS, the likelihood of multiple brands being available for a small patient population (estimates are that less than 10,000 patients are Medicare beneficiaries) is diminished, thus deterring patient access to this therapy. It is this logic that led Congress to exempt IVIG from the CAP. We believe that logic should be extended to the other immune globulins, like SCIG, as well.

Manufacturers of plasma therapeutics are unlike those in the pharmaceutical or medical equipment sectors. Manufacturing life-saving therapies from human blood plasma require high material and manufacturing costs. Today, only a few manufacturers provide therapies for a small population of patients with serious genetic disorders. We believe a rational, consistent payment policy that excludes all forms of immune globulin from all varieties of competitive bidding regimes is the best way to accurately reimburse providers and ensure a stable supply of therapies.

Conclusions

Historically, CMS has shown sensitivity to the needs of patients reliant on blood-plasma therapies such as immune globulin by excluding such therapies from competitive bidding programs. We believe similar treatment should extend to the competitive bidding program for DMEPOS with respect to SCIG. While a competitive bidding program may be appropriate for durable medical equipment or other Part B drugs, we believe it is inappropriate for plasma therapies like immune globulins that treat serious rare diseases and chronic conditions. ZLB Behring believes that CMS should apply a broad exclusion to all immune globulins, regardless of administration method, from all competitive bidding programs.

ZLB Behring would be very happy to meet with you and/or professional staff from the durable medical equipment program to discuss in greater detail. You are welcome to contact Patrick Collins at 610-878-4311 or myself if we may be of any assistance or answer questions. Thank you for your consideration and we appreciate CMS efforts to date in recognizing the uniqueness of immune globulins and the patients who rely on this therapy.

Sincerely,

Dennis Jackman
Senior Vice President, Public Affairs

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Tennessee Pharmacists Association

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June 23, 2006

Centers for Medicare & Medicaid services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Sir or Madam:

On behalf of pharmacists in all practice settings in Tennessee and the patients they serve, the Tennessee Pharmacists Association (TPA) appreciates the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. We offer the following comments for consideration as CMS develops the final regulation.

Competitive Bidding Access

TPA urges CMS to develop the competitive bidding program in such a manner as to ensure beneficiaries' continued access to needed items from the provider of their choice. TPA urges CMS to not implement the CMS alternate proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers. This proposal could severely restrict beneficiaries' access to needed items and supplies. Restricting beneficiaries' access to mandatory mail service only is not appropriate for DME such as diabetic testing supplies, including lancets and glucose testing strips, and, also, ostomy supplies, items to which beneficiaries need convenient and frequent access. Beneficiaries also frequently need hands-on, face-to-face education and assistance in use of these items. In addition, ostomy patients require immediate and convenient access to the supplies they need. Ostomy patients frequently develop problems requiring an immediate change in ostomy appliances and supplies being used. These problems include the development of allergies to the products being used, a change in the ostomy opening requiring either a temporary or permanent change in the size of the product being used, or a change in output requiring the patient to obtain additional supplies. In these instances, patients need to be able to obtain supplies and assistance from a local provider. TPA also urges CMS to exercise its authority to exempt from this process those rural areas with low population density in particular. If this is not done, beneficiaries will be at risk of having their access restricted. Beneficiaries value their established provider/patient relationships, and CMS should take steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain these provider/patient relationships.

Criteria for Item Selection

TPA recommends that the competitive bidding program not include common DMEPOS supplies such as diabetic testing supplies. TPA believes CMS should limit the competitive bidding program to those unique products that could be provided by a central supplier and for which beneficiaries will not need ongoing, face-to-face education and assistance to use. Diabetic testing supplies were not included in either of the two competitive bidding demonstrations in Florida and Texas.

Determining Single Payment Amounts

While TPA understands that CMS is required to set a single payment amount for each item, we are concerned that using the median bid will set an artificially low payment rate that many small suppliers, such as community pharmacies, will not be able to accept. CMS must review the process to determine the single payment amount and ensure that the payment rate is adequate to cover a supplier's costs to acquire and provide the product. CMS must periodically examine the payment rate as it compares to supplier acquisition costs. Obviously, there is no increase in volume that can make up for a loss on items that are being provided and reimbursed below cost.

TPA recommends CMS reconsider its intention to update the single payment rate based on the consumer product index during the second and third years of the supplier contract. This proposal does not address situations in which the manufacturer or distributor raises the acquisition cost of the product. Under the current CMS proposal, providers would be required to continue providing the product at the single payment rate, even if the reimbursement amount is significantly less than their acquisition cost. Suppliers will not be able to continue providing DMEPOS supplies when they are being reimbursed below their acquisition cost. CMS must make provisions for re-evaluation and adjustment of payment amounts during the year, if acquisition costs change.

Participation by Small Suppliers

TPA urges CMS to take steps to ensure that small suppliers, which include the majority of pharmacy-based suppliers, can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to compete in a larger competitive bidding area.

CMS should make every effort to streamline the competitive bidding process. A complex, time-consuming bidding process will seriously hamper the ability of small community pharmacy providers to participate in the process. The CMS estimated cost of $2,187 for submitting a bid will be cost-prohibitive for many of the smaller rural community pharmacy providers in our state. Because of this barrier to participation, after

CMS establishes the single payment amount for each item of DMEPOS, any smaller supplier willing to accept the payment should also be allowed to join the competitive bidding program as a contracted supplier.

TPA urges CMS to take these steps to preserve beneficiaries' convenient access to quality DMEPOS supplies and related services and to maintain established provider/patient relationships.

Thank you for your consideration of the views of the Tennessee Pharmacists Association on behalf of our members who serve Medicare beneficiaries every day.

Sincerely,

Baeteena Black

Baeteena M. Black, D. Ph.
Executive Director

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Lowry Drug Company's and AAHOMECARE SUMMARY OF COMMENTS
Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Program Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Opportunity to Comment on the Supplier Standards

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

At the very least, CMS should schedule a PAOC meeting after it publishes the standards. AAHomecare strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Timeline

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to adopt a realistic timeline and not rush through the process. The remaining steps include:

- Publication of the supplier standards

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived form competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under §1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

Limitation on Beneficiary Liability

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and

bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" *as defined under §1834a(13)* for which payment would otherwise be made under §1834(a) *and "supplies used in conjunction with durable medical equipment*;" enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings

CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger CA for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Additional Criteria for Item Selection

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

CMS should publish the items it will include in the initial competitive bidding program in an interim final rule. CMS should also schedule a meeting of the PAOC to solicit

that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.
- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology

not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance

> services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

Bulletin at 1.

CMS proposes two ways to ameliorate the fraud and abuse issues inherent in the rebate program. First, CMS would require any contract supplier that offers rebates to offer the rebate to all Medicare beneficiaries in the competitive bidding area. The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not offer the rebate only to patients with a specific chronic diagnosis requiring long-term rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

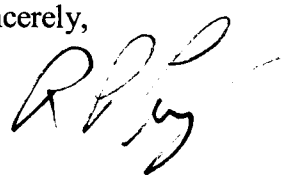
> The "inducement" element of the offense is met by *any offer* of valuable . . . goods and services as part of a marketing or promotional activity, *regardless of whether the marketing or promotional activity is active or passive.* For example, *even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.*

Bulletin at 5 (Emphasis supplied).

CMS' proposal to allow contract suppliers to offer rebates fundamentally conflicts with the longstanding rationale underlying the prohibitions on inducements and kickbacks in federal health care programs. This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote *exactly* what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) – competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Please get a hold of this process before it is to late.

Sincerely,



Paul Lowry
VP Lowry Drug Company, Inc..

Top Rehab, Inc.

2110 N. Jackson St.
Tullahoma, TN 37388

251

June 28, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Mark B. McClellan:

We are writing this letter in reference to the proposed rule for competitive acquisition of certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). We are physical therapists at Top Rehab in Tullahoma, Tennessee. Top Rehab is primarily an outpatient orthopedic clinic with physical, occupational, speech, and aquatic therapy. Top Rehab also offers industrial rehabilitation and health and fitness. In addition to outpatient orthopedics, Top Rehab offers treatment for ob/gyn, burns, wounds/ulcerations, vestibular disorders, sports and traumatic injuries, speech and swallowing disorders, and neurological conditions.

As therapists, we have a standard of care to provide the best care for our patients. Therapists tend to see patients on a regular basis which allows a therapist to make adjustments often. Therapists play an important role in providing equipment and supplies to patients to help with the patient's plan of care. The availability of products increase efficiency & timeliness for the patient. The patient can be fitted for an item before or after therapy.

Patients are often fitted for orthotics by therapists, and regular changes can be made as needed secondary to the therapist regularly seeing the patient. Fixing equipment becomes part of a therapist's job to encourage patient care, and this includes bending, trimming, molding, or assembling. There are many times a patient comes into the clinic after damaging or losing equipment that is needed immediately, and during these moments, a therapist offers the expertise of making the necessary adjustments. This is often convenient for the patient as well, and the patient feels comfortable with someone whom he has grown to trust.

Not only is this convenient for the patient, but the convenience is also for the therapist. Often the orthotics are needed to increase the patient's safety during activities. For example, a patient may need orthotics during walking to keep the patient's foot from rolling. Without the orthotic, a second individual may be required during therapy or the activity may not be possible.

We urge you to reconsider the proposed regulation and allow therapists to continue to supply orthotics to provide the best care possible to our patients. Thank you for your time and concerns.

Sincerely,

Angela Wehrle, PT
Dana Quick, PT
Lisa Hatfield, PT
Andrea Turner, PT
Rada Fults, PT

252

1330 Fragrant Spruce Ave
Las Vegas NV 89123-5357
6/19/06

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am a physical therapist in Nevada. I teach at the University of Nevada, Las Vegas. Just prior to coming on board here at UNLV full time last fall, I did home care full time in Las Vegas and Boulder City, Nevada and did per diem work for the hospital in Boulder City, a nursing home in Boulder City, and a hospital here in Las Vegas.

I just learned from a colleague that your Agency is going to competitive bidding for some DMEPOS. I understand that physical therapists might be precluded from providing orthotics and some supplies to their patients as part of their plan of care.

During the course of my clinical work, I occasionally fit and provide assistive devices and orthotics for my patients. The patients I see are elderly and they are usually homebound or nursing home bound. As a result, it is very difficult and often very expensive for them to get to durable medical equipment providers and facilities providing orthotics. Being able to provide these items quickly and efficiently to my patients promotes safety in performing activities of daily living in their living situation and allows them to regain their mobility and return to self care more quickly. Most of these items require adjustments to fit each patient. Again, being able to do some molding of a wrist or hand orthosis for a patient with rheumatoid arthritis or a foot orthosis for a patient with plantar fasciitis in the home or nursing home can both assure a good fit (and thus function of the device) and save the patient or the facility a great deal of money in terms of patient transportation. In addition, over the course of time, I have learned which products work best for my older patients such as which spine orthoses for vertebral compression fractures due to osteoporosis. I can contact the physician and make recommendations as to those products which are easier for older clients to don and doff.

May I encourage your Agency to consider a revision of the proposed regulations so that physical therapists could continue to furnish orthotics in situations such as those described earlier? Thank you for your time and consideration of this request.

Sincerely,

Sue Schuerman

Sue Schuerman, PT, GCS, PhD

,Certified Wound Specialist™

7301 N. University Drive, Suite 305, Tamarac, Florida 33321
(954) 721-4806 (954) 721-9841 (FAX) Drwound@aol.com.

Robert J. Snyder, D.P.M., C.W.S.

Diplomat, American Board of Podiatric Surgery
Diplomat and Board of Directors, American Academy of Wound Management
Fellow, American College of Foot and Ankle Surgery
Fellow, College of Certified Wound Specialists
Member and Board of Directors, American Association of Wound Care
Medical Director, Wound Healing Center at University Hospital
Medical Director, Wound Healing Center at Northwest Medical Center

June 26, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: Competitive Bidding and Negative Pressure Wound Therapy

To Whom It May Concern:

This correspondence will address my concerns regarding competitive bidding for, Negative Pressure Wound Therapy (NPWT), as well as the confusion "swirling about" relating to The VAC from KCI vs. the Versatile 1 from Blue Sky.

I am a Doctor of Podiatric Medicine (DPM) and a Certified Wound Specialist (CWS). I have been practicing for 31 years. My entire practice for the last 12 years has been strictly devoted to wound care, and I see hundreds of wounds per year. I have been using KCI's VAC Therapy (NPWT) for 3 years with extreme success. I believe in this therapy and have a concern that this will potentially be taken away from me and my patients as a result of the competitive bidding initiative. My concern stems from both my personal wound care experience and understanding the Competitive Bidding process as outlined on your website.

The following cases suggest the differences between two of the devices in the NPWT category:

1. A patient developed a large wound dehiscence status post Achilles tendon repair. After extensive debridement, VAC therapy NPWT from KCI was initiated while the patient remained hospitalized. After significant improvement was observed, that patient was discharged to a nursing facility and orders were written for continuation of VAC therapy from KCI. On a subsequent visit, however, it was noted that the wound failed to progress and in fact looked worse; further investigation uncovered that the nursing facility had substituted the Blue Sky Versatile 1 NPWT device for VAC NPWT. After

discharge, VAC therapy from KCI was re-instituted and the wound dramatically improved; treatment culminated with a split thickness skin graft and the ulcer completely healed.

2. A different patient presented to the wound care clinic with a cavernous lesion at the lateral aspect of his right leg. VAC therapy NPWT was ordered,; however, the nursing facility substituted the Blue Sky Versatile 1 NPWT. The Blue Sky device continues to sit idle in a plastic bag at the side of the patient's bed two weeks after delivery because no training was offered to personnel regarding application of the device.

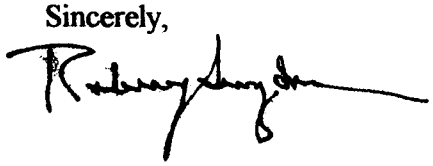
It is my understanding that the proposed competitive bidding rules do not mandate the level of clinical studies, or clinical support for personnel, education/training programs, or service that would need to be provided with this and other therapeutic offerings. It is therefore likely that all non-essential services would be eliminated to reduce costs to the lowest possible threshold. This will surely lead to untrained personnel and inappropriate usage of NPWT specifically culminating in potential harm to my patients, longer lengths of stay (and increased costs), and ultimately, poor outcomes. KCI offers extensive support and educational endeavors representing the keys to successful therapy with the use of VAC. To the best of my knowledge, the Blue Sky DMEs do not!

Finally, and maybe most importantly, no significant research has been done utilizing the Blue Sky Versatile 1 device vs. VAC therapy from KCI whose extensive randomized controlled studies remain ongoing and publications continue to permeate the medical literature regarding the most appropriate uses of VAC therapy for healing complex wounds.

I respectfully request that Negative Pressure Wound Therapy be excluded from the competitive bidding process until more research can be undertaken and analyzed relating to the Blue Sky Versatile 1, or any other device using NPWT with gauze.

Thank you.

Sincerely,



Robert J. Snyder, DPM, CWS

Rehabilitation Medical Supply, Inc.

Bayamón Tel. 779-1681 Fax: 995-3761
Arecibo: Tel. 878-2915 Fax: 878-2917

254-D
(2)

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
P.O. Box 8013
Baltimore, MD 21244-8013

June 23, 2006

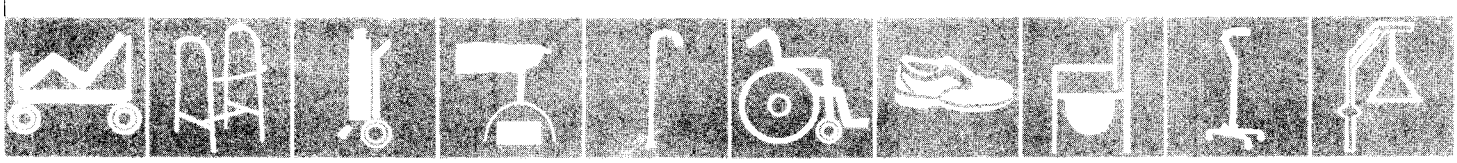
Dear Sirs:

During 2003 and 2004 CMS allowed charges to Puerto Rico were higher than in the States due to the recognition of the added cost involved in importing DME Supplies, such as local importation taxes, shipment and transportation expenses, and freight insurance charges, but in year 2005 this Fee Schedule was reduced by CMS and presently the DME suppliers have to absorb this previous added costs, therefore the use of the Allowed Charges of 2004 to place us in the first 10 Metropolitan Statistics Areas for the Competitive bidding on 2007 is not correct.

Please consider this to fix the wrong calculated situation. Thanks you in advance for your consideration.

Cordially,

Jose I. Cruz
Delivery Technician



Calle 1 A-36 Marginal Urb. Magnolia Gardens, Bayamón, PR 00956 • Ave. José C. Barbosa Local #58 Arecibo, PR 00612

(255)

971 Maytum Avenue
Sebastopol, CA 95472
June 27, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: "Proposed Rule for Competitive Acquisition of Certain DMEPOS".

I am writing to provide my comments regarding the Proposed Rule for Competitive Acquisition of Certain DMEPOS". I believe the proposed changes will have negative long term effects on rehabilitative health care for Medicare patients who are involved in a rehabilitation plan and under the care of a occupational therapist, physical therapist or speech therapist.

My Rehabilitation Credentials:

I have been an occupational therapist for 34 years and am licensed as an occupational therapist in California. I am a recognized expert in the field of hand rehabilitation. I have worked in a variety of settings, treating complex injuries of the hand including replants, crush injuries, tendon repairs, neurological and orthopedic conditions. I have established several successful clinics in Northern California including Vector Regional Hand Center, Eureka, ARMS (Associated Rehabilitation Medical Services) in Redwood City and SHARE (Spine Hand Arm Rehabilitation & Ergonomics) in Oakland. I have coordinated and presented at numerous continuing education courses for therapists, nurses, physicians in the area of hand rehabilitation, industrial rehabilitation and ergonomics.

Key Point:

As an occupational therapist, I urge CMS to revise the proposed regulations and establish a process that will enable rehabilitation therapists, i.e. occupational therapists, physical therapists, and speech therapists to continue to furnish orthotics, adaptive equipment for activities of daily living and home exercise equipment. These items are critical to the care of our patients and their ability to gain greater function enabling independence in their home environment. This rule could significantly impact the ability of therapists to furnish off-the shelf orthotics, wheelchairs, ambulatory assistive devices, and other items to their patients.

Although these products have been identified as products that require minimal adjustment and therefore have been included in the DME bid process, my 34 years experience as a therapist suggest that choices offered to a disabled seniors need criteria. These criteria

are generated through a thorough evaluation of the patient's physical limitations and the goals of their therapy program.

I urge CMS to allow physicians and therapists who have authorization to provide rehabilitation care to use all treatment procedures and supplies, orthotics and equipment necessary to facilitate independence in self care, ambulation, and promote safety in their home and community.

Patient Access to Rehabilitative Supplies and Equipment:

The allowable rehabilitation visits for Medicare patients are based on medical necessity, and a $ 1740 financial cap, and therefore it is imperative that a therapist be involved at an early stage to effectively manage a patient's care.

Within these visit parameters, the therapist evaluates the patient's need for orthotics, ambulatory aids, self-care and ADL needs. A product that has been previously tested for its effectiveness is tried with a patient in the clinic setting. Sometimes, several over the counter orthotics need to be evaluated due to secondary complications such as skin condition, allergies, and peripheral neuropathies before a splint is chosen. Although there may be only a few adjustments to make, there is a great deal of patient education to know when to wear the splint, to identify pressure spots, and to recognize symptoms of inflammation.

Many of these rehabilitative products and aids are needed at the time of the initial evaluation. For example, a splint to support the wrist fracture or a cane/walker to begin ambulation. These devices are made available to the patient in the therapy setting to be taken home and used. No devices are issued without a clinical evaluation by the therapist and patient to determine efficacy for their specific diagnosis and rehabilitation plan. DME providers would not be able to determine which of many different products would benefit a specific patient.

In addition, mandating that these over the counter devices be provided outside of their rehabilitation provider will cause delays in their rehabilitation progress. Having to go elsewhere is burdensome to the patient and family member who must transport the patient somewhere else for the device. If the device does not meet the specifications that the physician and therapist feel are required of the over the counter product, such as a splint, much time has been wasted.

The idea of sending a away from the supervised rehabilitation provider to a DME provider without medical credentials to evaluate the need of a specific product will reduced the effectiveness of the patient's rehabilitation plan.

Therapists Routinely Make Adjustments to Orthotics:

Splints that are currently being proposed in the regulation are described as items that require "minimal self-adjustment." They define items requiring more than minimum self-adjustment as adjustments to items (e.g. bending, trimming, molding, or assembling) that must be made by a certified orthotist.

Occupational and Physical Therapists perform adjustments to both pre-fabricated splints and custom made splints as a routine part of their practice. Occupational therapists are trained in splinting in college and many states offer certification of occupational therapists as the clinician who evaluates and provides patients with orthotics.

The patient's response to a pre-fabricated splint, one size that does not fit all, may require inserts and management of the effects on skin. In addition, the Medicare population and their families need frequent and repetitive education to use the splints appropriately and to be able to recognize warning signs of misuse.

The Importance of Specific Brands:

Therapists and physicians collaborate to assess the patients and specify certain products that address the individual needs of patients. As an experienced occupational therapist, I urge CMS to revise the regulations to recognize the need for occupational therapists and physical therapists to be able to specify brands to prevent adverse medical outcomes. There is a difference in splints, self-care and ADL equipment, ambulatory equipment, and exercise equipment. The lease expensive could constitute an "adverse medical outcome".

Summary:

I am proud to identify myself as an occupational therapist specializing in hand and upper extremity injuries. I promote the practice of occupational therapy that means the therapeutic use of purposeful and meaningful goal-directed activities which engage the individual's body and mind in meaningful, organized, and self-directed actions that maximize independence, prevent or minimize disability, and maintain health. I know how necessary it is to my Medicare's patient's successful rehabilitation that their treating therapist be able to evaluate and provide prefabricated splints, custom made splints, home exercise items, ambulatory and sleeping aids, and activity of daily living products. To limit and obstruct the rehabilitation process will diminish the efficient use of therapy visits and be burdensome to our patients with limited mobility and function.

I again request CMS to revise the proposed regulations and establish a process that will enable occupational and physical therapists to continue to furnish orthotics, self-care and activity of daily living products, and home exercise equipment that are critical to the care of our Medicare patients.

Thank you for your attention.

Sincerely,

Linda J. Johnson, OTR/L, HTC
California Licensed Occupational Therapist
California Hand Therapy Certified

256

Director
PO Box 2049
1 Vizcarrondo St.
Aibonito, P.R. 00705-2049
Tel. 735-8830

31 Dr. Veve Street
Coamo, P.R. 00769
Tel. 825-2929

Plaza San Cristóbal
Suite 216 - Second Floor
Barranquitas, P.R. 00794
Tel. 857-4090

June 22,2006
Aibonito, Puerto Rico

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs:

I am sending this letter to express that I believe we should not be considered in the competitive bidding process right now or at least not be considered in the first 10 MSA's (Metropolitan Statistic Area).

The language barrier that currently exists between Puerto Rico and the United States is an important factor that needs to be considered. Most of the people living in Puerto Rico are Spanish speakers. The implementation of this program will be at a high cost for many suppliers and will cause a decrease in supplier access to beneficiaries, resulting in a less competitive market.

I will appreciate if a review of the determination to include Puerto Rico now is reconsidered. That is not favorable for our beneficiaries at least in the next two or three years.

Thanks for your attention,

Cordially,

Awilda Torres
Awilda Torres
Director

257

PO Box 2049
1 Vizcarrondo St.
Aibonito, P.R. 00705-2049
Tel. 735-8830

31 Dr. Veve Street
Coamo, P.R. 00769
Tel. 825-2929

Plaza San Cristóbal
Suite 216 - Second Floor
Barranquitas, P.R. 00794
Tel. 857-4090

June 22,2006
Aibonito, Puerto Rico

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs:

I am sending this letter to express that I believe we should not be considered in the competitive bidding process right now or at least not be considered in the first 10 MSA's (Metropolitan Statistic Area).

Please analize that if the event of tropical storms, hurricanes, sudden flooding and other occurrences, the nearest suppliers are the only ones that could provide the beneficiaries with very important equipment as oxygen tanks that are needed in regular basis. The implementation of the Compettive Bidding Program would cause that we, the small, community-based suppliers could be displaced by larger chain suppliers who are going to take advantage of economies of scale. This Program will make impossible to the beneficiaries who want to continue with Traditional Medicare and is going to create confussion about their rights to do so. They will loss the benefit of choose his supplier, the one that know him /she as a particular person and know his/her necessities, not a mere number in a record.

It is the freedom of selection that is currently provided by Traditional Medicare that must be carefully safeguarded.

I will appreciate if a review of the determination to include Puerto Rico now is reconsidered. That is not favorable for our beneficiaries at least in the next two or three years.

Thanks for your attention,

Cordially,
Awilda Torres

258

234 Brenda Lane
Columbiana, Ohio 44408

June 27, 2006

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

I am a future pharmacist of this great nation writing in regards to recent CMS activities.

My first comment is in response to reimbursement cuts to community pharmacies. Decreasing reimbursement hurts the economic viability of pharmacies and ultimately results in the closure of businesses with subsequent pharmacist access limitations for all patients. It also reveals the sheer lack of appreciation that the government feels for pharmacists and the services we provide. The care that is afforded to each and every patient we serve is being publicly devalued when we are not adequately compensated. Instead of attacking the real problem, rampant fraud and abuse on the part of beneficiaries of these programs, you choose to punish the pharmacists who provide daily care to this population.

My second comment involves the recent DMEPOS proposal and my complete disapproval of it. It is not difficult to look back on both U.S. and world history to see that anywhere government regulations and rules take hold, the growth of the economy is stymied and businesses suffer. Free market competition is the only tried and true way to allow consumers/patients to benefit from the lowest prices possible whether it be related to health care products or otherwise. A completely free market succeeds 100% of the time. Government programs, particularly via CMS, have done enough damage to pharmacy already. Please let capitalism run its course. American businesses and consumers will be better off without your interference.

Sincerely,

Karli Gnipp, PharmD. Candidate

Karli Gnipp
PharmD Candidate

259

Option Care
8819 55th Place West
Mukilteo WA 98275

optioncare

June 30, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

File Code CMS-1270-P: Comments Related to Proposed Rule re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006)

Dear Dr. McClellan:

As Regional Director of Respiratory Services for Option Care Enterprises I am pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Option Care is a national infusion, specialty pharmacy, respiratory and home medical equipment services provider focused on meeting the needs of patients with acute and chronic conditions at home or in alternate site settings. We are a network of franchise and company owned locations and have been in operation since 1979. We have over 130 locations in 43 states and are growing.
Option Care has recently been recognized by *Fortune* as one of the 100 fastest-growing companies and by *Crain's* as one of Chicago's fastest-growing public firms.

We acknowledge that CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. We also agree with AAHomecare, NHIA and AARC that prior to implementation there are issues that need to be addressed regarding national competitive bidding and some of which I have listed below:

1. **Have Accreditation and Standards in Place before Starting**

Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs

to identify the criteria it will use to identify the accrediting bodies *now*. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

2. Getting It Right Is More Important than Rushing Implementation
CMS should stagger the bidding in MSAs in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Also, the initial MSAs and products selected should be identified in the final rule. And under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

3. Make Competitive Bidding Competitive, and Sustainable
CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. It should not be implemented as restrictive competition.

4. Don't Make it Harder for Providers to Sell their Businesses
The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

5. Consider the Impact on the Patient
CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 206-786-3508.

Sincerely,

Scott Alberts RRT
Regional Director Respiratory Services
Option Care Enterprises Inc.

260

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

5/15/06

I am visually impaired and also in very poor health. I use a CCTV, magnifiers, very bright light as well as very strong glasses. I am on disability with not much income coming my way.

Please give us some help with our seeing aids. Put yourselves in our place. We put you where you are! Thank You.

Sincerely,

M.K Carder

CARE PROVIDER SERVICES, INC.

261

June 29, 2006

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in **opposition** to the proposed rule of Competitive Acquisition for Certain Durable Medical Equipment, Prosthetic, Orthotics and Supplies, CMS-1270-P. As a supplier to residents of skilled nursing facilities I have first hand knowledge of the problems created by this proposal. My company serviced skilled nursing facilities in Polk County Florida during the first testing stages of this program. The owners and operators of skilled nursing facilities were not notified of their inclusion or exclusion in the test until days before the deadline to start Phase One of the competitive bidding test. The skilled nursing facilities were finally notified that they would be excluded from the testing phase. As providers we were notified that we could continue to provide products to residents of the skilled nursing facilities but would be paid based on a separate fee schedule established by the competitive bidding process.

During the next twelve months of testing we continued to receive payments at the national fee schedule rates instead of the competitive bidding rates. Multiple calls were made to the DMERC carrier to discuss the overpayment situation with them. We were told at that time the payments were accurate. We were overwhelmed when two years later we received notices of recoupment for large sums of money stating we had been over paid for the twelve month period for all patients served in the Polk County Florida area.

The test of competitive bidding in a skilled nursing facility environment proved to be a failure during Phase One of the Polk County Florida test. After twelve months enteral feeding supplies were removed and the report published by the committee overseeing the test stated "enteral nutrition is not as-well suited for competitive bidding as other products". To propose once again after tests have proven it is not suitable for skilled nursing facilities does not show an educated decision making process.

There are substantial differences between home bound patients and those that required skilled nursing care. The skilled nursing facility patients are more clinically complex requiring greater care than patients in their homes. To pass a law that requires a skilled nursing facility to obtain services and supplies from a select group of vendors that they have no choice in choosing puts the resident's of the skilled nursing facilities health at risk. The skilled nursing facilities will also have to concern themselves with the legal ramifications created by these regulations. They are ultimately responsible for the health and well being of their residents. If the companies that are awarded the competitive bidding contracts fail to meet the quality of care for these residents, the skilled nursing facilities would be legally responsible.

By proceeding with this proposed rule you are putting the health and well being of the elderly residing in skilled nursing facilities at risk. As a supplier we strive to provide the highest quality of products and care to the residents we serve. Removing the freedom of choice that allows the skilled nursing facilities to choose the supplier that provides the highest level of care and service will create a law that cause poor quality of care for our elderly.

Respectfully,

Elizabeth Fago

2979 PGA Boulevard • Suite 225 • Palm Beach Gardens, FL 33410

262

William M. Hensley, PT, CI
300 Castlewood Court
Johnson City, TN. 37601

June 27, 2006

Dr. Mark McClellan, MD, PhD
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
ATTENTION: CMS 1270P
P.O.Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

To start with, this looks like a long letter but if you will just read it through, you might see something you have not been told before.

I have been practicing Physical Therapy for fifty eight years and have seen a lot of changes, some changes good and some not so good. I finished School of Medicine in Physical Therapy at Duke and started practice in Johnson City in January 1950. There were less than 15 Physical Therapists in the state of Tennessee. Now we have four Physical Therapy schools in the state with several PT Assistant programs. There are now over 600 PTs in Tennessee. I a;so helpped establish the PT School at UT in Memphsis and the PT School at ETSU.

While working to improve programs and education in the state I have been in private practice in Johnson City, TN. I started and developed the PT Department at Johnson City Memorial Hospital, including the establishment of a polio center , keeping it functioning for four years through the epidemics. Worked with cripple children programs; started a prosthetic clinic covering four states; started many nursing homes and Home Health Agencies PT programs. I was the first in Tennessee to start home visits to patients who could not get into an outpatient clinic. So, I have had many years of experience in Physical Therapy.

Some of the bad things have shown up in greed. Doctors hiring Physical Therapist to work and perform therapy in their office, charging two or three times as much as a Private Practice Therapist can charge, using assistants at times. Limiting time for treatment of patients, therefore not doing a good full treatment of patients, limiting the possibility of a good outcome for the patient.
Home Health agencies that I helped start I found later that the owners were greedy and in order to make great profits insisted that the nurse, nursing aide, Physical Therapist, Occupational Therapist, Speech Therapist and some times the Social

worker visit the patient as soon and often as possible when the need was for only maybe two professionals to administer rehabilitation and bathing. There was a lot of waste in this type of operation.

With so many Home Health Agencies in the community, including new hospitals established, sending their own Home Health Care employees with the discharged patients, they manipulate the field by monopolizing health care. They over charge so that a private practice person who only does Physical Therapy, sees very few patients. The private practice Therapist can spend more time for rehabilitation of patients and relief of pain than one from an organization.

In my case of having my private office with many types of equipment for diagnosing and treating by the use of ultra sound and deep heat, I treat all types of patients. I was one of the first in the United States to use ultrasound in treatment of patients.

Medicaid in Tennessee would never pay me for seeing patients, but would pay hospitals in outpatient settings two or three times as much as I charged patients. I charged the small amounts so I could see them two to three times a week for faster follow ups, help prevent problems early and obtain better results.

Now Medicare has stopped paying for visits when patients have a chance to get a good recovery and keep functional.

I am at present seeing patients that have been discontinued by medicare, but I still see them and am supplementing the cost of keeping my office open with the use of my social security checks to help people .

Therefore it is time to do something about over charges in Home Health and Doctor's offices. Another thing, home health care will not see a patient in their home if a private physical therapist is giving them treatments. The private Physical Therapist must give up their patient to enable the patient to receive other needed care . In other words, the Home Health Care Agency wants to do all the care, not share. The same arrangement holds true in assistive living facilities.
This is wrong, because the patients have the right to chose and not lose their total care.

Please consider the points that I have made in this letter.

Thank you for considering the above points,
William M. Hensley P.T. CI
William M. Hensley, PT, CI
(Holder of License #I in the State of Tennessee)

263

PO Box 2049
1 Vizcarrondo St.
Aibonito, P.R. 00705-2049
Tel. 735-8830

31 Dr. Veve Street
Coamo, P.R. 00769
Tel. 825-2929

Plaza San Cristóbal
Suite 216 - Second Floor
Barranquitas, P.R. 00794
Tel. 857-4090

June 22,2006
Aibonito, Puerto Rico

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs:

I am sending this letter to express that I believe we should not be considered in the competitive bidding process right now or at least not be considered in the first 10 MSA's (Metropolitan Statistic Area).

The geographic location of Puerto Rico island, in the Caribbean Sea, should be bear in mind in the moment of the competitive bidding process . Yearlly our island is impacted by tropical storms and hurricanes. These cause so many problems to the roads, highways, and other access routes that many times interrupt the communication between towns. **We, the small suppliers** who are located in in different towns of the island are more accessible to the beneficiaries of that areas than the suppliers that are located in distant areas. The damage hurricanes, storms and floods cause to the island make impossible the accesibilty of distant suppliers and the beneficiaries are acostumed to seek for the nearest one. The beneficiaries are acostumed to a long-standing relationship between them and we as their familiar suppliers. The large chain stores are not interested in the beneficiaries necessities as we do. We are always there for them, in bad and good times.

I will appreciate if a review of the determination to include Puerto Rico now is reconsidered. That is not favorable for our beneficiaries at least in the next two or three years.

Thanks for your attention,

Cordially,
Awilda Torres
Awilda Torres
Director

264

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

This is in response to your proposal in Section 414.15. It is not fair to people with low vision to be excluded from medicare coverage for low Vision Aids and technologies. I have been aware of the fact that wheelchairs, crutches, and bathroom aids have been approved by Medicare. However, I do not understand why Medicare doesn't approve coverage for low Vision Aids such as magnifiers and CCTV systems. As you can see by the difference in the two types of handwriting that I am not able to see well enough to write my own letter. I am 86 years old and on a fixed income. I, like many others, need this Medicare coverage.

Dorma Dunkle

765

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

6-23-06

My husband has a Magni-Sight.

What a blessing to have this low vision aid.

Now he can see pictures, do puzzles, read and see the signature line on a check.

Fortunately we were able to purchase the Magni-Sight.

Even though this was not covered by Medicare | Medicaid we felt this was a necessary purchase. Would have been wonderful to have had some assistance.

Hopefully these magnifiers will be approved by those who have the authority to do so.

Sincerely,

Elsie Fern Harris
(Mrs. Lester Harris)

(166)

Mary Houtzel
10 Knox Ct
LODA, IL 60948

Centers for Medicare/Medicaid Services
Attention: CMS-270-P
RE: Low Vision Aid Exclusion

Dear Sirs,

I am legally blind - and
and will be 90 years old in December
I am hoping that Medicare and
will decide to help the
Many People that Cannot afford to
buy the low Vision devices that Could
help them. "Race" is good but many
still have to pay and many can not afford
them and Could be helped in "Policy
makers" in your decisions Please DO NOT
FORGET THE BLIND! Sincerely

109 Knox Ct
MARY HOUTZEL

MUNSON HEALTHCARE

267

June 27, 2006

Centers for Medicare and Medicaid
Department of Health & Human Services
ATTENTION: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: Centers for Medicare & Medicaid Services (CMS)
42 CFR Parts 411, 414, and 424
(CMS –1270-P) RIN 0938-AN14
Medicare Program, Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and other Issues

To whom it may concern:

Thank you for the opportunity to offer comment on the proposed changes being contemplated for competitive bidding and acquisitions.

The concept of competitive bidding makes perfect sense, and as a taxpayer I want to provide the best service at the best price for our neighbors. However, the proposed manner in which the bidding is to occur will leave several dealers out of the picture, and as a result, our citizens will have limited choices and resources from which to depend for their home healthcare needs.

A better proposal would be to allow all accredited dealers to provide services at an assigned price. The price could be arrived at by bidding or by fee screens. But once assigned, all dealers should be able to provide the service and accept the assigned price. This would accomplish several major objectives- 1. raise the overall quality of services provided by having only accredited dealers participate. 2. lower the overall cost of services for the government and the beneficiary 3. provide for a larger number of dealers capable of providing services thereby enhancing beneficiary choices for services 4. maintain a system that can support product innovation and distribution for the beneficiaries 5. save millions of dollars in cost for CMS for not having to implement the competitive bid process and roll it out over several years.

As for the acquisition proposals, I am okay with all of the proposals, except I am really troubled by the oxygen ownership proposal. I have over 20 years experience providing home oxygen and respiratory services, and am a Registered Respiratory Therapist. The ownership of the oxygen equipment could put undue stress on beneficiaries. What happens when problems arise with the equipment? Who do they call? Do they seek emergency treatment at a hospital? Do they go to an Urgent Care Center? Who can handle their issues without adding cost to the healthcare systems in which they live?

A better proposal would be to cap-rent the equipment at 36 months, but have the dealer retain ownership. CMS would no longer pay a rental fee, but perhaps could

1105 Sixth Street
Traverse City, Michigan
49684-2386
(231) 935-5000
www.mhc.net

pay a lower service fee once every three months to offset the cost of maintaining the equipment and portability. This would be an assigned agreement so the beneficiary would be protected. This too would accomplish several major objectives. 1. lower the overall cost to CMS and the beneficiary. 2. provide for a larger overall network of providers to service the beneficiaries. 3. removes the burden of maintenance and servicing of the oxygen equipment from the beneficiary and has it remain with the dealer 4. provides for continued service coverage 24/7/365 for the beneficiaries 5. provides for stability within the system for the beneficiaries and dealers 6. maintains traditional responsibilities for the dealers and beneficiaries.

Thank you for considering my inputs and comments.

Respectfully,

Daniel J. Mach
Manager
Munson Home Medical Equipment
3816 West Front Street
Traverse City, Michigan 49684

HOSKINS DRUG STORE NO. 2
111 N. MAIN STREET
CLINTON, TENNESSEE 37716

PH: 423-457-4340 FAX: (865) 463-0678

268

Memo
LETTER

Date 6-27-06

To CMS

Subject COMPETITIVE BIDDING PROGRAM

MY SISTER AND I OWN & OPERATE OUR FAMILY BUSINESS EST. IN 1930 BY OUR FATHER. WE COMBINED PHARMACY & DME IN MID 1960 INTO HIS STORES & THEY HAVE CONTINUED TO OFFER SERVICES IN ANDERSON, KNOX, LOUDON, ROANE & CAMPBELL COUNTIES TODAY. OUR MISSION HAS BEEN DEDICATION TO COMMUNITY W/ QUALITY SERVICE. PLEASE ALLOW US TO CONTINUE IN YEARS TO COME. WE ARE A FULL SERVICE PHARMACY & DME WITH TRAINED STAFF. ENCLOSED YOU WILL FIND OUR STORE HISTORY & MISSION STATEMENT.

IF IS IMPORTANT TO SUPPLY THE PATIENT W/ ALL THEIR DME NEEDS.

☐ Please reply ☐ No reply necessary

SIGNED Dudley H Bostic

Tennessee Pharmacists Association

TPA RESOLUTION 99.1

To Honor Rolland Carvel (Dudley) Hoskins

WHEREAS, R. C. (Dudley) Hoskins was the oldest living registered pharmacist in Tennessee and one of the oldest in the United States, and an outstanding leader in the pharmacy profession; and,

WHEREAS, he distinguished himself and his profession in active practice for nearly three-quarters of a century; and,

WHEREAS, he served on the Tennessee Board of Pharmacy from 1963 to 1968, and as President of the Tennessee Board of Pharmacy in 1967; and,

WHEREAS, Dr. Hoskins served many years in leadership positions with distinction and honor, on the Clinton Board of Education, the Clinton Civitan Club, the Clinton Housing Authority, and as the first President of the Clinton Chamber of Commerce; and

WHEREAS, he graduated from the University of Tennessee College of Pharmacy in 1926, and was named a lifetime member of the University of Tennessee College of Pharmacy Alumni Association Board of Directors; and

WHEREAS, he was co-founder of the Center for Pharmacy Management and Research at the UT College of Pharmacy and endowed the Katherine and Dudley Hoskins Scholarship Fund; and,

WHEREAS, Dudley Hoskins was name Tennessee Pharmacists Association's Pharmacist of the Year in 1984; and,

WHEREAS, Dr. Hoskins' life profoundly enriched his community, his state, and his profession,

THEREFORE, BE IT RESOLVED that the Tennessee Pharmacists Association recognize and memorialize the life of this dedicated pharmacist.

BE IT FURTHER RESOLVED that a copy of this resolution be properly prepared and presented to the family of R. C. (Dudley) Hoskins.

Submitted by
Senator Randy McNally, D.Ph
Representative Shelby Rhinehart, D.Ph.

Adopted on proper motion by the Tennessee Pharmacists Association House of Delegates
February 9, 1999, Nashville, Tennessee

MISSION STATEMENT

Our Mission as a Family owned and operated business is to provide quality care and exceptional service that is second to none. Everyday may we strive to provide family friendly service and always go above and beyond to ensure the satisfaction of each and every customer.

Pharmacist and healthcare providers are at and near the top of the list of most trusted professionals. Protecting a patient's health information is essential to maintaining a patient's trust and keeping the providers reputation. At Hoskins Drug Store we pride ourselves in our sincerity and ability to help patients while maintaining a strong sense of confidentiality.

Under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973, Hoskins Drug Store protects the civil rights of all patients. Benefits will not be denied, nor do we discriminate on the grounds of race, color, national origin or handicap.

If we do not have an item in-stock, or if we are unable to help a patient, it is our policy to refer the patient to an entity that can fulfill their needs.

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...to bandages and compression stockings. We have it all!

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JAS

269

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June 30, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, Maryland 21244

Re: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues

Dear Dr. McClellan:

We are Joint Active Systems, Inc. (JAS). We are an Illinois corporation and currently employ about 70 workers. In addition, more than 160 individuals in other States work for JAS throughout the country. We manufacture clinically-proven, patented, static progressive stretch devices/orthosis used to treat restricted range of motion in the shoulder, elbow, wrist, forearm pronation/supination, knee, ankle, and finger joints secondary to trauma, surgery, immobilization, burns, or neurologic injury. More importantly, we have enrolled in the Medicare Program for the sole purpose of supplying and billing only the devices that we manufacture. JAS requested and obtained the following Healthcare Common Procedure Coding System (HCPCS) codes for its devices: E1801, E1806, E1811, E1816, E1818, and E1841. We respectfully submit our comments to the proposed rule regarding the Competitive Acquisition for Certain DMEPOS and Other Issues (CMS-1270-P), which was released on May 1, 2006 (71 Fed. Reg. 25654).

1. General Comments

We strongly urge the Centers for Medicare and Medicaid Services (CMS) to delay the implementation of the competitive acquisition program (CAP) for DMEPOS items until the Supplier Quality Standards (Quality Standards) are finalized and released by CMS. CMS must not require suppliers to make a competitive bid on any DMEPOS item without affording them the opportunity to be informed about the additional cost that they must incur in order to comply with the new Quality Standards. The benefits of true competition as Congress intended can only be realized if the suppliers have all of the facts that are necessary to make informed bids.

As you know, even the Program Advisory and Oversight Committee (PAOC) recommended that CMS delay the CAP until the Quality Standards are made available to the suppliers, especially given that, according to CMS, significant revisions have been made to the draft Quality Standards that were introduced on September 26, 2005. Furthermore, CMS has stated that it would release the final version of the Quality Standards in June of 2006. To date, CMS has not done so. Therefore, JAS requests that CMS accept the recommendation of the PAOC.

2. Criteria for Item Selection

If an entity that is the sole manufacturer and supplier of a particular DMEPOS item is unable to bid or participate in CAP, then the Medicare Program has effectively eliminated access to this DMEPOS item by the beneficiaries. This clearly is not the intent of Congress. Therefore, CMS must exempt such manufacturer-suppliers from the proposed requirement that all suppliers bid for all items in a particular product category to be finalized and announced by CMS. Instead, in order to protect each beneficiary's access to such single-source DMEPOS items, manufacturers like JAS that supply only those DMEPOS items that they manufacture should be afforded the same exemption proposed for skilled nursing facilities (SNFs) and physicians. Like SNFs and physicians providing DMEPOS items only to their patients, manufacturer-suppliers are not "commercial suppliers" because they do not supply every DMEPOS item reimbursable by the Medicare Program.

Alternatively, CMS should phase in such single-source DMEPOS items and manufacturer-suppliers after 2009. Delaying the inclusion of such items and suppliers will allow CMS to not only learn about the effects of CAP in general but also address the unique issues of single-source DMEPOS items and manufacturer-suppliers in particular. Likewise, CMS must designate the product categories narrowly. CMS must permit suppliers to bid for those DMEPOS items that only they can supply. By requiring suppliers to bid for every DMEPOS item in a product category, CMS would hinder true competition and fail to assure the most savings because the one manufacturer-supplier that could provide the lowest bid would actually not be able to bid because it only supplies those DMEPOS items that it manufactures.

In addition, CMS must comply with the Congressional mandate of Section 1847(b)(7) of the Social Security Act and actually "consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals." CMS must seriously consider excluding from CAP those DMEPOS items that are supplied only by the manufacturer. Congress did not intend CAP to prevent Medicare beneficiaries from accessing DMEPOS items that CMS has coded and has been reimbursing prior to either the enactment of the Medicare Modernization Act of 2003, which mandated the CAP, or the implementation of CAP itself.

3. Submission of Bids under the Competitive Bidding Program

CMS must only apply CAP to "commercial suppliers." Just as CMS realized that SNFs and physicians are not "commercial suppliers," CMS must understand and acknowledge that manufacturers that only supply the DMEPOS items that they manufacturer are not "commercial suppliers." While SNFs and physicians supply the full range of DMEPOS items only to their

patients, manufacturer-suppliers supply only those DMEPOS items that they manufacture. Therefore, because of the limited type of DMEPOS items that such manufacturer-suppliers provide to Medicare beneficiaries, they are less of "commercial suppliers" than even the SNFs and physicians supplying every type and quantity of DMEPOS items.

Again, CMS must designate the product categories narrowly. CMS simply must permit suppliers to bid for those DMEPOS items that only they can supply. It is not only logical but also beneficial to the Medicare beneficiaries. For JAS, it would be particularly ironic if it could not bid or participate in CAP. In 2005, JAS met with CMS (Joel Kaiser and a few DME Regional Carrier medical directors) to discuss the pricing of the codes for its devices that JAS has requested and obtained through the HCPCS coding process. CMS has not yet responded to the request to increase the reimbursement rates. Now, JAS is struggling with the painful requirement that all bids must be lower than the current Medicare rates. It would indeed be a slap in the face if CMS were to deny JAS, the sole supplier of the devices that it manufacturers, the opportunity to even bid because CMS defined the product categories broadly. Most importantly, the Medicare beneficiaries would be denied access to these clinically effective and cost efficient devices, which require 3 months of wear-time on average and not the 15 (now 13) months permitted by CMS.

4. Conditions for Awarding Contracts

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

5. Opportunity for Participation by Small Suppliers

CMS must consider the small manufacturers like JAS that have enrolled in the Medicare program only to be able to supply the DMEPOS items that they manufacture. These manufacturers have accepted this course, despite the risk of being subject to various additional Medicare restrictions (e.g., Stark self-referral prohibitions), because they have experienced problems merely selling their DMEPOS items to Medicare "commercial suppliers." They want to ensure that their DMEPOS items are properly delivered to, fitted by, and used by the Medicare beneficiaries. CMS must not penalize such manufacturer-suppliers.

Section 1847(b)(6)(D) addresses the "protection" of small suppliers and not just the identification of such suppliers. Therefore, CMS must treat small suppliers differently. Manufacturers that only supply the DMEPOS items that they manufacture are not "commercial suppliers" that supply the full and complete list of DMEPOS items. CMS must actively help small suppliers, including manufacturer-suppliers, so that they may participate in CAP and provide the Medicare beneficiaries access to such single-source DMEPOS items.

6. Opportunity for Networks

CMS must provide sufficient time for suppliers to establish and work collaborative in the networks permitted by CMS under the proposed rule if CMS truly wishes to allow suppliers to form networks in order to bid competitively. CMS must not erroneously believe that the potential fo

volume is the motivating factor for the suppliers. Instead, CMS must realize and accept the fact that suppliers want to and need to bid and participate in CAP to merely stay in the Medicare program.

7. Quality Standards and Accreditation

Again, CMS must delay implementation of the CAP until it has finalized and published the Quality Standards. Alternatively, CMS should phase in single-source DMEPOS items and manufacturer-suppliers after 2009.

* * * * *

On behalf of over 230 hard-working families of JAS, we thank you for the opportunity to comment on the proposed CAP for DMEPOS items. We hope that CMS will truly consider each of our comments.

Sincerely,

Dean Kremer
President

cc: Sandra Bastinelli (via e-mail)
Carol Blackford (via e-mail)
Stacy Coggeshall (via e-mail)
Joel Kaiser (via e-mail)
Martha Kuespert (via e-mail)
Herb Kuhn (via e-mail)
Walt Rutemueller (via e-mail)
Linda Smith (via e-mail)

270-D
(2)

Westlake Hospital
1225 West Lake Street
Melrose Park, Illinois 60160

Resurrection Health Care

Tuesday, June 20, 2006

To: Mark B. McClellan, MD, PhD

From: Joyce Westfall

Occupational Therapist
Westlake Hospital
1225 W. Lake Street
Melrose Park, IL 60160

Subject: ***NOT in support of the current draft language re: qualified providers & accreditation standards for orthotics. NOT in support of competitive bidding for prefabricated orthoses.***

In compliance with the Medicare Modernization Act of 2003, I understand that the Secretary of Health and Human Services is responsible for establishing a competitive bidding system and quality standards for certain durable medical equipment, prosthetics and orthotics (DMEPOS). Furthermore, I understand the quality standards, which include the professionals recognized as qualified suppliers are being developed for approval by your Program Advisory Oversight Committee.

As a therapist, I have great concern for the language regarding who is qualified to provide orthoses to beneficiaries. The current draft language specifically indicates orthotics and prosthetics "require the qualifications and expertise of a certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". This **language *does not include occupational therapists and physical therapists. The language does not correspond with the existing language outlined in the Social Security Act, Section 1834(a)(20).***

I cannot understand why CMS would consider restricting providers to orthotists and prosthetists and mandate accreditation standards through the O & P boards. The omission of therapists does not correspond with current CMS regulations. TODAY, occupational therapists and physical therapists are recognized as qualified CMS providers for evaluating patients, designing, fabricating, and dispensing the appropriate orthosis, along with educating the patient (e.g. applying/removing the orthosis, understanding the wearing schedule and precautions). **Occupational therapists and physical therapists are specifically identified as qualified practioners in the Social Security Act, Section 1834(a)(20), and our status as a practitioner also qualifies us as suppliers for these devices.** TODAY, there are thousands of therapists throughout the country fabricating customized orthoses and issuing prefabricated orthoses to patients. We are highly trained and highly qualified professionals who have a long-standing history of fabricating orthoses in this country.

It is important to know the minimal educational standards for occupational therapists and physical therapists are either a bachelor or master's degree. Orthotics is included in our academic curriculum. Both occupational therapists and physical therapists must successfully pass national boards at the completion of the academic experience before applying for licensure or certification at a state level. These examinations are administered through national testing companies accredited by NOCA and ANSI, which

are recognized by CMS today. This academic background is complemented with clinical experience and ongoing medical education. We serve as authors for peer-review journals, manuals and books on orthoses, and have lectured to our profession and others on the subject. In addition, beyond our high academic standards, many therapists choose to have additional certifications, one example being the certified hand therapist (CHT). CHTs have a minimum of five years of practice experience and have successfully passed an examination specific to the upper quarter (shoulder, elbow, wrist and hand). Specific questions related to orthotics are included in the examination. Once certified, recertification is mandated each five years to retain the CHT designation. This is accomplished through medical education requirements and practice involvement (i.e. clinical practice, research or education) related to the upper extremity. The Hand Therapy Certification Commission (HTCC), is responsible for the administration process for becoming a certified hand therapist and subsequently recertifying. Their website can be accessed at www.htcc.org.

We are sought out by patients, businesses, industry, case managers, referring physicians and therapists to treat patients with special medical problems. There are lofty expectations and demands placed on us to provide the highest level of patient care and remedy their medical condition. Often, we are the last opportunity to improve the patient's medical condition and quality of life. The physicians and therapists communicate closely about the patients and their medical condition or surgery. As therapists, we have a strong working knowledge of the medical conditions/surgeries and anatomy of the affected area. With this expertise we can carefully craft the proper rehabilitation program and determine the necessary orthosis. I cannot begin to imagine that my patients would receive an initial evaluation and treatment by the physician/surgeon, subsequently be referred to therapy for a portion of the therapy services and then go to another facility to receive the orthosis or orthoses they need. Evaluating the patient, fabricating and dispensing the orthosis, determining the wearing schedule and educating the patient about their orthosis is an integral part of hand therapy. Often it is the orthosis that is key to a successful outcome! It is those frequent, little adjustments that can result in terrific functional outcomes!

It is equally important to understand that sending patients to another provider fragments and disrupts the continuity of patient care. It is difficult enough for our Medicare and Medicaid patients to drive to office visits and therapy, let alone requiring them to drive to another location for additional services. During the course of therapy most of the patients require a number of adjustments to their orthoses, which would result in multiple trips to the DME distributor. These adjustments are necessary due to frequent dressing changes, fluctuation in edema, progression of the treatment plan, and patient progress. I can only imagine the burden and confusion this would cause for the patient and family.

With respect to competitive bidding for prefabricated orthoses, how could therapy providers possibly participate in the competitive bidding process? We are at a huge disadvantage. Therapists are not in the business of manufacturing and supplying high volumes of medical equipment. Individually, each therapist and/or therapy facility dispenses small volumes of medical supplies to their patients. There is no way therapists could compete with respect to wholesale pricing, volume warehousing, and having the business infrastructure for wide-scale distribution within their medical model today. The small amount of profit generated from these prefabricated orthoses serves, at best, as a very small source of revenue.

I must believe there has been an accidental oversight on behalf of the committee as the quality standards and accreditation process for orthotics and prosthetics has evolved. It is strongly recommended the language state: "orthotics and prosthetics require the qualifications and expertise of ***a licensed, certified or registered occupational therapist, physical therapist OR*** certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". In addition, I do not believe there can be a genuine interest in the small volume suppliers (i.e. therapists) participating in competitive bidding. ***Therapists should be exempt from the competitive bidding process.***

It is so important for the committee to understand how instrumental occupational therapists and physical therapists are in providing both custom-made and prefabricated orthoses to patients, your beneficiaries. Respectfully, I ask that you give this letter full consideration and act on these major concerns.

Joyce Westfall OTR/L, CHT

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ORGANIZATIONS LISTED ON LAST PAGE

Goldberg, Ralph (CMS/CMM)

From: Blackford, Carol W. (CMS/CMM)
Sent: Friday, June 30, 2006 2:09 PM
To: Ballantine, Lorrie T. (CMS/OCSQ); Keane, Michael P. (CMS/CMM); Rutemueller, Walter E. (CMS/CMM); Kaiser, Joel E. (CMS/CMM); Goldberg, Ralph (CMS/CMM); Jacobs, Karen N. (CMS/CMM); Meholic, Alexis (CMS/CMM); Smith, Linda D. (CMS/CMM)
Cc: Kuespert, Martha D. (CMS/CMM)
Subject: FW: Comments on DMEPOS Competitive Acquisition Proposed Rule - Sign-on Letter
Attachments: Written Comments2 DME comeptitive bidding 63006 - final.pdf

FYI

Carol Blackford
(410)786-5909
carol.blackford@cms.hhs.gov

From: Mari Johnson [mailto:Mari.Johnson@ama-assn.org]
Sent: Friday, June 30, 2006 12:07 PM
To: Blackford, Carol W. (CMS/CMM); Kaiser, Joel E. (CMS/CMM); Bromberg, Barry J. (CMS/OFM); Bossenmeyer, James M. (CMS/OFM); Brandt, Kimberly L. (CMS/OFM); Zone, Lisa C. (CMS/OFM)
Cc: Margaret Garikes; Katie Tenoever; Sharon McIlrath; Dawn Robinson
Subject: Comments on DMEPOS Competitive Acquisition Proposed Rule - Sign-on Letter

Attached, please find comments in the form of a sign-on letter on the Proposed Rule on *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*, 71 *Fed. Reg.* 25,654 (May 1, 2006).

Please feel free to contact me if you have any questions.

Mari

Mari Rose Johnson, MPA
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June 30, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator McClellan:

The undersigned organizations appreciate the opportunity to provide our views concerning the Centers for Medicare and Medicaid (CMS) Services' proposed rule *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*, 71 *Fed. Reg.* 25,654 (May 1, 2006).

Under the DMEPOS proposed rule, CMS would implement a competitive bidding program for certain Medicare-covered items of DMEPOS. We have several important concerns about the proposed rule, which we raise to protect our patients from any unintended harmful effects of the new initiative.

EXEMPTION FOR PHYSICIANS AND NON-PHYSICIAN HEALTH CARE PRACTITIONERS FROM DMEPOS COMPETITIVE BIDDING PROGRAM

In accordance with the mandate under the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) to implement a DMEPOS competitive bidding program, CMS is proposing that physicians who supply DMEPOS must submit bids and be awarded contracts in order to furnish the items included in the competitive bidding program.

We urge CMS to exempt from the DMEPOS competitive bidding program physicians and certain other health professionals, *e.g*, podiatrists, optometrists, physical and occupational therapists, physician assistants (collectively referred to hereinafter as "practitioners"), who provide their own patients with DMEPOS. Instead, when these practitioners are licensed by their state board to practice in that state, they could be "deemed" as qualified to provide patients with DMEPOS, and current payment policy would apply to these practitioners for these items of DMEPOS.

Practitioners generally operate as small businesses (and small suppliers of DMEPOS), and the financial and administrative burden of complying with the new competitive bidding program, simply to supply DMEPOS to their own patients, likely will be too great. Yet, practitioners must be integrally involved in providing DMEPOS to their patients to ensure that (i) a particular item of DMEPOS meets the "size and fit"

specifications for that particular patient; and (ii) the patient is properly instructed concerning the use of that DMEPOS. This is necessary to provide patients with the highest quality of care, achieve patient compliance, reduce risk of further injury and avert liability concerns as well.

For example, if a patient is diagnosed with a foot fracture, a walking boot and crutches may be required upon leaving the physician's office. If the patient is unable to acquire the item from the treating physician and must obtain the item from another supplier due to the new competitive bidding program, serious adverse consequences could result, including a delay in care, continuous or exacerbated pain, or the patient could be at risk for additional, increased injury, which would increase costs to the Medicare program. This could also result in fragmented care, which could disrupt the patient-practitioner relationship. Moreover, in some cases, Medicare allows only one item of DMEPOS per patient. In this event, if the item is not initially properly fitted and sized, the patient may later have to pay out-of-pocket for a replacement item.

Further, the clinical judgment and expertise of the treating practitioner in selecting a particular item is essential and should be based on the evaluation of the patient at the time of dispensing. This would also be the appropriate time to instruct the patient and address any questions or concerns on the utilization of the item. If a patient is sent elsewhere to obtain an item and the fit is incorrect or the patient receives insufficient information about an item, the patient will likely return to the practitioner's office with questions or for assistance. This will result in increased costs to the Medicare program and will increase utilization under the sustainable growth rate (SGR). **Thus, practitioners should be exempt from the DMEPOS competitive bidding program for the purpose of providing their own patients with DMEPOS.**

In the alternative, if CMS does not provide this exemption, CMS, at the very least, should phase these practitioners into the bidding process after 2009. In accordance with the MMA DMEPOS mandate, CMS will phase-in this program with respect to certain Metropolitan Statistical Areas (MSAs) in 2007 and 2009, with additional competitive bidding occurring in other areas after 2009. A phase-in for certain areas, with an additional phase-in after 2009 for practitioners who provide their patients with DMEPOS would also conform to the spirit of the MMA mandate, which contains a provision to protect small suppliers of DMEPOS.

As discussed above, practitioners operate as small businesses and the cost of complying with the competitive bidding program and related requirements could effectively prohibit them from supplying patients with DMEPOS that is most appropriate when supplied at the time of the patient visit. Thus, these practitioners should have lead time before applying the competitive bidding program to them. If patients do not have access to enough suppliers who offer the needed product categories, this could seriously impact access to appropriate care. Finally, this phase-in time will allow practitioners time to identify those DMEPOS items that should not be part of the competitive bidding program, as further discussed below.

If practitioners are phased-in over time, however, CMS should provide a less burdensome process for practitioners, including an exemption from the accreditation standards that may be appropriate for a large regional or national DMEPOS supplier, but are much too burdensome for practitioners who merely provides DMEPOS to their patients.

EXEMPTION FOR CERTAIN ITEMS FROM THE DMEPOS COMPETITIVE BIDDING PROCESS

Under the proposed rule, as discussed above, physicians that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items included in the competitive bidding program for the area in which they provide medical services. The rule also states that physicians must ensure that any arrangement under which they refer for and furnish DMEPOS under a competitive bidding program must be in compliance with the physician self-referral law.

We understand that certain DMEPOS arrangements may be prohibited by the physician self-referral law. While we are not advocating for a repeal of this provision of the self-referral law, we, nevertheless, note that there is an exemption from the law for certain items of DME. Some items, such as canes, crutches, walkers and folding manual wheelchairs, were exempted because the patient requires the item to depart from the physician's office. In addition, there is a separate exemption from the physician self-referral law for implants furnished by an ambulatory surgery center (ASC), including, but not limited to, cochlear implants, intraocular lenses and other implanted prosthetics, implanted prosthetics devices and implanted DME that meet certain requirements. Certain other services and prosthetic devices, such as eye glasses or contact lenses following cataract surgery, were exempted to avoid significant inconvenience to Medicare patients and because they are already subject to frequency and payment limits.

Similar to this physician self-referral law, we urge CMS to apply current payment policy to and exempt from the competitive bidding program the above-listed and other similar items (including, but not limited to, wrist, ankle and finger splints; shoulder, elbow and hand splints; aircasts; cervical collars; orthotic inserts; spine stabilization braces; corsets; and rib belts) that practitioners provide to their patients. It is our understanding that prosthetics devices are not among the items covered in the MMA's competitive bidding provision. However, we note that even if prosthetics were covered under the law, there should be an exemption for physicians providing these devices to their patients. This will ensure quality of care and patient safety. We also urge CMS to work closely with the undersigned organizations to develop an appropriate list of exempted DMEPOS to ensure patient care is not impeded. To maintain transparency and equity in this process, CMS should provide an opportunity for review and public comment with regard to this list.

ELIGIBILITY TO PARTICIPATE IN THE DMEPOS COMPETITIVE BIDDING PROGRAM

The proposed rule states that "providers that furnish Part B items and are located in a competitively bidding area and are also DMEPOS suppliers" must submit bids in order to

furnish competitively bid items to Medicare beneficiaries (emphasis added). The proposed rule does not define the term "provider." In the event that CMS does exempt practitioners from the DMEPOS competitive bidding program as requested above, we urge CMS to clarify that certain health care professionals who are not MDs or DOs and who regularly provide their patients with DMEPOS would be considered "providers" for purposes of participating in the DMEPOS bidding process and could be awarded a contract as a DMEPOS supplier. Some of these practitioners may provide their patients with Medicare DMEPOS, and thus should be permitted to participate in the competitive bidding process.

QUALITY STANDARDS AND ACCREDITATION FOR SUPPLIERS OF DMEPOS

The proposed rule provides that DMEPOS suppliers will be required to meet applicable quality standards specified by the Secretary of the Department of Health and Human Services. Although quality standards are set forth under existing law, the Program Advisory and Oversight Committee (PAOC) was mandated by the MMA to advise the Secretary with respect to certain functions, including (i) the implementation of the Medicare DMEPOS competitive bidding program; and (ii) the establishment of quality standards for DMEPOS suppliers. In fact, the PAOC has already held meetings concerning the development of new quality standards for suppliers. In addition, draft proposed quality standards are posted on the CMS web-site.

We have strong concerns about implementing a regulation that requires suppliers to meet quality standards that are in transition and have yet to be finalized. Public comments can only focus on existing quality standards, yet, we understand that new standards will be applied on top of the existing standards. This creates confusion and does not provide physicians and other impacted parties an opportunity for meaningful review and comment, as required by the Administrative Procedures Act. **We urge CMS to clarify the quality standards that suppliers must meet under the DMEPOS competitive bidding program, and if new quality standards are developed, CMS should issue a formal proposed rulemaking before moving forward with the DMEPOS competitive bidding program to ensure proper notice and opportunity to comment on any new quality standards.**

OPPORTUNITY FOR NETWORKS

CMS proposes that suppliers may form networks for DMEPOS bidding purposes. Such networks would be comprised of several companies joined together through a legal contractual relationship to submit bids for a product category under competitive bidding. CMS notes in the proposed rule that although no networks submitted bids for the demonstration project, it may be a useful option for suppliers in some cases.

We believe that this option would be very unrealistic for physicians who supply patients with DMEPOS. It would require: (i) expensive legal resources to set up the network while guarding against anti-competitive and other antitrust concerns, as well as (ii)

additional, significant administrative resources. Thus, it is unlikely that physicians would be able to take advantage of this option.

PHYSICIAN AUTHORIZATION/TREATING PRACTITIONER

The MMA mandate for the DMEPOS competitive bidding program allows the Secretary to establish a process by which a physician may prescribe a particular brand or mode of delivery of an item within a particular HCPCS code if the physician determines that use of the particular item would avoid an adverse medical outcome on the individual. CMS is proposing that the physician or treating practitioner would be able to determine that a particular item would avoid an adverse medical outcome, and that the physician or treating practitioner would have the discretion to specify a particular product brand or mode of delivery. The proposed rule further states that when a physician or other treating practitioner requests a specific item, brand, or mode of delivery, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the competitive bidding area (CBA) that can provide that item, or consult with the physician or treating practitioner to find a suitable alternative product or mode of delivery for the beneficiary.

We agree with CMS that the physician or treating practitioner should have the sole discretion to make these kinds of determinations about the individual medical needs of their patients and that suppliers should be required to furnish the particular item requested by the physician or treating practitioner.

The proposed rule further states that if, after consulting with the contract supplier, the physician or treating practitioner is willing to revise his or her order, that decision must be reflected in a revised written prescription. However, if the contract supplier decides to provide an item that does not match the written prescription from the physician or treating practitioner, the contract supplier should not bill Medicare as this would be considered a non-covered item.

We urge CMS to aggressively monitor contract suppliers to ensure that they do not: (i) unilaterally provide a different item than that specified in the physician's or treating practitioner's written prescription, thereby depriving patients of access to the most appropriate care, as determined by their physician or treating practitioner; and (ii) burden physicians with unnecessary or repeated requests to revise their orders, thus delaying necessary care for a patient and leaving a patient at risk of further injury.

REBATE PROGRAM

CMS is proposing to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid amount and the single payment amount.

Although we appreciate that beneficiaries have the opportunity to benefit from system-wide savings, the rebate program, as structured, is unfair to physicians. This would allow some physicians, who win a supplier contract award, to provide patients with a rebate, while other physicians, who do not win a contract, may be unable to provide their patients with a particular item of DMEPOS. **The inherent inequity in this system underscores the need to exempt physicians who provide their own patients with DMEPOS from the competitive bidding program.**

OFF-THE-SHELF ORTHOTICS

Items subject to the DMEPOS competitive bidding program would include, among others, off-the-shelf orthotics (OTS). CMS sets forth a proposed definition of OTS in the rule and states that the agency will consult with a variety of individuals, including experts in orthotics, to determine which items and/or HCPCS codes would be classified as OTS orthotics. **We encourage CMS to include medical organizations that represent physicians who provide off-the-shelf and custom-made orthotics in that consultation process, and we look forward to further clarification of this issue.**

MONITOR IMPACT OF DMEPOS COMPETITIVE BIDDING PROGRAM

We urge CMS to aggressively monitor the impact of the DMEPOS competitive bidding program on patient access to care. This is an entirely new and complex program that will significantly change the market dynamics for supplying DMEPOS to patients, and CMS must ensure that these market changes do not unintentionally limit the current variety of DMEPOS available to patients, thereby adversely impacting patient access to these important Medicare items.

In addition, CMS should ensure that patients have adequate choice of suppliers within their locality, in addition to any mail order options. Patients (especially when injured) or their caretaker should not have to travel long distances to obtain needed DMEPOS as this could put patients at risk and increase Medicare costs. **Thus, we urge CMS to ensure that suppliers are available across competitive bidding areas, and not concentrated in one or a few areas of a locale.**

We appreciate the opportunity to comment on this new Medicare competitive bidding program for DMEPOS, and look forward to working with CMS to address the critical issues raised above.

Sincerely,

American Academy of Nurse Practitioners
American Academy of Ophthalmology
American Academy of Physician Assistants
American Academy of Sleep Medicine
American Association of Orthopaedic Surgeons

American College of Osteopathic Surgeons
American College of Surgeons
American Gastroenterological Association
American Medical Association
American Occupational Therapy Association
American Optometric Association
American Osteopathic Academy of Orthopedics
American Physical Therapy Association
American Podiatric Medical Association
American Society of Cataract and Refractive Surgery
American Society of Hand Therapists
American Society of Plastic Surgeons
American Urological Association
Child Neurology Society
Medical Group Management Association
National Association of Spine Specialists

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June 26, 2006

Mark B. McClellan, M.D., PhD
Administrator
Centers for Medicare & Medicaid
Dept. of Health & Human Services
7500 Security Blvd.
Baltimore, MD 21244

Attention: CMS-1270-P

Dear Mr. McClellan:

As a Certified Pedorthist who has been in practice for 10 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would implement a new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). In addition to being a Certified Pedorthist, I am also an ABC Certified Fitter of Orthotics and a Fitter of Breast Prosthetics and Bras.

Presently, I am experiencing difficulty with the Medicare Plus Blue program in Michigan which allows Blue Cross Blue Shield of Michigan to oversee this federally funded Medicare program. I am located in the Upper Peninsula and BCBS awarded all DMEPOS supplies to Wright & Filippis, excluding all other DME providers. Wright & Filippis, as I have recently been informed, is on the Board of Directors for BCBS of Michigan and ABP, the facilitator for this program, is a subsidiary of Wright & Filippis as stated on their reimbursement checks.

I visit outlying clinics as well, which are in excess of 50 miles from the closest Wright & Filippis office, but ABP will not make an exception even for these areas. Since I am out-of-network, even though I've been seeing many of these patients for 5 to 10 years, they are no longer able to see me unless they pay 50% out-of-pocket. Now, this just doesn't seem to make a lot of sense to me.

The economy being such that it is, seems to be putting many small businesses out-of-business. I recently had to close my store and am now employed by a podiatrist. However, I have to reapply for a new DMERC number for my breast and orthotics fitter claims since this is not covered under the scope of practice for a podiatrist. I do

understand this and I am in the process of doing the same. However, I feel that in order to cut insurance costs, you will be causing many companies to either go bankrupt or quit business and allow a large conglomerate to monopolize the DME industry. I do feel this should be investigated and re-evaluated. I accept assignment from DME and BCBS so I guess I don't see how any money is being saved. Plus, many of my patients, especially women who have had mastectomies, do not feel they get a proper fit and many of them claim that they are not even being measured. They do not want to go to Wright & Filippis, but they have no other choice.

I hope you will not allow this situation to continue. Many businesses are being hurt by this and one large corporation is being allowed to grow even larger.

Thank you for your anticipated cooperation in this very important matter.

Sincerely,

Sharon L. Tabor

Sharon L. Tabor, CPed/CFo

Cardiovascular Institute OF THE SOUTH

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June 26, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:

The process of competitive bidding by CMS that may effect how I, as a physician, am able to deliver healthcare has come to my attention. As a cardiothoracic and vascular surgeon with over 20 years of clinical experience, I have relied heavily on the wound VAC from KCI in San Antonio, TX for almost all of my surgical wound complications and even more so recently in our work to heal wounds and save limbs in the treatment of critical limb ischemia (CLI) where > 80% of all amputations are preceded by an open wound or ulcer. The clinical and economics of CLI and amputations are greatly misunderstood and underappreciated. I will enclose some recent work we have done on this subject. There are an estimated 220,000 - 240,000 amputations yearly in the US and Europe and the estimated costs of CLI yearly are between $10-20 billion US dollars. Unfortunately we are limited in the number of effective clinical tools to treat the CLI and especially the wound complications after complex surgical procedures.

I am concerned that the CMS competitive bidding may result in an inability to recommend the highly effective VAC therapy in my patients despite the fact that there is mounting clinical evidence in its safety and efficacy in treating this patient population. VAC therapy has been scientifically proven to heal wounds and save legs and has extensive worldwide positive results. I know of no other as effective treatment for my patients and improved outcomes always translate into saved dollars and cost effectiveness.

I have knowledge of the Blue Sky Versatile 1 medical product that has claims to delivering negative pressure wound therapy but I am not aware of any scientific data regarding its merits. I do not believe this is an equivalent therapy to the VAC and if forced to use this therapy versus VAC therapy, I am concerned that

the patient outcomes will be negatively impacted. Simply stated, I do not think the Blue Sky technology is nor any other similar product is as safe and effective as the well-proven VAC therapy.

It is my strong suggestion that CMS strongly consider delaying the competitive bid process in this clinical area until more information can be accumulated comparing similar therapies. New therapies come and go but only therapies that have appropriate scientific data and a long-term positive track record should be involved in any competitive bidding when clinical outcomes, lives and limbs of our patients are at stake. I am concerned about the lack of data with the Blue Sky product and I am keenly aware of my results with the wound VAC and their proven results. I respect the work of the CMS and respectfully make these comments and suggestions.

Sincerely,

David E Allie, MD
Director of Cardiothoracic and Endovascular Surgery
Cardiovascular Institute of the South/Lafayette

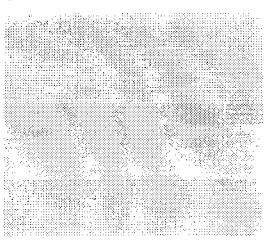
DEA/kt

Enclosures

Critical Limb Ischemia: A Global Epidemic A Critical Analysis of Current Treatment Unmasks the Clinical and Economic Costs of CLI

David E. Allie, MD; Chris J. Hebert, RT, R-CIS; Mitchell D. Lirtzman, MD; Charles H. Wyatt, MD; V. Antoine Keller, MD; Mohamed H. Khan, MD; Muhammad A. Khan, MD; Peter S. Fail, MD; Krishnamoorthy Vivekananthan, MD; Elena V. Mitran, MD; Sonja E. Allie, MBA; Gary Chaisson, RT, R-CIS; Samuel J. Stagg, III, MD; Adam A. Allie, MS; Michael W. McElderry, MD; Craig M. Walker, MD

KEYWORDS
Critical Limb Ischemia, Current Treatment, Primary Amputations, Interventional Revascularization, Costs



Abstracts

Background: Multiple reports document the higher costs of primary amputation (PA) compared to infrainguinal bypass surgery (IBS). Recent reports document 40-50% cost-effectiveness for percutaneous transluminal angioplasty (PTA) compared to IBS. The literature suggests appropriate initial treatment for critical limb ischemia (CLI) to be IBS = 38%, PTA = 28%, and PA = 16%. The encouraging 6-month Laser Angioplasty for Critical Limb Ischemia (LACI) 93% limb salvage rate prompted an independent CLI and LACI clinical and economic analysis. ***Methods:*** Between 1999-2001 a reference amputation population (RAP) of 417 patients with at least one infrainguinal amputation were identified from a 2.5 million patients Medicare/insurance dataset. Clinical data and all medical cost claims for 18 continuous months, 12-month prior and 6-month post-amputation, were analyzed for PTA, IBS, and PA treatment pathways. Based on multiple assumptions and the LACI phase II results, economic outcomes were used for a LACI pathway analysis compared to PTA, IBS and PA pathways by substituting the LACI trial pathway as the initial treatment in lieu of the RAP actual treatment. ***Results:*** Initial treatments for CLI RAP were PA = 67%, IBS = 23%, PTA = 10%; A majority of wound complications (80%) and myocardial infarction 7/9 (77.7%), stroke 13/16 (81.2%), and death 2/2 (100%) occurred in the PA RAP. Only 35% of the RAP had an ankle brachial index (ABI) and only 16% angiography before PA. 227/417 (56%) of the RAP had multiple procedures. Average total costs / patient = $31,638 without LACI and $25,373 with LACI. Average savings/patient with LACI = $6,265. ***Conclusion:*** The most common current treatments in the US for CLI are still characterized by high rates of primary amputations, multiple procedures, and high rates of procedure-related complications. Despite the limitations and assumptions of this analysis, the utilization of a LACI pathway first revascularization treatment strategy may provide clinical and economic cost savings in treating patients with CLI.

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Introduction

Critical limb ischemia (CLI) remains incompletely characterized in the clinical literature. Therefore information, knowledge, and awareness surrounding the clinical impact of CLI remains obscure. There exists an even greater paucity of data and less understanding regarding the clinical costs of treating CLI and amputation to the patient, family, and to society. It is estimated that between 220,000 - 240,000 major and minor lower extremity amputations are performed in the United States (US) and Europe yearly for CLI[1-5]. In the US the amputation rate has increased from 19 to 30 per 100,000 persons years over the last two decades primarily due to an increase in diabetes and advancing age[6-7]. Despite advances in cardiovascular treatment, in patients over 85 year of age an amputation rate of 140 per 100,000 persons/year has been reported with a primary amputation (PA) still carrying an excessively high mortality rate of 13-17%[7-9]. In the highest risk patients, 30-day periprocedural mortality after amputation can range from 4 - 30% and morbidity from 20 - 37%[10], because many end-stage CLI patients will suffer from sepsis and progressive renal insufficiency. Successful rehabilitation in patients after below knee amputation is achieved in less than two-thirds and in less than one half after above knee amputations and overall, less than 50% of all patients requiring an amputation ever achieve full mobility[11-14].

CLI: The Natural History

Wolfe *et al.* classically described the natural history of CLI in a collation of 20 publications on 6118 patients by stratifying them into a low-risk cohort of 4089 patients (rest pain only and ankle pressure > 40mmHg) and a high-risk cohort of 2029 patients (rest pain and tissue loss with or without ankle pressure < 40mmHg)[15]. At 1 year, 95% of the high-risk group and 73% of the low-risk group required a major amputation without revascularization. A 75% limb salvage rate was achieved at 1 year in the high-risk group with revascularization. The cumulative probability of survival for the entire group was 74% at 1 year, 58% at 2 years, 56% at 3 years, 48% at 4 years, and 44% at 5 years. Multiple reports have repeatedly documented the poor overall prognosis for the CLI patient with mortality rates greater than 50% after three years[16-17]. Within one year of the diagnosis of CLI, 25% will require a major amputation and another 25% will be dead[5,18].

Interestingly, recent reports by Panayiotopoulos *et al.* and Kalra *et al.* have shown significantly improved long-term survival after revascularization and limb salvage as compared to CLI patients following revascularization failure and amputation[6,19]. Statistically significant five-year survival rates were achieved after limb salvage in the Kalra *et al.* report[6]. Clearly the clinical costs to the CLI patient are extremely high underscoring the need for a characterization of the clinical and economic costs involved in treating CLI especially considering the incidence of CLI is expected to significantly increase yearly approaching global epidemic proportions.

CLI: The Data?

Inherent problems in obtaining pertinent economic outcome information in CLI include a lack of standardization of reporting, definitions, hospital and payer charges and costs, changing technology and the lack of a consensus CLI treatment pathway between clinicians and institutes in both the US and Europe[5]. CLI is often treated differently by each medical specialty and treatments can vary between geographical locations. Several European CLI economic reports appeared in the late 1980's and early 1990's and were included in the cost analysis of the TransAtlantic Inter-Society Concensus (TASC) document reported in January, 2000[16]. This document though did not include any of the new technologies and strategies used today in a more "modern" revascularization approach to treating CLI, limb salvage, and Primary Amputation (PA). Unfortunately, since 2000, few data have reported the clinical and economic costs of CLI further demonstrating a need for information. Furthermore, divergent reports exists in the literature regarding the economic treatment costs of infrainguinal bypass surgery (IBS) and PA with sparse data available reporting the costs of percutaneous revascularization procedures for treating CLI including percutaneous transfemoral angioplasty (PTA) or excimer laser revascularization

The purpose of this analysis was to determine the clinical characteristics of treating CLI in a more "modern" US patient population and to determine the potential to improve clinical and economic care with the use of excimer laser revascularization (Laser Angioplasty for Critical Ischemia or LACI) in the treatment of CLI. To this end, we investigated standard-of-care clinical treatment pathways of patients with CLI; examined population characteristics and actual treatment patterns of a reference population of 417 CLI patients who ultimately experienced amputations; and estimated the expected clinical impact on their care if a LACI first pathway had been used in lieu of the first PTA, IBS, or PA. During this study, we examined 18 months of medical claims prior to each patients qualifying amputation from a 2.5 million patient Medicare and insurance dataset, and identified incidence and costs associated with three clinical treatment pathways, including PTA, IBS, or PA. The LACI assumptions were based on the Laser Angioplasty for Critical Limb Ischemia (LACI) Phase II clinical outcomes.

Methods

Study Population

Between 1999-2001, a Reference Amputation Population (RAP) of 417 patients with at least one infrainguinal amputation was identified from a data source of 2.5 million patients in a large Medicare and commercial insurance dataset. Clinical data elements evaluated included all patient records covering inpatient hospital care, in patient rehabilitation, skilled nursing services, hospital patient care (including ambulatory surgery), physician data, pharmacy claims and other outpatient services including podiatry and home health. The data review and analysis was conducted by Strategic Health Resources®, an independent consulting and data-mining firm, and commissioned by The Spectranetics Corporation. To qualify as part of the RAP patients had to meet all of the following criteria:

A. A lower amputation of any kind during the final six months of the 18-month study period. The final amputation during this period became the "qualifying amputation" for the purpose of establishing

the study period. This resulted in a data evaluation for 18 continuous months on each RAP, 12-month period prior and 6-month post amputation.

B. Continuous insurance eligibility for 18 months prior to the date of the qualifying amputation.

C. Documented CLI based on having at least one qualifying diagnosis or specified combination or diagnosis and procedure codes in the patients record prior to or concurrently with the amputation.

To be included in the RAP at least one of the following diagnostic criteria had to be documented:

A. Documentation of lower extremity atherosclerosis with rest pain or ischemic ulceration or gangrene; or,

B. Documentation of gangrene alone, only if it occurred in conjunction with hospital records specifying amputation associated with peripheral vascular disease (PVD), or,

C. Documentation of diabetes with manifestation of PVD, if and only if it was present as the principle diagnosis for the qualifying amputation.

To avoid inadvertent inclusion of patients whose amputations could relate to non-CLI etiologies, specific exclusions included:

A. All patients with a cancer diagnosis.

B. Any "accident or injury" codes.

C. All patients with a paraplegia or quadriplegia code.

Utilizing these criteria, a RAP of 417 CLI patients was obtained with an average age of 70.9 years. The RAP was 59% male and overwhelmingly 82% diabetic.

CLI Treatment Pathways Categories

To characterize the process of care, we defined treatment care pathways identifying common sequences of key procedures and grouped them according to the first index key procedure recommended for CLI treatment including PA, IBS, and PTA. We identified common sequences of subsequent key procedures and grouped them into nine treatment care pathways (Table 1).

Based on our comparisons of recommended treatment of CLI to the clinical pathways identified in the study, it appears that PA was used to a much greater extent than the clinical literature suggests, while PTA and IBS procedures appear underutilized. Specifically, 67% of patients in our study population had a PA as their first index treatment, while the literature suggests this approach would be best for approximately 16% of CLI patients[20-23]. In contrast, 23% of patients had an IBS as their first CLI treatment, while the clinical literature suggests this approach for an estimated 38%[20-23]. Likewise, in the RAP, 10% of CLI patients had a PTA first treatment, while the clinical literature recommends this approach for an estimated 28%[20-23].

Table 1. Treatment Care Pathways.

Pathway Group	Pathway Description	# Patients	% Total Population
Amputation First	Single primary amputation	190	46%
	Multiple primary amputations	67	16%
	Primary amputation + additional revascularization procedures	24	6%
Bypass First	Primary bypass followed by single amputation	56	13%
	Primary bypass + revisions and additional revascularization procedures	18	4%
	Primary bypass followed by multiple amputations	22	5%
PTA First	Primary PTA followed by single amputation	17	4%
	Primary PTA + additional revascularization procedures	7	2%
	Primary PTA followed by multiple amputations	16	4%
		417	100%

Claims Analysis

For each of the 417 CLI patients in the RAP, all claims for 18 continuous months *prior* to the qualifying amputation were evaluated. For patients with multiple amputations, all claims for 18 months prior to the first qualifying amputation occurring during the final six months of the study period, continuously through the last qualifying amputation were included. All claims related to procedures for the treatment of CLI were evaluated and divided into the following categories:

- ***Diagnostics and Evaluation*** - PVD assessment and patient evaluation for treatment prior to or concurrent with the first key procedure - identified by best practice clinical algorithms taken from literature review.
- ***Pre-op care*** - Visits coded as pre-op exams prior to a key procedure.
- ***Revascularization procedures/amputations*** - Any amputation, IBS, or PTA ("Key Procedures").
- ***Key Procedure Episode*** - Services provided during the outpatient or inpatient stay (including rehabilitation) for any key procedure, excluding dialysis-related care.
- ***Post-Procedure care*** - Defined as routine post-procedure care (relevant physician visits, home health, revisions, and appropriate services) to amputated stumps, verified through discussions with clinicians.
- ***Procedure-related complications*** - Defined as all complications occurring within closely defined time periods following a relevant key procedure, or infections. Complication definitions were taken from the literature analysis and verified through discussions with clinicians.
- ***Pharmaceutical use*** - Defined as CLI-related medications taken during the study period.

Results

Clinical Data Analysis

Procedure-related complications were a frequent occurrence in the RAP. Overall 290 complications were identified with 80% associated with an amputation. Wound infections and stump dehiscence were the most frequent complications and myocardial infarction, stroke and death were associated with amputations (Table 2). Multiple amputations and revascularization were also frequent in the RAP (Table 3).

An analysis of the CLI patient noninvasive and invasive diagnostic pre-procedural work-up prior to a PA was performed. Shockingly, less than one half (49%) of the RAP had ***any*** diagnostic vascular

Table 2. Number of Complications Associated with each Type of Key Procedure.

Complication Category	Key Procedure Group: Amputation	Bypass Graft	Combo with Amp	PTA	PTA-Bypass Graft	Grand Total
Wound Infection	47	4	1	2		54
Complication with stump	53					53
Major Infection - Sepsis	32	3	3			38
Major Infection - UTI	20	1	1			22
Early Graft Occlusion/Malfunction	9	4	2	2	1	18
Major Infection - Pneumonia	14	3				17
Deep Vein Thrombosis	11	2		3		16
Stroke	13	2		1		16
Procedure-Related Bleeding/ Wound Healing	9			2		11
Myocardial Infarction	7	1	1			9
Renal Failure	4	1	3			8
Leg Edema	4	1		1		6
Myointimal hyperplastic lesions	3	2	1			6
Other Complication	4	1				5
Graft Infection		2	1			3
Hematoma Puncture Site		2	1			3
Aortaenteric fistula		2				2
Death	2					2
False Aneurysm			1			1
Grand Total	232	31	15	11	1	290

Table 3. Average Revascularizations and Amputations per Patient by Pathway.

Pathway	Average Number of Procedures per Patient: PTA	Bypass	Amp	PTA-Bypass Graft	Combo Including Amp[1]	Grand Total
Single primary amputation			1.0			1.0
Multiple primary amputations			2.3			2.3
Primary amputation + additional revascularization procedures	0.2	0.6	2.4	0.042	0.4	3.6
Primary bypass followed by single amputation		0.8	0.8		0.2	1.8
Primary bypass followed by multiple amputations		0.9	2.0		0.1	3.0
Primary bypass + revisions and additional revascularization procedures	0.1	1.9	1.5		0.3	3.9
Primary PTA followed by single amputation	0.9		0.9		0.1	1.9
Primary PTA followed by multiple amputations	0.9		2.1		0.1	3.1
Primary PTA + additional revascularization procedures	1.2	0.7	1.1	0.063	0.1	3.1
Grand Total	0.1	0.3	1.4	0.005	0.1	1.9

[1] A procedure is included in the "Combo" column if two or more procedures were performed on the same day, or if they were performed during the same admission and data to separate them was insufficient.

evaluation prior to a PA with the incidence of ABI, angiography and MRA being 35%, 16%, and 1% respectively (Table 4-5).

Clinical Practice Analysis

An evaluation of the physician and medical service providers / specialties seen by the RAP during and between episodes of CLI treatment was obtained (Table 6). The percentage of radiology, cardiology, and vascular surgery services provided were 39%, 26%, and 21% respectively.

LACI Clinical Outcomes

The Laser Angioplasty for Critical Limb Ischemia (LACI) trial was a prospective registry to evaluate limb salvage rates in poor or non-surgical candidates (patients who were likely to receive an amputa-

Table 4. Vascular Assessment Prior to First Key Procedure.

First Key Procedure	# Patients with Vascular Assessment	Total # Patients in Pathway Group	Percent of Patients Receiving Vascular Assessment Before First Key Procedure
Amputation	138	281	49%
Bypass	67	96	70%
PTA	33	40	83%
Total	238	417	57%

Patients are considered to have had vascular assessment if a qualifying ICD-9 procedure code or CPT Code appears anywhere in the patient's claims records during the study period on or before the date of the first Amputation, Bypass Graft, or PTA.

tion) who underwent excimer laser assisted revascularization. The LACI phase II trial enrolled 145 patients with 155 critically ischemic limbs (rest pain and/or ischemic ulceration with established tissue loss) with 423 lesions treated with excimer laser at 15 US and German sites[25]. Periprocedural results included no deaths or acute limb ischemia and a 96% laser/PTA success rate with 90% receiving "straight-line follow" to the foot. Results at 6 months included only a 2% requirement for IBS, 16% overall secondary reintervention rate, and 93% limb salvage rate. The LACI phase II study demonstrated that laser assisted endovascular intervention in this fragile CLI population results in excellent limb salvage rates with low complication and secondary intervention rates without adding excessive clinical risks.

CLI Treatment Pathways with LACI

As mentioned above, all patients treated in the LACI II trial were poor surgical candidates who would have required PA if revascularization was not performed. As such, the LACI patient population may resemble this RAP series. These 417 patients were analyzed to impute the potential outcomes if the LACI procedure were performed. Potential outcomes of the LACI procedure were defined in three pathways: LACI with total limb retention; LACI with a reintervention; and LACI, with or without a reintervention, followed by an

Table 6. Mix of Medical Service Providers/Specialties Rendering Care.

Provider Category	# Patients	% Patients Having a Visit [1]	Average # Visits
Home Health Care	162	53%	20
Internal Medicine	120	39%	9
Radiology	118	39%	6
DME/Prosthetics/Supplies	100	33%	4
Independent Lab	96	31%	5
Other	95	31%	3
Nephrology	87	29%	21
Cardiology and Cardiovascular Disease	78	26%	7
General Surgery	72	24%	5
Laboratory	70	23%	5
Family/General Practice	65	21%	5
Emergency Medicine	64	21%	2
Cardiovascular/Thoracic/ Vascular Surgery	63	21%	3
Ambulance/Transportation	63	21%	5
Pathology	58	19%	5
Podiatry	58	19%	4
Anesthesiology	54	18%	3
ER	49	16%	2
Surgery	43	14%	2
Orthopedics/Orthopedic Surgery	33	11%	4
Infectious Diseases	33	11%	8

[1] Percentages are based on the 305 patients (of 417 in study population) who had provider visits during and after the first episode of care for a PTA, Bypass Graft, or Amputation.

Table 5. Vascular Assessment Prior to First Key Procedure: Detail.

Pathway Group	Assessment Type	# Patients [1]	# Patients with Vascular Assessment	% of Assessed with Type of Assessment	Total # Patients	% of Total
Amputation First	ABI	98	138	71%	281	35%
Amputation First	Angiography	45	138	33%	281	16%
Amputation First	MRA	3	138	2%	281	1%
Amputation First	Other	74	138	54%	281	26%
Bypass First	ABI	48	67	72%	96	50%
Bypass First	Angiography	42	67	63%	96	44%
Bypass First	MRA	1	67	1%	96	1%
Bypass First	Other	44	67	66%	96	46%
PTA First	ABI	25	33	76%	40	63%
PTA First	Angiography	16	33	48%	40	40%
PTA First	MRA	1	33	3%	40	3%
PTA First	Other	19	33	58%	40	48%

amputation. Based on LACI Phase II results, we allocated the LACI patients into the three pathways as follows:

- LACI with total limb retention (62%)
- LACI + downstream reintervention (13%)
- LACI +/- downstream reintervention + amputation (25%)

Thus, the 65% of patients converting to LACI are expected to have the following distribution:

- 40% LACI with total limb retention
- 9% LACI + downstream reintervention
- 16% LACI +/- downstream reintervention + amputation

Accordingly, we estimate the average CLI patient costs treated with LACI in lieu of the first PTA, IBS or PA for the three LACI pathways. The cost for LACI with total limb retention was developed from the following components:

- The cost of "simple" PTA (with serious adverse events and a length of stay of four days or less);
- Additional physician and outpatient facility reimbursement under standard Medicare policy for use of the laser (we assume that commercial insurers will adopt the same differential on average);
- Normal follow-up care (for a simple PTA);
- An allowance for treatment costs of SAE in patients who did not experience post-hospital reintervention or amputation. (Post-hospital reintervention or amputation moves the patient to a different pathway);
- An allowance for treatment costs of subsequent lesions, which we identified in 6.5% of our study population. (Use of LACI in one lesion is assumed to have no impact on the development of disease in another lesion).

Economic Data Analysis

The total average cost of each of the nine CLI treatment pathways was calculated beginning with the first key procedure and included all services, complications, procedures and related costs.

Applying the LACI assumptions and calculations, we estimated the average CLI patient treated with LACI in lieu of first PTS, IBS, or PA would generate $20,487 in medical costs for CLI-related procedures and costs over a period of six months during and after the LACI treatment. A detailed breakdown of costs by pathway was calculated for the LACI first group as compared to the standard therapies evaluated in the RAP group (Tables 7 and 8).

Across the entire RAP, the average costs per patient for CLI-related treatment was $31,638. Extrapolating the data from the LACI trial and applying it to 65% of the RAP group, it is estimated that use of LACI would result in an average cost per CLI patient of $20,487 therefore generating a savings of $6,265 per patient across the entire CLI population (Table 9).

Discussion

Clinical CLI data on the treatment of CLI suggest that almost all patients should undergo a vascular assessment and a high percent of CLI patients should be recommended revascularization to avoid amputation. Despite this noble ideal, an analysis of actual reimbursement claims data suggests that a significant majority of patients in the U.S. are still "treated" with primary amputation (PA). The clinical and economic costs of PA as a standard therapy are high, when compared to revascularization and limb salvage[26-29].

In 1978, Stoney *et al.* proposed a PA as the best cost-effective solution to treating CLI[26]. However, it has never been demonstrated scientifically that a PA is a cost-effective solution in CLI. The costs of a PA reported between 1985-1994 were found to vary from $12,397 by Yin *et al.* who excluded rehabilitation to $40,563 ± $4,729 reported by Mackey *et al.* in 1985 who included rehabilitation and longer term follow-up[12,27].

In 1997, Luther *et al.* analyzed the cost of PA in a population of institutionalized, nursing home, patients versus previously active noninstitutionalized patients[28]. The costs were highly variable from $13,000 in the institutionalized to $70,000 for the noninstitutionalized PA patient still living at home. The professional nursing care costs after an amputation in the US home has been estimated at $100,000 per year[29]. Johnson *et al.* attempted to characterize the costs to the patient and family of home alterations to accommodate an amputee and item ranged from $700 for a toilet seat to $25,000

Table 7. Average Cost per Patient - LACI First Pathways.

LACI First	Pathway	Dx/Eval and Pre-Op Care	Revascularization and/ or Amputation	Post-Op Care	Complications	CLI-Related Rx	Grand Total
40% LACI1	Primary LACI with total limb retention	$160	$5,213	$217	$0	$256	$5,840
9% LACI2	Primary LACI + Reintervention	$352	$44,438	$367	$593	$3,487	$49,237
16% LACI3	Primary LACI with or without reintervention + Amputation	$206	$36,699	$652	$784	$2,944	$41,285
65% LACI	First Subtotal	$197	$18,315	$346	$271	$1,359	$20,487

Table 8.

Clinicale Pathway	No of Patients	% of Pop.	Dx/Eval and Pre-Op Care	Revascularization and/ or Amputation	Post-Op Care	Complications	Related Rx	Total Cost
Amputation First	281	67%	$31	$22,837	$276	$1,672	$1,474	$26,289
Bypass Graft First	96	23%	$116	$37,271	$668	$1,727	$3,815	$43,598
PTA First	40	10%	$206	$35,922	$652	$784	$2,944	$40,508
If LACI First	N/A	65%	$197	$18,315	$346	$271	$1,539	$20,487

Table 9.

LACI Financial Impact Summary Pathway			Cost/Patient	% of Population Study Pop	With LACI	Converted to LACI	Savings with LACI
Amputation First	75%	LACI Use					
		Amp First Subtotal	$26,289	67%	16,8%	50,5%	$5 802
Bypass Graft First	50%	LACI Use					
		Bypass First Subtotal	$43,598	23%	11,5%	11,5%	$23 211
PTA First	35%	LACI Use					
		PTA First Subtotal	$40,508	10%	6,2%	3,4%	$20 021
LACI First		LACI First Subtotal	$20,487		65,4%		

Summary

Average Total Cost Per CLI Patient	
W/out LACI	$31,638
With LACI	$25,373
Average Savings per CLI Patient with LACI adoption	$6,265

[1] Estimated Total Cost per CLI patient, assuming LACI is used 65% of CLI patients, as detailed in model

Percentages DNF due to rounding

for concrete wheelchair ramps[30]. Clearly there are indications that amputations result in a high cost to society by requiring long-term care for the amputees that cannot be rehabilitated to mobility, especially in the elderly age patient[11-14,29-30].

PA is associated with high mortality and morbidity and the functionality and quantity of life is reduced for the amputee[30-32]. IBS and resultant limb salvage have been reported as excellent solutions for treating CLI. Reported advantages of IBS versus PA for CLI include: significant limb salvage rates, decreased 30 day mortality and morbidity, improved functional status and quality of life, cost effectiveness, and improved long term survival[6,19,31,32-33]. Reports by Thompson *et al.*, Chetter *et al.*, and Johnson *et al.* have consistently shown improved functional outcomes and quality of life scores in patients after limb salvage versus amputations[30,34-35].

In 1992, Cheshire *et al.* reported that IBS, including secondary procedures, was 47% more cost effective than PA when using autologous vein and 6% more cost effective when utilizing a prosthetic conduit[35]. In 1997, Panayiotopoulos *et al.* reported PA as three times more costly that IBS and limb salvage in both diabetics and nondiabetics with costs being PA = $24,460 and IBS = $8,640[36]. Several other reports document the costs of successful IBS as between $16,000 and $20,000[37-40]. Mackey *et al.* reported a 2 year follow up cost for successful IBS of $20,300 if uncomplicated but quoted costs of $42,000 when secondary amputations were required[13]. Korn *et al.* reported the IBS results in CLI patients with end stage renal disease (ESRD) on dialysis and reported 67% 1-year limb salvage rate. Cost analysis was determined to be $44,308 per year of limb salvage[41].

Kalra *et al.* reported the long-term survival after IBS (pedal bypass) in 256 CLI patients. Amputation and ESRD predicted higher mortality ($p = 0.014$, $p = 0.0001$, respectively) and overall 5-year survival rates after IBS and limb salvage were 60%[6]. The 5-year survival rate after an amputation was 26% therefore confirming earlier reports and documenting significantly worse long-term survival for patients suffering an amputation versus those CLI patients achieving limb salvage[19].

Data has only recently been reported on nonsurgical revascularization for treating CLI, despite a greater than fivefold increase in the use of PTA[42]. These early reports evaluate PTA only procedures therefore a cost analysis of more "modern" CLI treatment with the use of stents, plaque excision, endopharmacotherapy, or laser (LACI) does not exist. In 1995, Hunink *et al.* compared the in hospital costs only for CLI patients treated with PTA or IBS[37]. The costs of PTA and IBS were respectively $11,353 ± $7,658 and $15,059 ± $7,313 if uncomplicated. Additional revascularization procedure increases the costs by a mean of $9,003 in both groups and any amputation or wound debridement further increased the costs by a mean of $24,766 ± $2,241. In 1998, Jansen *et al.* compared IBS and PTA in hospital costs in 583 patients for CLI[43]. The mean cost of PTA and IBS were $8,855 and $12,550 respectively for uncomplicated procedures with additional costs of $9,345 to $11,675 for nonfatal and fatal complications. In 2000, Laurilla *et al.* reported a 41% cost effectiveness of PTA versus IBS in 772 CLI patients[44]. The mean costs of PTA were $8,855 versus $16,470 for IBS. The cost of a reoperation-free year was $4,466 with PTA and $7,748 with IBS and the costs of a leg-year saved at 3 years was reported at $3,877 for PTA and $6,055 with IBS. These recent reports consistently demonstrate the cost-effectiveness of PTA versus IBS.

A comprehensive review of the clinical and economic CLI literature has lead us to several conclusions including:

- There is no evidence that a PA is an overall cost effective treatment for CLI or is more cost effective than revascularization with or without limb salvage. A PA should only be considered in the already institutionalized, immobile advanced CLI patient at high risk for IBS or PTA.
- PTA is more costs effective than IBS.
- PA, IBS, and PTA all require frequent secondary procedures and/or amputations, which are associated with added overall costs.
- There exists no consensus CLI treatment pathway.
- There remains poor understanding of the overall clinical and economic impact of CLI or amputation to the patient, the family, and to society.

• There exists a need for clinical information and education and even greater need for economic data regarding the treatment of CLI. This independent 2.5 million US patient dataset analysis revealed several interesting clinical practice patterns. An extraordinarily high percentage, 67%, of the RAP received PA as their index or first treatment recommendation. The first treatment recommendation for IBS and PTA were 23% and 10% respectively. This RAP's initial treatment recommendation differed drastically from a 1995 British audit in which 67% of their patients received revascularization. The index procedures in the British series consisted of 38.5% IBS and 28.5% PTA, and only 16% PA[22-23]. A similar report from the LEICESTER ROYAL Infirmary revealed a PA rate of only 10% with revascularization attempted in 79% of 188 CLI patients[24]. It remains disturbingly unclear as to the reason for these differences in clinical practice patterns between our RAP versus other published series.

Further insight into clinical practice patterns can also be obtained from a 1997 report by Hallett *et al.* in the Olmstead County Research Study evaluating IBS, PTA and PA between 1973 and 1992 in a defined community. Approximately 50% of the CLI patients presented with advanced Rutherford Class 4-5-6 and of those requiring amputation, 60-70% were as PA with no vascular assessment or revascularization procedure being performed therefore implying that CLI patients worldwide are treated similarly to the Olmstead County report and this RAP[47].

Additional clinical practice pattern data was analyzed in our RAP regarding the CLI diagnostic work up and physician and healthcare provider consultations. An extraordinarily low percentage of CLI patients, 49% of this RAP, had any vascular assessment before a recommendation for PA. The RAP pathway had a recommendation of ABI and angiography in only 35% and 16% respectively before a first treatment recommendation for PA. This clinical practice pattern is especially disturbing when considering the excellent limb salvage results reports with pedal bypass, PTA, and LACI[23,33,45]. A 50% limb salvage rate has even been reported with "blind exploration" and pedal bypass in severe CLI patients without identifiable distal bypass targets during angiography[50].

From the economic standpoint, this practice pattern is also disturbing when considering that the total costs of treating CLI in the US alone is estimated at between $10-20 billion per year[3]. It is estimated that just a 25% reduction of amputations could save $2.9-3.0 billion in US healthcare expenditures[3]. Further economic data supporting limb salvage include the known higher costs of amputations and related periprocedural rehabilitation as compared to IBS and PTA and limb salvage. Additionally, the annual cost of follow-up or long-term care and treatment for a patient has been estimated at approximately $49,000 after an amputation and $600 after limb salvage after PTA or IBS[3,16,48-49].

Study Limitations

• The 18-month study period represents a retrospective cross-section of time. The analysis did not prospectively collect data on the procedures included in the RAP or LACI patient populations.

• Procedure coding is not lesion or limb specific.

• Rates and costs of complications in the RAP may be understated because inpatient records typically contain many diagnosis codes and the first few codes are normally devoted to the underlying condition and major comorbidities.

• Procedure and CPT codes are specific to problems with an amputated stump, it was possible to identify amputation-related complications more thoroughly than PTA or IBS complications.

• The RAP analysis did not include CLI patients who did not receive an amputation.

• The RAP and LACI trial patients were both highly selected and different groups, not truly comparable groups, therefore obviating any definitive conclusions.

• There were significant assumptions made regarding the LACI phase II trial and their applicability to this RAP therefore conclusions based on these calculations are subject to bias.

Conclusion

In conclusion, the clinical and economic costs and consequences of CLI and amputations are both staggering and unappreciated and it is likely that CLI is approaching global epidemic proportions. Strong clinical and economic data currently exists supporting an aggressive approach for revascularization and limb salvage in almost every patient with CLI. A reasonable assumption for this study's disturbing clinical practice pattern favoring a PA versus a revascularization first pathway is that many CLI patients are seen first, or referred first, to clinicians who cannot provide revascularization and therefore provide a pathway for amputation. As is true in most global healthcare epidemics, if a positive impact is to be made then it must start with information and education and progress to global commitments to enhance awareness and provide clinical and economic cost effective treatment. Despite the stated limitations, assumptions and potential biases of this analysis, the utilization of a LACI pathway first treatment strategy may provide clinical benefits and economic cost savings in treating patients with CLI.

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June 20, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am concerned regarding Medicare's consideration to implement a competitive acquisition program for vendors of durable medical equipment. As an Occupational Therapist, I evaluate and supply pre-fabricated on a daily basis to surgical and medical patients. As a trained professional, I can fit and distribute an effective and comfortable splint without any delay. This allows adequate healing and compliance from the patient, minimizes complications, and prevents problems as seen by ill-fitted splints.

Appropriately fitted splints in a timely fashion will save healthcare dollars. It is felt that our splint application, pricing, education and instruction are appropriate and necessary for Care of our Medicare and Medicaid patients. Untrained individuals are not able to provide this healthcare service that will maintain or obtain functional outcomes in their hand use with activities of daily living.

Thank you for your time and attention to this important matter.

Sincerely,

JoAnn Shropshire, OTR/CHT
Occupational Therapist/ Certified Hand Therapist

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Caribbean Home Medical Equipment, Corp

Venta y Alquiler de Equipos Medicos
8155 Calle Concordia Suite 104
Ponce, P.R. 00717-1599
Tel/Fax: (787) 284-5058

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270P
PO Box 8013
Baltimore, MD 21244-8013

Dear Sirs,

I am writing this letter to express that one of the reasons why we should not be considered in the competitive bidding process or at least not to be considered in the first 10 MSA's (Metropolitan Statistic Area); is the language barrier that currently exists between Puerto Rico and the United States, given that the majority of the islanders are native Spanish speakers. And the implementation of this program will be at a high cost for many suppliers and it will cause a decrease in supplier's access to beneficiaries, resulting in a less competitive market.

Respectfully yours,

PEDRO A. SANTIAGO
Presidente

Jill Hentrup
3027 Pebble Brook
Jeffersonville, IN 47130

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June 19, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dr. McClellan:

I am a physical therapist practicing in the states of IN and KY. I have been a licensed PT for 15 years and have a wide range of clinical experience including inpatient hospital, inpatient rehab, home health and long-term care and outpatient services. In those various settings, I have evaluated and treated many patients with orthopedic and neurological problems that affect their daily lives in the way of impaired mobility, impaired activities of daily living and impaired ability to perform their necessary job duties. I currently am focusing my practice in an outpatient clinic where I make recommendations for and modifications to orthotics and other durable medical equipment on a regular basis. Recommending appropriate equipment and devices is an integral part of the plan of care for physical therapy.

As a physical therapist, I am often the professional who recommends a certain device to assist a patient with their impairment. The adjustment and/or modification of the device should be based on *clinical* assessment of correct fit, correct use of the device by the patient and if the device is providing the expected outcome. This clinical assessment can only be performed by a licensed physical therapist. At times, the recommended device does not provide the outcome I originally expected and a different type of device must be tried. For example, a patient comes to me with a recent fracture or severe sprain and will need immobilization. If we try one splint or brace and it does not provide appropriate stabilization, another one must be available to try immediately. This is in the best interest of the patient to prevent further injury. Requiring the patient to travel to another site to receive a brace that may or may not provide proper immobilization is a detriment to him/her. Even when an off-the-shelf item works for a particular patient, it still may need some type of adjustment or modification to fit properly. For example, a patient with hemiplegia may use an ankle-foot orthosis (AFO) to assist with ambulation. A pre-fabricated AFO may work fine except for one area of the foot where there is friction or pressure. I adjust the orthotic or modify it to eliminate the risk of skin breakdown. This is something I routinely do in the clinic.

Another situation that occurs is when one brand of brace, splint or other DME does not work for the patient. Each brand fits differently, has various features and some are not available in the size the patient needs. For example, a patient with a fractured ankle

comes to me for a CAM walker. The first one I apply does not fit properly and does not provide adequate stabilization. I apply a different brand; it fits well and provides adequate stabilization. If the patient's only option was the first brace, the fracture would likely not heal properly. Since I deal with various types and brands of DME on a regular basis, I am able to make an informed *clinical* decision regarding which brand and device is the best for that individual patient. Often I discuss specific patient issues with the attending physician and together we determine which brand will work best for that individual. Many physicians recognize my expertise in this area and ask my opinion about the options.

In addition to issuing the DME and adjusting it as needed, I also provide education and instructions to the patient regarding purpose of the item, care of the item, proper use of the item, a wearing schedule if appropriate and what to do in case any complications or questions arise. In the case of an ambulatory device, it is my professional responsibility to ensure patient safety with the device. Gait training may be necessary if they are using a device for the first time or adjustments may be needed if there are co-morbidities that may affect their ability to use the device correctly. If the patient is only dealing with a DME supplier, who is going to answer questions, inform them of the above and make clinical judgments as above? Again, such *clinical* judgments can only be made by a licensed physical therapist.

As a practicing physical therapist that recommends, adjusts, modifies and issues various DME on a daily basis, I urge CMS to revise the regulations and recognize the need for licensed physical therapists to:

- Furnish DME that are critical to the care of our patients
- Issue DME in a timely and safe manner
- Adjust and modify orthotics and other DME
- Recommend specific brands of DME to prevent adverse medical outcomes

Dr. McClellan, I want to thank you for considering my opinions and comments. I hope the clinical examples I provided will assist you and the agency in making a decision that will be in the best interest of all patients covered by Medicare.

Sincerely,

Jill Hentrup PT

Jill Hentrup, PT, MHS

—Family—
Foot Care
When your feet need a specialist...

Kevin McDonald, D.P.M.
Diplomate, American Board of Podiatric Surgery
Diplomate, American Board of Podiatric Orthopedics
Fellow, American College of Foot and Ankle Surgeons
Fellow, American Academy of Podiatric Management

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June 26, 2006

Mark McClellan, MD, PhD
Administrator, CMS
P.O.B. 8013
Baltimore, MD 21244-8013

Re: CMS-1270-P

Dear Dr. McClellan,

I practice podiatry in two small towns in North Carolina – neither town has an orthopedist and both towns have limited options for DME products. Many of my patients are elderly, have limited mobility and are unable to drive. Making a trip to the doctor is quite an ordeal for many of them. Thus, it would be best for them to receive any medically required DME products at the time of their podiatric visits and not have to then travel out of town for their treatments.

I believe that CMS should use the 1861(r) definition of a physician when finalizing the regulations for dispensing DME products from physician offices. This is the most efficient and beneficial use of CMS resources. It is also best for my patients.

Please use definition 1861(r) in regulating the competitive acquisition program for DME.

Sincerely,

Kevin McDonald, DPM

1881 Dale Earnhardt Blvd.
Kannapolis, NC 28083
Phone: 704.938.5656
Fax: 704.938.8281

familyfootcare@ctc.net

6706 Roberta Road
Harrisburg, NC 28075
Phone: 704.454.5558
Fax 704.938.8281

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JUNE 19,2006

TO: CENTERS FOR MEDICARE AND MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ATTN: CMS-1270-P: PO BOX 8013

FR: IV CARE OF SAN ANTONIO
D.B.A.: NETCARE PHARMACY
6428 BANDERA RD
SAN ANTONIO, TX 78238
PROVIDER ID: MEDICARE: 1237510002
MEDICAID: 167964901 / 16796402

AS A DME SUPPLIER , NETCARE PHARMACY STRONGLY OBJECTS TO THE IDEA FOR A DME COMPETITIVE BIDDING PROPOSAL. REASON #1: MANY BENEFICIARIES ARE IN NEED OF DME SUPPLIES IMMEDIATELY AND CAN NOT WAIT FOR THEIR SUPPLIES TO COME IN BY MAIL. THEY ALSO REQUIRE SOME KIND OF DEMONSTRATION ON HOW TO USE THEIR PRODUCTS AND SUPPLIES, WHICH REQUIRES A PHARMACIST TO PHYSICALLY SHOW THE PATIENT HOW TO PROPERLY USE THESE ITEMS. REASON #2: WHEN IT COMES TO DME SUPPLIES PATIENTS TEND TO WAIT TILL THE LAST FEW DAYS , IF NOT THE LAST DAY , WHEN THEY ARE GOING TO RUN OUT. USUALLY THEY ARE UNABLE TO WAIT THE EXTENDED MAIL ORDER TIME TO RECEIVE SUPPLIES BY MAIL. REASON #3: MANY PHYSICIANS SWITCH OUT THE PATIENTS DME PRODUCTS AND SUPPLIES OFTEN WHEN EVER UPDATED VERSIONS ARE AVAILABLE, WHICH CAUSES THE PATIENT TO BE IN NEED OF NEW SUPPLIES AND OR DEVICES. REASON #4: WE DISAGREE WITH CMS' ALTERNATIVE PROPOSAL THAT WOULD LIMIT BENEFICIARIES' CHOICE OF A DME PROVIDER. THIS PROPOSAL WOULD SEVERELY RESTRICT BENEFICIARIES' ACCESS TO NEEDED ITEMS AND SUPPLIES. LIMITING BENEFICIARIES' ACCESS OF CHOICE TO MANDATORY MAIL SERVICE IS NOT APPROPRIATE FOR DME PRODUCTS AND SUPPLIES, ITEMS THAT BENEFICIARIES NEED CONVENIENT AND FREQUENT ACCESS TO. THE COMPETITIVE BIDDING PROGRAM SHOULD NOT INCLUDE COMMON DMEPOS PRODUCTS AND SUPPLIES.

THANK YOU,

Mike Buchmeier

MIKE BUCHMEIER RPH, PHARM-D
NETCARE PHARMACY

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Mark B. McClellan, MD. PhD
Administrator
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attn. CMS-1270-P
P. O. Box 8013
Baltimore, MD 21244-8013

6/25/06

Dr. McClellan,

The purpose of my letter is to express some concerns I have relative to the "Proposed Rule for Competitive Acquisition of Certain DMEPOS."

I am a physical therapist with a hospital based practice in rural North Dakota. There are only 2 DME providers in my area with 1 located 90 miles from here and the other a 120 miles from my facility. I frequently work with patients who have diagnosis of plantar fascitis, Achilles tendonitis, and posterior tibial tendonitis. After a thorough biomechanical assessment and evaluation the use of a trial with orthotic is often a portion of the recommended treatment/intervention. Often this does involve modification to a pre-fabricated off-the-shelf orthotic in order to customize to the patient's individual needs. If my patients are required to travel to obtain their orthotic I am concerned that it would have a negative impact for them. There certainly would be a delay to starting treatment and secondly I am sure some would not even make the trip. With gas prices as they are a 180-240 mile round trip causes a financial hardship for persons on a limited/fixed income.

Another concern I have is with knee orthosis used in the treatment of patello-femoral syndrome and patellar malalignments. There are a variety of orthosis on the market with a variety of features. I am finding that the DME providers are only caring certain brands and do not have the access to all types and brands. This would limit my choices as a clinician.

I appreciate having the opportunity to provide you with my concerns and wish to thank you for your help with this important issue.

Sincerely,

Wade Burgess, PT

Wade Burgess, PT
P. O. Box 503
Rolla, ND 58367

DERIC LORDS, D. P. M.
1310 NORTH KRAEMER BOULEVARD
PLACENTIA, CA. 92870
714 - 996-7601 Fax 714 - 996-0745

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June 30, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN; CMS-1270-P
P. O. BOX 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan:

I am writing you to express how important it is for CMS to change the definition from 1861®(1) to 1861®(3).

I have been practicing in Placentia, California for the past 25 years and have a current DME supplier number.

It is so important when treating my patients that I have control over the type of supplies that are being dispensed. This cuts down on the recovery time and decreases the risk for complications.

Therefore, I urge CMS to modify the physician definition from 1861®(1) to 1861®(3).

Thank you for your consideration.

Sincerely,

Deric Lords, DPM

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2944 Salem Circle
Racine, WI 53406-1828
June 26, 2006

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

To All It May Concern:

I am a Registered Occupational Therapist and a Certified Hand Therapist. As such I have specialized skills and expertise in the disease process of upper extremity disorders. A component of the care that I provide is the fabrication/provision and fitting of orthoses. The patient's needs are thoroughly evaluated in order to determine the appropriate orthoses. Factors include the disease process, extent of injury, structures involved, functional and ADL needs, ergonomics, purpose/goal of orthotic, precautions, monitoring and future orthotic needs.

I am writing to address my concerns regarding the Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a particular orthosis. As a result, it is not guaranteed that a beneficiary will be able to obtain a specific orthosis in their local area, potentially limiting their access to the needed orthosis. Delays in the supply of an orthosis will interfere with clinical reasoning and patient treatment. Frequently we as therapists must respond immediately to changing conditions in a patient's medical condition. When these occur we must alter or make modifications to their orthosis.

I am concerned about the legal and ethical issues I may face when a patient comes to me after they have been issued an inappropriate orthosis by another entity. Do I adjust the orthosis myself and assume liability for an orthosis that I did not supply to this patient? Or do I send the patient back to the original supplier knowing that they may be inadequately cared for? Neither scenario is acceptable.

I ask that this proposal be abandoned and that we as qualified, trained therapists continue to meet the needs of our patients including evaluation, selection, fitting and monitoring of their orthotics.

Sincerely,

Ruth M. Chiapetta-Kulbacki, OTR/L, CHT

Ruth M. Chiapetta-Kulbacki, OTR/L, CHT

Melbourne Podiatry Associates
Surgery of the Foot and Ankle
Briant G. Moyles, D.P.M. Richard C. Wilson, D.P.M.
Diplomate American Board of Podiatric Surgery • Fellow American College of Foot and Ankle Surgeons

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June 8, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services ATTN: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program, Competitive Acquisition for DME

Dear Dr. McClellan:

As a podiatric physician who has been in practice for over 25 years, I am writing to seek your opposition to the proposed rule Medicare Program – Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and Other Issues.

As you know, this rule would include physicians in a competitive acquisition program for certain DME items. I urge CMS to reconsider its original proposal and to exclude physicians, including podiatric physicians, from the competitive bidding requirement.

Having provided DME supplies for both Medicare and non-Medicare patients for many years, I have found that the physician as supplier is in the best position to provide appropriate care for patients. As a supplier of these devices, I am able to select the devices that I consider to be the best quality for the patient and individualize it for that patient. I am also able to make sure that the patient uses the devices properly. This provides appropriate care for patients, as well as giving them the convenience of getting the devices at the office. I have seen too many cases where patients under managed care contracts have been forced to go elsewhere for their DME items, only to be given substandard items and in some cases, the completely wrong item, regardless of my prescription. The competitive bidding proposal that CMS is considering would greatly reduce the quality of care for patients. This being the case, it is essential that physicians be excluded from this rule.

Physicians currently are responsible only for about 3.1% of the total DME POS allowed charges. Their exclusion from competitive bidding would not result in any significant savings to CMS, but would harm patient care. I strongly urge you to exempt physicians from this competitive bidding rule.

Thank you for your attention to this matter.

Sincerely,

Richard C. Wilson, DPM
RCW/jmp

211 East New Haven Avenue • Melbourne, Florida 32901 • (321) 723-2022 • 723-3500 • Fax (321) 723-1945
1310 W. Eau Gallie Blvd., Suite E • Melbourne, Florida 32935 • (321) 255-3338 • Fax (321) 253-9643

NORTHERN INDIANA
FOOT AND ANKLE
ASSOCIATES

JEFF NIESPODZIANY D.P.M., F.A.C.F.A.S.
DOUG KOLMODIN, D.P.M.
4455 Edison Lakes Parkway, Suite 200A • Mishawaka, IN 46545
(574) 259-9668 • Fax: (574) 259-9671'
Email:ninftcare@aol.com

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June 26, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P

Dear Dr. McClellan:

We are writing in response to the requested changes concerning Podiatric physicians and their ability to prescribe and dispense DMEPOS type items. Podiatric physicians are licensed by each and every state in the United States to diagnosis and treat their patients. Very often these patients are elderly or lacking the means to go from place to place to receive prescribed medical supplies or equipment. Eliminating this very necessary service may reduce the level of care received by patients. Then, of course, patients would suffer at various levels.

Please continue to allow Podiatric physicians to function at the capacity of fellow physicians.

Sincerely;

Dr. Jeff Niespodziany
Dr. Doug Kolmodin

Name: Michele Martin RN, CDE, MSN

Institution: Inbody Clinic The Cambridge Hospital

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes (284)

I have used the excellent services of the Neighborhood Diabetes Shoppe since it opened up for business. I have worked both as a nurse practitioner (for 12 years) and an RN (for 1½ years) in the field of Diabetes care. Diabetes is a very complicated medical disease with grave consequences when people do not have good control of their disease. It is so very important to have the services of the Neighborhood Diabetes Shoppe because they are knowledgeable on diabetes and understand diabetes well which is very beneficial to our patients with diabetes. Competative Bidding would be a way to decrease

Written comments must be received by June 30th, not just postmarked!

services to people with diabetes as a place like the Neighborhood Diabetes Shoppe would not be able to continue to provide the high quality products and in-home meter training that they provide. Competitive Bidding probably means to the lowest bidder which does not mean quality care for ~~DES~~ patients on Medicare.

Sincerely,

Michele Martin

Michele Martin, RN, CDE
Zinberg Clinic

Cambridge Health Alliance
A COMMUNITY OF CARING

1493 Cambridge Street • Cambridge, MA 02139

Name: Heather Perkins

Institution: HCS

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To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

Quality of services will be impacted by over-aggressive competition will affect quality of excellent service that current providers give.

Home Healthcare, Hospice & Community Services
PO Box 564, Keene, NH 03431

Written comments must be received by June 30th, not just postmarked!

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Name: Lynne CRAWFORD RN ANP

Institution: SHC - Cambridge Health Alliance

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

This is a great patient centered program that is cost effective + truly understands Care to our patients needs. They are efficient, prompt, caring - + get the job done well.

Please support the continued existence of this very needed work by Neighborhood Diabetes. Patients need a group to depend on + support their self care goals.

Written comments must be received by June 30th, not just postmarked!

Lynne Crawford RN ANP

Cambridge Health Alliance
A COMMUNITY OF CARING

Somerville Primary Care
26 Central St. • Somerville, MA 02143

Name: Pat Kimball MSN RN CCRN

Institution: Boston Medical Center

Why implementing Co[illegible] supplies is inadvisable, and why it is advisable [illegible]e Neighborhood Diabetes.

Geriatrics Section
88 East Newton Street
Robinson 2
Boston, MA 02118-2393

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

287

I am a Geriatric Nurse Specialist and work in a large Geriatric Section - We use NeighborHood Diabetes supply because of their ability to educate our patients & caregivers in use of equipment and advising us in specialized equipment to accomodate our patients various losses - This service assist us in Patients Home

Written comments must be received by June 30th, not just postmarked!

Name: Catherine Bulman RN

Institution: Geiger Gibson Health Center

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

288

I believe we need to keep relationships with our community providers. We are a community Health Center and to reach the community these companies - that can go into the community - do in home teaching with glucometers are important to my community. We as a society can not afford to let our health care go to the highest bidder

Geiger Gibson
Community Health Center
250 Mt. Vernon St.
Dorchester, MA 02125
617-288-1140

Written comments must be received by June 30th, not just postmarked!

Name: Terri Walsh - Shine Counselor

Institution: SHINE PROGRAM

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes

289

It's important to me to have a Reliable Resource to help my Clients. The Neighborhood Diabetes Team Receives high marks for the great job they do. I've Referred to many clients over the years, NOT one Complaint! My clients are Always Completely Satisfied with these Services. Please Reconsider instituting Competitive Bidding for durable medical products. I don't think competitive bidding is a good idea for diabetes supplies.

Terri Walsh
SHINE PROGRAM
558 Plymouth Street
Middleboro, MA 02346

Written comments must be received by June 30th, not just postmarked!

Name: ANGELA VILLAMAN - CURRAN

Institution: GREATER LAWRENCE FAMILY HEALTH CT

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Write comment below, detach, and mail to
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Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes: 290

OUR PATIENTS ARE HAPPY WITH THE SERVICES OF NDS BECAUSE THEY GET THEIR SUPPLIES AND MEDICATIONS ALWAYS ON TIME. WHEN IS A PROBLEM THEY CALL PHYSICIAN AND PT TO KEEP THEM INFORMED

Greater Lawrence Family Health Center
2nd Floor Nursing Department
34 Haverhill Street
Lawrence, MA 01841-2884

Written comments must be received by June 30th, not just postmarked!

Name: Melanie Dawes RN Pt Care Co-ordinator

Institution: Baystate Endocrinology & Diabetes
Springfield, MA 01199

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

291

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PO Box 8013
Baltimore, MD 21244-8013

Diabetic pt's have individual needs & abilities to learn. Diabetic supplies need to address individual needs neuropathy, retinal damage, cognitive abilities, etc. Also they don't like being "clumped in same category" Each patient is an individual. Do not regionalize them. RN & CDE's spend a lot of time teaching for this very reason. Melanie Dawes RN

Written comments must be received by June 30th, not just postmarked!

Name: _____

Institution: _____

Ann W. Bodkhe, MSN, NPC
Jefferson H. Dickey, M.D.
51 Sanderson St. Suite 10
Greenfield, MA 01301

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Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes: (29P)

Neighborhood Diabetes provides a valuable service to our patients in helping them keep their diabetes under control. After receiving the initial home visit to evaluate which meter is best for the patient + to do initial training, I have seen better compliance + better understanding of DM mgt.

Ann Bodkhe MSN, NPC

Written comments must be received by June 30th, not just postmarked!

Name: Susan Allison

Institution: VNA of Greater Lowell

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

293

- Quick response to ordering
- Physician paper work done by company
- Small company develops rapport with each client
- Avoid Monopoly

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

VNA

VNA of Greater Lowell

Care You Can Trust

VNA of Greater Lowell
336 Central Street
Lowell, MA 01852-2609

Written comments must be received by June 30th, not just postmarked!

Name: Annette D Bernard, RNC

Institution: Boston Visiting Nurse Association

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes: (294)

Competitive Bidding for supplies does not guarantee quality or responsibility for accessibility. The Neighborhood Diabetes Shop is responsible & reliable in sending supplies to pts. & returning phone calls. They have done many inservices at the Boston VNA to make us acquainted with new products & how to use them. When they make (make) mistakes they quickly rectify them. Their customer service is excellent.

MS ANNETTE D BERNARD
9 TEMI RD
FRAMINGHAM MA 01701-3344

Written comments must be received by June 30th, not just postmarked!

Name: [redacted]

Institution: [redacted]

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

(295)

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PO Box 8013
Baltimore, MD 21244-8013

It is important that consumers with vision problems have access to vendors familiar with adaptive equipment. As a diabetes educator working with people who are visually impaired I often find them not able to get recommended equipment as the HMO pharmaceutical vendors don't have a clue.

Thank you Morgan McCoy

Written comments must be received by June 30th, not just postmarked!

Name: _____

Institution: MCHC

MANCHESTER COMMUNITY HEALTH CENTER
1415 ELM STREET, MANCHESTER, NH 03101

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Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes (296)

I work in a Community Health Ctr. I feel this would be a disaster. Many of our patients are of various ethnic backs. Language barriers, adapting to new medical Tx, literacy, visual problems etc. The less complicated meters we can use we give the patients that meter. We get discount coupons from Drug companies & discounted test strips. I feel our added expenses to SMBG would occur. Lets Stop Closing everything & everybody.

Written comments must be received by June 30th, not just postmarked!

Name: Jean Christopher RN

Institution: Boston VNA

Why implementing Competitive Bidding for diabet
and why it is advisable to protect small companies l

Visiting Nurse Association of Boston
Metronorth Office
500 Rutherford Avenue
Charlestown, MA 02129

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ters for Medicare & Medicaid Services
artment of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

291

I have used Neighborhood diabetes Shop for years. They provide a service to my patients free of charge to them. They will give a free in service in their home to teach them how to use machines. Send someone who speaks their language also. Call them when supplies are running low so patient do not do without. By doing this for free this cuts down on expensive nursing visits saving the government money. I feel they are a very important spoke in the wheel to cut costs & prevent Costly hospitalization. The service they provide is not provided by any else!

Written comments must be received by June 30th, not just postmarked!

Name: Antonia Makosky, APRN, BC

Institution: Cambridge Health Care for the Homeless and Martha Eliot Health Center in Boston, MA

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

298

I work with homeless patients and Latino patients in Boston and Cambridge, Mass. Neighborhood Diabetes (poor) Shoppe has provided consistent outstanding service to these challenging patient populations. They have been flexible and are willing to go the extra mile for their customers. I can truly say that without them my patients would not have the support that they need to get supplies on time and training at home on how to use their equipment.

Antonia Makosky APRN, BC

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Baltimore, MD 21244-8013

Name: Patricia Roberge

Institution: Mass. Gen. Hosp. - Revere health Center

300 Ocean Avenue • Revere, Massachusetts 02151

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Wh ...able, and ...iabetes: 299

I do not think competitive bidding is a good idea we have a good regime & neighborhood Diabetes Shoppe & Take advantage of there outreach services, teaching, nutrition etc.

Patricia Roberge LN
MGH - Revere Health Center

Written comments must be received by June 30th, not just postmarked!

Name: Linda Haynes

Institution: Home Health VNA

Ms. Linda Haynes
40 Tanglewood Dr
East Hampstead NH 03826

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes: 300

I am a visiting nurse + my father is diabetic. He needed help with a glucometer and I had difficulty teaching him. In just one visit Neighborhood diabetes shop got him back on track. Their service is invaluable to me

Written comments must be received by June 30th, not just postmarked!

Name: MARY JOYCE RN MSN

Institution: HALLMARK HEALTH VISITING NURSE ASS'N
100 Hospital Road
Malden, Massachusetts 02148

Why implementing for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes (301)

NEIGHBORHOOD DIABETES PROVIDES IN HOME METER TRAINING & NAME BRAND METERS TO THEIR CLIENTS, WHICH IN THE LONG RUN ARE LIKELY TO SAVE MONEY BECAUSE CLIENTS WITH BETTER TRAINING ARE LIKELY TO MONITOR GLUCOSE TESTING & FOLLOW TREATMENT GUIDELINES MORE CLOSELY, AVOIDING ER VISITS & LONG TERM COMPLICATIONS

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

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Name: Donna Christen RN, C CDE

Institution: Elliot Health System, Manchester NH.

To submit feedback via mail:
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Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

302

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes (NDS)

Neighborhood Diabetes Shoppes provides a free service to my patients by making a home visit and instructing patients in proper use of their meter. Using the "competitive bid" method may save a few pennies, but dollars of service + care would be lost. NDS also provides free support/information groups. If my patients are not able to utilize the supplier of their choice, - as every elderly population is - Confusion issues + care will suffer. patients will fall through the cracks.

Written comments must be received by June 30th, not just postmarked!

Name: Sharon Johnson RN CDE

Institution: Lakes Region General Hospital

Lakes Region General Hospital • 80 Highland Street, Laconia, NH 03246

To submit feedback via mail:
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes: (303)

Small companies offer support, assistance & extra-ordinary services with brand name meters chosen specifically to the pts needs and choice.
Having low cost providers provide generic equipment, little Training & support will lead to high cost for CMS in inaccurate blood sugar results, user error dissatisfaction & product etc - ultimately poorer care & resulting higher down-stream medical care (ie hospitilizations etc). Please do NOT further Kick our chronically ill public with so called "cost savings" like this!!!

Written comments must be received by June 30th, not just postmarked!

Name: _____

Institution: _____

Why implementir
and why it is advi

RCAM
425 Union Street,
Executive Office Center,
West Springfield, MA 01089
Attn: Mila Dubinchik

upplies is inadvisable,
Neighborhood Diabetes:

~~To submit feedback via mail:~~
Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

304

We started to work with Weight Diabetes Team from Boston, but they did not keep any promises to Russian community. All other clients came back to their original providers like CVS. This program did not work for us at all

Written comments must be received by June 30th, not just postmarked!

Name: Kathleen Murray RN

Institution: MGH Charlestown Health Care Center

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes: (305)

I am writing this letter against Competitive Billing for diabetes supplies. We have worked very closely with The Neighborhood Diabetes Team. They have provided our patients with in home meter training, On time delivery service and patients can call with questions and receive prompt, accurate answers. I feel competive billing will put a small company with excellent service out of business

Kathleen Murray RN

Written comments must be received by June 30th, not just postmarked.

Name: S Shustack

Institution: Gtr New Bedford Community Health Center

Greater New Bedford
Community Health Center, Inc.
874 Purchase Street
New Bedford, MA 02740-6232

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Write comment below, detach, and mail to
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

mpetitive Bidding for diabetes supplies is inadvisable, to protect small companies like Neighborhood Diabetes

306

This particular company knows the community - Spanish Portuguese which is important in our area + provides support + problem solving for me + my clients - Dealing with nationwide companies has been difficult at times - They will at times send a meter not useable for a particular client It is difficult to get problems solved. Also, preserving small businesses helps the local economy

Written comments must be received by June 30th, not just postmarked!

Name: JOSEPH KEREZ

Institution: _____

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

(307)

To submit feedback via mail:
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~~Department~~ of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Some good companies at this time may lose out in the bidding process. Neighborhood Diabetes provide very good service to diabetes patients. It also may lead to higher costs and less good service.

Joseph Kerez
16 Stuart Pl
Westfield, MA 01085

Joseph Kerez

Written comments must be received by June 30th, not just postmarked!

Name: Loretta Boudreau

Institution: Mary Immaculate Apartment
LAWRENCE, MA

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

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Department of Health and Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

308

I am very grateful to "Neighborhood D." for the wonderful service it provides for me. I would probably have to go without testing my blood sugar because strips and lancets are not only expensive but also because I have no means of transportation. Please, CMS, continue allowing "Neighborhood Diabetes" to serve me and others with their very helpful services.

Written comments must be received by June 30th, not just postmarked!

Name: Keri Morrison LPN

Institution: Parkland Physician Services
Salem, NH

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

309

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PO Box 8013
Baltimore, MD 21244-8013

The Company with the "winning" bid may not be the best. This seems like a way of "privatizing" DME supplies. In the setting it seems as though big bussiness may win out, thus putting smaller, local based companies out of bussiness. Patients should have the write to ~~touch~~ Elior choose a company, not have the decision made for them.

Written comments must be received by June 30th, not just postmarked!

Name: DAVID BARON MD

Institution: CAMBRIDGE HEALTH ALLIANCE

310

Why implementing Competitive Bidding for diabetes supplies is inadvisable, and why it is advisable to protect small companies like Neighborhood Diabetes:

Neighborhood Diabetes has been an outstanding source of reliable full service care to partner with my practice in caring for my diabetic patients. I am writing because I am deeply concerned with Opening DME service to competitive bidding process which would likely erode this excellent service. Please protect N.D.S. to allow to function unchanged

David B. Baron MD

Written comments must be received by June 30th, not just postmarked!

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PO Box 8013
Baltimore, MD 21244-8013

311-0
(12)

Tri State Hand and Occupational Therapy, Inc.
P. O. Box 1517 ■ Cumberland, MD 21501-1517

June 27, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P

To Whom It May Concern:

This letter is response to your proposed rule on Competitive Bidding System for Certain Durable Medical Equipment including Prefabricated Orthoses (splints).

Therapists are unique from other suppliers of DMEPOS. They work as a provider and a supplier. As a therapist, they commonly treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of the patients care. This regulation, as stated above, could significantly interfere with the therapist ability to address these changes, putting repairs and patients at risk.

Delays in the supply of an orthosis will interfere with clinical reasoning and patient treatment. There are many times when a therapist must respond immediately to changing conditions in a patient's medical condition and/or recovery from that condition. It is critical that the therapist must be able to respond to that need immediately.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. A specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. There is no guarantee that a beneficiary will be able to find a specific orthosis in their area which is potentially limiting their access to an important orthosis.

I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical orthoses unimpeded by a competitive bidding process.

Sincerely, Mary L MacDonald

Name Mary L. MacDonald
Address P.O. Box 71
City Barton State MD Zip Code 21521-0071

312

Date: June 28, 2006

Organization: DME

Category: Medical Equipment

Issue: Participation/Accreditation requirements

Thank you for the opportunity to submit comments on the proposed regulations for a competitive bidding program.

I object to the proposal that would require beneficiaries to use designated providers. This would limit their access to certain items as most suppliers do not provide all services to beneficiaries.

Any small supplier willing to accept the payment amount determined by CMS should be allowed to join the program.

I am opposed to additional accreditation requirements for small DME companies. These accreditation requirements are expensive and are not easily absorbed into the budget for small DME companies. Each supplier should be expected to meet medicare standards, which could be revised if necessary.

Thank you.

Neil Grice
Pharmacotherapy Center
#4865940001
Martinez, GA

(I was unable to get email to work

313

Date: June 27, 2006

Organization: Independent Pharmacy

Category: Pharmacist

Issue: Participation/Accreditation requirements

Thank you for the opportunity to submit comments on the proposed regulations for a competitive bidding program.

I object to the proposal that would require beneficiaries to use designated providers. This would limit their access to certain items and may compromise patient outcomes.

Any small supplier willing to accept the payment amount determined by CMS should be allowed to join the program.

I am opposed to additional accreditation requirements for small independent pharmacies. These accreditation requirements are expensive and are not easily absorbed into the budget for small independent pharmacies. Each supplier should be expected to meet medicare standards, which could be revised if necessary.

Thank you. Neil Grice

Neil Grice, RPH
Martinez Apothecary
#4966780001

(I was unable to get email to work) no

ETHICA
HEALTH & RETIREMENT
COMMUNITIES

213 Third Street • Macon, GA 31201 • Post Office Box 63 • Macon, GA 31202-0063 • (478) 621-2100 • Fax (478) 743-0954

314

June 22, 2006

Department of Health & Human Services
Attention: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

Re: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies

To Whom It May Concern:

We would like to express our concerns regarding Competitive Bidding in skilled nursing facilities. Suppliers of enteral nutrition products, urological, ostomy and surgical dressings to skilled nursing facility patients are highly specialized. The potential for a facility to lose their choice of a preferred supplier or the ability to provide the products on their own has the potential of putting the patient's health & safety at risk.

The acuity levels and care plans of skilled nursing facility residents are much more complex than patients cared for at home. The disruption to the patient's access to quality products and services as a result of Competitive Bidding has the potential to increase the overall cost of care in skilled nursing facilities.

Based on the data that we have reviewed from previous demonstration projects in which is was determined that it was best to concentrate on non-institutional settings, we feel very strongly that skilled nursing facilities should be excluded from competitive bidding in order to ensure that our patients continue to have access to quality enteral nutrition, ostomy, urological and surgical dressing supplies.

We appreciate your time and consideration of our concerns regarding this important issue.

Sincerely,

Kim Herron
Director of Resource Management

June 26, 2006

Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Attention: CMS-1270P
P.O Box 8013
Baltimore, MD 21244-8013

315

R.E. CMS-1270-P

Dear Sir or Madam:

I have a few comments on the proposed regulations to implement a competitive bidding program for DMEPOS.

My Pharmacies are located in small rural towns. Any proposal that would require beneficiaries to get their DMEPOS supplies such as diabetic testing supplies by "mail order" would be serious problem for my patients. Many of my patients are older and often don't realize they are low or out of their diabetic supplies. If they had to wait for a "Mail order" provider to get them to them, they would run out. What savings you realized from competitive bidding could be lost on increased Dr and hospital charges that could result from the patient not receiving their supplies on time.

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies

The CMS must take steps to preserve beneficiaries easy access to DMEPOS supplies and to maintain established provider / patient relationships.

Small suppliers should be allowed to designate a smaller market area in which to provide DMEPOS. Small suppliers can't compete in large metropolitan areas.

Please revise your regulations in a manner that would allow small Pharmacies to compete in the rural areas and continue the excellent service they have been providing their patients.

Thank you.

John C. Herda Reg Ph

Valley Drug Co
P.O. Box 107
Chewelah, WA 99109

Kettle Falls Pharmacy
P.O. Box 435
Kettle Falls, WA 99141

316

Stefanie Schultz Doyle, BS, OT/L
Visiting Nurse Association of Maryland
7008 Security Boulevard
Baltimore, Maryland 21244
410-594-2600

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P-Mail Stop C4-26-05
Baltimore, Maryland 21244-1850

June 29, 2006

RE: 1270P – Regulatory Impact Analysis-Effect on Beneficiaries

To Whom It May Concern:

I am writing in response to the recent decision by Medicare to place durable medical equipment up for 'competitive bid' for delivery and payment to the consumer. I am a practicing occupational therapist with more than twenty five years experience in my field. I have worked with adults with all types of medical diagnoses who require durable medical equipment. By the time anyone requires adaptive equipment they are physically compromised to the degree that skilled intervention is required. It is my opinion that this decision will be much more costly to Medicare and grossly injurious to the consumer.

I evaluate clients for power mobility devices on a somewhat regular basis as a course of my employment. It is not uncommon for my clients to have pressure wounds severe enough to require prolonged nursing intervention to heal sacral, thigh, calf, or heel wounds that have been caused by significant pressure due to ill fitting wheelchairs. Clients who require power mobility devices require them because they lack the ability to reposition themselves and are physically compromised by the course of their disease, injury or illness. In addition to evaluating clients for power mobility devices the clients also need teaching on how to use them after they are delivered. The primary caregiver also requires teaching on use and management of the device. They require teaching for proper seating and positioning to prevent pressure wounds, provide repositioning and seating safety.

I have seen the results of clients who have received power mobility devices from commercial vendors who do not have the skill to evaluate postural control, strength and daily needs of the client. These results are much more costly to Medicare because of the degree of medical care required by the client as a direct result of ill fitted wheelchairs.

For example:

- A 54 year old woman with Multiple Sclerosis had been placed in a power wheelchair that was too large for her. As a result she used one arm to 'hang' onto to side of the chair. She would slide forward causing undue pressure on her sacrum and upper back which caused severe pressure wounds. As a result she required a specialty hospital bed, wound vac, prolonged home nursing for wound care, a home health aide because the family was overwhelmed with all the additional medical tasks, and a second power mobility device correctly fitted to her physical needs to prevent more injury.
- A 68 year old man with severe rheumatoid and osteoarthritis who was hoyer lift transferred out of bed daily by his wife into his power chair. His hands, torso and cervical spine were severely weakened and deformed by arthritis. He received a power device from a television advertisement. This device had no seat belt or head support. He had not been assessed to determine his physical needs further than asking his weight and height. No consideration regarding his torso stability, hand control for the joy stick, floor to seat height for leg/foot supports had been assessed. During a routine ride on a mobility bus to a medical appointment he slid down in the chair and was unable to recover his posture. As a result he suffered an anoxic event that required a five day hospitalization with follow up home care nursing, nursing aide, physical and occupational therapy. He also required a second and appropriate power mobility device. He is now able to get out of bed daily and use his new wheelchair for activities of daily living. He can now attend to medical appointments without fearing hospitalization as a result of the ride.

These are just two examples of clients who receive ill fitting, expensive wheelchairs that were much more costly in the long run. They were costly to Medicare because of more hospitalizations and additional medical services needed; however, they were most costly to the client and their families due to increased debility from unnecessary medical ailments caused by 'competitive bid' vendors. These clients usually require more skilled intervention after they have received equipment from non skilled agencies.

In addition to power mobility devices, clients who have purchased or received all types of durable medical equipment from commercial vendors have been seen for injury caused by various types of injury. Clients who purchase manual wheelchairs from pharmacies frequently receive incorrect chairs which cause pressure wounds or increase debility.

Clients who receive tub benches are more likely to suffer falls in the bathroom due to lack of education with transfer techniques, safety education, and placement technique of the seat. This is also true for clients who lack grab bars and use towel bars for transfer assistance. Clients also need teaching for safe placement, use, and transfers for bedside commodes.

The frail and ill clients that I serve need teaching and good skilled intervention in order for them to continue to live at home and avoid nursing home placement. If these clients were not able to get the education needed in evaluating and providing such medical equipment they would not be able to live independently at home. I urge you to consider long term ramifications of competitive bid vending for durable medical equipment for Medicare recipients.

Respectfully submitted,

Stefanie Schultz Doyle, OT/L

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June 27, 2006

To: Centers for Medicare and Medicaid Services

From: Theresa Mandela RN BSN CWCN
VNA Home Health of Maryland
7008 Security Blvd.
Baltimore, Maryland 21244

Re: CMS-1270-P – Regulatory Impact Analysis – Effect on Beneficiaries Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Please accept this letter as a response to Medicare's proposed Competitive Bidding for durable medical equipment (DME) providers. As a registered nurse specializing in wound care, I am concerned that by restricting the number of DME providers, many of my patients will no longer have access to appropriate services and equipment. CMS has stated that as many as 50% of small local DME providers will no longer be in business once competitive bidding is initiated.

For over twenty four years I have been providing nursing care to the elderly population of Maryland. Patients with pressure ulcers are frail and medically compromised. They require specialized equipment such as low air loss mattresses, specialty gel cushions and unique seating and positioning wheelchair systems to heal and prevent further bedsores.

Small local providers specializing in wound care and rehabilitation equipment offer a higher level of service, accountability and expertise than large chain "superstore" DME providers. As business members of the community they service, these small DME providers live and work around their patients.

Large chain DME providers (who will be the likely recipients of competitive bidding awards) often do not have the skill and proficiency required to assess, select, fit, and deliver the most appropriate medical equipment for the patient. Additionally they lack the know-how to properly train caregivers. Of great concern is the large chain DME providers unwillingness to timely deliver and set up equipment in crime-ridden sections of Baltimore and the rural areas of St. Mary's county. This lack of capabilities translates into poor patient outcomes and increased cost to the Medicare program.

Examples include:

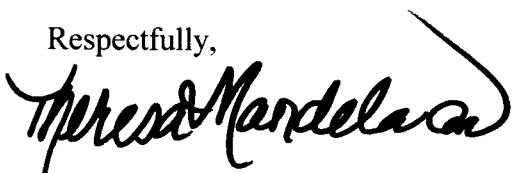
1. A patient being discharged to home on a Thursday afternoon requires a low air loss mattress, hospital bed and pressure-relieving seat cushion. The large chain DME -provider upon hearing where the patient lives quickly changes their delivery date from Thursday evening to Monday morning. The patient must go home Thursday afternoon. The patient requires a bed and mattress upon arrival to the home to prevent a fall, to have proper positioning and to prevent the wound from deteriorating quickly. It is important to note that the large chain DME is not refusing to deliver to the patient's neighborhood; they are refusing to deliver timely thereby creating the potential for injury and decline. As a visiting nurse, I then arranged the mattress, bed and cushion for delivery within four hours from the local wound-focused DME provider.

2. A patient in the home has had a stroke and requires a wheelchair. The patient is a frail 86 year old female under five feet and weighing 90 pounds. She is now leaning severely to the left creating the potential for choking, joint contracture and pressure ulcers. A call is placed to a large regional DME supplier for the wheelchair and a pressure relieving cushion. The large supplier delivers a standard wheelchair and cushion. The delivery driver obtains a signature from the elderly caregiver but refuses to take the wheelchair up to the third floor of the un-airconditioned row house and leaves it in the first floor living room. The visiting nurse takes the wheelchair and cushion upstairs to the patient the next day, but then realizes that the regional DME supplier has delivered a "standard" wheelchair that would be suitable for an adult male. The wheelchair is too wide, too tall and has no adaptation to the arm and chair back to prevent the patient from falling out of the chair since she leans left. A call by the nurse to the local mobility specialty company (considered a DME provider by definition who would likely not survive competitive bidding) results in an on-site assessment by a rehabilitation technology specialist. The patient required a smaller manual wheelchair, smaller cushion, "build up" of the chair's left arm and a tilt chairback feature. Unfortunately the regional DME supplier had already billed Medicare for the improper chair, and getting the proper equipment for the patient was delayed. The patient started to lose the ability to self propel during this three week period since her feet could not touch the floor in the original wheelchair.

The wound care patients I care for require specialized assessments for their durable medical equipment. This level of service is available from many small local providers who focus their skills and product line in a particular area such as wound care, rehabilitation equipment, mobility, and bathroom safety. Patients who receive the most appropriate equipment and caregiver training by these dedicated DME suppliers avoid re-hospitalization and nursing home placement.

Please consider my request to revise Competitive Bidding for DME suppliers for Medicare recipients to include and allow for these local companies with skilled expertise.

Respectfully,



Theresa Mandela, RN BSN CWCN
VNA Home Health of Maryland

SIDLEY AUSTIN LLP
SIDLEY

MEMORANDUM

TO: Centers for Medicare and Medicaid Services

FROM: Richard D. Raskin

RE: Proposed Rule; Competitive Acquisition for DMEPOS; CMS-1270-P ("Opportunity for Networks") – Concerns Regarding Anticompetitive Conduct by Bidding Networks

DATE: January 23, 2007

On behalf of Apria Healthcare, we wish to call to your attention a matter of significant concern regarding the proposed rules for competitive acquisition of certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The concern relates to proposed § 414.418, "Opportunity for Networks." Specifically, we believe that the provision, as proposed, may require clarification or expansion to protect against a very real threat of competitive harm from the operation of bidding networks in local and national DMEPOS markets. Indeed, we are already aware of situations where the formation of bidding networks in response to the proposed rule appears to raise serious antitrust concerns. We urge CMS to consider modifying the rule, or issuing additional guidance concurrently with the final rule itself, to make clear that the rule is not intended to create a safe harbor from antitrust prosecution.

Proposed § 414.418(a) allows two or more suppliers to "collectively submit a single bid to furnish the items included in a product category under a competitive bidding program." 71 Fed. Reg. 25701. Subsection (b)(4) of the rule states: "The network cannot be anticompetitive. The network members' market shares for a product category, when added together, cannot exceed 20 percent of the Medicare market within a competitive bidding area." Id.

As indicated in its previous comments to CMS, Apria supports the 20 percent limit set forth in subsection (b)(4). It is concerned, however, that the proposed rule as currently stated may be misinterpreted as creating a safe harbor from antitrust prosecution for networks that stay within that limit. Such an interpretation would be inconsistent with antitrust principles, and potentially damaging to competition in markets for DMEPOS.

Federal antitrust enforcers have addressed the antitrust principles applicable to contracting networks. While market share is one important consideration, it is not the sole determining factor. Before competing providers may jointly submit a proposed price to a purchaser, they must also demonstrate that they are sufficiently integrated financially or clinically to justify a joint agreement on price. See Department of Justice/Federal Trade Commission, Statements of Antitrust Enforcement Policy in Health Care, Statements 8-9 (1996) ("Health Care Statements"). In particular, the Health Care Statements establish a "safety zone" for exclusive networks where the provider members constitute 20 percent or less of the providers in the market and the providers "share substantial financial risk." Id., Statement 8.

The proposed rule contains no requirement of risk-sharing among the members in a DMEPOS network formed for the purpose of submitting collective bids. Just as important, the proposed rule does not require the network to establish that it has safeguards in place to protect against the risk that the agreed-on bid prices might be inappropriately used outside of the Medicare acquisition process. The absence of additional guidance leaves open the very real risk that the regulations will be misinterpreted as sanctioning price-fixing by competing DMEPOS providers.

In that regard, Apria is particularly concerned about reports in the trade press that networks are already in formation that pose a threat of anticompetitive behavior. Recent articles in HME News and HomeCare (copies attached) report that 35 home medical equipment providers in Tampa have formed a network to submit bids to CMS. But the network's activities will not stop there. The articles quote the network's leader as stating that the network will also be used to approach commercial insurance companies. The articles further note that an affiliated network has taken shape in Miami that includes 90 home medical equipment providers, and that additional affiliates are planned for Jacksonville and Orlando. Nothing in the articles suggests that these networks will have sufficient integration among the provider members to justify joint bidding under well-established antitrust standards.

Following the publication of these articles, Apria was approached by one of its competitors regarding the possible formation of a network in one of the competitive bidding regions. Pointing to the Tampa situation, the competitor proposed that, by joining together in a bidding network, Apria and other providers could "prevent unnecessary price erosion" and "greatly reduce our collective loss." The competitor apparently had the impression that the mere formation of a network would "circumvent any impropriety such as collusion." (Copy attached; names redacted).

In light of these circumstances, we urge CMS to make clear – in the rules themselves, or at the very least in guidance issued concurrently with the regulations – that nothing in the rules is intended to supplant or in any way alter the antitrust principles applicable to provider networks. Absent such guidance, we are concerned that providers may continue to labor under the false impression that, so long as they maintain compliance with the 20 percent limit, they will be free to collectively price their services without antitrust risk to both government and commercial payors.

Thank you for considering these comments. If you have any questions or would like any additional information, please let us know. You may contact me at (312) 853-2170 or rraskin@sidley.com.

R.D.R.

HOMECARE

Independent HMEs Muscle Up to NCB

Jan 8, 2007 2:24 PM

TAMPA, Fla.--With national competitive bidding looming, some HME providers are banking on networks or rollups to give them the muscle to compete--and to survive.

Thirty-five small to medium providers in the Tampa, Fla., area in December formed Med Trust Tampa Bay LLC, a sister to Med Trust Corp. of Southern Florida, which was organized early last year.

Med Trust Tampa Bay is aggressively preparing for competitive bidding, said Robert M. Arado, administrator. His company, Caremed Respiratory Services, is spearheading the effort.

"[We are] forging ahead to meet all the requirements to satisfy CMS guidelines for the competitive bid," he said, noting that most of the Med Trust members are accredited. "We are rigorously working with those who are not to get them accredited."

Arado said he hopes all members of Med Trust will be accredited in four months.

In addition, he said, "We're asking all members to increase the credit lines with their vendors. We need to come in as a network with big dollars in credit lines ... Medicare will see that we are a strong player."

Meanwhile, three South Carolina providers--Adaptive Medical in Spartanburg, ApneaRx in Clemson and Mobile Health Care in Greenville--were rolled up into the newly formed Southern Home Medical, a publicly held company that debuted last month. Nearly a dozen more companies are considering joining SHM, according to Greg Tucker, owner of Adaptive Medical and president and CEO of the new company.

Dennis Nowak, RT, owner of ApneaRx, believes the move positions his company and the others for competitive bidding.

"It's a great alternative for anyone who is worrying about competitive bidding and other things that are facing us in DME," he said, noting that under the Southern Home Medical umbrella, "you can purchase better equipment, get better pricing and make a profit at lower charge rates."

Besides, he noted, "There's a chance I wouldn't be in business if I didn't do it."

Waterloo, Iowa-based VGM Group is also forming a network for its members who want to participate.

"We decided to do this because we knew [providers] were going to need help and, simultaneously, we were

getting requests," said Jim Walsh, president and general counsel for the buying group.

Walsh sees some benefits, especially for small providers. Being in a network could mean they wouldn't have to work outside their geographical area or service needs they are not equipped or accustomed to handling, he said.

But not everyone favors networks. In a September *HomeCare* magazine survey, 61 percent of providers said they planned to bid on their own rather than as part of a network, with 32 percent saying they'll take the network route. While 49 percent of respondents said they think networks are workable, 43 percent said they aren't, giving as their main concerns too much dependence on other companies and headaches with administration and billing. (See "Ready or Not," *HomeCare*, September 2006.)

Walsh also had some cautions for providers. "We are concerned that smaller providers might fall into networks that don't get the job done," he said. The network "has to be able to technically handle the business ... do the paperwork associated with this, get the payments out to the individual providers without tripping over the obstacles CMS is famous for putting in your way ... Network adrninistrators are going to be holding their money."

Providers must choose wisely, Walsh said. "They're putting their business at risk. Once that deadline goes by, they aren't doing Medicare for a long while." When the bid contracts are awarded, they will extend for three years.

Arado is confident his network has its ducks in a row. "The only drawback we see is if the whole thing is a wash with Medicare and they aren't able to take care of competitive bidding, and we would have put in all this money. But without [the network], we're going to see a fallout of providers that we haven't ever seen before. We have a better chance as a group than by ourselves."

Meanwhile, VGM, under its Last Chance for Patient Choice organization, remains poised to file a federal lawsuit challenging competitive bidding on constitutional and other grounds. All it's waiting for is the announcement from CMS of the 10 MSAs.

"Once those unfortunate entities have been announced," said John Gallagher, VGM's vice president, government relations, "we'll be looking for articulate end-users who would be willing to sign onto a class-action lawsuit."

For more information on Last Chance, visit www.lastchanceforpatients.org.

For more on Southern Home Medical, see "Taking Stock of the Market," *HomeCare*, December 2006.

Find this article at:
http://www.homecaremag.com/news/hme-ncb-med-trust/index.html

☐ Check the box to include the list of links referenced in the article.

HME News

THE BUSINESS NEWSPAPER FOR HOME MEDICAL EQUIPMENT PROVIDERS

NEWSWIRE

Florida network forms to tackle NCB

01.01.2007

TAMPA, Fla. - A group of 35 home medical equipment providers in and around Tampa have created a network to take advantage of buying power and other economies of scale intended to help them survive and thrive.

Med Trust Tampa Bay is a direct, but separate, offshoot of Med Trust Corp. of South Florida, which was developed in Miami early last year. Approximately 90 HME providers belong to the Miami organization, said Javier Talamo, who spearheaded that group.

STORY CONTINUES BELOW

Med Trust members plan to submit bids for national

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OIG plans multip DME investigatio

competitive bidding as a network. CMS plans to kick off competitive bidding some time this year.

Additionally, by helping members get accredited and enforcing a strict standard of conduct, Med Trust aims to ensure compliance with all state and federal requirements, said Robert M. Arado, owner of CareMed Respiratory Services in Tampa, the force behind the new group.

"I've been in this business for 37 years and over the last 20 years, Florida has had a bum rap: a few (bad apples) have labeled the whole industry in Florida as a questionable industry," he said. "This is an excellent opportunity for us to clean this up. We are going to be very strict in who we accept in to the network."

In addition to the Tampa- and Miami-based Med Trust groups, Arado has plans to start up similar networks in Orlando and Jacksonville.

"We will be able to go into insurance companies and say, 'We are a member of Med Trust and have statewide coverage,'" he said. "We have an opportunity to compete with large companies."

HME RESOURCES

SOURCE BOOKS

State of the Industry 2006
As you prepare bids for competitive bidding, we think it's only right that you get a snapshot of who's doing how much of what in any given marketplace. This is a start. We hope it's useful.

2005 HME Excellence Awards
Background on the

CALENDAR

January 2007
11 PAMS
PAMS is holding an oxygen safety and regulatory seminar a the Holiday Inn, Harrisburg-Hersey, PA. For more info g to www.pamsonline.or

30-31 Winter Legislative Conference
TAHC is holding its Winter Legislative

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