Submitter : Emily Niederman

Date: 06/30/2006

Organization : ITEM Coalition

Category : Consumer Group

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Please see attached document.

CMS-1270-P-1161-Attach-1.PDF

#1161

June 30, 2006

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

RE: Comments on "Low Vision Aid Exclusion" in Proposed Rule Regarding Medicare's Competitive Acquisition for DMEPOS and other Issues (CMS-1270-P):

Dear Dr. McClellan:

The ITEM Coalition would like to focus our comments on the DMEPOS Competitive Acquisition Proposed Rule issued May 1, 2006 to the "low vision aid exclusion." This provision is completely unrelated to competitive bidding and is the only part of this proposed rule that directly impacts coverage of assistive devices for Medicare beneficiaries with disabilities. We take strong exception to the proposed "low vision aid exclusion" for the reasons outlined in this response. The ITEM Coalition strongly urges CMS to reconsider this proposed rule and to evaluate the medical/functional purpose of each assistive device and technology at issue and establish individualized coverage decisions.

The ITEM Coalition is a consumer-led coalition of 75 disability-related organizations with the purpose of raising awareness and building support for policies that will improve coverage of assistive devices, technologies, and related services for people of all ages with disabilities and chronic conditions. From coverage for hearing aids to augmentative communications devices (AACs) to advanced artificial limbs to screen readers for people with vision impairments, the Coalition's mission is a broad one with implications for virtually every person with a disability who relies on assistive devices to be healthy, functional, and independent.

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Members of the ITEM Coalition are extremely concerned by the "low vision aid exclusion" segment of the regulation. The proposed exclusion states that all devices, "irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision" will be hereafter excluded from Medicare coverage based on the statutory "eyeglass" exclusion. The ITEM Coalition believes that this extremely expansive exclusion would decrease access to important assistive technology for people with vision impairments now and in the future, as well as perpetuate a harmful precedent that impacts access to assistive technology for all people with disabilities.

Impact of "Low Vision Aid Exclusion" on Individuals with Vision Impairments:

The ITEM Coalition believes that this proposal will have a significant impact on beneficiaries with vision impairments who depend on assistive technology that incorporates "one or more lens" to aid in their vision. This represents a preemptive wholesale denial of benefits for an entire subpopulation of people with disabilities.

Initially, the expansion of the eyeglass exclusion would prevent access to devices such as hand-held magnifiers, video monitors, and other such technologies that utilize lens to enhance vision. These tools are often essential for individuals with low vision who, without the aid of assistive technology, cannot read prescriptions, financial documents, mail, recipes, and other important materials. In short, these devices allow individuals with low vision to live independently and safely.

While the immediate impact this expansive interpretation of the eyeglass exclusion may be a decrease in access to current devices for individuals with low vision, the proposal will have an even more detrimental impact in the term. The expansion of the statutory eyeglass exclusion to include *any* technology that uses "one or more lens for the primary purpose of aiding vision," serves as a preemptive and unwarranted coverage denial for any new technology designed to assist individuals with vision impairments.

The ITEM Coalition believes that this preemptive coverage denial is particularly problematic because it serves as a tremendous disincentive to manufacturers and innovators to develop new and progressive vision technology. Not only does Medicare provide health care coverage for its beneficiaries, but it also serves to influence to private health insurers, impacting a much larger population. Therefore, Medicare coverage policies are indicative of the market for devices and technologies and influential when it comes to investments in research and development. If Medicare establishes this broad coverage exclusion for low vision aids, we would undoubtedly see a decrease in innovation in this area – harmful effects on those currently experiencing vision impairments or who will experience such impairments in the future.

Recommendations:

The ITEM Coalition recommends that rather than establishing preemptive coverage denials for all devices that utilize a lens to aid in vision, CMS instead evaluate the medical/functional purpose of each assistive device and technology at issue and establish individualized coverage decisions.

Although we recognize that the Centers for Medicare and Medicaid Services (CMS) has the authority to reasonably interpret the Medicare statute, the ITEM Coalition believes this broad exclusion to be unreasonable and unsupported by the facts and circumstances surrounding the low vision aid issue. In fact, the proposed decision, if left intact, is harmful to the health and independence of Medicare beneficiaries.

The ITEM Coalition believes that if the Congress had originally intended the eyeglass exclusion to apply to *all* devices with "one or more lens" to aid in vision, it would have explicitly expressed that with statutory language. However, nowhere in the statute or legislative history does Congress suggest anything but a plain reading of the term "eyeglasses." Instead, we believe that Congress' use of the term "eyeglasses" was simply meant to apply to traditional eyeglasses that fit on one's nose and around one's ears.

This interpretation has been supported by several federal courts. In one relevant case, *Currier v. Thompson*, 369 F. Supp. 2d 65 (D. Me. 2005), the U.S. District Court for the District of Maine found that a video monitor is *not* excluded from Medicare coverage based on the "eyeglass" exclusion and remanded the case back to the Secretary of Health and Human Services (HHS) to determine if a video monitor is considered under the Medicare benefit "durable medical equipment" or as a "prosthetic device."

Consistent with this decision, the ITEM Coalition argues that all vision aids with one or more lens, other than traditional eyeglasses, should be considered for a Benefit Category Determination (BCD). We recommend that the agency consider not just the common features between eyeglasses and other devices with lenses, but the differentiating features as well that may lend themselves to coverage under the program for specific populations with low vision needs. Some of these devices may use a power source or a video screen to augment vision. These are features that Congress was clearly not addressing in the statutory language regarding eyeglasses when this language was included in the statute years ago. After such an individualized evaluation, if it is determined that the device falls under a Medicare benefit category, coverage criteria should be established by CMS.

For example, a video monitor used to aid extremely low vision clearly meets Medicare's four-pronged definition of durable medical equipment (DME) in that it can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to an individual in the absence of an illness or injury and is appropriate for use in the home. Therefore, Medicare should develop a set of coverage standards for video monitors allowing appropriate individuals with low vision access to this medically necessary technology. CMS should assess other technologies through a similar process for purposes of Medicare coverage.

Conclusion:

The ITEM Coalition strongly recommends that CMS reconsider its proposal to preemptively disqualify all low vision aids which utilize a lens from Medicare coverage. Many of these types of devices could assist individuals in completing activities of daily living, thereby improving their health and independence. This proposed coverage exclusion will prevent access to currently available vision aids for people with vision impairments as well as decrease the development of new and innovative vision technology for people with disabilities. We encourage CMS to evaluate the medical/functional purpose of each assistive device and technology at issue and establish individualized coverage decisions.

Additionally, the ITEM Coalition would be remiss if we did not relate this proposal to the general pattern being displayed by CMS when it comes to coverage of assistive technology and the interpretation of the Medicare statute and regulations. While we recognize the need for budgetary restraint on the part of the agency, we believe that that agency does not adequately weigh the real-life value of assistive technology for people with disabilities against the cost of covering such technology for appropriate beneficiaries. For many people with disabilities, assistive technology is often an essential factor in improving or maintaining one's health status, maintaining independence, living safely, returning to work or school, and participating in community activities.

Members of the ITEM Coalition have been vocal in their opposition to Medicare's restrictive interpretation of the "in the home" language under the definition of DME. Members have also expressed serious concern with the recent iBOT Mobility System proposed coverage decision which essentially denies coverage of this device. Now, CMS is proposing an expansive exclusion of all vision technology which contains a lens of any kind because of statutory language that narrowly excludes Medicare coverage of "eyeglasses."

The ITEM Coalition urges Medicare to seriously consider the impact of its restrictive interpretations of the statute and regulations on the basic health and independence needs of people with disabilities. The fluidity and, often, ambiguity of the Medicare statute allows CMS important opportunities to provide beneficiaries with life-changing and innovative assistive devices. We request that Medicare embrace these opportunities for the benefit of people with disabilities.

Thank you for this opportunity to comment.

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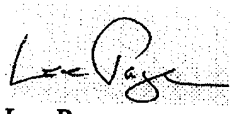
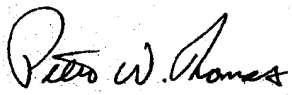
Sincerely,

The ITEM Coalition Steering Committee

Mark Richert
American Foundation for the Blind



Lee Page
Paralyzed Veterans of America



Peter Thomas
CCD Health Task Force

Alaine Perry
United Spinal Association

Zi-Xiang Shen
Medicare Rights Center

CC: Lorrie Ballantine
Joel Kaiser
Michael Keane
Walter Rutemueller
Linda Smith

Attachments: List of ITEM Coalition Members

ITEM Coalition Members

Adapted Physical Activity Council

Advancing Independence

Advanced Medical Technology Association

Alexander Graham Bell Association for the Deaf and Hard of Hearing

Alpha One

American Academy of Audiology

American Academy of Neurology

American Academy of Physical Medicine and Rehabilitation

American Association for Homecare

American Association of People with Disabilities

American Association on Health and Disability

American Congress of Community Support and Employment Services

American Congress of Rehabilitation Medicine

American Foundation for the Blind

American Medical Rehabilitation Providers Association

American Music Therapy Association

American Network of Community Options And Resources

American Occupational Therapy Association

American Physical Therapy Association

American Speech-Language-Hearing Association

American Therapeutic Recreation Association

Amputee Coalition of America

Assistive Technology Industry Association

Association for Education and Rehabilitation of the Blind and Visually Impaired

Association for Persons in Supported Employment

Association of Tech Act Projects

Association of University Centers on Disabilities

Blinded Veterans Association

Brain Injury Association of America

Center for Disability Issues and Health Professionals

Center for Independent Living Inc., Berkeley, California

Center for Medicare Advocacy, Inc.

Christopher Reeve Paralysis Foundation

Consortium of Developmental Disabilities Councils

Council of Citizens with Low Vision International

Council of State Administrators of Vocational Rehabilitation

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Disability Service Providers of America

Easter Seals

Epilepsy Foundation

Families USA

Goodwill Industries International, Inc.

Helen Keller National Center

Inclusion Research Institute

Long Island Center for Independent Living

Medicare Rights Center

The Miami Project to Cure Paralysis

National Association for Home Care and Hospice

National Association for the Advancement of Orthotics and Prosthetics

National Association of Councils on Developmental Disabilities

National Association of Protection and Advocacy Systems

National Association of Rehabilitation Research and Training Centers

National Campaign for Hearing Health

National Coalition for Disability Rights

National Council on Independent Living

National Family Caregivers Association

National Multiple Sclerosis Society

National Organization on Disability

National Rehabilitation Hospital – Center for Health and Disability Research

National Respite Coalition

National Spinal Cord Injury Association

National Stroke Association

National Vision Rehabilitation Association

NISH

Paralyzed Veterans of America

Research Institute for Independent Living

Rehabilitation Engineering and Assistive Technology Society of North America

Self Help for Hard of Hearing People

Service Employees International Union

Spina Bifida Association of America

The Arc of the United States

Topeka Independent Living Resource Center

United Cerebral Palsy Associations

United Spinal Association

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Submitter :

Date: 06/30/2006

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Gap-filling

Gap-filling

See attachment.

CMS-1270-P-1162-Attach-1.DOC

ATTACHMENT TO #1162

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier- "Gap-filling"

Comments:

The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. There can be no assurance that suppliers would submit bids for new technologies at the level that would be inferred through Gap Filling. Rather, issues of Gap Filling should be addressed in a separate NPRM and/or special competitive acquisition process.

The three methodologies proposed to replace Gap Filling are neither objective nor directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and their financial status or other support data. Rather, functional and medical benefit assessments would be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer in the process

Submitter : Mr. Carl Foster **Date:** 06/30/2006

Organization : Dependable Medical Equipment

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

I am a R.N., ATS Rehab Equipment Specialist and General Manager for a DME company in Tucson AZ. Throughout my 30 plus years of participating in the provision of health care services and as a user of services a very important variable stands out; THE ABILITY TO HAVE CHOICE IN WHO PARTICIPATES AS THE PROVIDER OF SUPPLIES AND SERVICES.
MANY OF THE INVIDUALS IN NEED OF OUR EQUIPMENT AND SERVICE ARE DEALING WITH SOME DEGREE OF LOSS TO THEIR WELL BEING, AND LIMITING THE CHOICE OF WHO PROVIDES CARE IS AN ADDITIONAL UNNECESSARY BLOW TO THEM. The importance of managing finances and costs is understood. Limiting provider options through COMPETITIVE BIDDING IS NOT THE MEANS TO THAT END. I recommend an approach that either has CMS redetermine Allowable Fee Rates, or that rates once established, be available for all providers who meet the Supplier Standards to participate. On Additional note please change back to a non capped fee schedule for Oxygen. Thank You.

Submitter : Dr. Jeffrey Petrinitz

Organization : The Triad Foot Center, PA

Category : Physician

Date: 06/30/2006

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

Mark B. McClellan, MD, PHD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
Electronic Claims

Dear Mr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise 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).

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 judgement 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, 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. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negative impacted.

Sincerely,

Jeffrey A. Petrinitz, DPM
The Triad Foot Center, PA

Submitter : Anthony J. Filippis **Date:** 06/30/2006

Organization : Wright

Category : Home Health Facility

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

We would like to comment on beneficiary services and MSA areas which have not been defined. We see daily examples of how beneficiaries choose Wright & Filippis over other providers due to quality and superior clinical services. We work diligently through Product Evaluation Committees to ensure the quality of product is maintained while working through already reduced reimbursement rates. We have added clinical services in spite of these reductions, because it is in the best interest of the beneficiary. We realize these added services are in the best interest of the beneficiary and will reduce costs in the long term for all, including CMS. Under the bid process, will we be able to maintain this level of care for the beneficiaries? Will any provider be able to maintain this level of care? What will be compromised for this reduction in reimbursement to the winning bidder? Will the equipment provided be up to the standard the physician expects for proper therapeutic benefit? How will we continue to meet the needs of the community, as community support is and always will be one of our most important Core Values?

Community Support and Customer Service our values that are integrated and celebrated throughout our organization. However, not having MSA s clearly identified has made the corporate planning process cumbersome. When you look at the proposed Supplier Business Quality Standards, strategic planning allows providers to accomplish the goals set forth. Not knowing where competitive bidding will be applied has temporarily curtailed plans of increasing services to better meet the needs of the beneficiary and the community we support.

Submitter : Ms. Mary Nicholas **Date:** 06/30/2006

Organization : Healthcare Quality Association on Accreditation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1166-Attach-1.DOC

CMS-1270-P-1166-Attach-2.DOC

#1166

Healthcare
QUALITY
ASSOCIATION ON ACCREDITATION

June 30, 2006

To Whom It May Concern:

The Healthcare Quality Association on Accreditation submits this document as our response to the NPRM proposal issued on May 1, 2006. We continue to have serious concerns about a competitive bidding program that requires providers to become accredited, but the quality standards that the accreditation programs must enforce continue to be delayed. They were stated to be released in "June 2006". As of the submission of this document on June 30, 2006, nothing has been released and the process is further delayed and encumbered.

As an accreditation organization that has been working closely with HME providers, there exists a tremendous amount of confusion in the industry as to the expectations from CMS and for accreditation organizations in general. We are where HME providers look to and communicate with in regards to any information and provision of guidelines. It becomes increasingly difficult to attempt to interpret the direction when the issuance of the NPRM offers contradictory information.

HQAA will choose too apply for recognition from CMS as an approved accreditation organization. As with the proposed Competitive Bidding guidelines, we hope that CMS does not create or impose guidelines that restrict the application of organizations that are new, or smaller in scope. As was reported at the most recent meeting of the PAOC and CMS, companies that provide equipment and services to Medicare beneficiaries number in the tens of thousands. If the expectation is to not choke the system, then the pipes of provision of service and accreditation must remain open.

HQAA has included the text written in the NPRM (in italics) and has formulated a response to each section of text that refers to accreditation. Our responses are listed in bold text and follow the italicized NPRM text below. At the conclusion of the NPRM text and comments are the comments we would like to express regarding the information presented at the Professional Advisory and Oversight Committee (PAOC) meetings held on May 22 and 23, 2006, where it was also requested that these comments be submitted in writing.

Part 1

We are developing quality standards as required by section 1834(a)(20) of the Act, to address suppliers' accountability, business integrity, provision of quality products to beneficiaries, and performance management. These standards will measure the effect of suppliers' services on beneficiaries. The supplier quality standards will include product specific requirements that will focus on a

consumer-directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS.

It is critical to identify that from a global and industry perspective, "standards" are not meant to be a measurement of effect. "Standards" are set as a benchmark, as a model of quality, efficiency, accuracy, etc. Within standards should be requirements for individual companies to measure their own effects. If it is the desire of CMS to understand and receive this information as to the effects of suppliers on beneficiaries, then a "standard" should be set to identify, measure, collect and report this information; a process that is required by accreditation organizations.

The more specific CMS makes the "rules" or the standards, the more intensive administration that must accompany such requirements. Standards are the benchmarks to achieve with all products within a company, not just specific products. In order to have an effect on the overall quality of a company, why should standards only apply to some of the products it offers? Is it not possible that beneficiaries purchase products independently of their Medicare benefits and shouldn't CMS also have a vested interest in their overall care, not just that which it pays for? If the beneficiary is the focus, then to the accreditation organization, the whole company is the focus, not just that portion that does business with one payer source. Companies should be accredited for all that they provide, not just a portion. How confusing that could become to the beneficiary. Allow accreditation to impose standards of quality to the whole, not just parts.

The quality standards will include performance management requirements to ensure the development, implementation, monitoring, and evaluation of policies, procedures, and products so that suppliers can maintain compliance with regulatory requirements and our policy instructions.

Additionally, the supplier quality standards will include requirements for monitoring beneficiary satisfaction with products and suppliers' responses to beneficiary complaints. As is authorized under section 1834(a)(20)(E), we will be establishing the supplier quality standards through program instructions and will publish them on our website.

The supplier quality standards will include product specific requirements that will focus on a consumer directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS. We believe these requirements will empower beneficiaries to make better-informed choices regarding equipment selection and the proper and safe use of DMEPOS, which we believe will lead to increased beneficiary satisfaction, safe and appropriate use of purchased equipment, and positive health outcomes.

HQAA fully supports the release of the quality standards and the measurements that will be required. We would like to state that without knowing what the final standards are, it is not possible to affirm our unconditional support. A consumer-directed model is the tenet to an effective quality management system, which HQAA fully supports.

We are using contractor support and input from industry suppliers and national associations to develop the quality standards.

HQAA would encourage CMS to offer a roundtable discussion with industry accreditation providers and additional experts from the field to discuss how CMS expects this program to be administered, the time line of expectations and the review of the accreditation providers themselves. It appears that the contractor has not provided a broad enough review of current industry practices, accreditation standards and input from industry experts to render judgment and make informed decisions. The "national industry associations" that were contacted outside of the specific services of orthotics and prosthetics, was the American Association for Homecare, who were only contacted for assistance with respiratory standards, which are only one component of this very diverse business.

Additionally, section 1865(b) of the Act sets forth the general procedures for CMS to designate national accreditation organizations to deem providers or suppliers to meet Medicare conditions of participation or coverage if they are accredited by a national accreditation organization approved by CMS.

Although, the statute itself does not require us to issue a rulemaking or provide notice in the ***Federal Register*** *in order to designate and approve DMEPOS accreditation organizations, we believe that the Administrative Procedure Act does require us to give notice and an opportunity for comment before we institute our procedures for designating and supervising these organizations.*

HQAA supports the expectation that Medicare will grant "deeming status" to accreditation organizations. However, the deeming regulations were written for home health (Part A) providers and requirements in many sections are not applicable in the field of Durable Medical Equipment. Additionally, the current regulations require that applicants submit a lengthy history of companies that have been accredited. This does not allow for new companies to enter the market in a timely manner. While we have received verbal reassurance that these items will be addressed in the application process, the delay in the release of this information is cause for great concern.

To accommodate suppliers that wish to participate in the Medicare DMEPOS Competitive Bidding Program, we will phase-in the accreditation process and require accreditation organizations to prioritize their surveys to accredit suppliers in the selected MSAs and competitive bidding areas.

1. Quality Standards and Accreditation (proposed §414.414(c))
Section 1847(b)(2)(A)(i) of the Act specifies that a contract may not be awarded to any entity unless the entity meets applicable quality standards specified by the Secretary under section 1834(a)(20) of the Act. Section 1834(a)(20) instructs the Secretary to establish and implement quality standards for all DMEPOS suppliers in the Medicare program, not just for suppliers in the competitive bidding areas. All suppliers will have to meet these quality standards to be eligible to submit claims to the Medicare program, irrespective of the competitive bidding program.

The quality standards are to be applied by recognized independent accreditation organizations designated by the Secretary under section 1834(a)(20)(B) of the Act. A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid.

There are many payers across the country that require organizations to be accredited in order to participate in payer networks. Many managed care organizations require accreditation, as many are required to do so through their own NCQA accreditation requirements. Additionally for example, the State of Florida is requiring that by 2007, all licensed providers must become accredited. Additionally, accreditation companies will have renewal companies scheduled ongoing who must also have priority for re-accreditation surveys. Every accreditation provider conducts un-announced and unplanned surveys to investigate complaints or incidents reported. These unplanned events must also take priority. As is any business, accreditation providers are always limited by their resources and capabilities. Each can serve a certain capacity, which include staff availability and travel issues. By what authority can CMS require an accreditation provider to prioritize accreditation to providers in the MSA areas? In light of this statement by CMS, how can the underlined statement above be supported, if the intent is for all providers to become accredited, "not just in the competitive bidding areas...to submit claims to Medicare" The business of accreditation organizations is to serve the companies who select their particular company, not the payer, including Medicare. Just as the CMS focus is the beneficiary, the focus of any business is their customer, who for the accreditation organization, are all companies that apply regardless of region.

The length of time for the grace period will be determined by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area. The length of time of the grace period will be specified in the RFB for each competitive bidding program. We solicit public comments on the length of time for the grace period.

HQAA would like to express concern over the consideration of any type of "grace period". The problem lies with those HME companies who do not "pass" on their first attempt. Accreditation can only be awarded to companies when standards are met and this can only be evaluated after the on-site review. There is a certain percentage of failure for every realistic accreditation program in every line of business, from manufacturing to healthcare. After all, that is the point of this mandated process, everyone does not pass successfully without demonstrating compliance. A "grace period" leads one to believe that the on-site review is merely a formality. The reality is that organizations can not fully know what their administrative expenses truly are until they complete the accreditation process successfully. If an organization is unsuccessful in their first attempt and needs to devote additional time and effort to achieving accreditation, these additional resources will contribute to their overall administrative expenses. Providers will not know what their individual cost to provide goods and services will be as they submit bids in a competitive bidding program. This will result in providers winning bids and then being

unable to provide the products at the winning price, thus defeating the intent of the program.

The term "grace period" and "grandfathering" has caused many HME companies to choose to wait to begin their accreditation process. Without CMS announcing the companies it will recognize for accreditation, many, many companies are waiting to begin the process. This waiting will absolutely cause future complications to the effective implementation of this project. HQAA would recommend that CMS consider a methodology to preliminarily accept current accreditation organizations into this process, just as the "grandfathering" clause is intended for DMEPOS companies. Require submission of a complete description of an accreditation organizations operations, policies, procedures, requirements, standards, and methods. Identify preliminary criteria that the AO has to meet in order to be considered accepted in to the application pool. If accepted with the intent to apply, communicate to the DMEPOS industry that preliminary approvals have been granted.

To promote consistency in accrediting providers and suppliers throughout the Medicare program, we would use existing procedures for the application, reapplication, selection, and oversight of accreditation organizations detailed at Part 488 and apply them to organizations accrediting suppliers of DMEPOS and other items. We would make modifications to the existing requirements for accreditation organizations to meet the specialized needs of the DMEPOS industry. These modifications may require an independent accreditation organization applying for approval or re-approval of deeming authority to –

- *Identify the product-specific types of DMEPOS suppliers for which the organization is requesting approval or re-approval;*
- *Provide CMS with a detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare quality standards (for example, a crosswalk);*
- *Provide a detailed description of the organization's survey processes including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements;*
- *Describe the decision-making processes; describe procedures used to notify suppliers of compliance or noncompliance with the accreditation requirements;*
- *Describe procedures used to monitor the correction of deficiencies found during the survey; and*
- *Describe procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.*

HQAA supports these requirements, but restates the concern with these requirements as listed above. As the deeming requirements were written for home care providers under Part A, there are many irrelevant and non-applicable requirements found in Part 488. The 488 requirements would

need to be re-written to clearly define the expectations for a business that does not provide a similar type of intermittent, skilled service.

We may request detailed information about the professional background of the individuals who perform surveys for the accreditation organization including: the size and composition of accreditation survey teams for each type of supplier accredited; the education and experience requirements surveyors must meet; the content and frequency of the continuing education training provided to survey personnel; the evaluation systems used to monitor the performance of individual surveyors and survey teams; and policies and procedures for a surveyor or institutional affiliate of an accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which this individual or institution is professionally or financially affiliated .

HQAA has developed our own policies and requirements for the surveys and will be pleased to submit this information with our deeming status application.

We may require the accreditation organization to submit the following supporting documentation:

- *A written presentation that would demonstrate the organization's ability to furnish CMS with electronic data in ASCII-comparable code;*
- *A resource analysis that would demonstrate that the organization's staffing, funding and other resources are sufficient to perform the required surveys and related activities; and*
- *An acknowledgement that the organization would permit its surveyors to serve as witnesses if CMS took an adverse action against the DMEPOS supplier based on the accreditation organization's findings.*

When conducted on a representative sample basis, the survey would be comprehensive and address all Medicare supplier quality standards or would focus on a specific standard. When conducted in response to an allegation, the CMS survey team would survey for any standard that CMS determined was related to the allegations. If the CMS survey team substantiated a deficiency and determined that the supplier was out of compliance with Medicare supplier quality standards, we would revoke the supplier's billing number and re-evaluate the accreditation organization's approved status. A supplier selected for a validation survey would be required to authorize the validation survey to occur and authorize the CMS survey team to monitor the correction of any deficiencies found through the validation survey.

HQAA supports these requirements if they are indeed required.

Ongoing Responsibilities of CMS Approved Accreditation Organizations.

A DMEPOS independent accreditation organization approved by CMS would be required to undertake the following activities on an ongoing basis:

- *Provide to CMS in written form and on a monthly basis all of the following:*

++ Copies of all accreditation surveys along with any survey-related information that CMS may require (including corrective action plans and summaries of CMS requirements that were not met).

++ Notice of all accreditation decisions.

++ Notice of all complaints related to suppliers of DMEPOS and other items.

++ Information about any suppliers of DMEPOS and other items for which the accrediting organization has denied the supplier's accreditation status.

++ Notice of any proposed changes in its accreditation standards or requirements or survey process. the organization implemented the changes before or without CMS approval, CMS could withdraw its approval of the accreditation organization.

- *Submit to CMS (within 30 days of a change in CMS requirements): ++ An acknowledgment of CMS's notification of the change; ++ A revised cross-walk reflecting the new requirements; and*

++ An explanation of how the accreditation organization would alter its standards to conform to CMS' new requirements, within the time frames specified by CMS in the notification of change it received.

- *Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.*
- *Provide CMS with written notice of any deficiencies and adverse actions implemented by the independent accreditation organization against an accredited DMEPOS supplier within 2 days of identifying such deficiencies, if such deficiencies pose immediate jeopardy to a beneficiary or to the general public.*
- *Provide written notice of the withdrawal to all accredited suppliers within 10 days of CMS's notice to withdraw approval of the accreditation organization.*
- *Provide, on an annual basis, summary data specified by CMS that related to the past year's accreditation activities and trends.*

HQAA fully supports providing CMS with information that indicates the accreditation status of DMEPOS companies and the demographics of those companies. It is again, difficult to fully opine due to the lack of knowing the standards as of this writing.

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HQAA supports a reporting process to CMS regarding the accreditation status of companies that provide services and/or equipment to beneficiaries. To require full disclosure of an accreditation report of each company is believed to be a complete invasion of privacy about a customer and a breech of proprietary information. Managed care organizations do not require the privileged information about the companies that they contract with. By what authority can CMS require full disclosure about a customer of a private business? By setting this requirement, it implies that the private accreditation organizations exist to be an extension of a government entity. Do not require this full disclosure, but in the CMS authority to grant recognition, review the processes in place to assist and ensure companies comply with the standards. Information such as

accreditation status and the dates of accreditation are within the limits of public information.

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To receive monthly reports from accreditation organizations will require a great deal of administrative oversight on behalf of CMS. Where is the indication as to how that oversight will be administered, the responsibilities of those entities receiving the reports and who has access to the information after it is submitted? Will this not also increase the administrative costs of CMS for this project? To require notice of all complaints could be an extremely cumbersome portion in and of itself. CMS would have to clearly define "complaint", companies would implement their own internal process based upon this decision, and then by the description above, the accreditation organizations would have to become the recipients of all complaints and in turn submit a compilation to CMS. In doing so, this dilutes the purpose and philosophy of accreditation organizations. Standards and the act of accreditation should validate that a complaint process exists and is effectively implemented within an organization. CMS should validate that the accreditation organizations have this requirement. It should not be the intent of a payer source to be the recipient of all complaints from all companies via a third party.

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a. Equivalency Review

We would compare the accreditation organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes when: CMS imposed new requirements or changed its survey process; an accreditation organization proposed to adopt new standards or changes in its survey process; or the term of an accreditation organization's approval expired.

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A CMS survey team would conduct a survey of an accredited organization, examine the results of the accreditation organization's own survey procedure onsite, or observe the accreditation organization's survey, in order to validate the organization's accreditation process. At the conclusion of the review, we would identify any accreditation programs for which validation survey results indicated:

- *A 10 percent rate of disparity between findings by the accreditation organization and findings by CMS on standards that did not constitute immediate jeopardy to patient health and safety if not met;*
- *Any disparity between findings by the accreditation organization and findings by CMS on standards that constituted immediate jeopardy to patient health and safety if not met; or*
- *There were widespread or systemic problems in the organization's accreditation process such that the accreditation no longer provided assurance*

that suppliers met or exceeded the Medicare requirements, irrespective of the rate of disparity.

HQAA supports these requirements if they are indeed required. However, it is not possible to agree to validation surveys and the like when, at this point, we are not provided with the final quality standards with which we must comply.

Part 2

HQAA's comments regarding the material and testimony presented at the PAOC meeting:

It was said that there are 150,000 providers in this category who bill Medicare. This number was never quoted before. It was always stated as being close to 30,000. The description was broken down as follows: 40,000 O&P providers, 50,000 Pharmacy providers and 60,000 DME providers. If this is true, how are this many providers going to become accredited by 2012?

We are very concerned with report of information garnered from focus groups that was presented. Specifically:

- It was stated that there were 44 participants from 27 states; there is no breakdown of the types of services these beneficiaries were receiving. Were any of these beneficiaries bed bound or homebound? 44 participants is not a statistically significant number to make ANY conclusions or to deem valid the information received in comparison to the total number of beneficiaries receiving DMEPOS.
- The concern was expressed that these beneficiaries saw their DME providers as "drop off" or "delivery persons". If these were not bed bound, homebound, or medically compromised beneficiaries, of course they would see their supplier as a delivery service only. If they were receiving diabetic or wound supplies, cane, blood pressure device, these would naturally be considered as a "drop off". An oxygen concentrator, a hospital bed, a CPM device, etc. is not perceived as "dropped off". Again, the data was statistically insignificant to draw any conclusion.
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The document refers often reference a requirement of "unannounced" surveys. We feel strongly that CMS should allow scheduled triennial surveys to be announced, but then require a percentage of "unscheduled" surveys as re-visits or validations. With such a large group of providers who are new to this process, it seems unfair to now require that the surveys are unannounced, when they have been announced for the previous 20-year history and are also announced for those becoming accredited for Part A home care. Unannounced visits should occur when there is an investigative reason. The demonstration of quality management and ethical business practices should have a less adversarial

connotation to them, particularly for the DMEPOS industry that has not ever experienced the survey practice before.

Again, we reiterate our concerns with implementing anything prior to release of final quality standards and very concerned about what those standards will entail. Specifically:

- Providers can't bid on items without knowing what there costs are (need to include all costs of accreditation)
- It usually takes an organization 4 – 6 months to become accredited, in the best-case scenario.
- Many providers are waiting to see who will be "approved" as deemed status providers before they move ahead. This delay is causing grave concerns and in the larger focus, could cause a ripple effect that would ultimately negatively impact the beneficiaries.

We are concerned with the text and verbal statements made that CMS expects 50% of the providers to "go out of business". There were numerous assurances early in this process of the protections for small businesses. This would provide evidence to the contrary.

Finally, we would like to express our concern that the current proposed program is dramatically different from the demonstration projects the Congress reviewed when voting for Competitive Bidding. We feel that pursuing this more expanded and potentially exclusionary program is unwarranted and we encourage CMS to reduce the burden on providers and expedite the process.

If you have any questions about our concerns, please contact me in my office at 866.909.4722. We look forward to your timely response to our provider's concerns.

Respectfully Submitted,

Mary Nicholas

Mary Nicholas
Executive Director
Healthcare Quality Association on Accreditation

CC: Herb Kuhn, Director, Center for Medicare Management
Dr. Mark McClellan, CMS Administrator
The Honorable Charles Grassley

#1166

Healthcare
QUALITY
ASSOCIATION ON ACCREDITATION

June 30, 2006

To Whom It May Concern:

The Healthcare Quality Association on Accreditation submits this document as our response to the NPRM proposal issued on May 1, 2006. We continue to have serious concerns about a competitive bidding program that requires providers to become accredited, but the quality standards that the accreditation programs must enforce continue to be delayed. They were stated to be released in "June 2006". As of the submission of this document on June 30, 2006, nothing has been released and the process is further delayed and encumbered.

As an accreditation organization that has been working closely with HME providers, there exists a tremendous amount of confusion in the industry as to the expectations from CMS and for accreditation organizations in general. We are where HME providers look to and communicate with in regards to any information and provision of guidelines. It becomes increasingly difficult to attempt to interpret the direction when the issuance of the NPRM offers contradictory information.

HQAA will choose too apply for recognition from CMS as an approved accreditation organization. As with the proposed Competitive Bidding guidelines, we hope that CMS does not create or impose guidelines that restrict the application of organizations that are new, or smaller in scope. As was reported at the most recent meeting of the PAOC and CMS, companies that provide equipment and services to Medicare beneficiaries number in the tens of thousands. If the expectation is to not choke the system, then the pipes of provision of service and accreditation must remain open.

HQAA has included the text written in the NPRM (in italics) and has formulated a response to each section of text that refers to accreditation. Our responses are listed in bold text and follow the italicized NPRM text below. At the conclusion of the NPRM text and comments are the comments we would like to express regarding the information presented at the Professional Advisory and Oversight Committee (PAOC) meetings held on May 22 and 23, 2006, where it was also requested that these comments be submitted in writing.

Part 1

We are developing quality standards as required by section 1834(a)(20) of the Act, to address suppliers' accountability, business integrity, provision of quality products to beneficiaries, and performance management. These standards will measure the effect of suppliers' services on beneficiaries. The supplier quality standards will include product specific requirements that will focus on a

consumer-directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS.

It is critical to identify that from a global and industry perspective, "standards" are not meant to be a measurement of effect. "Standards" are set as a benchmark, as a model of quality, efficiency, accuracy, etc. Within standards should be requirements for individual companies to measure their own effects. If it is the desire of CMS to understand and receive this information as to the effects of suppliers on beneficiaries, then a "standard" should be set to identify, measure, collect and report this information; a process that is required by accreditation organizations.

The more specific CMS makes the "rules" or the standards, the more intensive administration that must accompany such requirements. Standards are the benchmarks to achieve with all products within a company, not just specific products. In order to have an effect on the overall quality of a company, why should standards only apply to some of the products it offers? Is it not possible that beneficiaries purchase products independently of their Medicare benefits and shouldn't CMS also have a vested interest in their overall care, not just that which it pays for? If the beneficiary is the focus, then to the accreditation organization, the whole company is the focus, not just that portion that does business with one payer source. Companies should be accredited for all that they provide, not just a portion. How confusing that could become to the beneficiary. Allow accreditation to impose standards of quality to the whole, not just parts.

The quality standards will include performance management requirements to ensure the development, implementation, monitoring, and evaluation of policies, procedures, and products so that suppliers can maintain compliance with regulatory requirements and our policy instructions.

Additionally, the supplier quality standards will include requirements for monitoring beneficiary satisfaction with products and suppliers' responses to beneficiary complaints. As is authorized under section 1834(a)(20)(E), we will be establishing the supplier quality standards through program instructions and will publish them on our website.

The supplier quality standards will include product specific requirements that will focus on a consumer directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS. We believe these requirements will empower beneficiaries to make better-informed choices regarding equipment selection and the proper and safe use of DMEPOS, which we believe will lead to increased beneficiary satisfaction, safe and appropriate use of purchased equipment, and positive health outcomes.

HQAA fully supports the release of the quality standards and the measurements that will be required. We would like to state that without knowing what the final standards are, it is not possible to affirm our unconditional support. A consumer-directed model is the tenet to an effective quality management system, which HQAA fully supports.

We are using contractor support and input from industry suppliers and national associations to develop the quality standards.

HQAA would encourage CMS to offer a roundtable discussion with industry accreditation providers and additional experts from the field to discuss how CMS expects this program to be administered, the time line of expectations and the review of the accreditation providers themselves. It appears that the contractor has not provided a broad enough review of current industry practices, accreditation standards and input from industry experts to render judgment and make informed decisions. The "national industry associations" that were contacted outside of the specific services of orthotics and prosthetics, was the American Association for Homecare, who were only contacted for assistance with respiratory standards, which are only one component of this very diverse business.

Additionally, section 1865(b) of the Act sets forth the general procedures for CMS to designate national accreditation organizations to deem providers or suppliers to meet Medicare conditions of participation or coverage if they are accredited by a national accreditation organization approved by CMS.

Although, the statute itself does not require us to issue a rulemaking or provide notice in the ***Federal Register*** *in order to designate and approve DMEPOS accreditation organizations, we believe that the Administrative Procedure Act does require us to give notice and an opportunity for comment before we institute our procedures for designating and supervising these organizations.*

HQAA supports the expectation that Medicare will grant "deeming status" to accreditation organizations. However, the deeming regulations were written for home health (Part A) providers and requirements in many sections are not applicable in the field of Durable Medical Equipment. Additionally, the current regulations require that applicants submit a lengthy history of companies that have been accredited. This does not allow for new companies to enter the market in a timely manner. While we have received verbal reassurance that these items will be addressed in the application process, the delay in the release of this information is cause for great concern.

To accommodate suppliers that wish to participate in the Medicare DMEPOS Competitive Bidding Program, we will phase-in the accreditation process and require accreditation organizations to prioritize their surveys to accredit suppliers in the selected MSAs and competitive bidding areas.

1. Quality Standards and Accreditation (proposed §414.414(c))
Section 1847(b)(2)(A)(i) of the Act specifies that a contract may not be awarded to any entity unless the entity meets applicable quality standards specified by the Secretary under section 1834(a)(20) of the Act. Section 1834(a)(20) instructs the Secretary to establish and implement quality standards for all DMEPOS suppliers in the Medicare program, not just for suppliers in the competitive bidding areas. All suppliers will have to meet these quality standards to be eligible to submit claims to the Medicare program, irrespective of the competitive bidding program.

The quality standards are to be applied by recognized independent accreditation organizations designated by the Secretary under section 1834(a)(20)(B) of the Act. A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid.

There are many payers across the country that require organizations to be accredited in order to participate in payer networks. Many managed care organizations require accreditation, as many are required to do so through their own NCQA accreditation requirements. Additionally for example, the State of Florida is requiring that by 2007, all licensed providers must become accredited. Additionally, accreditation companies will have renewal companies scheduled ongoing who must also have priority for re-accreditation surveys. Every accreditation provider conducts un-announced and unplanned surveys to investigate complaints or incidents reported. These unplanned events must also take priority. As is any business, accreditation providers are always limited by their resources and capabilities. Each can serve a certain capacity, which include staff availability and travel issues. By what authority can CMS require an accreditation provider to prioritize accreditation to providers in the MSA areas? In light of this statement by CMS, how can the underlined statement above be supported, if the intent is for all providers to become accredited, "<u>not just in the competitive bidding areas...to submit claims to Medicare</u>" The business of accreditation organizations is to serve the companies who select their particular company, not the payer, including Medicare. Just as the CMS focus is the beneficiary, the focus of any business is their customer, who for the accreditation organization, are all companies that apply regardless of region.

The length of time for the grace period will be determined by the accrediting organizations' ability to complete the accrediting process within each competitive bidding area. The length of time of the grace period will be specified in the RFB for each competitive bidding program. We solicit public comments on the length of time for the grace period.

HQAA would like to express concern over the consideration of any type of "grace period". The problem lies with those HME companies who do not "pass" on their first attempt. Accreditation can only be awarded to companies when standards are met and this can only be evaluated after the on-site review. There is a certain percentage of failure for every realistic accreditation program in every line of business, from manufacturing to healthcare. After all, that is the point of this mandated process, everyone does not pass successfully without demonstrating compliance. A "grace period" leads one to believe that the on-site review is merely a formality. The reality is that organizations can not fully know what their administrative expenses truly are until they complete the accreditation process successfully. If an organization is unsuccessful in their first attempt and needs to devote additional time and effort to achieving accreditation, these additional resources will contribute to their overall administrative expenses. Providers will not know what their individual cost to provide goods and services will be as they submit bids in a competitive bidding program. This will result in providers winning bids and then being

unable to provide the products at the winning price, thus defeating the intent of the program.

The term "grace period" and "grandfathering" has caused many HME companies to choose to wait to begin their accreditation process. Without CMS announcing the companies it will recognize for accreditation, many, many companies are waiting to begin the process. This waiting will absolutely cause future complications to the effective implementation of this project. HQAA would recommend that CMS consider a methodology to preliminarily accept current accreditation organizations into this process, just as the "grandfathering" clause is intended for DMEPOS companies. Require submission of a complete description of an accreditation organizations operations, policies, procedures, requirements, standards, and methods. Identify preliminary criteria that the AO has to meet in order to be considered accepted in to the application pool. If accepted with the intent to apply, communicate to the DMEPOS industry that preliminary approvals have been granted.

To promote consistency in accrediting providers and suppliers throughout the Medicare program, we would use existing procedures for the application, reapplication, selection, and oversight of accreditation organizations detailed at Part 488 and apply them to organizations accrediting suppliers of DMEPOS and other items. We would make modifications to the existing requirements for accreditation organizations to meet the specialized needs of the DMEPOS industry. These modifications may require an independent accreditation organization applying for approval or re-approval of deeming authority to –

- *Identify the product-specific types of DMEPOS suppliers for which the organization is requesting approval or re-approval;*
- *Provide CMS with a detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare quality standards (for example, a crosswalk);*
- *Provide a detailed description of the organization's survey processes including procedures for performing unannounced surveys, frequency of the surveys performed, copies of the organization's survey forms, guidelines and instructions to surveyors, quality review processes for deficiencies identified with accreditation requirements;*
- *Describe the decision-making processes; describe procedures used to notify suppliers of compliance or noncompliance with the accreditation requirements;*
- *Describe procedures used to monitor the correction of deficiencies found during the survey; and*
- *Describe procedures for coordinating surveys with another accrediting organization if the organization does not accredit all products the supplier provides.*

HQAA supports these requirements, but restates the concern with these requirements as listed above. As the deeming requirements were written for home care providers under Part A, there are many irrelevant and non-applicable requirements found in Part 488. The 488 requirements would

need to be re-written to clearly define the expectations for a business that does not provide a similar type of intermittent, skilled service.

We may request detailed information about the professional background of the individuals who perform surveys for the accreditation organization including: the size and composition of accreditation survey teams for each type of supplier accredited; the education and experience requirements surveyors must meet; the content and frequency of the continuing education training provided to survey personnel; the evaluation systems used to monitor the performance of individual surveyors and survey teams; and policies and procedures for a surveyor or institutional affiliate of an accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which this individual or institution is professionally or financially affiliated .

HQAA has developed our own policies and requirements for the surveys and will be pleased to submit this information with our deeming status application.

We may require the accreditation organization to submit the following supporting documentation:

- *A written presentation that would demonstrate the organization's ability to furnish CMS with electronic data in ASCII-comparable code;*
- *A resource analysis that would demonstrate that the organization's staffing, funding and other resources are sufficient to perform the required surveys and related activities; and*
- *An acknowledgement that the organization would permit its surveyors to serve as witnesses if CMS took an adverse action against the DMEPOS supplier based on the accreditation organization's findings.*

When conducted on a representative sample basis, the survey would be comprehensive and address all Medicare supplier quality standards or would focus on a specific standard. When conducted in response to an allegation, the CMS survey team would survey for any standard that CMS determined was related to the allegations. If the CMS survey team substantiated a deficiency and determined that the supplier was out of compliance with Medicare supplier quality standards, we would revoke the supplier's billing number and re-evaluate the accreditation organization's approved status. A supplier selected for a validation survey would be required to authorize the validation survey to occur and authorize the CMS survey team to monitor the correction of any deficiencies found through the validation survey.

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If you have any questions about our concerns, please contact me in my office at 866.909.4722. We look forward to your timely response to our provider's concerns.

Respectfully Submitted,

Mary Nicholas

Mary Nicholas
Executive Director
Healthcare Quality Association on Accreditation

CC: Herb Kuhn, Director, Center for Medicare Management
Dr. Mark McClellan, CMS Administrator
The Honorable Charles Grassley

Submitter : Mrs. Norma Arras **Date:** 06/30/2006

Organization : Mrs. Norma Arras

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an O.T. who is a certified hand therapist. I have concerns with the Medicare Proposed Competitive Bidding System. For example, there are numerous wrist splints available. Some limit finger motion. Another entity may win the bid to supply a splint. My order to increase finger range of motion may be compromised with the splint provided. If the splint needs adjustment, do we send the patient back and forth between facilities? If it were my splint, I could adjust it as part of treatment.

Submitter : **Date: 06/30/2006**

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Opportunity for Networks

Opportunity for Networks

See attachment.

CMS-1270-P-1168-Attach-1.DOC

#168

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier- "Opportunity for Networks"

Comments:

If the network utilizes an "administrative entity" to be responsible for billing Medicare, receiving payment on behalf of the network suppliers, and for appropriately distributing reimbursements to the other network members, is this entity required to be accredited?

What if this legal entity ensures its provider network members are appropriately accredited?

What is the accreditation process?

Can a sub-contractor / provider submit a bid and be a sub-contractor in another product category?

Can a provider whom submits a bid and loses then become a sub-contractor?

Submitter : **Dr. Norman Regal** **Date: 06/30/2006**

Organization : **The Triad Foot Center, PA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

Mark B. McClellan, MD, PHD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
Electronic Claims

Dear Mr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise 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).

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 judgement 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, 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. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negative impacted.

Sincerely,

Norman S. Regal, DPM
The Triad Foot Center, PA

Submitter : Mr. STEPHEN JALBERT **Date:** 06/30/2006

Organization : BEVERLY MEDICAL SUPPLIES INC

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTATCHMENT

CMS-1270-P-1170-Attach-1.DOC

Have Accreditation and Standards in Place before Starting

We recently went through the process of accreditation, and it took 7 months from the time we submitted our application until our initial site visit. We expected it to take 3 months. We still have not heard the official word yet. I for one welcomed the idea of, and enjoyed the process of accreditation. We are a small (1.1 million in annual sales) family run DME, and it was a great opportunity to improve they way we operate and do business. We love the idea of weeding out the rouge dealers, but let's not rush things. From my experience, there is simply no way to accomplish this by the end of 2006. 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 also needs to establish quickly who will be the bodies overseeing this undertaking, and it better be all 4 of the large accreditation bodies. It would really concern me if we went through the whole costly process only to find out that the organization we chose was not selected by Medicare as a contractor. O, why does CMS need to establish a department to monitor the accreditation bodies. There only function is to ensure that the standards set forth by both themselves, Medicare, and OSHA are adhered to. This seems like an enormous waste of time and money. how an accreditation body that has been doing this for years should set there standards. Unnecessary cost if you just select quality organizations to oversea the accreditation process. 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.

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. This is a gross overstepping of what should be your boundary.

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.

"Composite Score" Methodology

The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should make clear that it will provide suppliers with the weighting factors that CMS will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS within a category using the same criteria as CMS.

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.

Rebates sounds like a kick back and screams of fraud and abuse

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. Furthermore, if an organization elects to go through with the reduction in revenue by accepting the rebate program they cannot advertise it or promote it in any way. However, CMS will do that for them. That makes no sense at all.

Providing rebates also is contrary to the statutory requirement that beneficiaries incur 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.

CMS said the rebates would allow providers to be "more competitive", but PAOC

member Dave Kazynski, president of VGM's Homelink, noted that beneficiaries are mainly concerned about quality, not a small rebate.

Limitation on Beneficiary Liability for Items Furnished by Non-contract Suppliers

The Standards state that "if a non contract supplier located in a competitive bidding are furnishes an item included in the competitive bidding program for that area to a beneficiary who maintains a permanent residence in the area, the beneficiary would have no financial liability to the noncontract supplier unless the grandfather exception applies". There is no way to enforce this, nor does this really have any merit at all. If an organization loses out on the bid or chooses based on the dire consequences that competitive, CMS cannot tell them that not to market and sell their products to anyone. It is a free market, and though they can not bill to Medicare for that item, they can sell it cash wise to anyone they see fit. At that point there is no contract in place, and CMS no longer holds jurisdiction over that organinization.

Product Selection

Small companies that serve the community really need to know what items you plan on selecting. All that has been said is that the product up for bid will be based on potential savings. The agency will begin with items that have the highest volume and highest cost. The rule also proposes grouping similar items into product categories, such as hospital beds and accessories, so that beneficiaries would be able to get all related items in that category from one supplier. Suppliers will then be required to submit a bid for all items included in any product category.

A competitive bidding product group may include products (and more specifically HCPCS codes) from multiple medical policies. The intent of the law is to exclude products where bidding would affect access or quality, but this protection is lost if medical policies are combined. In order to ensure quality of care, CMS should ensure that providers that specialize in specific conditions are able to bid. If medical policies are combined, then the only providers eligible to bid would be those that carry the broadest product offering, regardless of their expertise.

The Bid Process

Suppliers cannot bid higher than the current fee schedule amount, even if they incur additional administrative or operational costs serve the competitive acquisition area (Example: Surgical dressings in the Polk County demonstration were of higher costs.) The proposal's use of "capacity" is non-specific & variable. Utilization can change, e.g., patients moving in & out of HMOs. While the demonstrations used the median of all bids to determine the single price, the proposed rule uses only the capacity concept.

Further, there is no incentive to exclude extreme 'lowball' bids, as bidders assume they will be paid an amount higher (i.e., the "pivotal" bid) than their bid. Some have suggested CMS require bidders to accept their actual bid price for the duration of the contract, acknowledging that additional administrative procedures and hurdles may be affected with multiple payment amounts. Other suggests disallowing statistical outliers (e. g. bids that fall outside X standard deviations of the mean). Some industry analysts have likened the traditional competitive bidding scenarios in which the lowest bidder generally "wins".

Determination of Number of Suppliers

CMS' process to determine the number of suppliers to meet projected demand in a MSA and its methodology to estimate supplier capacity are stacked in favor of large, high volume regional suppliers despite CMS' assertion that the NPRM provides opportunity for small suppliers to participate. Moreover, there are no guarantees that any of the winning bidders is a small business or a network of small businesses.

CMS needs to consider the negative impact the NPRM will have on small DME businesses and on the competitiveness of the second and third rounds of competitive bidding. You folks have made the point that beneficiaries will really not be affected, by a potential 50% reduction in DME companies, but frankly you cannot make that statement until you know how many suppliers will be allowed in each MSA.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses.

Clarification of "Competitive" and Potential Savings

CMS should explain and clarify what methodology will be used to determine whether a MSA is "competitive" during the 2008 - 2009 expansion.

CMS should explain and clarify what specific measures will be used to decide whether an item's potential savings as a result of competitive bidding?

* 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 varies 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?

Gap filling

The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. There can be no assurance that suppliers would submit bids for new technologies at the level that would be inferred through Gap Filling. Rather, issues of Gap Filling should be addressed in a separate NPRM and/or special competitive acquisition process.

The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, functional and medical benefit assessments would be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer in the process.

Networks & Sub-contractors

If the network utilizes an "administrative entity" to be responsible for billing Medicare, receiving payment on behalf of the network suppliers, and for appropriately distributing reimbursements to the other network members, is this entity required to be accredited? What if this legal entity ensures its provider network members are appropriately accredited? What is the accreditation process?

Can a sub-contractor / provider submit a bid and be a sub-contractor in another product category?
Can a provider whom submits a bid and loses then become a sub-contractor?

Submitter : Anthony J. Filippis **Date:** 06/30/2006

Organization : Wright & Filippis

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

Thank you for the opportunity to comment. Wright & Filippis is a provider of Prosthetics, Orthotics & H.M.E. for well over 60 years. Wright & Filippis is accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the American Board for Certification in Orthotics and Prosthetics (ABC). Our Organizational Improvement and Corporate Compliance staff support standards compliance form these two organizations as well as our Corporate Compliance Policies and Procedure

Wright & Filippis is concerned about a couple specific issues. Our first concern is the proposed rebate provision in the proposed rule; we feel this needs further evaluation, especially from the standpoint of the OIG Guidance for DMEPOS. Under the rebate program, providers who submit a bid below the single payment amount that is set would be allowed to offer a rebate to beneficiaries equal to the difference between their actual bid and the payment amount. Rebates sound like inducements. We have stressed Corporate Compliance and routine waiver of co-pay and deductible amounts for years. We chose a path of compliance and have realized successes. However, this changes with the rebate program. Whether we actively promote a rebate program or not under the proposed rule, the mere fact that it is available will add costs to the program from a Fraud & Abuse standpoint. More calls will have to be answered by CMS implying providers are paying beneficiaries for using them, for the beneficiary will truly not understand the program. Although CMS proposes to distribute program materials in the competitive bidding area that would identify contract providers who offer rebates, beneficiaries are going to call in with more questions why one provider is offering rebates and another provider is not. Perhaps, there will be differing rebates offered for the same procedure code by different providers. More suspected fraud and abuse. More calls, more confusion, added costs to implementation on sustaining the bid program will be the result.

Wright & Filippis believes Medicare should not allow providers to bid while they are in process of achieving accreditation rewards providers for not having externally measured standards in place prior to the bid process. What about the providers who have had accreditation all along? What about providers who have followed OIG Guidance all along? To only allow providers with a proven track record of accreditation and compliance will certainly reduce program administration costs; evaluating providers against new Supplier Standards will increase program costs; added costs to implement and sustain the bid program.

There is still the challenge of how you are going to prevent beneficiaries from having to deal with two or three companies for the same Plan of Care. If someone needs a hospital bed, a wheelchair and an oxygen concentrator, theoretically they could have to deal with three different companies under the bid concept. We don t see how this really benefits the beneficiary but will certainly increase costs to implement and sustain the bid program. In addition to this, standards required under Joint Commission accreditation mandate that from a continuity of care standpoint in home care, there should be a concerted effort to limit providers, not expand the providers who service the patient.

Submitter : Mr. Gordon Gund **Date:** 06/30/2006

Organization : Foundation Fighting Blindness

Category : Other Association

Issue Areas/Comments

Issue

Issue

Low Vision Aid Exclusion

CMS-1270-P-1172-Attach-1.DOC

1172

Foundation
Fighting Blindness
Driving research to save & restore sight

To cure RP (retinitis pigmentosa), macular degeneration, Usher syndrome and related retinal degenerative diseases

June 29, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicaid & Medicare Services
200 Independence Avenue SW, Suite 314G
Washington, D.C. 20201
Fax: (202) 690-6262

Dear Dr. McClellan:

I am writing to express my concern regarding the "Low Vision Aid Exclusion" rule as set forth in the Federal Register, May 1, 2006.

As you are aware, the Centers for Medicare & Medicaid Services has announced its intention to bar coverage of low vision devices as cited in CMS-1270-P. As specifically cited in Section Q of the Federal Register, the eyeglass exclusion for the Medicare program applies to eyepieces, hand-held magnifying glasses, contact lenses and other instruments, such as closed-circuit televisions and video magnifiers that use lenses to aid vision. Furthermore, Section 1862 (a) (7) of the Social Security Act excludes payment for expenses that are for eyeglasses, and/or procedures performed to determine the refractive state of the eyes.

More than 6.5 million Americans aged 55 and older are either blind or suffer from severe visual impairment. Visually impaired individuals depend on low vision aids not only to maintain their active and independent lifestyles, but also to gain or retain employment, earn an education or participate in community activities. Low vision aids can cost thousands of dollars, which is a hefty investment for seniors and those with disabilities, many of whom are faced with financial constraints. Denying coverage for low vision assistive technology will have far-reaching effects by discouraging innovators and manufacturers from investing in and developing cutting-edge vision technology. More importantly, the health and safety of visually impaired individuals may be compromised if they do not have access to these devices. Furthermore, preserving the health, safety, and independence of Medicare beneficiaries will also reduce the burden they place on taxpayers.

Barring these low vision devices will have devastating effects on the quality of life of Americans with low vision, and I respectfully urge you to reconsider this proposed rule. I welcome an open discussion with you on this matter and hope the "low vision aid exclusion" rule can be adjusted so individuals with visual impairments will not be deprived of the materials they require to live healthy, safe, and independent lives.

Thank you for your consideration of my concern and request.

Sincerely,

Gordon Gund
Chairman of the Board
The Foundation Fighting Blindness

Submitter :

Date: 06/30/2006

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

See attachment.

CMS-1270-P-1173-Attach-1.DOC

#1173

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier- "Opportunity for Participation by Small Suppliers"

Comments:

- Acquisition-There is no question that the next several years will prove to be a time of consolidation within the DME sector .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 and unfair restriction on the provider's property rights. The broad discretionary right that CMS can impose as it relates to preventing an acquired company from participating needs to be more clearly defined. 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.

Submitter : **Date: 06/30/2006**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Businesses should be required to pass quality standards before, not after they are allowed to bid.

The level of care for the Medicare beneficiary will greatly decline with competitive bidding. There will be no incentive for the company with the winning bid to maintain any quality of care since they will have no competition. The Medicare beneficiary will not be able to go to someone else for service if they are unhappy with the service they are being provided.

Small businesses will be forced out of business since larger national companies have stronger buying power.

Providers can not submit a realistic bid without knowing well in advance which region, and what equipment is being considered for competitive bidding.

CMS should just adjust the current allowables rather than go to the expense and trouble to create and maintain this competitive bidding process.

The rebate offering goes against current Medicare guidelines. Why would this be allowed?

Poor quality service for Medicare oxygen patients could mean additional emergency room visits and hospital stays. These stays are much more expensive for the Medicare program. Maintaining a level of quality care is the main focus of today's Home Care companies, because Medicare allowables are the same for each company and no one is allowed to offer kickbacks or rebates. If competition is eliminated there is no incentive for quality care. These patients can not maintain their own equipment. These patients also require 24hr emergency service to be available.

Submitter :

Date: 06/30/2006

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

See attachment.

CMS-1270-P-1175-Attach-1.DOC

#1175

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier-"Determining Single Payment Amounts for Individual Items"

Comments:

- Rebates-The NPRM includes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. This concept will be extremely confusing for the provider as well as the beneficiary. There is no legal basis under the law for permitting or providing rebates and is contrary to other laws applicable to the Medicare program. (namely the Anti-Kickback Statute and the Beneficiary Inducement Statute) We also strongly believe that furnishing rebates is contradictory to the statutory requirement governing our industry that states all efforts must be made to collect the remaining 20% after Medicare payment is received (understand the point and makes sense but sentence is a huge run-on and needs to be broken up). We would suggest determining other avenues in which to lower beneficiary out of pocket expense (preferred formulary items, for example).

Submitter :

Date: 06/30/2006

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Please see attached general comments relating to the competitive bidding process for certain DMEPOS covered items.

CMS-1270-P-1176-Attach-1.DOC

#1176

University of Michigan
Hospitals and
Health Centers

MedEQUIP – Home Care Services
2705 S. Industrial Hwy., Suite 300
Ann Arbor, MI 48104
(734) 971-0975 – (800) 530-0714
(734) 971-1004 fax

June 30, 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: Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule CMS-1270-P; General Comments and Recommendations

Dear Sir or Madam:

MedEQUIP, the DME provider at the University of Michigan Hospitals and Health Centers (UMHHC) would like to thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for certain covered items of DMEPOS. We are writing to express our concern regarding the potential impact that a competitive bidding system would have on Medicare beneficiaries, providers, and the entire healthcare delivery system.

We are especially concerned with the impact that the National Competitive Bidding requirement would have on hospital-based DME providers that operate as part of a self-contained, fully integrated healthcare system.

Hospital-based DME providers are uniquely positioned as vital partners when they operate within an integrated health system. The University of Michigan Hospitals and Health Centers is an example of an integrated health system. The UMHHC is considered an integrated healthcare provider because it is comprised of hospitals, a faculty group practice component, outpatient clinics, free-standing community health centers, and a full-service DME and home infusion provider.

There are many advantages to the integrated health system model. The most significant advantages relate to cost effectiveness, favorable length of stay outcomes, efficiency, quality of care, and continuity of care. When all components of health care are integrated across the entire health care spectrum, patients are allowed more seamless access to the full continuum of care in an efficient, cost-effective manner. Integrated health systems are able to maximize cost savings and ensure efficiency by maintaining the continuum of care and coordinating its use.

Providing home care services (DME) to patients that enter into an integrated health system is a vital part of the continuum of care. While there are many tangible benefits to the integrated approach, the provision of quality, effective, and timely DME services helps to ensure favorable treatment outcomes. If hospital owned and operated DME providers are no longer able to provide DME services to their patients upon discharge due to being blocked out because of competitive bidding requirements, there would be an unfavorable ripple effect throughout the many health systems and other organizations that utilize the integrated delivery model.

Patients accessing services within an integrated health system continue to be a part of the continuum of care upon discharge. Hospital-based DME providers are an extension of care in the home or the non-hospital setting. Hospital-based DME providers are not simply a separate, detached component of care.

We urge CMS to consider the following negative outcomes that would result if integrated health systems were not allowed access to their patients throughout the entire continuum of care:

Length of Stay

The UMHHC, like many other large, integrated providers, receives a disproportionately large number of high acuity transfer patients due to our numerous specialty services. As such, we often employ the most advanced and the most difficult-to-find home care products and medical supplies. If large, complex health systems such as UMHHC were forced to rely solely on external DME providers due to competitive bidding requirements, delays in discharges would be inevitable as additional time and resources would be spent attempting to find DME providers that can provide the difficult-to-find products that higher acuity patients often require. Delayed discharges can and often do result in additional inpatient days.

Increased lead times for discharges will be required and there will be instances where providers may not be able to provide the required equipment. For example, smaller providers may not have access to the more expensive specialty beds or pressure relief support surfaces that patients may require upon discharge.

Throughput

If we are unable to appropriately manage length of stay, throughput will be adversely affected. Our hospitals have maintained an extremely high census for the past twelve months and we anticipate that our census counts will continue to be at or near capacity for

the foreseeable future. Efficient patient flow throughout our system is essential to maintaining access to services. The ability of our discharge planners to utilize our DME service has been very helpful in facilitating discharges. Having access to DME services within our hospitals has greatly reduced lead times for discharges and our DME service has helped to make the entire discharge process more streamlined.

Maintaining our status as a fully integrated health system compliments our academic mission- we rely on healthy margins to help drive our educational mission, research, patient care, and the building of new infrastructure. Our ability to return money back into our health system ultimately benefits the communities we serve on a local, regional, national, and international basis by advancing healthcare and how we deliver it.

Cost Shifting

When discharges are delayed and result in an increased length of stay, no real cost savings are achieved. Costs are merely shifted within the health care continuum. CMS proposes to save money by reducing spending on DMEPOS; however, any cost savings that result from reduced expenditures for DMEPOS would be negated by the potential increase in costs in other parts of the healthcare continuum. In addition, the increased administrative costs that would almost certainly accompany the competitive bidding program would more than negate any potential savings based on reduced DMEPOS expenditures.

Unfunded Mandate

If fully integrated health systems become forced to rely exclusively on external DME providers to provide DME service for their patients, the discharge and order process will become more cumbersome and delayed. In addition, each transaction will require increased effort by staff and additional resources will be required to process discharges and routine DME service requests, especially in instances where the approved DMEPOS provider is unable to meet the need due to not having access to specific products.

The current pathway for ordering DME services for existing UMHHC patients is very efficient and linked with the major clinical pathways within our health system. Removing the integrated portion of the DME service from our health system would effectively eliminate the built-in advantage of seamless communication, coordination, and planning.

Delays and added difficulty in performing routine discharges and the processing of DME service requests will result in an additional administrative burden for integrated healthcare providers and many other healthcare providers as well. An additional administrative burden will equal increased costs for many entities within the healthcare continuum.

Quality of Care

If integrated hospitals and health systems are required to utilize external DME providers, the overall level of quality care could decrease. If CMS relies on the low-cost bid winners

to provide services, there is no incentive for the winning bid providers to deliver quality service that includes proper instruction on the safe and effective use of equipment.

Approved DME providers may not place sufficient emphasis on ensuring that the correct and appropriate equipment and/or supplies are provided for the patient. For example, if a provider is focused primarily on cost effectiveness (due to the low-bid nature of their provider status) they may provide equipment that is either inappropriate or of inferior quality to the patient. Providers have been known to provide improperly sized wheelchairs; inadequate and inferior support and pressure relief surfaces; and other equipment and supplies that do not provide any real benefit to the patient. In fact, improper use and supply of equipment can actually result in hospital readmissions. These types of preventable admissions are far less frequent when DME providers work as part of an integrated health system as there is more accountability, communication, control, and commitment to quality.

Providers who submit low bids will not be motivated to provide the appropriate level of service or care. Low bid providers will be forced to minimize their face-to-face contact with patients so they can move on to the next patient and maintain a viable margin. Providers selected on the basis of low cost will focus their efforts on true value-added activities. Value-added activities are those that will bring in revenue to the provider, i.e., number of deliveries- not the amount of time spent on patient education activities.

There is no question that effective and adequate patient education leads to more favorable clinical outcomes. When low bid providers place less emphasis on face-to-face patient interactions, the probability for successful outcomes is reduced. Winning bid providers may not be able to resist the temptation to "cut corners" when it may mean the difference between profitability and loss.

A recent American Association of Homecare study indicates that indirect services such as patient assessments, intake, maintenance, and regulatory compliance make up more than 70% of the costs of providing home oxygen therapy. Providers will be forced to reduce the amount of money spent on the activities associated with providing DME services if they operate as a low-bid provider.

Continuity of Care

The UMHHC operates its own DME service in order to take advantage of the complete continuum of care. Our internal DME department enables us to provide service to our patients 24 hours per day, 365 days per year. This 24 hour access to DME service has helped us extend quality care beyond the inpatient setting. As patients transition into the homecare setting, the ability to seamlessly coordinate care across multiple services within our health system has yielded benefits in service level, cost-savings, treatment outcomes, and patient satisfaction.

If integrated health systems are no longer allowed the ability to provide all of their patients with the same seamless access to DME services, all of the benefits that come with being able to coordinate care will be lost.

Preserving Patient Access to Care

Requiring Medicare beneficiaries to obtain services from certain providers will limit access to care. Restricting patient choice will also threaten long-standing patient and provider relationships. Up to 50% of all DME providers could be forced out of the market if the current proposed rules take effect. Limiting choice and limiting access is simply bad medicine. Restricting beneficiaries' choice could potentially negatively impact health outcomes.

Recommendations

We recommend that CMS consider the following changes to the proposed rule:

1. Allow hospital-owned and operated DME suppliers the option to participate at the winning bid rate. This would enable hospital-owned and operated suppliers to maintain access to their patients and it would also meet CMS' goal of addressing cost-savings concerns that the competitive bidding process was intended to accomplish.

2. The term "Contract Supplier" should be modified to include all hospital-owned and operated DMEPOS suppliers. The expanded definition would enable hospital-owned suppliers the ability to maintain access to their patients throughout the entire continuum of care.

3. Final and specific accreditation/quality standards should be formalized and required before a supplier is allowed to participate in the bidding process. From a patient perspective, suppliers that already meet certain quality standards is an important consideration. Suppliers that receive an adequate level of reimbursement for the service they provide is the best way to ensure quality; a government bureaucracy cannot "force" quality standards via a bidding mechanism that centers around low costs. Natural competition within the context of a free market will result in sustainable quality standards that far exceed those of a government mandate.

4. CMS should consider the patient perspective: limited provider panels restrict choice and will negatively impact access to care. CMS should allow beneficiaries the option of continuing their care by expanding the provider panels as much as possible.

5. CMS should eliminate the rebate proposal. Allowing beneficiaries the option to receive services from suppliers that can offer rebates will lead to inefficient and inappropriate utilization of services. Additionally, the use of rebates may result in an unfair competitive advantage among suppliers. The use of rebates in a program that is intended to result in cost-savings is counter-intuitive.

6. A National Business Services, Inc (NBS) study indicates that the current proposed rule will require that CMS increase its staff by nearly 1600 personnel and substantially grow the CMS bureaucracy. We urge CMS to conduct further cost-savings analysis that focuses on the program's incremental administrative costs prior to implementing the competitive bid program.

Conclusion

We urge CMS to seriously consider the many negative effects that a national competitive bidding program would have on fully integrated health systems. Integrated health care providers rely on the availability of information and the seamless transitions from one care setting to another. A competitive bidding program that would prevent certain providers from accessing their patients would result in increased administrative costs, increased inpatient days, decreased patient satisfaction, and unfavorable treatment outcomes.

Integrated health systems must be allowed to maintain access to their patients throughout the entire continuum of care. Providing DME services to patients as they transition into the homecare setting is a vital segment of the continuum of care. Hospitals and health systems that are able to provide DME services are able to maintain quality standards that often result in more favorable treatment outcomes.

If CMS does not exempt or provide special consideration to integrated hospitals and health systems that own and operate their own DME service, all of the inherent benefits that are associated with the integrated healthcare model would be severely diminished.

Again, MedEQUIP (University of Michigan Hospitals and Health Centers) would like to thank you for the opportunity to offer our comments on the proposed rule to implement a competitive bidding program for certain covered DMEPOS items.

Sincerely,

Kenneth Bandy
Administrative Director
Home Care Services
University of Michigan Hospitals and Health Centers
kbandy@med.umich.edu

Submitter : **Date: 06/30/2006**

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

See Attachment.

CMS-1270-P-1177-Attach-1.DOC

#1177

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier- "Conditions for Awarding Contracts"

Comments:

- Accreditation- We agree with the fact that only accredited providers should be eligible to submit bids. We do, however, feel that due to the short timeframe, any accrediting agency that is approved by CMS will require a 9 to 12 month process. It has been especially difficult, in the past, to identify an accreditation process for a supplier with a mail-order model. CMS should allow proper time for providers to analyze quality standards in conjunction with the rule and the costs that those standards would require of the contractors. We would suggest that vendors can chose their accreditation from either a state agency or any of the private health care services accreditation agencies (NCQA, URAC etc.) We would also recommend that CMS allow up to one year for accreditation, provided that the vendor can show "in good faith" that they have initiated the accreditation process. Also, as the initial phases are stabilized and become more "compartmental", it may be beneficial to have accreditation programs specifically for certain product categories to assure beneficiary quality and access. .

- Evaluation of Bids- The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. We would ask that CMS present a clear and specific overview for suppliers that includes the weighting factors that CMS will use to evaluate the bids in each MSA, so that suppliers are able to determine how best to bid each HCPCS within a category. .

  There is also no incentive to exclude extreme 'lowball' bids, as bidders assume they will be paid an amount higher (i.e., the "pivotal" bid) than their bid. Some have suggested CMS require bidders to accept their actual bid price for the duration of the contract, acknowledging that additional administrative procedures and hurdles may be affected with multiple payment amounts while others suggest disallowing statistical outliers. (e. g. bids that fall outside X standard deviations of the mean)

  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.

Submitter :

Date: 06/30/2006

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

See attachment.

CMS-1270-P-1178-Attach-1.DOC

#1178

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier- "Criteria for Item Selection"

Comments:

CMS does not specify what products will be put up for bid, but it does say that selection will be based on potential savings. The agency will begin with items that have the highest volume and highest cost. The rule also proposes grouping similar items into product categories, such as hospital beds and accessories, so that beneficiaries would be able to get all related items in that category from one supplier. Suppliers will then be required to submit a bid for all items included in any product category.

A competitive bidding product group may include products (and more specifically HCPCS codes) from multiple medical policies. The intent of the law is to exclude products where bidding would affect access or quality, but this protection is lost if medical policies are combined. In order to ensure quality of care, CMS should ensure that providers that specialize in specific conditions/areas are able to bid. If medical policies are combined, then the only providers eligible to bid would be those that carry the broadest product offering, regardless of their expertise thus eliminating the seasoned specialty providers with long-standing patient relationships and years of experience with the products.

Submitter : Mrs. Kelly Brussell

Date: 06/30/2006

Organization : Homecare Concepts

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-1179-Attach-1.DOC

#1179

HOMECARE CONCEPTS, INC.
1095A Route 110
Farmingdale, NY 11735
1-800-434-0555

June 29, 2006

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

Comments Delivered via Electronic Submission

Re: Comments on the Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]

We would like to take this opportunity to provide comments on the Proposed Rule Making, CMS-1270-P. As requested, we have indicated the "issue identifier" at the beginning of each comment. The following are our comments and recommendations:

General

1.) "General" - Implementation Needs to Be Delayed. CMS should push back the implementation date of October 1, 2007 and look to 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. In addition, under the timeline currently proposed by CMS, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate, creating another reason for a delay in planned implementation.

2.) "General - CMS Needs to Establish an Implementation Timeline. CMS needs to establish an implementation timeline that at a minimum identifies the following steps and expected completion dates:

- Publication of Supplier Standards
- Approval of accrediting organizations
- Issuance of interim final and final regulation
- Publication of final 10 MSAs and product categories
- Commencement of bid solicitations
- Conclusion of bid solicitations
- Announcement of winning bidders
- Education of beneficiaries and medical community
- Implementation within each MSA.

It is expected 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.) "General" - Additional Comment Period reflective of DRA Implementation Regulations for Oxygen and Capped Rental Equipment Without having established the scope of this new requirement and how it will affect competitive bidding, our ability to comment is limited in this respect. We are aware that CMS will be publishing regulations to implement the DRA in the near future. We need an opportunity to assess and comment on how the new rules will apply under the framework for competitive bidding. We suggest that CMS issue an interim final rule to allow additional comments on this issue.

5.) "General" - Additional Comment Period reflective of Quality Standards Without having published Supplier Standards it is difficult to comment on areas of the NPRM that are directly reflective of standards that have not yet been finalized. We again suggest that CMS issue an interim final rule to allow additional comments on these issues.

6.) "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.

7.) "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? A company should not be permitted to claim a capacity greather than 25% over the number of products provided to Medicare beneficiaries in the previous year, anything more would be unrealistic. Only after the satisfactory completion of these three steps should a company's bid be processed for further review and consideration as to pricing.

8.) "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. CMS must specifically address the inflation update process and how the bid price will be updated by the CPI-U.

9.) "Conditions for Awarding Contracts" - Do Not Make It Harder For Providers To Sell Their Businesses. (proposed §414.414(e)) 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 review a change of ownership to determine whether the new entity meets the quality standards before granting the new company contract supplier status, CMS cannot reasonably withhold its approval of a change of ownership and should not deny contract supplier status to the new entity on the basis that its capacity is not necessary within the competitive bidding area. CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement, that contracted supplier and its new ownership should retain its contract. The needed approval for capacity from CMS unfairly lowers the value of the company to an owner who has spent his/her life growing the company with the goal to someday sell, or in the case of hiers who may need ot sell to cover estate taxes.

10.) "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.

11.) "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.

12.) "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,"or "review," report from an independent Certified Public Accountant who is a member of A.I.C.P.A. or a local state society. (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 and the potential borrowing capacity of the company. (d.) Letters from two primary product suppliers. Once received, CMS should review all submitted documentation for completeness and appropriateness.

13.) "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 payors, 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.

14.) "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 products provided to Medicare beneficiaries the previous year.

15.) "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. Some MSA's cross over state lines making it unrealistic for some single state smaller companies to compete.

16.) "Criteria for Item Selection" - Product Selection Must Be Conducted With Beneficiary Welfare In Mind. CMS must be sensitive to and implement provisions to prevent the many problems competitive bidding may create for beneficiaries. These include an individual beneficiary having to deal with multiple suppliers. The inappropriateness of including items that are custom and service oriented in nature must also be recognized. CMS cannot rely solely on costs and volume for product selection. Issues such as supplier access and medical necessity of beneficiaries who use the items must be addressed. Competitive bidding should not be a substitute for appropriate medical policy.

17.) "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.

18.) "Criteria for Item Selection" - Brand-Specific Requirements The NPRM proposes to allow physicians to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a specific brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered. We believe it is unnecessary for CMS to include this requirement as part of a competitive bidding program as the physician is always free to order a specific item. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consume advertising. The current HCPCS codes do not support brand specificity. We recommend that CMS not include this provision in the final rule

19.) "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. Only those entities should be eligible for consideration in the bidding process.

20.) "Submission of Bids Under the Competitive Bidding Program" - 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 product 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 could be very problematic. Suppliers who do not specialize in rehab may not carry more complex wheelchairs, whereas suppliers who do specialize in this area may not focus on basic equipment. In addition, the Wheelchair Accessories and Wheelchair Seating Categories are directly associated with ensuring the appropriate wheelchair, with the appropriate accessories are provided to the beneficiary. In theory, a supplier could be awarded a winning bid in the Wheelchair category, however, they could end up not being a winning bidder for the associated seating and accessories. In effect, many patients will end up having to deal with two or more providers for a single wheelchair. We recommend that CMS look to ensure that providers with a winning bid for the base wheelchair are also permitted to provide the associated accessories and seating for that item under Medicare.

21.) "Terms of Contract" - Eliminate Requirement That Winning Supplier Must Repair Patient-Owned Equipment. (proposed §414.422(c)) It is appropriate for winning suppliers to be required to service any equipment they provide. However , this requirement should not be placed on equipment that is supplied by others. 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.

22.) "Terms of Contract" - Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment. (proposed §414.422(c))

23.) "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 bidding program receive.

24.) "Terms of Contract" - Do Not Require Winning 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 as it is impossible to predict whether beneficiaries will decide to switch suppliers. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a winning supplier.

25.) "Opportunity for Participation by Small Suppliers" - Require That A Minimum Number Of Small Suppliers Be Included In The Winning Contract 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.

26.) "Opportunity for Participation by Small Suppliers" – Small Business Opportunity The presumption that simply providing small businesses an opportunity to form networks meets the MMA mandate to include small businesses in the competitive bidding process is outright prejudice against the majority of businesses in the country. We recommend that CMS determine the total capacity required in an MSA or portion thereof and then add 30 to 50 percent. Designate the "excess" for small business set aside. (Note: Small Businesses who elect to participate in this program must bid but not be part of the equation to determine the pivotal bid. Have them designate themselves up front as applying for the set aside and separate them from the other bids.) When the number of required contract providers is determined to meet 100% of the total capacity, provide for an equal number of small businesses to cover the "excess" capacity. As long as a small business is otherwise qualified to bid, even thought they have bid at or above the pivotal bid, rank them according to a separate set of standards amongst themselves and offer the required number of contracts at the final bid price. This would guarantee the survival of some companies for the next round, without them here there will be no real competition in subsequent processes; only national companies will prevail.

27.) "Opportunity for Networks" - Clarify Network Regulations. (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?

28.) "Opportunity for Networks" – The Market Share Limitations of Networks Should Be Increased To 50%. (proposed §414.418) Market share limitations should be increased to 50%. Anything less than that places network members at a disadvantage as compared to other large

single legal entities that may bid. This would penalize small suppliers. Capping it at 50% still provides adequate competition in the area and also meets the legislative requirement that there be at least two winning bidders.

29.) "Opportunity for Networks" - Network Bidding Allow the members of a network to also bid as an individual company. Somehow, you have to allow smaller businesses a chance against the national corporations. We recommend that businesses be able to designate themselves as small businesses and be considered both in the small business category and as part of a network in regular consideration with other bidders.

30.) "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 allowable amount that corresponds with the beneficiary's permanent residence for up to five months.

31.) "Payment Basis" - Provide Details On How Pricing Will Be Used After January 1, 2009. CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to use the payment information determined under that competitive bidding programs to adjust payments amount for the same DMEPOS in areas not included in the competitive bidding program. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

32.) "Payment Basis: - Inflation Update. CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

33.) "Payment Basis" - Limitation of 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 them that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABN's will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABN's. CMS needs to clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for a competitively bid item furnished by that supplier.

34.) "Rebate Program" - 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 published guidance in the form of advisory opinions, fraud alerts and special advisory bulletins to assist providers and suppliers in understanding their obligations to comply with the statutory prohibition on beneficiary inducements.

35.) "Gap-filling" - Different Alternatives To Gap Filling Must Be Used. (proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the Gap Filling pricing methodology. The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process.

36.) "Gap-filling" - Develop More Equitable System To Price HCPCs Changes. CMS 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. This is not equitable solution and a more appropriate procedure must be developed.

Thank you for this opportunity to submit our comments and concerns on the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues.

Submitter :

Date: 06/30/2006

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See attachment.

CMS-1270-P-1180-Attach-1.DOC

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier- "Competitive Bidding Areas"
Comments:

- MSA Staggering- CMS should consider the staggering of MSAs throughout the 2007 implementation period. This will allow CMS to identify issues and problems and correct them before they are widespread.

- Nationwide or Regional Mail Order Competitive Bidding Program- Beginning in 2009, CMS will develop a national or regional mail order program for items such as diabetes testing supplies that the majority of beneficiaries receive from national mail order suppliers. The program would then take effect January 1, 2010 and would award contracts to suppliers who furnish these items across the nation to beneficiaries who elect to receive their supplies by mail. Phase in would begin in 2009 and payment will be based on the bids submitted and accepted for the furnishing of items through mail order. All suppliers that currently utilize this model will be required to submit bids to participate in any competitive bidding program implemented for the furnishing of mail orders items. In addition, suppliers that do not utilize mail order will be allowed to continue to provide these items as long as they are selected as a contract supplier in their CBA. CMS is asking for comments on the following topics related to this proposed program:

1.) Products
Items that are suitable for a mail order competitive bidding program: There are, in addition to the items used for daily home blood glucose monitoring, products that can be conveniently and economically delivered to the patient in a mail order setting. Several of these are already provided using this model.

- Ostomy supplies
- Urological supplies
- Nebulizer circuits and tubing
- Enteral feeding supplies

2.) Implementation

We feel that patient care and access to supplies are two very important factors in deciding how and when this portion of the program is implemented. Consistent self-monitoring of blood glucose levels by patients is critical to the effective care and management of diabetes and to avoiding its serious and costly complications. Most patients are in control of their own care regimen, in which they rely on self-monitoring to maintain control of their glucose levels.

One major area of consideration and concern is the determination of which products are included and who determines or dictates which items a beneficiary receives. While we understand the need to provide the beneficiary with blood glucose testing supplies that offer the appropriate level of technology and ease of use, the cost associated with the product and inventory requirements also need to be taken into consideration. It should be outlined how a manufacturer participates in the program so that suppliers are aware and govern themselves appropriately. Participation in this segment of the program should be contingent on prior experience specific to this business model. Since there is no real credentialing process for a mail-order provider, it may be necessary to establish criteria based on experience, past compliance history with CMS, physical location and technology.

Submitter :

Date: 06/30/2006

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Payment Basis

Payment Basis

See attachment.

CMS-1270-P-1181-Attach-1.DOC

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier-"Payment Basis"
Comments:

- Grandfathering Statutes- The "grandfathering process" will allow providers of oxygen and certain DME items for which payments are made on a rental basis to be grandfathered into the competitive bidding program, provided they serviced the beneficiary before the start of the program. If the supplier does not want to continue servicing their customer because of the adjusted fee schedule, the supplier has the right not to service the beneficiary. This chain of events can also occur in the second round of bidding causing suppliers to cease servicing a particular category. We feel the major area of concern with this statute is the education and overall well being of the Medicare beneficiary. This will become extremely confusing, especially for an individual who is receiving more than one product category from a supplier. Because the delivery of oxygen is such a critical process, this has to be a seamless transition.

- Pricing Methodology-The fact that suppliers cannot bid higher than the current fee schedule amount, even if they incur additional administrative or operational costs to serve the competitive acquisition area, should be more thoroughly investigated. We saw examples of this in the Polk County demonstration where surgical dressings were of higher costs than the actual published amount reimbursed by Medicare. The proposal's use of "capacity" is vague and needs to be more clearly defined. Also, with the grouping of product categories, each caveat of servicing that particular disease state should be taken into consideration (dispensing fee with unit dose nebulizer drugs, certified diabetes educator involvement in the servicing of insulin pump patient) Utilization can change due to factors that are out of the control of the provider (e.g., patients moving in & out of HMOs, natural disasters) While the demonstrations used the median of all bids to decide the single price, the proposed rule makes use of only the capacity concept.

- Limitation on Beneficiary Liability for Items Furnished by Noncontract Suppliers- If a noncontract supplier furnishes an item covered by competitive bidding to a beneficiary in a MSA, the beneficiary will have no financial liability to the supplier (except in the case of the grandfathering rule). Language needs to be included that provides for some form of an advanced beneficiary notice in the event they wish to pay cash for an item, and acknowledge it will not be a covered item. Also, because a physician can prescribe an item by manufacturer specificity, there may instances where an item is furnished that is not included in the product category.

Submitter : **Date: 06/30/2006**

Organization : **NationsHealth**

Category : **Other Health Care Provider**

Issue Areas/Comments

Implementation Contractor

Implementation Contractor

See attached.

CMS-1270-P-1182-Attach-1.DOC

#1182

Comments Regarding Federal Register Publication
42 CFR Parts 411, 414, and 424
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

Prepared by NationsHealth

File Code CMS-1270-P

Issue Identifier-"Implementation Contractor"
Comments:

- CBIC-The manner in which the "Competitive Bidding Implementation Contractors" (CBIC's), DMERCs and providers having constant and consistent methods of communication is key to making this program successful. Because the CBIC is going to be such a vital part of the entire process, suppliers need to know more about the credentialing process for this newly formed entity and what type of authoritative power it will possess. We do agree, however, that this form of oversight is better alternative than the other two options explored; using the DMERC's to begin to conduct competitive bidding in their respective areas or the second option of using the CCMO to implement the program.

Submitter : **Mrs. carol ann greene** **Date: 06/30/2006**

Organization : **university orthopedics**

Category : **Occupational Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

My name is Carol Ann Greene and I am a COTA specializing in hand therapy. I currently work at University Orthopedics and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses. Therapist are unique from other suppliers of DMEPOS. When supplying an orthosis, we look also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation. CarolAnn Greene, COTA/L

Attachments

Submitter : Mr. David Chesnut **Date:** 06/30/2006

Organization : Pennyrile Home Medical

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1184-Attach-1.DOC

ATTACHMENT TO #1184

Pennyrile HOME MEDICAL

David Chesnut
Paducah 270.575.0550
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To: CMS-1270-P

From: David Chesnut
President of Pennyrile Home Medical

Subject: NPRM Comments on CMS-1270-P

I am writing these comments with duress and grave concern for the future of quality healthcare for our senior citizens, our industry and the healthcare system as a whole. I believe there is a gross misunderstanding of our industry and the value we give both economically and to the enhancement of quality of care we provide to our country's seniors.

First let me express my opinion on how we economically help the Medicare system. We are the only aspect of healthcare that provides services such as training, instruction, delivery and education at no charge to Medicare, We only get reimbursement for the product itself. Most every time we provide products for ostomy, diabetic, knee surgery, oxygen, ventilator, sleep apnea and most other patients, we are the ones explaining how to use the products, why you need them and how they will benefit you health wise, all this at NO COST to Medicare. The doctors, hospitals, home health agencies that get paid to provide these services aren't doing the job Medicare pays them for every day. Medicare now even pays the doctors $21.00 to fill out 2 minutes worth of paperwork for wheelchairs while we get paid nothing for the time we spend doing home and patient assessments, measuring and choosing the proper products to fit the patient, fitting, assembling and explaining the proper means to use the product and preparing multiple pages of paperwork just to hopefully get paid for just the product only. This always takes at least 2 hours and up to 30 hours of employee time for a high end rehab patient at no cost. A hospital gets paid over $400.00 to do a wheelchair assessment. A CPM unit we provide for post total knee surgery only cost Medicare $21.00 a day, however a physical therapist gets paid over a $100.00 to do a ½ hour of therapy that is not as effective as a CPM unit. We provided wound care dressings and training on application and usage at a fraction of the cost that Medicare pays wound care centers (over $3,000.00 a month) to do the same service. The list of examples goes on and on. Our products and the free services we provide help keep Medicare patients out of hospitals, nursing homes and home health agency services all of which are 10 to 100 times more expensive than our services. Another good example is when Medicare makes it difficult to provide an E0192 (Roho or Jay type) cushion to help prevent decabities ulcers on an elderly patient who is confined to a wheelchair, is incontinent and eats poorly. Cost $300.00 plus. However the average cost to Medicare to heal a stage 3 decubities ulcer is over $30,000.00 and all that money goes to doctors, hospitals, wound care centers and home health agencies. I've always heard "an ounce of prevention is worth a pound of cure." I know you believe that way also and it just makes good CENTS!

I have been in this industry for over 23 years and have seen the good, the bad and the ugly of it. I would like to paint you a rosey picture but I know there are a few thorns out there. It's the few bad apples that apparently has given you a bad taste. I believe I can honestly say that over 90% of the independent suppliers out there are trying to do the best job possible in an honest manner for the small reimbursement we receive; however there is that 5% plus that tries and does fraud Medicare and manipulates the system. However instead of shutting down those companies, they seem to be getting

rewarded. They have been turned in 1000's of times by other suppliers and beneficiaries for fraud, with open/shut evidence but nothing seems to being done. Instead, the current policy seems to be to punish all suppliers instead o f the guilty ones. In the last 24 years, CMS has enacted (I believe) 25 cuts in reimbursement which has resulted in my company receiving 50% of the pay I received 23 years ago for the same number of services. During this same time my paperwork has quadrupled. Also during this same time all other aspects of healthcare reimbursement has increased 100 to 1000%.

To summarize, has the scales of CMS reimbursement been fairly and wisely appropriated to the proper segments of healthcare services. With all this said let me comment on certain specific areas of the competitive bidding proposal for HME.

First, regarding the issue of supplier standards and accreditation, I have read the new proposed standards and analyzed their impact on my company. Last year I didn't make a profit and the new standards I predict would cost my company between $100,000 to $150,000 dollars to implement which means my company would have a net loss of 8% of gross receipts. Why, because I would have to hire a minimum of 2 to 3 more paperwork personnel, just to do needless "standards" work that does nothing to enhance the quality of products I provide. Remember CMS pays us nothing for services and training. I try to buy everything I can American made not those Chinese imports. The proposed standards are not standards but a step by step procedure book of free services not quality issues. No other aspect of healthcare covered by CMS has detailed standards such as these. I believe in a set of quality issue standards but not 200 plus pages when currently we have one page.

Concerning accreditation I believe the current proposal is a farce and let me tell you why. The Apria's, Rotech's, Scooter stores, Liberty medicals, Lincare's and AHP's are all accredited but all of them have been convicted of fraud, yet they are still accredited. Your intent was this would curb fraud and abuse yet all I see is these companies are gaining a larger piece of the market share and the rest of us keep struggling. I do believe there should be some sort of licensure, preferably on the state level where they can keep a closer eye on things. If you loose you license you're out of business, not so with accreditation as history proves. Also our industry now becomes the only CMS covered entity that would have mandatory accreditation by private for profit companies that have no ultimate authority on your business license. At best this seems discriminatory if not illegal. If CMS is going to require this of one covered healthcare entity, then it should be mandatory for all healthcare services. The cost of accreditation has proven to cost a company my size at least $50,000.00 the first year. Another expense with no CMS reimbursement. I was previously a lab director in a hospital and know first hand that all accreditation does is inspect the paperwork you do, not the hands on quality of our products and the manufacturers. I provide quality products and quality services currently and our policy is to service our patient as if you were providing it to your grandmother. You know, the personal touch.

Now on the issue of competitive bidding. It is quiet apparent from all the preliminary information released, that the bottom line on this issue is the lowest prices win and nothing is being said, except for lip service, on the quality of the product or the quality of the service. Is the goal of this to reward the national and regional companies and eliminate or reduce the number of small local HME's that pay local taxes, employee local people, support local charities, go to church with and socialize with the same people they are servicing on a daily bases? Is the goal to line the pockets of the large corporate executives, because that is what will happen? I cannot compete with the Lincares on a competitive bid bases but I can and do excel and beat them at the level of quality of care. We provide the whole gammit of DME products not just cherry pick the most profitable or least service intensive products. Who is going to provide the tens of thousands of other products to your senior neighbors that are less profitable when the bids are awarded to the National companies. Not the small independent HME, because CMS put them out of business and the Nationals won't sell those items.

The federal government has studies that show the only growth in employment numbers is in the small business segment. This puts more tax dollars back into the Medicare budget which in turn pays for the products we provide. The real issue here is do you want the lowest price or the best cost? Is part of this process that all the products have to be manufactured in America since American tax

dollars are paying for them? This makes since by keeping our dollars circulating internally instead of exporting them to Asia. Five years ago 90% of the products in the HME industry sold in the USA were American made. Now with all the cuts in reimbursement at least 50% of them are now made in Asia. Are you wanting to export our Medicare system to Asia because that is currently what is happening.

I could go on and on but I will stop. Please think hard on what you are proposing. STOP NOW and lets retool this together. KEEP AMERICA STRONG because United We Stand, Divided We Fall. I believe changes should be made in our healthcare system. I also believe when you look at the total financial picture, I think you would agree that instead of cuts, you should enhance the HME benefits to save CMS money, Thank you.

Submitter : **Dr. Larry Cohen** **Date: 06/30/2006**

Organization : **Podiatric Surgical Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30,2006

Mark B. McClellan, MD,PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Att: 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).

As a podiatric physician, I supply and occasionally prescribe DMEPOS items to Medicare beneficiaries as an integral part of patient care. These patients 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. I should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my paitents only and the right to execute a physician authorization.

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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

Sincerely,

Larry Cohen,DPM

Submitter : Mr. John Geller **Date:** 06/30/2006

Organization : Medical Service Company

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1186-Attach-1.DOC

ATTACHMENT TO #1186

SUBMITTED ELECTRONICALLY
http://www.cms.hhs.gov/eRulemaking

June 29, 2006

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Medical Service Company is pleased to submit comments on CMS' Notice of Proposed Rulemaking for Competitive Acquisition for Certain DMEPOS and other Issues. We are an oxygen and home medical equipment provider located in Cleveland, Ohio. Since 1950, Medical Service Company has provided equipment and supplies to residents of northeast Ohio. We operate one location that serves a twelve county area.

We offer a wide array of products including oxygen concentrators, portable oxygen, liquid oxygen, nebulizers and aerosol medications, sleep therapy products, home care beds and support surfaces, wheelchairs, ambulatory aids and other similar equipment and related supplies. Much of our product offering is considered "durable medical equipment" as defined under Part B of the Medicare Program.

Medical Service Company submits our comments for consideration. CMS requested that we reference the area of comment by including the specific issue identifier and placed it in "quotes" as a part of each item below:

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. 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. This is another reason for a delay in planned implementation.

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 regulation; 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. It is expected that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

We recommend that CMS, once it receives comments for issues for which it now has no proposal, issue those proposals in another set of proposed regulations, thereby giving commenters ample opportunity for comment prior to final regulation.

3. "General" Need to Address Competitive Acquisition in conjunction with DRA Issues
CMS' implementation of the DRA provisions on capped rental equipment and the "rent to purchase" of oxygen equipment will have a significant impact on the bid process and bid amounts. These new reimbursement provisions impact winning and losing bidders and beneficiaries. CMS should allow stakeholders to address these issues together when it publishes the DRA NPRM later this year.

> 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 Professional 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

4. "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.

Because there are so many issues not addressed in the NPRM, we recommend that CMS convene a meeting of the PAOC as soon as the final regulation is published. CMS should insure that the geographic locations (MSAs) and products to be included in the competitive acquisition programs are known and the detailed implementation scheduled, too is known.

5. "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.

   Because the final DMEPOS Supplier Quality Standards have not been published as of this time, we believe the comment period for this NPRM be extended for sixty (60) days after the issuance of Quality Standards. Or, at a minimum, allow for a sixty (60) day comment period **specifically for** Quality Standards.

   CMS needs to allow stakeholders an opportunity to comment on the Quality Standards before they are finalized. Because competitive acquisition is such a new concept for bidders, it is crucial that we understand the ramifications of the Quality Standards.

6. "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. Bids from disqualified suppliers should not be considered in selecting the winning bid point or setting the payment amount.

   We disagree with CMS's proposal in which CMS states it will allow a "grace period" during which unaccredited providers can participate in the bidding process. We strongly recommend that CMS not allow unaccredited providers to complete accreditation during an unspecified grace period. By doing so, CMS would allow spurious bid information to be meshed into the calculations, including the important issue of supplier capacity for a MSA. As stated earlier, we believe, however, that CMS should "grandfather" all providers already accredited by organizations that meet the criteria CMS identifies. Those criteria must be better described.

7. "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.

Once bids are received, CMS should examine the array of bids and analyze the composite, discarding those that are unreasonably low.

8. "Conditions for Awarding Contracts"- Do Not Make It Harder For Providers To Sell Their Businesses. (proposed §414.414(e)) 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. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement that contracted supplier and its new ownership should retain its contract.

9. "Payment Basis"- Medicare Advantage Beneficiaries Should Be Included Under The Grandfathering Provision. The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

10. "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 allowable amount based on the beneficiary's permanent residence for up to five months.

11. "Payment Basis"- Provide Details On How Pricing Will Be Used After January 1, 2009. CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to use the payment information determined under that competitive bidding programs to adjust payments amount for the same DMEPOS in areas not included in the competitive bidding program. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

12. "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. We oppose any criteria CMS might propose to use to annex adjacent areas to an MSA.

13. "Criteria for Item Selection"- How Potential for Savings Will Be Determined Must Be Specified. CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of competitive bidding. Specifically, CMS should address the following: (A.) *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger inclusion in a product category? (B.) *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category? (C.) *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects? (D.) *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? (E.) *Allowed Charges*: Does this mean paid claims?

14. "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.

15. "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.

16. "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.

17. "Determining Single Payment Amounts for Individual Items"- Provide More Details On The "Composite Bid" Calculation. The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should provide suppliers with

the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

Under the methodology proposed, CMS would array composite bids from lowest to highest and count up form the bottom until it identifies the point where bidders' cumulative capacity is sufficient to service the MSA. This will be the winning or "pivotal" bid. Accordingly, almost 50% of the winning bidders would have to accept an amount less than their bid amount to participate in the program, even if those bidders above the median would be providing most of the items and services in the competitive bidding area due to a higher level of capacity.

This methodology does not include any mechanism to discard any unreasonably low bids. Although the competitive bidding process is based on the premise of "best" bid, there may be suppliers with small individual capacity that may submit a very low bid speculating that they will be awarded in the range, based on other bidders' capacity.

We also recommend that CMS consider using 130+% of anticipated Medicare volume from an MSA as a threshold for the number of suppliers. This would promote greater competition from suppliers and ensure better competition for future rounds of bidding. CMS should seek to select more suppliers than necessary to meet capacity requirements, allowing for greater capacity and unexpected demand for services.

18. "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. CMS should develop bid review criteria that measures existing capacity for an individual supplier within the targeted MSA. That test of "reasonableness" must be performed to determine individual and MSA wide capacity.

19. "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. Specific steps also need to be established to allow a consistent evaluation of all suppliers.

20. "Conditions for Awarding Contracts"- A Factor Of 130% Should Be Used 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 payors, 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.

21. "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.

22. "Conditions for Awarding Contracts"- Judicial and Administrative Remedies Must Be Provided. CMS should include a procedure for debriefing suppliers who did not win a bid and provide an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

23. "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.

24. "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.

25. "Terms of Contract" – Length of Contracts (proposed §414.422). We urge CMS to have the same length of contract for all products in a particular competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As proposed, the rules will create considerable confusion for stakeholders and different terms of bid would just add to the confusion.

26. "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.

27. "Opportunity for Networks"- Clarify Network Regulations. (proposed §414.418) The regulations covering networks should be clarified to provide for the following: (A.) CMS should permit existing legal entities to coordinate the formation of networks and to establish whatever participation criteria they choose so long as they meet the related bidding standards and criteria. These entities should be responsible for forming the network, submitting bids, quality control, and ongoing communication and management. (B.) individual network members should be able to do their own billing and collecting operating under the awarded Network Contract. This would protect small supplier from having to incur additional network expenses from having to pay a network to do the activities they are capable of performing. (C.) If a network member falls out of compliance with accreditation or quality standards, the network should be able to terminate that member's contract and, if necessary, recruit one or more new members to provide coverage in the terminated member's service area. This would also apply if a network member elects to drop out of the network. Provisions must be made should these events occur within the contract period.

    CMS proposes to allow suppliers the option to form networks for bidding. Several criteria would have to be met for there to be a recognized and valid network. However, more information about what qualifies as a network and how a network can be organized needs to be forthcoming. It is unrealistic to expect the legal entity of a proposed network to be in place in time for the first bidding cycle. Therefore, we strongly suggest CMS provide significantly more time between its announcement of the initial ten selected MSAs and the date by which suppliers will have to submit bids. The additional time will allow suppliers to form networks and establish the legal entities as required by final regulations.

28. "Opportunity for Networks" - The Market Share Limitations Of Networks Should Be Increased To 50%. (proposed §414.418) Market share limitations for networks should be increased to 50%. Anything less than that places network members at a disadvantage as compared to other large single legal entities that may bid. This would penalize small suppliers. Capping it at 50% still provides adequate competition in the area and also meets the legislative requirement that there be at least two winning bidders.

29. "Gap-filling"- Different Alternatives To Gap Filling Must Be Used. (proposed §414.210(g)) We acknowledge CMS' recognition of the inadequacies and inappropriateness of the existing and current gap filling pricing methodology. The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors

who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process. We strongly suggest CMS separate the gap-fill methodology from their implementation of competitive acquisition and give it separate consideration, public comment and related procedures.

30. "Gap-filling"- Develop More Equitable System To Price HCPCs Changes. CMS 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. This is not equitable solution and a more appropriate procedure must be developed.

Thank you for the opportunity to provide comments on the aforementioned Notice of Proposed Rulemaking for competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and other Issues. I would be pleased to discuss these issues in further detail. Please feel free to contact me at 440-735-3255 or via electronic mail at jgeller@medicalserviceco.com.

Sincerely yours,

John E. Geller
President
Medical Service Company
24000 Broadway Avenue
Cleveland, OH 44146
440-735-3255 fax 440-232-3411

Submitter : **Dr. Edward Fryman** **Date: 06/30/2006**

Organization : **Seaford Foot Care Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Edward Fryman, DPM, DABPOPPM
Seaford Foot Care Center
3650 Merrick Road
Seaford, NY 11783-2811
Tel: 516-221-5982 Fax: 51-221-0729
Email: EFrymanDPM@gmaill.com

June 30, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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).

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. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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 to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Edward Fryman, DPM, DABPOPPM

Submitter : Mr. Kevin Kruse **Date:** 06/30/2006

Organization : Iowa Podiatric Medical Society

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1188-Attach-1.PDF

ATTACHMENT TO # 1188

IOWA PODIATRIC MEDICAL SOCIETY

525 S.W. 5TH STREET • SUITE A • DES MOINES, IA 50309-4501

PHONE 515-282-8192 • FAX: 515-282-9117

E-MAIL: IPMS@IPMS.ORG • WEB: WWW.IPMS.ORG

June 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

On behalf of the Iowa Podiatric Medical Society, the association that represents the podiatrists in Iowa, I would like to offer the following comments in reference to the Centers for Medicare & Medicaid Services' (CMS) proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

- We believe that all physicians should be exempt from the competitive bidding program, even though we acknowledge Medicare agency's position that it is required by statute to establish a competitive bidding program for all DMEPOS suppliers.
- We believe that the physician definition used in the proposed rule needs to be changed to the more inclusive physician definition used by Medicare, which includes podiatric physicians. [Change the proposed definition in the rule from 1861(r)(1) to 1861(r)(3).] 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. Podiatrists should have those same rights. Many of our member podiatrists prescribe and supply select DMEPOS items as part of patient care. They do not supply items to individuals who are not their patients. They are subject to the Stark requirements as well as other regulatory requirements that apply to MD and DO suppliers. With the change in the physician definition, they would be treated the same as an MD or DO in regards to this DMEPOS proposal.
- We are concerned about patient risks if this rule is implemented as drafted. If a member podiatrist treats a patient with an ankle injury, they may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weight bearing on the injured extremity. If they were not selected as a DMEPOS supplier in the new competitive acquisition program because they submitted an unsuccessful bid to supply to the entire MSA, the patient would need to go elsewhere to obtain the medically necessary items. In this situation, the patient risks converting the existing injury into one that is more severe, with greater recovery time, increased risks for complications, and more costs imposed upon Medicare.

We appreciate the opportunity to submit our comments to this proposed regulation.

Sincerely,

Gregory S. Duncan DPM

Gregory Duncan, DPM, FACFAS
President, Iowa Podiatric Medical Society

Submitter : **Susan Emmerling** **Date: 06/30/2006**

Organization : **Susan Emmerling**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I encourage you to take a closer look at what will happen DAY TO DAY to Medicare beneficiaries with competitive bidding. Many small, privately owned DME companies exists only because the people don't like the service they get from the large national DME! Their clients love personalized, PERSONABLE individual service. Think about it. If you KNEW you were one of only TWO people who would get ALL of the business for a specific geographic area, how hard would you work on your customer service? Remember the old ad from Avis? They touted being #2 and trying harder. Yes, in an ideal world, everyone would provide great customer service, but we all know we don't live in an ideal world. Think about you, or your parents or aunts and uncles being required to go to a specific supplier. What happened to choice? What happened to free enterprise and the competitive marketplace?

Ok, so a company wins the bid and is able to find product A from a discounted distributor for less (thereby increasing their profit margin) but it is a woefully inferior version. What is to stop them? Well, it certainly isn't the customer being able to choose from a supplier who has higher quality product WHO IS ALSO WILLING TO ACCEPT THE MEDICARE ALLOWABLE AMOUNT.

Unfortunately, I see this competitive bidding proposition forcing small businesses out of the market. I would draw a parallel to Walmart. Yes, they provide products and services to the community, but in the process, they have run the smaller stores out of business. The difference in this comparison is that both Walmart and the "Mom and Pop" stores are selling the products for the same price...that is the price set by Medicare.

Think it about the perspective of how it will affect the beneficiary...not just how it will affect the budget.

Thank you for reading my comments.

Susan Emmerling

Submitter : Julie Johnson **Date:** 06/30/2006

Organization : Detroit Oxygen & Medical Equipment Co.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1190-Attach-1.DOC

ATTACHMENT TO #1190

Detroit Oxygen's Comments For the Notice of Proposed Rulemaking on Medicare Competitive Bidding

Based on Detroit Oxygen's review of the Notice of Proposed Rulemaking on Medicare (NPRM) competitive bidding, we are proposing the following:

Implementation

The NPRM does not address if CMS will implement competitive bidding simultaneously or whether CMS will phase-in the bidding. We recommend that CMS should phase-in competitive bidding in the top 10 MSA's.

Accreditation

Only accredited providers should be eligible to submit bids. All providers who are accredited should be grandfathered in until the providers have had a reasonable timeframe to implement the quality standards not yet published.

Bid Process

There is no incentive to exclude 'lowball' bids, as providers assume they will be paid an amount higher (i.e., the "pivotal" bid) than their bid. We recommend disallowing statistical outliers (e. g. bids that fall outside X standard deviations of the mean).

"Composite Score" Methodology

The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should make clear that it will provide suppliers with the weighting factors that CMS will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS within a category using the same criteria as CMS.

Product Categories

CMS does not specify what products will be put up for bid, but it does say that selection will be based on potential savings. The agency will begin with items that have the highest volume and highest cost. The rule also proposes grouping similar items into product categories, such as hospital beds and accessories, so that beneficiaries would be able to get all related items in that category from one supplier. Suppliers will then be required to submit a bid for all items included in any product category.

A competitive bidding product group may include products (and more specifically HCPCS codes) from multiple medical policies. The intent of the law is to exclude products where bidding would affect access or quality, but this protection is lost if medical policies are combined. In order to ensure quality of care, CMS should ensure that providers that specialize in specific conditions are able to bid.

If medical policies are combined, then the only providers eligible to bid would be those that carry the broadest product offering, regardless of their expertise.

Determination of Number of Suppliers

CMS' process to determine the number of suppliers to meet projected demand in a MSA and its methodology to estimate supplier capacity are stacked in favor of large, high volume regional suppliers despite CMS' assertion that the NPRM provides opportunity for small suppliers to participate. Moreover, there are no guarantees that any of the winning bidders is a small business or a network of small businesses.

CMS needs to consider the negative impact the NPRM will have on small DME businesses and on the competitiveness of the second and third rounds of competitive bidding.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses.

Rebates

Allowing rebates is contrary to 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.

Networks

The NPRM states that a network cannot be anti-competitive. The network's members' market share cannot exceed 20% of the Medicare market within a competitive bidding area. Does this mean that a network can have 20% of the market share but a single provider could potentially have 80% of the market share? The NPRM states that multiple providers must be chosen but could be limited to 2 providers in a competitive bidding area. CMS should allow more than the minimum level of suppliers to allow beneficiaries access to quality care.

Rental Reimbursement For Beneficiaries Transitioning From One Provider to Another

The proposed rule states that "the beneficiary could elect at anytime to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer". It is unreasonable for CMS to expect a contract supplier to service a patient when there may only be a few months of rental payments remaining on a particular piece of equipment. The proposal requests that the supplier factor this scenario into their bid. A supplier would not be able to factor this cost into their bid because the necessary data for doing so is not available to the supplier. We recommend that CMS issue a new rental period for those beneficiaries who transition to a contracted supplier.

Change of Ownership

CMS should not restrict a provider from merging or acquiring a contracted provider. CMS should ensure that the new provider meets the quality standards and financial standards before allowing the buyer to become a contracted supplier. Who has financial ownership of the entity should be irrelevant to CMS. In addition, for those providers who receive most of their revenue from Medicare it would place an undue financial hardship as it would for all intents and purposes make that owner's business near worthless.

Financial Standards

The financial standards have not been published. We cannot comment on the standards, however, we recommend that suppliers must prove financial viability prior to the submission of their bid.

Submitter : **Mrs. MARY SUE ADAMS** **Date: 06/30/2006**

Organization : **ADAMS PHARMACY INC**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

June 30, 2006

CMS
Dspt of Health & Human Services
Attn: 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.

I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers-this restricts beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies, such as blood glucose testing supplies and ostomy supplies and may compromise patient health outcomes.

I urge CMS to take steps to ensure that samll town community suppliers to be able to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitian areas.

CMS must take steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Submitter : **Ms. noel starzyk** **Date: 06/30/2006**

Organization : **Ms. noel starzyk**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

"Proposed Rule for Competetive Acquisition of Certain DMEPOS" CMS-1270-p

As an Occupational Therapist and Certified Hand therapist I am extremely concerned about DMEPOS suppliers deciding what type of orthotic and size is needed by my patient. I, as the therapist take extensive history on the patient, including lifestyle and activites as well as considering the disease/injury process. Many factors go into deciding what is appropriate for my patient. No supplier is credentialed in evaluation and treatment of a patient, so why should they be deciding on part of the treatment. I have unfortunately seen many patients arrive at therapy with ill fitting splints because their insurance did not allow me to provide the splint. In some cases, the patient got worse! Who is to provide any fitting adjustments? Who is to be liable? What about the issue of timing? My patients may have to wait for a prolonged period to get their splint. When a patient is in pain, any delay is too long. In a time where I, as the therapist, spends the most time with a patient I feel that any small savings from this action may possibly cost more in the long run. The inability to change my course of treatment as needed, relying on an unskilled professional to dispense a part of my patient's treatment will surely contribute to prolonged treatment and a partial disconnect in treatment continuity. This does not even take into account the added frustration and burden on my patient! Thank you for considering my comments.

Submitter : Mrs. Carolann Burke **Date:** 06/30/2006

Organization : NovaCare Rehabilitation

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

see attchment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Sandra Rindt **Date:** 06/30/2006

Organization : R

Category : Health Care Professional or Association

Issue Areas/Comments

Administrative or Judicial Review

Administrative or Judicial Review

We are asking for clarification of the last words in this section this Rule . It is unclear at what level reviews will be denied. We strongly disagree with the inability to tell our story. Removing administrative or judicial review takes away our freedom of speech which is clearly unconstitutional under the Equal Protection law.

Opportunity for Networks

Opportunity for Networks

Why do you limit a network to have 20% of the Medicare market within a competitive bidding area yet a single large company can have 80% of the Medicare market share? The statement that each member of the network must be independently eligible to bid defeats the entire purpose of networking. If we had the ability to service the entire MSA we would not rely on networking. We strongly disagree with the primary legal entity being responsible for billing Medicare and receiving and distributing payment. Why must we adjust our entire billing process if we want to network and participate in competitive bidding? We want to be responsible for our own financials. We strongly suggest that if CMS needs to decrease cost then simply lower the allowables and monitor the compliance of the current 21 standards. This would simplify this very complex, cumbersome and unfair Competitive Bidding Proposal.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

We strongly disagree with using the SBA s definition of small business. This definition puts small businesses under the definition of $6 million in annual sales. This section clearly states that 90% of DMEPOS suppliers had Medicare allowed charges of less than $1 million in 2003. If you increase this number to include all payers it would still be much less than $3 million. This is a clear contradiction to the SBA s definition of small business. Small businesses will have to endure large expenses in order to participate in Medicare billing, with 90% of us having less than $1 million in Medicare allowed charges this will put many of us out of business. Is your purpose to wean out small business? You have rejected the carving out of areas for small businesses because it could lead to confusion for the beneficiary if faced with multiple competitive bidding sub-areas. The entire concept of competitive bidding will do just that. Our beneficiaries may have to go to three different locations to obtain oxygen, a hospital bed and a wheelchair. This will also cause a tremendous burden on our discharge planners trying to coordinate these services before discharge. The ultimate burden may lie on the hospital with extended inpatient days. You claim to recognize the importance that small business plays in this industry yet you only propose two ideas to protect us, multiple winners and separate bidding competitions for product categories. There needs to be much more emphasis to protect those who do less than 3 million in sales a year. Things such as: " Implementing partial SBA " Allowing the small business owner to continue to service their area by accepting the current bid without having to participate in the bidding process. " Recognize the tremendous cost involved in the accreditation process and preparing for competitive bidding. " Redefining small business definition to under 3 million You must remember that eliminating the small businesses will affect our country negatively with a rise in both unemployment and public aide.

Submitter : Mr. Jim Martin **Date:** 06/30/2006

Organization : 60 Plus Association

Category : Health Plan or Association

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

If individual podiatrists are instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), their patients may no longer have available to them medically appropriate and necessary DMEPOS items.

Again, I strongly urge CMS to change the definition from 1861 (r) (1) to 1861 (r) (3). This will allow small office individual podiatrists to continue providing medically necessary and appropriate care to their patients. I urge CMS to carefully reconsider its definition of physician and to apply their broader definition that includes theatrics physician.

CMS-1270-P-1195-Attach-1.DOC

CMS-1270-P-1195-Attach-2.DOC

CMS-1270-P-1195-Attach-3.DOC

ATTACHMENT 1 TO #1195

The 60 Plus Association

1600 Wilson Blvd. • Suite 960 • Arlington, VA 22209
Phone 703.807.2070 • Fax 703.807.2073 • www.60Plus.org

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270-P

June 30, 2006

Dear Mark:

As you know, the 60 Plus Association was a strong advocate for the Medicare Part D prescription drug benefit proposed by President Bush.

I'm pleased to note that nearly 80% of seniors now approve of this wonderful new benefit, and I thank you for your leadership.

Mark, today I am writing you about another matter of particular importance to senior citizens. On behalf of podiatrists, I strongly urge CMS to modify the physician definition from 1861 (r)(1) to 1861 (r)(3) before finalizing the regulations for the competitive acquisition programs for podiatry. This will allow individual podiatrist to continue to supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to their patients. However, if individual podiatrists are instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), their patients may no longer have available to them medically appropriate and necessary DMEPOS items.

Again, I strongly urge CMS to change the definition from 1861 (r)(1) to 1861 (r)(3). This will allow small office individual podiatrists to continue providing medically necessary and appropriate care to their patients. I urge CMS to carefully reconsider its definition of physician and to apply their broader definition that includes podiatric physician.

Mark, I want to go on record to make it clear that my organization is not being compensated in anyway by the American Podiatric Medical Association (APMA). Instead, this matter has been brought to my attention by my wife who has managed a small podiatric practice for nearly 20 years and she makes a convincing case that their elderly patients in particular would suffer the most if this revision is not made. I respectfully urge you to give this your most careful and compassionate consideration.

Sincerely,
Jim Martin
President
60 Plus

The 60 Plus Association is a 15-year-old nonpartisan organization taking on important issues such as death tax repeal, saving Social Security, working to lower energy costs, affordable prescription drugs and other senior-friendly issues featuring a less government, less taxes approach. 60 Plus calls on support from nearly 4.5 million citizen activists. 60 Plus publishes a quarterly magazine, SENIOR VOICE, and a Scorecard, bestowing a Guardian of Seniors' Rights award on lawmakers of both parties who vote "pro-senior." 60 Plus has been called "an increasingly influential senior citizen's group" and "the conservative alternative to the AARP." 60 Plus has established a membership benefit program. To join 60 Plus or for further information, please go to our website at www.60plus.org or call 888-560-PLUS (7587).

ATTACHMENT 2 TO #1195

The 60 Plus Association

1600 Wilson Blvd. • Suite 960 • Arlington, VA 22209
Phone 703.807.2070 • Fax 703.807.2073 • www.60Plus.org

James L. Martin
President

Rep. Roger Zion (R-IN, 1967-75)
Honorary Chairman

Pat Boone
National Spokesman

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270-P

June 30, 2006

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Again, I strongly urge CMS to change the definition from 1861 (r)(1) to 1861 (r)(3). This will allow small office individual podiatrists to continue providing medically necessary and appropriate care to their patients. I urge CMS to carefully reconsider its definition of physician and to apply their broader definition that includes podiatric physician.

Mark, I want to go on record to make it clear that my organization is not being compensated in anyway by the American Podiatric Medical Association (APMA). Instead, this matter has been brought to my attention by my wife who has managed a small podiatric practice for nearly 20 years and she makes a convincing case that their elderly patients in particular would suffer the most if this revision is not made. I respectfully urge you to give this your most careful and compassionate consideration.

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ATTACHMENT 3 TO #1195

The 60 Plus Association

1600 Wilson Blvd. • Suite 960 • Arlington, VA 22209
Phone 703.807.2070 • Fax 703.807.2073 • www.60Plus.org

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Attention: CMS-1270-P

June 30, 2006

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Mark, I want to go on record to make it clear that my organization is not being compensated in anyway by the American Podiatric Medical Association (APMA). Instead, this matter has been brought to my attention by my wife who has managed a small podiatric practice for nearly 20 years and she makes a convincing case that their elderly patients in particular would suffer the most if this revision is not made. I respectfully urge you to give this your most careful and compassionate consideration.

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Jim Martin
President
60 Plus

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Submitter : Mrs. Carolann Burke **Date:** 06/30/2006

Organization : Novacare Rehabilitation

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attchment

CMS-1270-P-1196-Attach-1.PDF

ATTACHMENT TO # 1196

NovaCare™
REHABILITATION
a Select Medical company

Clinical Services Department

June 29, 2006

NovaCare Rehabilitation
680 American Avenue
King of Prussia, PA 19406

RE: "Proposed Rule for Competitive Acquisition of Certain DMEPOS"

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Comments submitted electronically to: http://www.cms.hs.gov/eRulemaking

Dear Dr. McClellan:

NovaCare Rehabilitation appreciates the opportunity to comment on the Proposed Rule for Competitive Acquisition of Certain DMEPOS. NovaCare Rehabilitation's highly respected clinical team provides preventative and rehabilitative services that maximize functionality and promote well-being. NovaCare Rehabilitation maintains an integrated local market network of approximately 500 convenient locations in 24 states and the District of Columbia. NovaCare Rehabilitation is a division of Select Medical Corporation and is comprised of licensed physical therapists, registered/licensed occupational therapists, physical therapist assistants, and certified hand therapists. Our clinical team devises individualized treatment plans to help achieve each patient's specific goals and maximize his or her functional independence.

On behalf of the licensed physical (P.T.) and licensed/registered occupational therapists (O.T.) and certified h and t herapists (CHT) em ployed by N ovaCare Rehabilitation, we r espectfully comment on the following concerns and issues that will adversely impact the patient community requiring an orthotic as a part of their plan of care, as well as set up an unfair market advantage for the larger supplier over the smaller community-based provider who happens to provide a minute percentage of orthotic devices to patients in need.

Duplication of Quality Standards:

- Physical and occupational therapists, by virtue of their education and training through an accredited educational program and comprehensive treatment of the patient, already are in the best position to understand human anatomy, beneficiary factors, and specific patient diagnoses and are able to uniquely fit each patient with the orthotic necessary for the continuation of the patient's care. Because physical and occupational therapists provide not just an orthotic, but develop an entire therapy plan of care specific to the individual patient and his/her condition(s), that plan of care requires the knowledge and understanding of human anatomy, beneficiary factors, specific diagnosis and the ability to make each fitting unique to that beneficiary. Furthermore, since the therapist is intimately involved in the beneficiary's plan of care, the therapist is in the optimal position to know the patient's broad range of treatment options and to ensure that the orthotic required and/or prescribed is optimal for the beneficiary's condition.

NovaCare Rehabilitation recommends that CMS consider physical and occupational therapists as already meeting the quality standards and accreditation for supplying DME supplies to their patients by virtue of their accredited education and state licensure requirements and not include them in future quality standards and/or accreditation process proposed as a part of the rule.

Supplier:

- Section I Terms of Contract (414.420) specifically lists physicians, nurse practitioners and clinical nurse specialists as being able to supply only to their patients, but does not include physical and occupational therapists as a potential supplier. Additional clarification is required to ensure that physical and occupational therapists are not able to supply to anyone other than their own patients. Therapists who have authorization to provide rehabilitation care should be able to use all treatment procedures and supplies including orthotics and equipment necessary to facilitate their patients' independence in self care, ambulation and safety in their homes and communities.

  NovaCare Rehabilitation urges CMS to allow physical and occupational therapists to provide orthotics to their patients as a part of a patient's individual and physician certified plan of care and not include them in the ruling for competitive bidding for orthotics. If CMS disagrees with this position and includes them in the ruling, they should be included with the physicians and have the ability to provide a small number of orthotic devices to their patients without providing DME services to the public.

Quality of Care:

- Medically appropriate and required skilled care will be delayed if the beneficiary is required to go beyond the rehabilitation provider for over-the-counter orthotic devices. Individual patient presentation and specific measurements taken during the initial evaluation are integral to providing the patient with the most effective and comprehensive care plan and appropriately fitting orthotic device. Additionally, it is necessary for the same evaluating clinician to provide the correct fitting splint based on the following clinical presentation indicators: treatment diagnosis, physical problem, functional limitations, pain, sensory loss, swelling, strength and skin integrity. Patients also require extensive education regarding the purpose of the orthotic, correct application, precautions, wear schedule, care instructions for splint as well for their skin, how to check for pressure points, and how to make self modifications if needed.

- Patients need to be observed using the extremity with the orthotic device on to assess if the device is meeting the goals/purpose of the orthotic. If not, the therapist needs to identify another style and repeat the fitting/assessment process, or decide if a custom splint is more appropriate.

- An incorrectly fitted orthotic can lead to:
  - Blisters, skin sores, tendon ruptures
  - Muscle "guarding"" and increased pain
  - Postural changes and symptom changes
  - Increased edema due to constriction or improper instructions
  - Decreased sensation due to nerve compression
  - Tendonitis due to "fighting against" an ill-fitting splint

- Occasionally, a patient may require more than one style orthotic to achieve his/her goals based on the patient's changing clinical presentation, for example a custom orthotic to immobilize for heavy tasks, and a prefabricated one to provide support but allow for light

ADLs. This can NOT be accomplished if the therapist is unable to provide ALL styles of orthotic devices and/or brands during the visit.

NovaCare Rehabilitation urges CMS to eliminate the potential for adverse consequences to occur to the Medicare beneficiary by allowing physical and occupational therapists to continue to supply their patients' orthotic devices as a part of quality skilled programming. Many therapists have observed prefabricated "universal" or "fits either hand" splints put on the wrong hand, upside down or backwards because of a lack of therapist involvement as described above. Patients may purchase the orthotic on their own, or receive it from a physician/nurse/DME supplier without proper instruction or good fit. These patients are eventually referred to therapy for the problems listed above, which ultimately costs the health care system additional money due to more visits, therapy and additional fitting of orthotic devices.

Small Supplier Burden/Competitive Disadvantage:

- The bidding process for the physical and occupational therapist is not clearly defined in the proposed regulation. This requirement would be very burdensome for each center providing physical or occupational therapy to fill out an application requiring an estimated 70 hours to complete and go through an accreditation process to provide an orthotic device already approved by the physician's written plan of care and in conjunction with the skilled treatment that is provided. Additionally, the smaller provider cannot compete with the bulk discounts provided to the large supplier.

NovaCare Rehabilitation urges CMS to exclude the small provider (10 clinical professionals or less in a particular center) from the competitive bidding and accreditation process based on the undue hardship this will place on the provider to access cost-effective devices and the patient's access to clinically superior outcomes provided by the physical and/or occupational therapist.

Thank you for your time and consideration of these comments. If you have any questions regarding these comments, please contact Carol Burke at cburke@HQ.novacare.com or 860-668-8741.

Respectfully,

Carol Burke, P.T., Director of Clinical Services
Kathy DeLacy, P.T., Director of Clinical Services
Lynn Bradley, P.T., Director of Clinical Services

Submitter : **Mrs. Susan Mannarino** **Date: 06/30/2006**

Organization : **American Society of Hand Therapists**

Category : **Occupational Therapist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See attached

CMS-1270-P-1197-Attach-1.DOC

ATTACHMENT TO #1197

To Whom It May Concern:

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Sue Mannarino and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in a hand and upper extremity treatment center as well as a long term care facility, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its

possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, 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. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Submitter : **Ms. Rose Porter** **Date: 06/30/2006**

Organization : **A-One Specialty Medical LLC.**

Category : **Home Health Facility**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

June 28, 2006

To Whom It May Concern:

All the changes going on in the Healthcare industry are scary enough without having to worry about whether we are going to be in business next year.

We are a small supplier that takes great pride in the services we offer to our customers. They are very important to us and we let them know it, which is very rare nowadays.

Small Business, NOT Big Business is the driving force behind the American economy and given this fact, CMS has not adequately considered the impact that competitive bidding will have on small business. Most Durable Medical Equipment Suppliers fall under the Small Business guidelines as outlined by the Federal government. Although CMS suggested small business create networks, the current timeline allowed to create a new entity is insufficient at best if not impossible. If a small business meets the required standards, they should be allowed to participate if they are willing to provide the products at the agreed upon bid price. Competitive bidding will only help establish a new industry where only the large survive. Sometimes bigger is not better, it s just bigger.

Thank you for taking the time to review our concerns.

Respectfully,

Rose Porter
Member

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

We are a small business and are currently not accredited. There are only a limited number of accrediting agencies and they are now setting appointments for Spring 2007. The requirement for accreditation has created a bottleneck in our industry that only additional time will correct. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

Thank you for taking the time to review our concerns.

Rose Porter

Submitter : **Jean Minkel** **Date: 06/30/2006**

Organization : **Minkel Consulting**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Jean Minkel. I am submitting comments to the Notice of Proposed Rulemaking for Competitive acquisition of certain DMEPOS, as a member of the PAOC.

I will focus my comment to only a few select areas of the proposed rule:
1. (Referencing 414,414(c) Quality Standards and Accreditation

There is a critical need for published Quality Standards to be implemented. These Standards need to be used by the yet to be named CMS approved accreditation agencies. It is critical that bid suppliers be accredited using the new quality standards. To achieve this critical goal, the agency is encouraged to:
a. Implement the initial Bid cycle in only 4 MAS one for each DMERC and the CMS approved accrediting organizations should focus on those 4 areas to insure Quality Standards applied to all qualified suppliers BEFORE bids are reviewed.
b. No Grace period should be adopted.
c. The agency may alternatively consider, grandfathering only those Suppliers who have earned accreditation by an approved organization within the last 18 months New survey should be scheduled before bid is accepted to insure compliance with any new Standards specified by CMS not in place at the time of the original accreditation.
d. Publish criteria for the selection of CMS approved accrediting agencies.
e. Demonstration of accreditation needs to done be prior to accepting Bids.

2. (Referencing 414.210 (g) Establishing Payment Amounts for New DMEPOS Items. The proposed functional technology assessment and a revised plan for determining pricing should have its own Regulatory announcement and separate Comment Period.

3. (Referencing 414.416) Proposed Rebate Program Just Say NO!

4. (Referencing 414.426) Payment Rules related to Coding changes
The Agency is encouraged to re-bid the Product category if there is a change in the coding of a Product category during a bid cycle, for example one code divided into two. New codes should receive new fee schedule prices when initially adopted that code should be available to all beneficiaries based on the Fee schedule until the Product group is re-bidded

Submitter : **Mr. Juan Izquierdo** **Date: 06/30/2006**

Organization : **Medical DEcision Services**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

It is illogical for CMS not to exclude Miami from the first round of bidding. On page 145 CMS states We exclude the three largest MSAs in 2006, excluding New York, Chicago and Los Angles. We exclude the three largest MSAs in 2006 because we are proposing not to include them in the initial phase implementation. We are excluding the three largest MSA because they are significantly larger than any of the area in which we implemented the competitive bidding demonstrations and we would like gain more experience in smaller markets before we enter into the largest markets. This statement is absolutely nonsensical. It is ridiculous to state that CMS wants to gain more experience in smaller markets, before they enter into the largest markets, but yet they do not exclude Miami which has the largest MSA market based on charges per beneficiary, suppliers per beneficiary, and total DMEPOS allowed charges. There is a big difference between the Medicare DMEPOS market in an MSA and the raw population of an MSA.

This illustrates either poor planning or incompetence in compiling information on behalf of CMS. It frightens me to think that CMS is concerned on soliciting an RFB in the 3 largest markets because of their lack of experience but yet they include the three largest Medicare DMEPOS MSA markets which are Miami, Houston, and Dallas not New York, Chicago and Los Angles.

CMS-1270-P-1200-Attach-1.DOC

ATTACHMENT TO #1200

Competitive Bidding Areas - Competitive Bidding Areas

It is illogical for CMS not to exclude Miami from the first round of bidding.

On page 145 CMS states *"We exclude the three largest MSAs in 2006, excluding New York, Chicago and Los Angles. We exclude the three largest MSAs in 2006 because we are proposing not to include them in the initial phase implementation. We are excluding the three largest MSA because they are significantly larger than any of the area in which we implemented the competitive bidding demonstrations and we would like gain more experience in smaller markets before we enter into the largest markets."* This statement is absolutely nonsensical. It is ridiculous to state that CMS wants to gain more experience in smaller markets, before they enter into the largest markets, but yet they do not exclude Miami which has the largest MSA market based on charges per beneficiary, suppliers per beneficiary, and total DMEPOS allowed charges. There is a big difference between the Medicare DMEPOS market in an MSA and the raw population of an MSA.

This illustrates either poor planning or incompetence in compiling information on behalf of CMS. It frightens me to think that CMS is concerned on soliciting an RFB in the 3 largest markets because of their lack of experience but yet they include the three largest Medicare DMEPOS MSA markets which are Miami, Houston, and Dallas not New York, Chicago and Los Angles.

Submitter : Mr. Barry Alexander **Date:** 06/30/2006

Organization : Nelson Mullins

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1201-Attach-1.DOC

ATTACHMENT TO #1201

Nelson Mullins

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July 5, 2006

VIA ELECTRONIC FILING

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1810-IFC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Comments Submitted Regarding Proposed Rule Entitled: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues

File Code CMS-1270-P

Dear CMS Administrator:

We represent a number of DMEPOS suppliers within the state of North Carolina and throughout the country and, as such, we are writing to submit a discrete group of comments with regard to the proposed competitive bidding rule referenced above (the Proposed Rule(s)).

Quality Standards for Suppliers of DMEPOS

The Proposed Rules indicate that CMS will be finalizing the quality standards shortly, and that these standards will be published on the CMS website. The Proposed Rules do not clarify whether the quality standards will be product-line specific and the relationship between the quality standards and the existing 21 supplier standards set forth at 42 C.F.R. § 424.57.

Among other questions, we encourage CMS to clarify whether a DMEPOS supplier will need to be accredited for *each type* of DMEPOS that it furnishes. In particular, we note that the draft quality standards issued on the CMS website include appendices for 14 different classes of DMEPOS. While we fully acknowledge that a supplier wishing to furnish any item within these different classes of DMEPOS may be required to meet additional or different quality standards applicable to that product line, we do not believe that the supplier should be required to be re-accredited each time it elects to add a new product line. We encourage CMS to

develop the final quality standards in a manner that will allow suppliers to meet the core criteria in Section 1 of the proposed quality standards, with a streamlined accreditation process if, for example, a supplier chooses to add wheelchairs as a complement to its accredited hospital bed business. Many of the ostensibly discrete quality standards for product lines have areas of overlap and the accreditation process should be established in a manner to recognize this fact.

Second, it appears that CMS expects to maintain the existing 21 supplier standards and treat the quality standards as a separate compliance requirement. We are concerned that there is a potential for contradiction and confusion since the current 21 supplier standards are loosely incorporated into the quality standards (e.g., delivery and set up criteria and maintenance and service) and because the direct quality standard appears to expand upon a number of these provisions. In addition, we are concerned that there is a potential for contradiction and inconsistency with regard to enforcement and interpretation since, at least currently, the supplier standards are enforced by CMS through its contract with the National Supplier Clearinghouse (NSC). Currently, suppliers are subject to an initial inspection by a representative of the NSC and a tri-annual inspection by the NSC to determine whether compliance with the 21 supplier standards continues. We would further note that the interpretation and enforcement of the supplier standards has been subject to great variability, with the NSC issuing interpretative guidance to guide its investigators without having promulgated this guidance through appropriate notice and comment rulemaking.[1]

As a result, we encourage CMS to allow the selected accreditation organizations to validate a supplier's compliance with *both* the quality standards and the interrelated 21 supplier standards. We understand that CMS would retain the right to separately investigate a supplier's compl iance with either the quality standards and/or the 21 supplier standards such as in the event of a substantial allegation of non-compliance, similar to the current accreditation process employed for Part A providers. That said, given the inter-relationship between the quality standards and the 21 supplier standards, we encourage CMS to permit accreditation organizations to validate a supplier's compliance with these requirements as part of a single accreditation review and to *eliminate* the tri-annual NSC revalidation visit.

Accreditation for Suppliers of DMEPOS and Other Items

Section 1834(a)(20)(B) of the Social Security Act requires that the Secretary issue quality standards and designate one more accreditation organizations to apply the quality standards to suppliers of DMEPOS and other items. The Proposed Rule indicates that CMS will be

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[1] In March of 2004, the NSC issued guidelines clarifying and interpreting the supplier standards establishing, among other issues, minimum amounts of inventory that suppliers must maintain. Although we understand that Palmetto GBA, the contractor which runs the NSC contract, was instructed by CMS to discontinue use of these guidelines, we are concerned that the guidelines continue to be used in an informal manner by the NSC even though they have not received clearance from CMS.

providing additional guidance at a later date regarding the agency's final selection of accreditation organizations that will determine whether suppliers meet the quality standards.

The Proposed Rules do not indicate whether any entity that supplies DMEPOS must meet the accreditation standards or whether certain providers and suppliers, such as hospitals or physicians which supply DMEPOS, also must be accredited or whether such entities may rely upon a more general accreditation or licensure status. It is our view that *any* entity which furnishes covered DMEPOS should be accredited by an approved DMEPOS accrediting organization for the DMEPOS that the supply. This should not, in our view, preclude a provider or supplier's accreditation organization from offering combined accreditation visits (e.g., home health and DMEPOS) so long as the accreditation organization separately validates compliance with the applicable quality standards and 21 supplier standards. We encourage the agency to respond to clarify this issue in the final Competitive Bidding Rules.

Lastly, we request that CMS clarify the relationship between accreditation organizations and CMS complaint investigations more broadly. In particular, if a supplier organization is deemed to be in full compliance with the quality standards and the 21 supplier standards by an approved accreditation organization, will CMS be permitted to separately revoke or suspend a supplier's participation status if CMS determines that the supplier is not in compliance with these requirements? Although it appears that CMS desires to reserve the right to investigate substantial allegations of non-compliance against accredited suppliers (similar to the manner in which the agency may survey or investigate an accredited Part A provider), there is a well-established process in the Part A context to deal with violations of the applicable Part A Medicare conditions of participation. There is nothing comparable in the Part B supplier context and, from our experience, the NSC often takes swift action against suppliers for an alleged failure to meet a supplier standard including, in some instances, suspension of a supplier's Medicare billing privileges.

In the Part A context, survey and certification is driven by a well-established regulatory framework which, as of yet, has not been proposed by CMS in the Part B setting. The Part A survey and certification process is set forth at 42 C.F.R. § 488 *et. seq.* These regulations establish provisions for validation surveys (42 C.F.R. § 488.7), a process to report alleged deficiencies to the provider, forms to be used by the state survey agency (e.g., the CMS-2567) and the general process for the submission of a plan of correction. Accordingly, while we acknowledge that CMS may elect to reserve the right to conduct a validation survey where substantial allegations of noncompliance may exist, CMS has failed to propose a comparable process to the Part A context a process t hat will allow suppliers to respond alleged deficiencies within an appropriate period of time before suspension or revocation actions are taken.

Determining Single Payment Amounts for Individual Items

Proposed Section 414.416 establishes a multi-step process for calculating the single payment amount for each item in each competitive bidding area based upon the bids submitted and accepted for that item. It is our view that the proposed process outlined by CMS will have the effect of distorting the bid submission process and, in our view, is unfair to suppliers that attempt, in good faith, to submit a bid price that reflects their ability to furnish a particular item or service for the beneficiaries in that area.

In particular, as we understand the Proposed Rule, CMS proposes to establish a single bid amount for a specific item that will be the median of the bids submitted by the contract suppliers. We acknowledge that the enabling statute dictates that CMS select a single payment amount for each item in a competitive bidding area; however, we believe that the process proposed by CMS will have the effect of distorting the bid prices submitted. Since the lowest bidding supp liers will realize that, irrespective of their submitted bid, they likely will receive a payment amount *above* their submitted bid, we are concerned that some suppliers will game the system by intentionally submitting bids with the sole and express purpose to ensure that the supplier will be one of the winning suppliers in the competitive bidding area. In other words, the game will be to submit a bid that gets the supplier at or below the pivotal bid with the understanding that, once selected, the price would be adjusted upward.

In our view, this is not true competitive bidding it is an exercise in game theory. Suppliers should be made to understand that the bid they submit, even if below the single payment amount established (however such determination is ultimately decided by CMS in the final rules), is the bid that they may be paid at. We do not view this approach as inconsistent with Congress' objective to have a single bid price in competitive bidding area. Given that CMS has the authority to adjust payment amounts in non-competitive bidding areas based on prices established in a competitively bid MSA, it is essential that the resultant single payment amount is reflective of a true market p rice.

The approach we suggest also is consistent with longstanding Medicare payment policies. In particular, Medicare makes payment for DMEPOS at the lower of the Medicare Fee Schedule or the supplier's actual charge. *See*, e.g., 42 C.F.R. § 414.210. Indeed, the standard CMS-1500 claim form has been developed so that the supplier's actual charge can be identified.[2] We understand that DMERC (soon to be DMAC) claims processing systems currently pay a supplier's claims at the *lesser* of the fee schedule or the supplier's actual charge for each and every claim adjudicated by the Part B contractor. Accordingly, it is our view that CMS can comply with the statutory mandate of establishing a single payment amount (this would be treated by the claims processing system as the fee schedule or maximum payment amount) and simultaneously hold suppliers responsible for the bids they submitted (by requiring that the

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[2] The revised CMS-1500 claim form requires placement of the provider/supplier's charge in block 24f.

supplier submit as their actual charge their bid price for that item). Bidders would be reimbursed no more than their bid price for an item and, in the case of a winning bidder that had submitted a bid above the single payment amount, such supplier would be reimbursed no more than the single payment amount.

In short, if a supplier certifies to CMS that they have the ability to provide a specified item of DMEPOS for $X per unit, we believe that the supplier has certified as to their actual charge and that such supplier should be paid the lesser of the single payment amount in the competitive bidding area *or* their actual charge as *certified* in their bid submission. We believe that this proposal is consistent with *both* longstanding DMEPOS payment policies as well as Congressional mandate that the agency establish a single payment amount for a competitive bidding area. Under the Proposed Rule, we are concerned that suppliers will be encouraged to submit artificially low bids solely in an effort to become an approved supplier in that competitive area with the clear understanding and expectation that the bid will be adjusted upward to the single payment amount. Competitive bidding must be established by CMS in a manner to ensure fair participation for all suppliers that elect to submit bids in a competitive bidding area and any supplier should be prepared to receive payment at the bid price they submit.

* * *

We respectfully request that these comments be placed in the record for the Proposed Rule and we appreciate the agency's consideration of same.

Respectfully submitted,

/s/

Barry D. Alexander

Submitter : Mrs. Deborah Mazza **Date:** 06/30/2006

Organization : Mrs. Deborah Mazza

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1202-Attach-1.TXT

CMS-1270-P-1202-Attach-2.TXT

ATTACHMENT 1 TO #1202

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Deborah Mazza, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in a hospital in the out-patient rehabilitation department, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its

possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, 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. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Deborah A. Mazza, OTR/CHT

ATTACHMENT 2 TO #1202

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Deborah Mazza, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in a hospital in the out-patient rehabilitation department, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, 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. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Deborah A. Mazza, OTR/CHT

Submitter : Dr. Adam Teichman **Date:** 06/30/2006

Organization : Lehigh Valley Foot and ANkle surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

PLease refer to the attachement.

Thank you

Dr. Adam Teichman

CMS-1270-P-1203-Attach-1.PDF

ATTACHMENT TO #1203

LEHIGH VALLEY
FOOT & ANKLE SURGEONS

Jay H. Kaufman, D.P.M., F.A.C.F.A.S.
Dean L. Sorrento, D.P.M., A.A.C.F.A.S.

Sports Medicine

Trauma/Reconstruction

Ankle/Foot Fractures

Joint Replacement

Peripheral Nerve Surgery

Diabetic Care

Pediatric Deformities

Wound Care

General Podiatry

Quantitative Sensory Testing

Doppler Studies

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June 30, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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).

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. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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 to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Dean L. Sorrento, DPM, FACFAS

LEHIGH VALLEY
FOOT & ANKLE SURGEONS

Jay H. Kaufman, D.P.M., F.A.C.F.A.S.
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Sincerely,

Jay H. Kaufman, DPM, FACFAS

LEHIGH VALLEY
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June 30, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

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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 to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Adam J. Teichman, DPM, AACFAS

Submitter : **Date: 06/30/2006**

Organization : **DJO Incorporated**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

Attachment

CMS-1270-P-1204-Attach-1.PDF

CMS-1270-P-1204-Attach-2.PDF

ATTACHMENT 1 TO #1204

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June 30, 2006

BY HAND DELIVERY

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445—G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments Regarding CMS—1270—P: "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues"

Dear Administrator McClellan:

On behalf of our client, DJO Incorporated ("DJO" or the "Company"), we submit these comments on the above-referenced proposed regulations, which implement the Medicare Part B DMEPOS Competitive Bidding Program and revise the gap-filling payment methodology used to set fee schedule rates for new codes for DMEPOS items and services.[1] As the world's largest manufacturer of orthotics, as well as a large Medicare supplier of orthotic products and manufactured bone growth stimulators, DJO expects to continue its participation in the Medicare program after the launch of competitive bidding. For this reason, the Company appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") as to the impact of these proposals on the Company and the continued access to orthotics and the DME industries generally.

The competitive bidding program will radically change how Medicare pays for DMEPOS items used by beneficiaries in the home. Payment rates that previously were set based on fee schedule amounts will instead be determined by bid amounts submitted by DMEPOS suppliers for competitive bidding areas. The success of this program depends on the ability of suppliers to submit accurate bids for products (and on CMS's ability to evaluate them appropriately and fulsomely). Of paramount concern to DJO is CMS's ability to accurately and appropriately evaluate the bid submissions for orthotic products. With the vast number of orthotic products

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[1] 71 Fed. Reg. 25654 (May 1, 2006).

and the large number of HCPCS codes describing these products, there is tremendous variability in the industry as to which products belong in which codes. Without more clarity in this area, suppliers will have difficulty determining appropriate products and bids for each HCPCS code and, as a result, the bid submission process (as well as CMS's evaluation process) will be extremely difficult, if not impossible. The resulting competitive bid payment amounts are likely to be irrational. DJO asks CMS to avoid premature inclusion of orthotic products in the competitive bidding program until such time as a satisfactory resolution can been devised. In addition, DJO has serious concerns with the proposed expansion of the statutory definition of off-the-shelf ("OTS") orthotics—which are the only orthotic products that may be competitively bid. The agency should and must hew to the line already drawn by Congress regarding which products are to be included.

DJO's concerns with the proposed regulations cover a number of areas:[2]

- Criteria for Item Selection
- Submission of Bids Under the Competitive Bidding Program
- Conditions for Awarding Contracts
- Determining Single Payment Amounts for Individual Items
- Terms of Contract
- Physician Authorization/Treating Practitioner
- Payment Basis
- Gap-filling
- Administrative or Judicial Review

Summary of Comments

If CMS decides to move forward with competitive bidding for orthotic products, DJO recommends that the following measures be taken:

(1) ***Define OTS Orthotics As Required By the Medicare Statute:*** DJO strenuously disagrees with CMS's proposed definition of OTS orthotics for competitive bidding. The proposed interpretation would broaden impermissibly the statutory definition of OTS orthotics to include all orthotics that do not require assistance of a certified orthotist. This proposal is an impermissible departure from congressional language. Perhaps more critically, the proposal directly conflicts with the existing Federal definition of "qualified practitioners" who possess expertise to furnish certain orthotics to Medicare beneficiaries. This over-broad definition, therefore, must not be finalized. DJO seeks inclusion of the statutory definition in the regulation. The Company also urges CMS to consult with the orthotic industry to determine which HCPCS codes describe OTS orthotics and, of those, which should be included in the initial phase of the program.

(2) ***Ensure Participation of Suppliers With Sufficient Capacity Regardless of Physical***

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[2] These are the subject headings that CMS requested commenters use to flag issues for the agency. Each of these subjects is noted as a heading in bold language and bracketed immediately preceding the relevant discussion. Please note that some subjects are addressed multiple times in this comment letter.

Location in the Service Area: DJO strongly supports CMS's proposal to allow suppliers to participate even if they do not necessarily have a separate physical location in a competitive bidding area ("CBA"), provided that they (a) offer services in the geographic area and (b) have a demonstrated ability to do so. CMS appropriately recognizes that more meaningful indicia than physical location should be determinative of capacity to serve a particular CBA.

(3) ***Categorize Competitively Bid Products Using Existing SADMERC Policy Groups and Use Sub-Groupings for Bidding Purposes:*** Under CMS's proposal, bidding for products would be conducted based on groupings of products into "product categories" and a supplier would need to submit a separate bid for each HCPCS code within a given category. DJO believes that there is no need to "re-invent the wheel" and existing Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") policy groups should be considered. A few of the SADMERC policy groups for orthotics correspond to existing medical policies, with meaningful relationships among grouped codes, while others group codes according to the body part treated. Suppliers who specialize in serving beneficiaries with certain medical conditions (*e.g.*, patients who need a knee orthosis, but not a spinal orthosis) may continue to do so. If broader categories are used, suppliers with specialization for particular parts of the body will not be able to offer competitively bid items and services.

Even if CMS were to use the SADMERC policy groups for orthotics, it would be difficult, if not impossible, to provide a bid amount for each HCPCS code. Most suppliers are unlikely to have a product for each code. In addition, as mentioned above, there is considerable uncertainty as to the appropriate HCPCS code for individual products, and this will make it nearly impossible for suppliers to submit bids on a code-by-code basis. If CMS includes OTS orthotics in the initial phase of competitive bidding, DJO recommends sub-groupings for which a single bid amount could be offered. This recommended methodology is described in further detail below.

(4) ***Ensure the Integrity of Bid Evaluations by Requiring Uniform Financial Standards & Accreditation, Allowing for an Extended Grace Period for Orthotics Suppliers:*** CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. Such steps should include publishing final quality and financial standards that must be met regardless of the size or type of organization. DJO applauds CMS for its recognition that, in the initial phase of competitive bidding, a grace period is needed so that suppliers can come into compliance with the quality standards. An extended grace period is particularly essential for industries such as orthotics in which accreditation is not currently the norm.

(5) ***Recognize That Suppliers Are Only Equipped to Provide Items From Their Own Inventories:*** DJO asks that CMS revise two of its proposals so that they address practical realities and limitations of the DMEPOS industry. First, proposed 42 C.F.R. § 414.422(c) places the onus for repairing and maintaining items previously furnished by non-contract suppliers on contract suppliers. This provision should not be adopted. In most instances suppliers are not equipped to handle such work for products not in their inventories. This is particularly the case for manufacturer/suppliers that typically only or predominantly sell the products they make. Second, proposed 42 C.F.R. § 414.420 would require contract suppliers to make a reasonable effort to furnish a particular brand

or mode of delivery of an item, as prescribed by the physician or treating practitioner. This provision should be revised so that contract suppliers do not need to offer the item if it is not in their inventory.

(6) ***Revise Change in Ownership Rules So That They Are Consistent With Existing Requirements For DMEPOS Suppliers:*** Proposed 42 C.F.R. § 414.422(d) would limit a contract supplier's ability to continue to participate in competitive bidding upon a change in ownership. Among other things, approvals are required. This provision should be revised to allow the supplier to continue to participate in the program, provided that the legal entity enrolled in the Medicare program does not change (*e.g.*, there has been only a change in stock or other equitable ownership). Furthermore, the timeframe for the notice requirement should conform to the existing regulation governing supplier notice of changes in ownership.

(7) ***Set Payment Amounts So That They Reasonably Reflect Actual Bids:*** CMS proposes to use the median of the winning bids (*i.e.*, those at or below the pivotal bid) to set the competitive bidding payment amount for each product. This may force contract suppliers either to furnish products at prices far below their submitted bids or to exit the Medicare program. DJO asks CMS to adopt a payment methodology for competitive bidding that does not artificially depress rates below the bid prices of a substantial number of the winning bidders. The Company asks that the methodology used in the competitive bidding demonstration projects, which was an alternative proposal discussed in the preamble to the proposed regulations, be adopted instead.

(8) ***Retain Competitive Bidding Payment Amounts Throughout A Bidding Cycle When Multiple HCPCS Codes Are Merged Into a Single Code:*** CMS proposes special payment rules to be used when HCPCS codes are revised in the middle of a competitive bidding cycle. DJO generally supports the proposed rules, with one exception. The Company believes that, where multiple codes describing similar products are combined into a single code, the prior codes and their competitive bid payment amounts should continue to be used until the end of the current contract. This would maintain stability in pricing for the products in the CBAs and not upset suppliers' expectations. The payment rates for a given product should not change in the midst of a contract.

(9) ***Refrain From Creating An "Any Willing Provider" Model If CMS Uses Competitive Bidding Rates to Adjust Payment Amounts in Non-competitive Bidding Areas:*** DJO asks that CMS proceed cautiously in implementing its authority beginning in 2009 to adjust payment in non-competitive bidding areas based on payment information determined under the competitive bidding program. This authority could result in a *de facto* "any willing provider" model, in which competitive bidding rates are used nationwide and any supplier that is able to provide services may do so (for reimbursement at those rates). Competitive bidding rates are set with the expectation of a significant increase in volume to offset lower prices. This will not exist in non-competitive bidding areas.

(10) ***Do Not Finalize the Proposed Rebate Program:*** DJO objects to CMS's proposal to allow suppliers to give rebates to beneficiaries for products provided through the competitive bidding program. This ill-advised proposal implicates and may run afoul of the Federal Anti-Kickback Statute and blurs the line between permissible and

impermissible rebates.

(11) ***Protect Existing Medicare Appeal Rights:*** Existing rights of beneficiaries and suppliers to appeal denied claims should not be affected by competitive bidding. DJO requests that proposed 42 C.F.R. § 414.424 be revised to clarify that the prohibition on appealing certain determinations made in the course of conducting the competitive bidding program in no way circumscribes or otherwise affects existing appeal rights.

(12) ***Revise the Proposed Gap-Filling Replacement to Follow Statutorily-Required Procedures & Ensure Fair Pricing:*** CMS's proposal in 42 C.F.R. § 414.210(g) to jettison the current gap-filling methodology for new DMEPOS items in favor of consideration of a variety of pricing data sources must not be adopted without significant revisions. As written, the proposed regulation is vague and impermissibly circumvents the procedural and substantive requirements to be used in any exercise of CMS's inherent reasonableness ("IR") authority. It is essential that any formula adopted here follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products. DJO believes that this new regulation deserves considerable attention that it likely will not receive because it has been appended to the proposed regulations for competitive bidding. DJO therefore asks that CMS postpone publication of a final regulation on this topic to provide time for suppliers to submit additional comments and/or to meet with the agency to discuss alternatives.

Finally, as to appropriate 2007 and 2008 payment updates for Class III devices paid under the DMEPOS fee schedule, DJO asks that CMS consider the comments of the Electrical Bone Growth Stimulators ("EBGS") Coalition, which are provided under separate cover. These comments urge the agency to adopt a specific fee schedule payment update for Class III devices based upon factors unique to Class III devices, and to provide a full CPI-U payment update for both years.

I. DEFINE OTS ORTHOTICS AS REQUIRED BY THE MEDICARE STATUTE

[Criteria For Item Selection]

Under the Medicare statute, OTS orthotics are among the categories of DMEPOS products that may be competitively bid.[3] CMS proposes to broaden the statutory definition of OTS orthotics to include all orthotics that do not require assistance of a certified orthotist. This is an impermissible departure from the definition prescribed by Congress. Not only that, the proposed definition *directly conflicts* with an existing statutory payment provision that defines the types of practitioners who are qualified to furnish certain orthotics to Medicare beneficiaries. DJO strenuously objects to CMS's proposal to put in place a sweeping interpretation of the statutory definition of OTS orthotics. We submit that CMS may not adopt an interpretation that goes well beyond the statutory language and certainly may not do so in a manner that contradicts existing statutory requirements regarding practitioner qualifications. There are practical concerns with the proposed definition as well. Rather than bringing clarity to which orthotics are considered off-the-shelf, the proposal would inject an additional layer of uncertainty by tying the definition to an amorphous standard (*i.e.*, necessary involvement of a certified orthotist).

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[3] 42 U.S.C. § 1395w-3(a)(2)(C).

DJO asks rather that the statutory definition be imported into the regulation, as written, and that CMS work with industry stakeholders including the National Orthotics Manufacturers Assocation (NOMA) to determine which HCPCS codes describe OTS products (and, of those, which should be included in the initial phases of competitive bidding).

CMS May Not Contravene Existing Medicare Requirements Regarding Qualified Practitioners

The Medicare statute defines OTS orthotics as those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[4] The proposed regulatory language at 42 C.F.R § 414.402 mirrors that language. Yet, CMS takes this definition multiple steps further in its discussions in the preamble. There, the agency states that the sole reference point for the definition is *whether needed adjustments would require the expertise of an orthotist.* CMS suggests that OTS orthotics are those that:

> (1) can be adjusted by a beneficiary, caretaker, or orthotic supplier without the assistance of an orthotist certified by the American Board for Certification in Orthotics and Prosthetics, Inc. ("ABC") or the Board for Orthotist/Prosthetist Certification ("BOC"); and
>
> (2) do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual, which, CMS states, are activities that can only be performed by certified orthotists.[5]

DJO contends that CMS must revise the proposal explained in the preamble because it is inconsistent with existing orthotics payment provisions in the Medicare statute. Indeed, the fact that the proposal is not included in the regulation itself raises questions about the extent to which the agency believes that the additional language is a permissible construction of the statute. It is problematic to hinge the definition of OTS orthotics on involvement of a certified orthotist because the Medicare statute already identifies a more expansive list of practitioners who are qualified to furnish certain custom-fabricated orthotic products to beneficiaries. Of note, this provision includes physicians and qualified physical and occupational therapists as qualified practitioners as well. CMS may not cherry-pick certain types of practitioners with expertise to provide orthotics fitting and adjustment services to beneficiaries. The move to exclude these practitioners is particularly troublesome given that the agency has not yet promulgated regulations to implement the existing statutory language (as was explicitly required by Congress).

By way of background, the Medicare statute contains special payment rules for certain custom-fabricated orthotics, which include a definition of "qualified practitioners" that possess

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4 *See* 42 U.S.C. § 1395w-3(a)(2)(C).

5 71 Fed. Reg. at 25669-70.

expertise to furnish such products to beneficiaries (the "BIPA provision").[6] Under the BIPA provision, Medicare payment for an item on a list of certain custom-fabricated orthotics is only to be made if it is (1) furnished by a qualified practitioner; and (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the HHS Secretary determines appropriate.[7] "Qualified practitioner" is defined to include physicians, qualified physical and occupational therapists, licensed orthotists (in states requiring orthotist licensure), and other individuals who are specially trained or educated in the area and certified by ABC, BOC or other approved credentialing programs (in states without orthotist licensure requirements).[8]

As mentioned above, the BIPA provision has yet to be implemented through regulation, as Congress required. However, the statute itself specifies the types of individuals that Congress believes possess the skills and experience needed to provide certain custom-fabricated orthotics to beneficiaries. This definition may not be ignored. A fundamental canon of statutory interpretation provides that "effect must be given, if possible, to every word, clause and sentence of a statute," and that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.[9] The BIPA provision clearly acknowledges that more classes of practitioners than only ABC- and BOC-certified orthotists possess expertise to trim, bend, mold, assemble, or customize certain orthotics to fit them to an individual. The list of products to which BIPA applies has yet to be determined, but the statute requires that it consist of a *sub-set of all custom-fabricated orthotics*, which means that it clearly excludes OTS orthotics. For CMS to include only ABC- and BOC-certified orthotists as practitioners with the expertise to fit non-OTS orthotics ignores the other practitioners that are congressionally-approved as having expertise to provide some custom-fabricated orthotics. CMS may not read the words "physician," "qualified physical therapist," and "qualified occupational therapist" out of the statute, and should not be circumventing implementation of the BIPA provision in this manner to begin with. Limiting the definition of OTS orthotics to those not requiring the expertise of an ABC- or BOC-certified orthotist directly contravenes Congress's definition of qualified practitioner and illogically treats their inclusion as

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6 42 U.S.C. § 1395m(h)(1)(F) (as added by Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")).

7 The devices falling under the ambit of the special payment rules are to be identified by CMS in a published list and are defined as that subset of custom-fabricated orthotics that are "individually fabricated for the patient over a positive model of the patient."

8 42 U.S.C. § 1395m(h)(1)(F)(iii).

9 NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION , § 46:06, 181-86 (6th ed. 2000); *See also Washington Hosp. Center v. Bowen*, 795 F.2d 139 (D.C. Cir. 1986) (concluding that, in order to fulfill "our obligation to construe a statute so as 'to give effect, if possible, to every word Congress uses,'" it must strike down the Secretary's regulation requiring hospitals to wait until completion of the cost year before appealing prospective payment amounts to the Provider Reimbursement Review Board because the regulation ignored the provision of the Medicare statute permitting such appeals prior to filing a cost report).

surplusage. In short, borrowing or importing some, but not all, of the BIPA provision to define OTS orthotics is ill-advised and impermissible.[10]

CMS Is Bound By The Congressional Definition of OTS Orthotics

Not only does the proposed definition of OTS orthotics contravene the BIPA provision, but also it exceeds the congressional mandate as to which products are to be included in competitive bidding. Congress provided a specific and narrow definition of OTS orthotics that may be competitively bid. The language clearly limits OTS orthotics to those that do not require much, if any, adjustment in order to be used appropriately and that do not require fitting and adjustment expertise in order to be fit to the patient. CMS's proposed definition linking OTS orthotics to the work of a certified orthotist would dramatically *expand* the list of products that are considered OTS and that are subject to competitive bidding. Such an approach may also result in quality of care issues for Medicare beneficiaries. This is because products furnished through the competitive bidding process that require more than minimal self-adjustment may result in a poor fit, product ineffectiveness or even potential injury.

CMS may not implement the OTS definition in a manner that exceeds the congressional mandate, as would the proposal here. In the seminal case concerning agency interpretation of congressional language, the U.S. Supreme Court held that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[11] In effect, CMS's proposal discards the statutory definition, replacing the task-related criteria (*i.e.*, minimal self-adjustment for appropriate use and no expertise in trimming, bending, molding, assembling, or customizing to fit to the individual) with a wholly different benchmark for determining when a product ought to be included in competitive bidding: the need for a certified orthotist's involvement. This benchmark differs from and is inconsistent with the statutory criteria, as evidenced by the fact that it would result in a much more expansive list of orthotic products being competitively bid than Congress intended. Indeed, a CMS official[12] speaking at the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting even acknowledged that this proposal goes *far beyond that* specified by Congress.

An elementary canon of statutory interpretation provides that words in statutes are to be accorded their "plain and obvious meaning" because "one must assume that the legislature knew

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10 We note that, through the BIPA provision, Congress intended only to *mandate* involvement of qualified practitioners for a small sub-set of custom-fabricated orthotics. What is important for this discussion of competitive bidding regulations, however, is that the BIPA provision recognizes that such practitioners *have the experience to adjust and fit non-OTS orthotics.* Thus, CMS may not define OTS products by reference only to certified orthotists.

11 *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984); *see also* NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 121-22 (6th ed. 2000) (stating that "[t]here is no safer nor better settled canon of interpretation that that when language is clear and unambiguous it must be held to mean what it plainly expresses").

12 Joel Kaiser, who presented on this topic at the PAOC meeting, commented that this proposed definition goes beyond the definition in the Medicare statute.

the plain and ordinary meanings of the words it chose to include in the statute."[13] The OTS definition was heavily negotiated at the time that the MMA was enacted, and Congress chose carefully the language it used. If Congress had intended that CMS use a broader definition, or one that used the qualifications of individuals furnishing the products as a proxy, it surely would have done so. Indeed, Congress used orthotist certification as a limiting requirement in the BIPA provision, indicating that, when the legislature wants to use this indicator, it does so. CMS may not go far beyond the statutory language in determining orthotic products that may be competitively bid.

CMS's Proposed Benchmark Is Impracticable

In addition to concerns that the proposed definition of OTS orthotics is not a reasonable construction of the statutory language, there are practical concerns with the proposal. It all together fails to bring clarity to which orthotics are considered off-the-shelf. In fact, DJO believes that tying the definition to whether the involvement of a certified orthotist is needed muddies the waters as to which products would be included. There is no Federal definition of orthotists or their scope of practice. A limited number of states have orthotist licensure or certification laws and, among those that do, the scope of practice varies considerably. Thus, there is no resource—beyond anecdotal evidence through discussions with certified orthotists—that CMS could use to understand what the proposed definition actually means. Involvement of a certified orthotist is not a meaningful, clear benchmark; rather, it is an amorphous, highly contentious standard that will not provide CMS with clear direction as to the orthotic products that could be competitively bid.

For these reasons, DJO believes that the proposed interpretation of OTS should not and may not be finalized. DJO recommends that the regulation tracking closely to the statutory language be finalized as written, but that the gloss added in the preamble not be used. If, however, CMS does seek to enhance the definition, the agency must recognize all other practitioners with expertise to provide orthotic products who are currently recognized under Federal law. Under this alternate approach, any orthotic that requires the assistance of a qualified practitioner (as defined under the BIPA provision) would not be considered OTS.

As to the codes to be included, DJO suggests that CMS consult with stakeholders, including the National Orthotic Manufacturers Association ("NOMA"), to determine the appropriate OTS orthotics codes. NOMA would be pleased to provide a list of OTS orthotics codes to the agency for its consideration upon request.

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[13] NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 124 (6th ed. 2000).

II. ENSURE PARTICIPATION OF SUPPLIERS WITH SUFFICIENT CAPACITY REGARDLESS OF PHYSICAL LOCATION IN THE SERVICE AREA

[Submission of Bids Under the Competitive Bidding Program]

DJO believes that large capacity suppliers currently provide a significant volume of DMEPOS items to beneficiaries and asserts that, unless they are included in competitive bidding, there will be a shortage or total lack of certain competitively bid items in the CBAs. Many of these large suppliers operate through central headquarters, yet offer services nation-wide. DJO thus supports CMS's proposal not to require that bidding suppliers be physically located in the CBAs in which they submit bids.

As CMS recognizes, location is an imprecise measure as to whether a supplier would be willing and able to serve Medicare beneficiaries in a given CBA.[14] Further, CMS's proposal accords with longstanding Medicare supplier standards. Many large capacity suppliers, including DJO, use a centralized operation (at which billing, patient contact, complaint and other matters are addressed), with sales representatives operating in locations throughout the country. Often, based on a prescription, orthotic products are shipped from the manufacturing plant or headquarters of a supplier to a patient's home or to a physician's office, the location at which they are provided to the patient. Under this longstanding physician's office model, the supplier does not maintain physical locations in all 50 states, but still ably serves locations across the country.

Medicare has a longstanding policy of accommodating such organizational structures. The Medicare statute provides that all suppliers furnishing medical equipment and supplies to beneficiaries must obtain a supplier number, showing that they meet supplier standards. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[15] Through Medicare Supplier Standard #7, CMS implements this requirement and recognizes that some suppliers will be operating in various geographic areas but that it can be organized using a centralized location.[16] In addition, DJO believes that centralized operations enable the Company to interact effectively and in a uniform manner with Medicare contractors and to provide consistent, high quality services to Medicare beneficiaries.

In short, physical location is an inappropriate gauge for supplier interest and ability to service a CBA. DJO supports the approach that CMS proposes to use, which combines review of the supplier's past business to beneficiaries in the CBA, with reference to the supplier's

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14 71 Fed. Reg. at 25672.

15 42 U.S.C. § 1395m(j).

16 *See* 42 C.F.R. § 424.57(c)(7). Supplier Standard #7 states that a supplier must certify that it: "Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location."

detailed business plan for expansion.[17] These indicia will enable CMS to more accurately measure supplier capacity than would an imprecise focus on the supplier's physical location. CMS proposes to collect this information through draft Form B (Bidding Sheet)—the form that bidding suppliers would complete in submitting a bid for each product category in a CBA. On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if they plan to do so.[18] DJO believes that this approach is sound, accurate and should be finalized as written.

III. CATEGORIZE COMPETITIVELY BID PRODUCTS USING EXISTING SADMERC POLICY GROUPS AND USE SUB-GROUPINGS FOR BIDDING PURPOSES

[Submission of Bids Under the Competitive Bidding Program]

CMS proposes to conduct bidding for products grouped into "product categories," defined as groups of similar items used in the treatment of a related medical condition. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category, with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[19]

It makes sense for CMS to use the existing SADMERC policy groups as the product categories for competitive bidding, rather than inventing new and broader categories. Some of the SADMERC policy groups for orthotics classify HCPCS codes according to the medical policy to which they belong, making them rational groupings from a clinical perspective. Other policy groups for orthotics reflect different areas of the body for which the products may be used. These groupings provide ready categories, with sound clinical bases and with which both CMS and suppliers are familiar, for use in competitive bidding.

Even if the SADMERC policy groups are used, DJO believes that it will be incredibly difficult from a practical perspective to implement competitive bidding for OTS orthotic products unless the categories are narrowly described. There are a significant number of HCPCS codes and considerable variation in the industry as to how the codes are interpreted. In addition, most suppliers are unlikely to have a product for each code. DJO is among the largest, if not the largest, suppliers of orthotic products in the U.S., and the Company believes that it might not have a product that fits into each code in a policy group. DJO therefore suggests that CMS not implement competitive bidding for orthotic products without also providing clarification of the

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17 71 Fed. Reg. at 25676.

18 *See* http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterbyDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052.

19 71 Fed. Reg. at 25672-73.

products to be bid under the codes selected. Unless this first step is undertaken, there would be such drastic variability in the bidding that the entire process would be tainted.

DJO also recommends that each OTS product category be further divided into sub-groupings. These sub-categories, or sub-groupings, could represent families of similar codes that would be reflective of the multiple functionalities of the various products, as well as the multitude of coding, coverage and reimbursement complexities necessary to support providing products to beneficiaries in the CBA. For instance, a select, small number of knee brace codes with products that perform the same clinical function could be grouped together. Rather than submitting a separate bid for each HCPCS code within a product category, the supplier would offer a single bid amount for the sub-grouping. Without such a mechanism, DJO is concerned that most suppliers, even large capacity suppliers that operate on a national basis, might be precluded from bidding.

To effect these changes, DJO asks that the applicable proposed regulations be revised as follows:

I. 42 C.F.R. § 414.412 should be revised so that subsection (c) reads (with proposed language in italics): "Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines that there is good cause to align items differently for a particular competitive bidding program*."

II. 42 C.F.R. § 414.412 should be revised so that subsection (d) reads: "Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program, *unless CMS permits a bid for a sub-category for bidding purposes.*"

III. ENSURE THE INTEGRITY OF BID EVALUATIONS BY REQUIRING UNIFORM FINANCIAL STANDARDS & ACCREDITATION, ALLOWING FOR AN EXTENDED GRACE PERIOD FOR ORTHOTICS SUPPLIERS

[Conditions For Awarding Contracts]

CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. DJO strongly supports CMS's proposal to require suppliers to meet quality and financial standards in order to be awarded bids. This should include the requirements that suppliers be subject to a uniform set of financial standards, regardless of the size or type of organization, and that they meet quality standards and be accredited in order to participate in the program.

For bid evaluation, CMS proposes a three-step process: (1) establish a single composite bid for each supplier for a particular product category; (2) array these composite bids from

lowest to highest; and (3) select a pivotal bid (based on estimated beneficiary demand), with winning bidders being those at or below the pivotal bid.[20] In addition, under proposed 42 C.F.R. 414.414, CMS would require that each supplier meet basic eligibility requirements (such as complying with existing Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. CMS does not clarify at what point in the bid evaluation process it would confirm that such standards have been met.

DJO notes that, as a practical matter, for this initial phase of competitive bidding, a large number of suppliers may be in the process of obtaining accreditation and coming into compliance with the quality standards. To address the initial phase, therefore, CMS proposes to allow a grace period for compliance with the quality standards.[21] DJO applauds CMS's recognition that a grace period is needed to assist many suppliers in becoming accredited, particularly given that the finalized standards have not yet been released. An extended grace period should be afforded to suppliers in industries like orthotics in which accreditation is not currently the norm. Suppliers in such industries lack experience with accreditation, and it will take additional time for them to become accredited. DJO strongly urges CMS to provide an extended grace period for orthotics suppliers.

IV. RECOGNIZE THAT SUPPLIERS ARE ONLY EQUIPPED TO PROVIDE ITEMS FROM THEIR OWN INVENTORIES

[Terms of Contract; Physician Authorization/Treating Practitioner]

DJO asks that CMS revise two of its proposals so that they address practical realities and limitations of the DMEPOS industry. Without the below-discussed changes to the proposed regulations, suppliers may face difficulties operating in a manner that makes good business sense and could be disincentivized from participating in the program. If existing large-capacity suppliers exit the Medicare program, this, of course, would have a devastating impact on beneficiaries' ability to obtain needed items and would jeopardize the success of competitive bidding.

Responsibility for Repairs/Maintenance of Items Furnished By Non-Contract Suppliers

CMS proposes to oblige contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers. In many, if not most, instances, suppliers have no experience in repairing or performing maintenance on items that were supplied by other suppliers and would not be able to perform such work themselves. Contract suppliers would, in effect, be forced to pay for a sub-contractor to perform the service—a result that would impose significant costs on winning suppliers. It is difficult to

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20 *See* 71 Fed. Reg. at 25674-75.

21 *See* 71 Fed. Reg. at 25675.

determine what these costs will be in advance of bid submission and, as a result, short of CMS providing the information as part of the Requests for Bids, there is no way for suppliers to weigh this cost in determining bid prices. Even if CMS is able to offer this information prior to bid submission, the proposal is particularly onerous for manufacturer-suppliers that only carry and sell their own products. Thus, DJO asks that CMS continue to pay for repair and maintenance of DMEPOS items performed by non-contract suppliers, as has been the agency's practice in the past. There is no reason to shift this burden to another supplier, particularly one who is likely to be unequipped to perform the services itself.

DJO suggests that 42 C.F.R. § 414.422(c) be revised to add a new subsection (3) which states: "*Contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the competitive bidding area are exempt from the requirement in paragraph (1) for purposes of items furnished by other suppliers.*"

Physician Authorization of Product Brand

DJO believes that revision is also warranted for proposed 42 C.F.R. § 414.420 to acknowledge business considerations for manufacturer/suppliers. Under this provision, contract suppliers would be required to make a reasonable effort to furnish a physician-specified brand (or mode of delivery). CMS notes that physicians and other treating practitioners could prescribe a particular product brand if they determine that it would avoid an adverse medical outcome for the beneficiary. If a treating practitioner specifies a particular product under these circumstances, the contract supplier would be required to "make a reasonable effort to furnish the particular brand." If the supplier is unable to furnish the designated product, it would need to work with the practitioner to find an alternate item that is appropriate and obtain a revised order.[22]

Manufacturer/suppliers maintain inventories that contain predominantly their own products and could have difficulty furnishing a brand other than their own. DJO believes that the regulation should be revised to make clear that the contract supplier need not be able to offer the item if it is not part of its inventory. This could be accomplished by adding a new subsection (b)(4) to 414.420, stating: "*The contract supplier is not required to furnish the particular brand or mode of delivery itself if such brand or mode of delivery is not in its inventory in order to be deemed to have made a reasonable effort under this paragraph (b).*"

V. REVISE CHANGE IN OWNERSHIP RULES SO THAT THEY ARE

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22 *See* 71 Fed. Reg. at 25684.

CONSISTENT WITH EXISTING REQUIREMENTS FOR DMEPOS SUPPLIERS

[Terms of Contract]

Proposed 42 C.F.R. § 414.422(d) would limit a contract supplier's ability to continue to participate in competitive bidding upon a change in ownership of its business. CMS proposes to require contract suppliers to notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized. CMS would only allow the successor entity to continue to furnish products in the competitive bidding area if (1) there is a need for the successor entity to function as a contractor in order to assure expected demand for a competitively bid item; (2) the successor entity meets all requirements applicable to contract suppliers; (3) the successor entity assumes the contract supplier's contract, including all obligations and liabilities; and (4) the successor entity executes a novation agreement.

This proposal is over-broad and would needlessly penalize business arrangements that may have no impact on the contract supplier's relationship with CMS. Furthermore, it would devalue contract suppliers' businesses. Existing standards—including the Medicare supplier standards and the forthcoming quality standards—already provide sufficient assurances to ensure that high quality services are provided to beneficiaries. This proposed notice requirement would not add to these assurances in any meaningful way.

DJO believes that the proposed regulation should be modified to clarify that the notification obligation and the limitations on continuing as a contract supplier apply only where the contract is being transferred to a new or different legal entity. The test would be the same as currently used to determine whether a new supplier enrollment application is needed under the instructions for Form CMS-855S. In those circumstances in which the legal identity of the contract supplier is not altered, by way of example, there may be no need to obtain the prior approvals. In contrast, where the legal identity of the acquired contract supplier would occur as a result of the change in ownership, CMS may want assurances that the new supplier will be able to meet all obligations of the former supplier and will assume all of its liabilities under the existing contract.

CMS could also borrow (as it has in the past) from the definition of "change of ownership" in the provider context under 42 C.F.R. § 489.18(a). With respect to corporations, by way of example, this regulation provides that:

> The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.[23]

DJO thus suggests adopting this definition in the proposed regulation. This would notify contract suppliers of the types of transactions that would trigger the completion of a new Form

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[23] 42 C.F.R. § 489.18(a)(3).

CMS-855S, as well as the change that would trigger the examination by CMS that a contract supplier can continue to meet the obligations under the existing contract.

In addition, DJO believes that there is no reason to depart from the existing 30-day post-change timeframe provided for suppliers to alert CMS as to changes of information, ownership or control. The current regulations do not require notice to CMS until *after the change has occurred*, and there is no reason why prior notice would be needed in this context. CMS recently re-affirmed this approach in newly finalized supplier enrollment regulations. Under 42 C.F.R. § 424.530, DMEPOS suppliers are required to report changes of information and changes of ownership or control within 30 days of their occurrence.

DJO thus suggests the following revisions to 414.422(d)(1): "A contract supplier must notify CMS in writing *within 30 days of* any change of ownership *(as such term is defined in section 489.18(a)) that would trigger completion of an entire new Form CMS-855S*."

VI. SET PAYMENT AMOUNTS SO THAT THEY REASONABLY REFLECT ACTUAL BIDS

[Determining Single Payment Amounts for Individual Items]

CMS's proposed methodology for setting competitive bidding payment amounts may not reasonably reflect actual bid amounts. Under proposed 42 C.F.R. § 414.416, CMS would use the median of winning suppliers' bids as the payment amount. This approach will by its nature result in a rate that is lower than the bid prices of half of the winning bidders. Many suppliers, including DJO, fear that they will not be able to continue to provide products to beneficiaries in the CBAs if the established rates are far below their bid prices. In order to raise the chances that they will be selected to participate in competitive bidding, suppliers are likely to submit bids at or near their margins. Thus, if CMS sets the payment rates at the median of winning bidders' bid prices, up to half of the winning bidders may consider these rates unacceptable and may not be able to continue to provide products to beneficiaries in those areas.

There are alternative approaches open to CMS that would lead to reasonable payment rates. These include the adjustment factor approach that was used in the demonstration projects, which is discussed in the preamble to the proposed regulations.[24] DJO urges CMS to adopt a methodology that ensures that contract suppliers are not being reimbursed at payment rates below their bid amounts on an overall basis. Contract suppliers should receive payment amounts that are at least as much as their bid prices. Suppliers may be less likely to leave the Medicare program if there is some assurance that payment rates will be sufficient.[25] DJO thus recommends that the median approach not be finalized and that an alternative approach resulting in reasonable payment rates be adopted.

VII. RETAIN COMPETITIVE BIDDING PAYMENT AMOUNTS THROUGHOUT

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24 *See* 71 Fed. Reg. at 25679-80.

25 DJO also suggests that CMS consider re-competing a product category in a CBA if a contract supplier with significant capacity exits the program mid-cycle.

BIDDING CYCLE WHEN MULTIPLE HCPCS CODES ARE MERGED INTO A SINGLE CODE

[Gap-filling]

CMS proposes special payment rules in 42 C.F.R. § 414.426 for competitively bid HCPCS codes that are revised in the middle of a competitive bidding cycle. The Company believes that, for the most part, these proposed rules strike the right balance. However, revision is needed for the proposal addressing the situation in which multiple codes describing similar products are combined into a single code. DJO asks that, in such situations, CMS maintain the status quo for until the contract ends to avoid significant decreases in payment rates that would upset suppliers' expectations as to the amounts they will receive for furnishing items to beneficiaries in the CBAs.

CMS proposes to calculate rates differently based on the nature of the coding change, so that:

- If a single code is split into multiple codes, the supplier would be paid the payment amount for the former code.[26] Therefore, the split into new codes would not impact payment. During the subsequent bidding cycle, suppliers would bid on the new separate and distinct codes.

- For codes for several components that are merged into a single new code, the payment policy would differ depending on whether the former codes described (a) components of a single product or (b) multiple products. If the former codes described components of a single product (scenario (a)), the supplier would be paid a rate equal to the total of the payment amounts under the former codes. If the former codes described multiple products (scenario (b)), the new payment amount would be the average (arithmetic mean) of the former payment amounts weighted by the frequency of payments for the former separate codes. For each of the two scenarios, during the subsequent bidding cycle, suppliers will bid on the new single code.[27]

DJO asks CMS not to finalize scenario (b) in the second point above. This formula could result in significantly different pricing for a product or products in the middle of a bidding cycle. Using the new code would up-end suppliers' expectations as to the payment that they would receive for furnishing products to beneficiaries in the CBA. It could also result in unfair payment changes mid-cycle that would be a disincentive to supplier participation. More significantly, adopting this proposal could cause contract suppliers to exit the program mid-cycle—which, in turn, could result in product supply issues for beneficiaries in the CBAs. If CMS decides to adopt this proposal despite these concerns, the agency should clarify how the

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26 This applies both to the circumstance in which the former code was for a single product and is split into codes for its components and that in which the former code was for two or more similar products and is split up.

27 *See* 71 Fed. Reg. at 25688-89.

weighting would occur (for instance, whether CMS would review payments for all suppliers in all jurisdictions or only contract suppliers in CBAs).

DJO thus suggests that, where multiple codes for similar items are merged to a single new code, CMS continue to use the former codes and payment rates for the remainder of the bidding cycle. The proposal in 42 C.F.R. § 414.426(d) would need to be revised as follows: "If multiple codes for similar items are merged into a single code, *the codes that were competitively bid and the established payment amounts for those codes, with any adjustments provided under § 414.408(b), will remain in effect for the remainder of the competitive bidding program.*"

VIII. REFRAIN FROM CREATING AN "ANY WILLING PROVIDER" MODEL IF CMS USES COMPETITIVE BIDDING RATES TO ADJUST PAYMENT AMOUNTS IN NON-COMPETITIVE BIDDING AREAS

[Payment Basis]

In 2009 or subsequent years, CMS proposes to use its statutory authority to adjust payment in other areas based on payment information determined under the competitive bidding program. CMS should implement this authority carefully. DJO asks that CMS provide industry stakeholders another opportunity to comment on how to implement this provision at a later date once CMS develops a particular proposal.

DJO fears that CMS may use this authority in a manner that would move the Part B DMEPOS benefit toward a *de facto* "any willing provider" model in which competitive bidding rates are used nationwide and any supplier that is able to provide services may do so (for reimbursement at those rates). Congress did not intend for competitive bidding to result in such a model. Because competitive bidding rates will be based on bid amounts that are calculated using an assumed increase in volume, suppliers' expectations are different than for non-competitive biding areas. The expectation is that there will be few suppliers in each CBA for competitively bid products and, accordingly, that the winning suppliers can offer lower prices because these prices will be offset by the higher volume of products they will furnish. In non-competitive bidding areas, this increase in volume would not necessarily exist to balance out decline in payment rates. Thus, competitive bidding payment rates do not translate to other areas and should not be applied there. DJO asks CMS to take this into account if it uses competitive bidding rates to set fee schedule amounts.

IX. DO NOT FINALIZE THE PROPOSED REBATE PROGRAM

[Determining Single Payment Amounts For Individual Items]

CMS proposes to permit contract suppliers that submitted bids for an item below the competitive bidding payment amount to provide voluntary rebates to beneficiaries. This rebate would be the difference between the supplier's bid amount and the competitive bidding payment amount for the product. As was evident based on the many PAOC committee members and industry representatives who objected to this proposal at the PAOC meeting, the industry is vehemently opposed to this proposal. DJO shares their concerns that this proposal implicates and may violate the Federal Anti-Kickback Statute (the "AKS") and, for that reason, strongly

urges that proposed 42 C.F.R. § 414.416(c), which describes the rebate program, not be finalized.

The AKS is a criminal prohibition that provides punishment for any person who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."[28] Rebates intended to induce beneficiaries to purchase a particular Medicare-covered item are generally prohibited under the AKS. DJO is concerned that adoption of the rebate program would generate significant confusion in the industry as to what is permissible under the AKS and what continues to be prohibited. DJO asks that the proposed regulation be deleted.

X. PROTECT EXISTING APPEAL RIGHTS

[Administrative or Judicial Review]

Under proposed 42 C.F.R. § 414.424, CMS prohibits appeals on most decisions made regarding competitive bidding, in line with the relevant statutory provision. For instance, decisions as to which suppliers are awarded contracts, the payment amounts established, and selection of items to be competitively bid are all not appealable.[29] DJO is concerned, however, that, as written, the proposed regulation does not make clear that existing rights of beneficiaries and suppliers to appeal denied claims are preserved.

In the preamble to the proposed regulations, CMS acknowledges that existing rights are undisturbed by competitive bidding. DJO requests that this be explicitly stated in the regulation itself so that appeal rights are safeguarded. This could be accomplished by adding the following subsection (c) to 414.424: "*All existing rights to appeal individual claims are unaffected by this provision.*" DJO also believes that the statement in the regulation that "[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart" is vague as written and could benefit from clarification (or should be removed).

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28 42 U.S.C. § 1320a-7b(b)(2).

29 71 Fed. Reg. at 25682.

XI. REVISE THE PROPOSED GAP-FILLING METHODOLOGY REPLACEMENT TO FOLLOW STATUTORILY-REQUIRED PROCEDURES & ENSURE FAIR PRICING

[Gap-filling]

[Gap-filling]

DJO applauds CMS for its recognition of the inherent flaws in the current gap-filling methodology and the agency's decision to replace the current formula with a new methodology that reflects the true prices for new technology. Portions of the proposal in 42 C.F.R. § 414.210(g), however, are so vague as to be unworkable. In addition, the effort to use a functional technology assessment without any procedural safeguards impermissibly circumvents CMS's IR authority. This is particularly troubling given that the IR regulations only recently became final and already are being treated as obsolete. It is essential that any formula adopted here be grounded in both substantive and procedural safeguards and follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products.

At the outset, DJO notes that many in the industry have urged CMS to devote considerable attention to this new regulation and specifically have requested that it be considered separate and apart from the proposed regulations for competitive bidding. DJO reiterates this request here, and asks that CMS postpone publication of a final rule to provide time for suppliers to submit additional comments and/or meet with the agency to discuss alternatives. The additional time is needed to give due consideration in separate comments. By including the proposal in the context of the competitive bidding rulemaking—a rule that CMS officials have publicly recognized is only tangentially related to gap-filling—CMS has created needless timing conflicts. Given the resources that need to be expended to comment fully on the competitive bidding rule, suppliers (and CMS, for that matter, since the same individuals are responsible for both competitive bidding and gap-filling) are being pressed to stretch those limited resources. Both rules are simply too important to risk presentation of rushed comments (and/or rushed review of those comments). DJO, therefore, requests an additional period of 60 days to comment on the gap-filling methodology.

In the absence of additional time, and to meet the current time line, DJO submits the following comments concerning the proposal.

Substantive Criteria

Under the gap-filling proposal, where a new HCPCS code is created and no price information is available from the base period, the fee schedule amount for the code would be calculated by taking into account one or more of the following three data sources: (1) median retail prices (from supplier price lists, manufacturer suggested retail prices, or wholesale prices, plus an appropriate mark-up), (2) existing fee schedule amounts for comparable codes, and/or (3) results of a functional technology assessment ("FTA") of products in the new code. DJO supports the move away from the current gap-filling methodology because it relies on deflation

factors that often result in drastic under-compensation for new products.[30] DJO believes, however, that the proposed criteria lack specificity sufficient to inform stakeholders as to the formula to be used.

A lack of specificity without proper safeguards offers the public inadequate notice of how the formula would be used. Two examples are illustrative: First, the proposal suggests that pricing for comparable codes could be used as a proxy for the rates applicable for the new code. How would CMS determine which codes are "comparable"? Would significant functional and clinical differences in the products categorized in these codes be considered? How would CMS account for and quantify these differences?

Second, CMS proposes to use median retail prices to set pricing. How will CMS identify retail prices and how will the agency weight the prices? Regardless of the source for the prices, DJO suggests that CMS use a *weighted median* so that pricing by outlier suppliers that do not provide a significant volume of items to the Medicare program is not given undue importance in setting pricing.

As to the FTA, the notice states that there were three main areas studied in the FTA conducted in CMS's pilot study: (1) Functional Assessment, which evaluated the device's operations, safety and user documentation relative to the Medicare population; (2) Price Comparison Analysis, which involved a cost analysis comparing the product to similar products or alternative treatment modalities; and (3) Medical Benefit Assessment, which focused on the effectiveness of the product using scientific literature and interviews of providers to determine if the product does what it purports to do. Not only is this vague explanation insufficient information for meaningful comments, the FTA analysis oversteps congressional mandates on when the agency can adjust fee schedule amounts and identify alternative "realistic and equitable" amounts. It is improper for CMS to cast aside Congress's grant of IR authority. Further, CMS should not resort to incorporating a coverage analysis to establish pricing. Here, as well, Congress has proscribed how to evaluate coverage. Simply, CMS cannot exercise powers that contradict Congress's specific language in specific statutory grants of authority.[31]

Pricing should be established using objective criteria that can be applied to all products in the same way. A transparent formula, capable of being reproduced for all products must be used. One approach might be to develop an algorithm with a sequential analysis. The FTA should be discarded all together as inappropriate and already addressed through CMS's IR authority.

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30 Gap-filling uses current pricing information, which is then deflated back to a base period to be in line with statutory payment methodology for DME and then inflated based on statutorily-prescribed update factors. CMS has traditionally used the percentage increase in the CPI-U to deflate current pricing—which can be an inappropriate deflationary factor if it is not in line with price increases (or lack thereof) over time in the industry.

31 *See, e.g., Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) (holding that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress"); *see also United States v. Haggar Apparel Co.*, 526 U.S. 380, 393 (1999) (confirming that "rules as to instances not covered by the statute should be parallel, to the extent possible, with the specific cases Congress did address").

Procedural Requirements

In addition to the substantive revisions that are needed, CMS's proposal to use an FTA also suffers from a complete lack of procedural safeguards to ensure that appropriate pricing results. Even though this proposal seeks to achieve the results of a coverage a coverage and IR analysis, it fails completely to offer any of the procedural safeguards of these latter processes. Particularly where, as here, CMS is moving away from its current objective gap-filling methodology to a vague, subjective set of criteria, procedural safeguards are even more critically needed.

As CMS describes in the preamble to the proposed regulations, the two FTAs that have previously been undertaken in its pilot study (the results of which have not been shared with stakeholders) involved evaluation of the device's safety and effectiveness in improving clinical outcomes. Both of these elements are considered in determining whether an item meets the Medicare statute's "reasonable and necessary" standard and will be covered under the Medicare program.[32] It is significant that over the years the coverage process has become more open. To that end, Congress recently mandated that CMS follow a defined process for making NCDs, including providing an opportunity to appeal the decisions.[33] There is now a fulsome appeals process available for aggrieved parties who believe an NCD provision is unreasonable.[34] Similar processes are available for challenges to local coverage determinations.[35] CMS must not and may not circumvent these procedural requirements by folding a coverage decision into the payment calculation process.

Perhaps most importantly, payment adjustments like those being proposed here are *statutorily required to undergo a notice and comment process* as well. Under the IR provisions, CMS must analyze a variety of factors and adjust pricing for an item or service upon a determination that the otherwise applicable payment amount is grossly excessive or grossly deficient, which is defined by its own regulations to include a threshold variance of fifteen

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32 42 U.S.C. § 1395y(a)(1)(A); *see also* Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapt. 15, § 110.1 (stating that the necessity of equipment is determined based on "when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member" and that reasonableness is determined based on considerations such as whether the expense of the equipment would not be clearly disproportionate to the therapeutic benefits that could ordinarily be derived from it).

33 Congress revised the Medicare statute to require CMS to issue a proposed decision on a request for an NCD within 6 months of the request for coverage (9 months for requests that require outside technology assessments or Medicare Coverage Advisory Committee deliberation). There is to be a 30-day public comment period from the date of release of the proposed decision and CMS is required to publish a final decision (including responses to comments received) within 60 days of the conclusion of this comment period. *See* 42 U.S.C. § 1395y(l).

34 NCDs can be reviewed by the HHS Departmental Appeals Board ("DAB"). To determine whether the NCD was reasonable, the DAB will review the record, may permit discovery and taking of evidence if it is lacking information, and may consult with scientific and clinical experts. *See* 42 USC § 1395ff(f)(1).

35 *See* Medicare Program Integrity Manual (CMS Pub. 100-08), Chapt. 13, § 13.13.

percent.[36] Once CMS has determined that a payment amount is grossly excessive or deficient, it may establish a payment amount only by considering certain factors, including pricing information and the resources required to produce the products. There is no reason to use an FTA when the robust IR authority exists. Significantly, CMS may not use its IR authority without first following the required procedural steps:

For payment adjustments of 15%, CMS must provide notice and opportunity to comment by publishing the proposed and finalized payment adjustment in the Federal Register.

For payment adjustments of greater than 15% in a single year, more rigorous reviews and procedures are to be undertaken. As to the procedures, CMS must consult with supplier representatives from the industry likely to be affected by the payment change. Notice of the proposed determination must also be published in the Federal Register, with a 60-day public comment period. The Federal Register Notice with the proposed determination must contain an explanation of the factors and data considered in determining that the payment amount is grossly excessive or deficient, list the proposed payment amount, and describe the factors and data used to set this adjusted rate. CMS is to consider any comments submitted prior to publication of a final determination, and discussion responsive to these comments is to be included in the Federal Register Notice announcing the finalized payment determination.[37]

Here, CMS would give itself authority to use the results of an FTA *at any time* to adjust previously-established prices and without identifying any standards. The agency would need only to determine that the pricing methods that were used resulted in payment amounts that do not reflect the cost of furnishing the product. This aspect of the regulation directly conflicts with and circumvents CMS's IR authority, and DJO strongly opposes finalization of this proposal. FTAs should not be used to determine pricing.

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[36] IR authority is implicated only where the overall payment adjustment needed to produce a realistic and equitable payment amount is 15% or more. CMS can make an adjustment of less than 15% in a given year under its IR authority, provided that it has been determined that an overall adjustment of 15% or more is warranted. *See* 42 C.F.R. § 405.502(g); 70 Fed. Reg. 73623, 73626 (Dec. 13, 2005).

[37] 42 USC § 1395u(b)(8)-(9); 42 C.F.R. § 405.502(g)-(h).

Thank you for your considerable efforts to date in implementing the program and for considering DJO's comments regarding the proposed regulations. Should you have any questions or comments, we can be reached at (202) 637-2200.

Truly yours,

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June 30, 2006

BY HAND DELIVERY

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Re: Comments Regarding CMS—1270—P: "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Other Issues"

Dear Administrator McClellan:

On behalf of our client, DJO Incorporated ("DJO" or the "Company"), we submit these comments on the above-referenced proposed regulations, which implement the Medicare Part B DMEPOS Competitive Bidding Program and revise the gap-filling payment methodology used to set fee schedule rates for new codes for DMEPOS items and services.[1] As the world's largest manufacturer of orthotics, as well as a large Medicare supplier of orthotic products and manufactured bone growth stimulators, DJO expects to continue its participation in the Medicare program after the launch of competitive bidding. For this reason, the Company appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") as to the impact of these proposals on the Company and the continued access to orthotics and the DME industries generally.

The competitive bidding program will radically change how Medicare pays for DMEPOS items used by beneficiaries in the home. Payment rates that previously were set based on fee schedule amounts will instead be determined by bid amounts submitted by DMEPOS suppliers for competitive bidding areas. The success of this program depends on the ability of suppliers to submit accurate bids for products (and on CMS's ability to evaluate them appropriately and fulsomely). Of paramount concern to DJO is CMS's ability to accurately and appropriately evaluate the bid submissions for orthotic products. With the vast number of orthotic products

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[1] 71 Fed. Reg. 25654 (May 1, 2006).

and the large number of HCPCS codes describing these products, there is tremendous variability in the industry as to which products belong in which codes. Without more clarity in this area, suppliers will have difficulty determining appropriate products and bids for each HCPCS code and, as a result, the bid submission process (as well as CMS's evaluation process) will be extremely difficult, if not impossible. The resulting competitive bid payment amounts are likely to be irrational. DJO asks CMS to avoid premature inclusion of orthotic products in the competitive bidding program until such time as a satisfactory resolution can been devised. In addition, DJO has serious concerns with the proposed expansion of the statutory definition of off-the-shelf ("OTS") orthotics—which are the only orthotic products that may be competitively bid. The agency should and must hew to the line already drawn by Congress regarding which products are to be included.

DJO's concerns with the proposed regulations cover a number of areas:[2]

- Criteria for Item Selection
- Submission of Bids Under the Competitive Bidding Program
- Conditions for Awarding Contracts
- Determining Single Payment Amounts for Individual Items
- Terms of Contract
- Physician Authorization/Treating Practitioner
- Payment Basis
- Gap-filling
- Administrative or Judicial Review

Summary of Comments

If CMS decides to move forward with competitive bidding for orthotic products, DJO recommends that the following measures be taken:

(1) ***Define OTS Orthotics As Required By the Medicare Statute:*** DJO strenuously disagrees with CMS's proposed definition of OTS orthotics for competitive bidding. The proposed interpretation would broaden impermissibly the statutory definition of OTS orthotics to include all orthotics that do not require assistance of a certified orthotist. This proposal is an impermissible departure from congressional language. Perhaps more critically, the proposal directly conflicts with the existing Federal definition of "qualified practitioners" who possess expertise to furnish certain orthotics to Medicare beneficiaries. This over-broad definition, therefore, must not be finalized. DJO seeks inclusion of the statutory definition in the regulation. The Company also urges CMS to consult with the orthotic industry to determine which HCPCS codes describe OTS orthotics and, of those, which should be included in the initial phase of the program.

(2) ***Ensure Participation of Suppliers With Sufficient Capacity Regardless of Physical***

[2] These are the subject headings that CMS requested commenters use to flag issues for the agency. Each of these subjects is noted as a heading in bold language and bracketed immediately preceding the relevant discussion. Please note that some subjects are addressed multiple times in this comment letter.

Location in the Service Area: DJO strongly supports CMS's proposal to allow suppliers to participate even if they do not necessarily have a separate physical location in a competitive bidding area ("CBA"), provided that they (a) offer services in the geographic area and (b) have a demonstrated ability to do so. CMS appropriately recognizes that more meaningful indicia than physical location should be determinative of capacity to serve a particular CBA.

(3) ***Categorize Competitively Bid Products Using Existing SADMERC Policy Groups and Use Sub-Groupings for Bidding Purposes:*** Under CMS's proposal, bidding for products would be conducted based on groupings of products into "product categories" and a supplier would need to submit a separate bid for each HCPCS code within a given category. DJO believes that there is no need to "re-invent the wheel" and existing Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") policy groups should be considered. A few of the SADMERC policy groups for orthotics correspond to existing medical policies, with meaningful relationships among grouped codes, while others group codes according to the body part treated. Suppliers who specialize in serving beneficiaries with certain medical conditions (*e.g.*, patients who need a knee orthosis, but not a spinal orthosis) may continue to do so. If broader categories are used, suppliers with specialization for particular parts of the body will not be able to offer competitively bid items and services.

Even if CMS were to use the SADMERC policy groups for orthotics, it would be difficult, if not impossible, to provide a bid amount for each HCPCS code. Most suppliers are unlikely to have a product for each code. In addition, as mentioned above, there is considerable uncertainty as to the appropriate HCPCS code for individual products, and this will make it nearly impossible for suppliers to submit bids on a code-by-code basis. If CMS includes OTS orthotics in the initial phase of competitive bidding, DJO recommends sub-groupings for which a single bid amount could be offered. This recommended methodology is described in further detail below.

(4) ***Ensure the Integrity of Bid Evaluations by Requiring Uniform Financial Standards & Accreditation, Allowing for an Extended Grace Period for Orthotics Suppliers:*** CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. Such steps should include publishing final quality and financial standards that must be met regardless of the size or type of organization. DJO applauds CMS for its recognition that, in the initial phase of competitive bidding, a grace period is needed so that suppliers can come into compliance with the quality standards. An extended grace period is particularly essential for industries such as orthotics in which accreditation is not currently the norm.

(5) ***Recognize That Suppliers Are Only Equipped to Provide Items From Their Own Inventories:*** DJO asks that CMS revise two of its proposals so that they address practical realities and limitations of the DMEPOS industry. First, proposed 42 C.F.R. § 414.422(c) places the onus for repairing and maintaining items previously furnished by non-contract suppliers on contract suppliers. This provision should not be adopted. In most instances suppliers are not equipped to handle such work for products not in their inventories. This is particularly the case for manufacturer/suppliers that typically only or predominantly sell the products they make. Second, proposed 42 C.F.R. § 414.420 would require contract suppliers to make a reasonable effort to furnish a particular brand

or mode of delivery of an item, as prescribed by the physician or treating practitioner. This provision should be revised so that contract suppliers do not need to offer the item if it is not in their inventory.

(6) ***Revise Change in Ownership Rules So That They Are Consistent With Existing Requirements For DMEPOS Suppliers:*** Proposed 42 C.F.R. § 414.422(d) would limit a contract supplier's ability to continue to participate in competitive bidding upon a change in ownership. Among other things, approvals are required. This provision should be revised to allow the supplier to continue to participate in the program, provided that the legal entity enrolled in the Medicare program does not change (*e.g.*, there has been only a change in stock or other equitable ownership). Furthermore, the timeframe for the notice requirement should conform to the existing regulation governing supplier notice of changes in ownership.

(7) ***Set Payment Amounts So That They Reasonably Reflect Actual Bids:*** CMS proposes to use the median of the winning bids (*i.e.*, those at or below the pivotal bid) to set the competitive bidding payment amount for each product. This may force contract suppliers either to furnish products at prices far below their submitted bids or to exit the Medicare program. DJO asks CMS to adopt a payment methodology for competitive bidding that does not artificially depress rates below the bid prices of a substantial number of the winning bidders. The Company asks that the methodology used in the competitive bidding demonstration projects, which was an alternative proposal discussed in the preamble to the proposed regulations, be adopted instead.

(8) ***Retain Competitive Bidding Payment Amounts Throughout A Bidding Cycle When Multiple HCPCS Codes Are Merged Into a Single Code:*** CMS proposes special payment rules to be used when HCPCS codes are revised in the middle of a competitive bidding cycle. DJO generally supports the proposed rules, with one exception. The Company believes that, where multiple codes describing similar products are combined into a single code, the prior codes and their competitive bid payment amounts should continue to be used until the end of the current contract. This would maintain stability in pricing for the products in the CBAs and not upset suppliers' expectations. The payment rates for a given product should not change in the midst of a contract.

(9) ***Refrain From Creating An "Any Willing Provider" Model If CMS Uses Competitive Bidding Rates to Adjust Payment Amounts in Non-competitive Bidding Areas:*** DJO asks that CMS proceed cautiously in implementing its authority beginning in 2009 to adjust payment in non-competitive bidding areas based on payment information determined under the competitive bidding program. This authority could result in a *de facto* "any willing provider" model, in which competitive bidding rates are used nationwide and any supplier that is able to provide services may do so (for reimbursement at those rates). Competitive bidding rates are set with the expectation of a significant increase in volume to offset lower prices. This will not exist in non-competitive bidding areas.

(10) ***Do Not Finalize the Proposed Rebate Program:*** DJO objects to CMS's proposal to allow suppliers to give rebates to beneficiaries for products provided through the competitive bidding program. This ill-advised proposal implicates and may run afoul of the Federal Anti-Kickback Statute and blurs the line between permissible and

impermissible rebates.

(11) ***Protect Existing Medicare Appeal Rights:*** Existing rights of beneficiaries and suppliers to appeal denied claims should not be affected by competitive bidding. DJO requests that proposed 42 C.F.R. § 414.424 be revised to clarify that the prohibition on appealing certain determinations made in the course of conducting the competitive bidding program in no way circumscribes or otherwise affects existing appeal rights.

(12) ***Revise the Proposed Gap-Filling Replacement to Follow Statutorily-Required Procedures & Ensure Fair Pricing:*** CMS's proposal in 42 C.F.R. § 414.210(g) to jettison the current gap-filling methodology for new DMEPOS items in favor of consideration of a variety of pricing data sources must not be adopted without significant revisions. As written, the proposed regulation is vague and impermissibly circumvents the procedural and substantive requirements to be used in any exercise of CMS's inherent reasonableness ("IR") authority. It is essential that any formula adopted here follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products. DJO believes that this new regulation deserves considerable attention that it likely will not receive because it has been appended to the proposed regulations for competitive bidding. DJO therefore asks that CMS postpone publication of a final regulation on this topic to provide time for suppliers to submit additional comments and/or to meet with the agency to discuss alternatives.

Finally, as to appropriate 2007 and 2008 payment updates for Class III devices paid under the DMEPOS fee schedule, DJO asks that CMS consider the comments of the Electrical Bone Growth Stimulators ("EBGS") Coalition, which are provided under separate cover. These comments urge the agency to adopt a specific fee schedule payment update for Class III devices based upon factors unique to Class III devices, and to provide a full CPI-U payment update for both years.

I. DEFINE OTS ORTHOTICS AS REQUIRED BY THE MEDICARE STATUTE

[Criteria For Item Selection]

Under the Medicare statute, OTS orthotics are among the categories of DMEPOS products that may be competitively bid.[3] CMS proposes to broaden the statutory definition of OTS orthotics to include all orthotics that do not require assistance of a certified orthotist. This is an impermissible departure from the definition prescribed by Congress. Not only that, the proposed definition *directly conflicts* with an existing statutory payment provision that defines the types of practitioners who are qualified to furnish certain orthotics to Medicare beneficiaries. DJO strenuously objects to CMS's proposal to put in place a sweeping interpretation of the statutory definition of OTS orthotics. We submit that CMS may not adopt an interpretation that goes well beyond the statutory language and certainly may not do so in a manner that contradicts existing statutory requirements regarding practitioner qualifications. There are practical concerns with the proposed definition as well. Rather than bringing clarity to which orthotics are considered off-the-shelf, the proposal would inject an additional layer of uncertainty by tying the definition to an amorphous standard (*i.e.*, necessary involvement of a certified orthotist).

[3] 42 U.S.C. § 1395w-3(a)(2)(C).

DJO asks rather that the statutory definition be imported into the regulation, as written, and that CMS work with industry stakeholders including the National Orthotics Manufacturers Assocation (NOMA) to determine which HCPCS codes describe OTS products (and, of those, which should be included in the initial phases of competitive bidding).

CMS May Not Contravene Existing Medicare Requirements Regarding Qualified Practitioners

The Medicare statute defines OTS orthotics as those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[4] The proposed regulatory language at 42 C.F.R § 414.402 mirrors that language. Yet, CMS takes this definition multiple steps further in its discussions in the preamble. There, the agency states that the sole reference point for the definition is *whether needed adjustments would require the expertise of an orthotist*. CMS suggests that OTS orthotics are those that:

> (1) can be adjusted by a beneficiary, caretaker, or orthotic supplier without the assistance of an orthotist certified by the American Board for Certification in Orthotics and Prosthetics, Inc. ("ABC") or the Board for Orthotist/Prosthetist Certification ("BOC"); and
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> (2) do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual, which, CMS states, are activities that can only be performed by certified orthotists.[5]

DJO contends that CMS must revise the proposal explained in the preamble because it is inconsistent with existing orthotics payment provisions in the Medicare statute. Indeed, the fact that the proposal is not included in the regulation itself raises questions about the extent to which the agency believes that the additional language is a permissible construction of the statute. It is problematic to hinge the definition of OTS orthotics on involvement of a certified orthotist because the Medicare statute already identifies a more expansive list of practitioners who are qualified to furnish certain custom-fabricated orthotic products to beneficiaries. Of note, this provision includes physicians and qualified physical and occupational therapists as qualified practitioners as well. CMS may not cherry-pick certain types of practitioners with expertise to provide orthotics fitting and adjustment services to beneficiaries. The move to exclude these practitioners is particularly troublesome given that the agency has not yet promulgated regulations to implement the existing statutory language (as was explicitly required by Congress).

By way of background, the Medicare statute contains special payment rules for certain custom-fabricated orthotics, which include a definition of "qualified practitioners" that possess

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4 *See* 42 U.S.C. § 1395w-3(a)(2)(C).

5 71 Fed. Reg. at 25669-70.

expertise to furnish such products to beneficiaries (the "BIPA provision").[6] Under the BIPA provision, Medicare payment for an item on a list of certain custom-fabricated orthotics is only to be made if it is (1) furnished by a qualified practitioner; and (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the HHS Secretary determines appropriate.[7] "Qualified practitioner" is defined to include physicians, qualified physical and occupational therapists, licensed orthotists (in states requiring orthotist licensure), and other individuals who are specially trained or educated in the area and certified by ABC, BOC or other approved credentialing programs (in states without orthotist licensure requirements).[8]

As mentioned above, the BIPA provision has yet to be implemented through regulation, as Congress required. However, the statute itself specifies the types of individuals that Congress believes possess the skills and experience needed to provide certain custom-fabricated orthotics to beneficiaries. This definition may not be ignored. A fundamental canon of statutory interpretation provides that "effect must be given, if possible, to every word, clause and sentence of a statute," and that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.[9] The BIPA provision clearly acknowledges that more classes of practitioners than only ABC- and BOC-certified orthotists possess expertise to trim, bend, mold, assemble, or customize certain orthotics to fit them to an individual. The list of products to which BIPA applies has yet to be determined, but the statute requires that it consist of a *sub-set of all custom-fabricated orthotics*, which means that it clearly excludes OTS orthotics. For CMS to include only ABC- and BOC-certified orthotists as practitioners with the expertise to fit non-OTS orthotics ignores the other practitioners that are congressionally-approved as having expertise to provide some custom-fabricated orthotics. CMS may not read the words "physician," "qualified physical therapist," and "qualified occupational therapist" out of the statute, and should not be circumventing implementation of the BIPA provision in this manner to begin with. Limiting the definition of OTS orthotics to those not requiring the expertise of an ABC- or BOC-certified orthotist directly contravenes Congress's definition of qualified practitioner and illogically treats their inclusion as

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6 42 U.S.C. § 1395m(h)(1)(F) (as added by Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")).

7 The devices falling under the ambit of the special payment rules are to be identified by CMS in a published list and are defined as that subset of custom-fabricated orthotics that are "individually fabricated for the patient over a positive model of the patient."

8 42 U.S.C. § 1395m(h)(1)(F)(iii).

9 NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:06, 181-86 (6th ed. 2000); *See also Washington Hosp. Center v. Bowen*, 795 F.2d 139 (D.C. Cir. 1986) (concluding that, in order to fulfill "our obligation to construe a statute so as 'to give effect, if possible, to every word Congress uses,'" it must strike down the Secretary's regulation requiring hospitals to wait until completion of the cost year before appealing prospective payment amounts to the Provider Reimbursement Review Board because the regulation ignored the provision of the Medicare statute permitting such appeals prior to filing a cost report).

surplusage. In short, borrowing or importing some, but not all, of the BIPA provision to define OTS orthotics is ill-advised and impermissible.[10]

CMS Is Bound By The Congressional Definition of OTS Orthotics

Not only does the proposed definition of OTS orthotics contravene the BIPA provision, but also it exceeds the congressional mandate as to which products are to be included in competitive bidding. Congress provided a specific and narrow definition of OTS orthotics that may be competitively bid. The language clearly limits OTS orthotics to those that do not require much, if any, adjustment in order to be used appropriately and that do not require fitting and adjustment expertise in order to be fit to the patient. CMS's proposed definition linking OTS orthotics to the work of a certified orthotist would dramatically *expand* the list of products that are considered OTS and that are subject to competitive bidding. Such an approach may also result in quality of care issues for Medicare beneficiaries. This is because products furnished through the competitive bidding process that require more than minimal self-adjustment may result in a poor fit, product ineffectiveness or even potential injury.

CMS may not implement the OTS definition in a manner that exceeds the congressional mandate, as would the proposal here. In the seminal case concerning agency interpretation of congressional language, the U.S. Supreme Court held that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[11] In effect, CMS's proposal discards the statutory definition, replacing the task-related criteria (*i.e.*, minimal self-adjustment for appropriate use and no expertise in trimming, bending, molding, assembling, or customizing to fit to the individual) with a wholly different benchmark for determining when a product ought to be included in competitive bidding: the need for a certified orthotist's involvement. This benchmark differs from and is inconsistent with the statutory criteria, as evidenced by the fact that it would result in a much more expansive list of orthotic products being competitively bid than Congress intended. Indeed, a CMS official[12] speaking at the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting even acknowledged that this proposal goes *far beyond that* specified by Congress.

An elementary canon of statutory interpretation provides that words in statutes are to be accorded their "plain and obvious meaning" because "one must assume that the legislature knew

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10 We note that, through the BIPA provision, Congress intended only to *mandate* involvement of qualified practitioners for a small sub-set of custom-fabricated orthotics. What is important for this discussion of competitive bidding regulations, however, is that the BIPA provision recognizes that such practitioners *have the experience to adjust and fit non-OTS orthotics*. Thus, CMS may not define OTS products by reference only to certified orthotists.

11 *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984); *see also* NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 121-22 (6th ed. 2000) (stating that "[t]here is no safer nor better settled canon of interpretation that that when language is clear and unambiguous it must be held to mean what it plainly expresses").

12 Joel Kaiser, who presented on this topic at the PAOC meeting, commented that this proposed definition goes beyond the definition in the Medicare statute.

the plain and ordinary meanings of the words it chose to include in the statute."[13] The OTS definition was heavily negotiated at the time that the MMA was enacted, and Congress chose carefully the language it used. If Congress had intended that CMS use a broader definition, or one that used the qualifications of individuals furnishing the products as a proxy, it surely would have done so. Indeed, Congress used orthotist certification as a limiting requirement in the BIPA provision, indicating that, when the legislature wants to use this indicator, it does so. CMS may not go far beyond the statutory language in determining orthotic products that may be competitively bid.

CMS's Proposed Benchmark Is Impracticable

In addition to concerns that the proposed definition of OTS orthotics is not a reasonable construction of the statutory language, there are practical concerns with the proposal. It all together fails to bring clarity to which orthotics are considered off-the-shelf. In fact, DJO believes that tying the definition to whether the involvement of a certified orthotist is needed muddies the waters as to which products would be included. There is no Federal definition of orthotists or their scope of practice. A limited number of states have orthotist licensure or certification laws and, among those that do, the scope of practice varies considerably. Thus, there is no resource—beyond anecdotal evidence through discussions with certified orthotists—that CMS could use to understand what the proposed definition actually means. Involvement of a certified orthotist is not a meaningful, clear benchmark; rather, it is an amorphous, highly contentious standard that will not provide CMS with clear direction as to the orthotic products that could be competitively bid.

For these reasons, DJO believes that the proposed interpretation of OTS should not and may not be finalized. DJO recommends that the regulation tracking closely to the statutory language be finalized as written, but that the gloss added in the preamble not be used. If, however, CMS does seek to enhance the definition, the agency must recognize all other practitioners with expertise to provide orthotic products who are currently recognized under Federal law. Under this alternate approach, any orthotic that requires the assistance of a qualified practitioner (as defined under the BIPA provision) would not be considered OTS.

As to the codes to be included, DJO suggests that CMS consult with stakeholders, including the National Orthotic Manufacturers Association ("NOMA"), to determine the appropriate OTS orthotics codes. NOMA would be pleased to provide a list of OTS orthotics codes to the agency for its consideration upon request.

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[13] NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 124 (6th ed. 2000).

II. ENSURE PARTICIPATION OF SUPPLIERS WITH SUFFICIENT CAPACITY REGARDLESS OF PHYSICAL LOCATION IN THE SERVICE AREA

[Submission of Bids Under the Competitive Bidding Program]

DJO believes that large capacity suppliers currently provide a significant volume of DMEPOS items to beneficiaries and asserts that, unless they are included in competitive bidding, there will be a shortage or total lack of certain competitively bid items in the CBAs. Many of these large suppliers operate through central headquarters, yet offer services nation-wide. DJO thus supports CMS's proposal not to require that bidding suppliers be physically located in the CBAs in which they submit bids.

As CMS recognizes, location is an imprecise measure as to whether a supplier would be willing and able to serve Medicare beneficiaries in a given CBA.[14] Further, CMS's proposal accords with longstanding Medicare supplier standards. Many large capacity suppliers, including DJO, use a centralized operation (at which billing, patient contact, complaint and other matters are addressed), with sales representatives operating in locations throughout the country. Often, based on a prescription, orthotic products are shipped from the manufacturing plant or headquarters of a supplier to a patient's home or to a physician's office, the location at which they are provided to the patient. Under this longstanding physician's office model, the supplier does not maintain physical locations in all 50 states, but still ably serves locations across the country.

Medicare has a longstanding policy of accommodating such organizational structures. The Medicare statute provides that all suppliers furnishing medical equipment and supplies to beneficiaries must obtain a supplier number, showing that they meet supplier standards. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[15] Through Medicare Supplier Standard #7, CMS implements this requirement and recognizes that some suppliers will be operating in various geographic areas but that it can be organized using a centralized location.[16] In addition, DJO believes that centralized operations enable the Company to interact effectively and in a uniform manner with Medicare contractors and to provide consistent, high quality services to Medicare beneficiaries.

In short, physical location is an inappropriate gauge for supplier interest and ability to service a CBA. DJO supports the approach that CMS proposes to use, which combines review of the supplier's past business to beneficiaries in the CBA, with reference to the supplier's

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14 71 Fed. Reg. at 25672.

15 42 U.S.C. § 1395m(j).

16 *See* 42 C.F.R. § 424.57(c)(7). Supplier Standard #7 states that a supplier must certify that it: "Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location."

detailed business plan for expansion.[17] These indicia will enable CMS to more accurately measure supplier capacity than would an imprecise focus on the supplier's physical location. CMS proposes to collect this information through draft Form B (Bidding Sheet)—the form that bidding suppliers would complete in submitting a bid for each product category in a CBA. On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if they plan to do so.[18] DJO believes that this approach is sound, accurate and should be finalized as written.

III. CATEGORIZE COMPETITIVELY BID PRODUCTS USING EXISTING SADMERC POLICY GROUPS AND USE SUB-GROUPINGS FOR BIDDING PURPOSES

[Submission of Bids Under the Competitive Bidding Program]

CMS proposes to conduct bidding for products grouped into "product categories," defined as groups of similar items used in the treatment of a related medical condition. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category, with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[19]

It makes sense for CMS to use the existing SADMERC policy groups as the product categories for competitive bidding, rather than inventing new and broader categories. Some of the SADMERC policy groups for orthotics classify HCPCS codes according to the medical policy to which they belong, making them rational groupings from a clinical perspective. Other policy groups for orthotics reflect different areas of the body for which the products may be used. These groupings provide ready categories, with sound clinical bases and with which both CMS and suppliers are familiar, for use in competitive bidding.

Even if the SADMERC policy groups are used, DJO believes that it will be incredibly difficult from a practical perspective to implement competitive bidding for OTS orthotic products unless the categories are narrowly described. There are a significant number of HCPCS codes and considerable variation in the industry as to how the codes are interpreted. In addition, most suppliers are unlikely to have a product for each code. DJO is among the largest, if not the largest, suppliers of orthotic products in the U.S., and the Company believes that it might not have a product that fits into each code in a policy group. DJO therefore suggests that CMS not implement competitive bidding for orthotic products without also providing clarification of the

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17 71 Fed. Reg. at 25676.

18 *See* http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterbyDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052.

19 71 Fed. Reg. at 25672-73.

products to be bid under the codes selected. Unless this first step is undertaken, there would be such drastic variability in the bidding that the entire process would be tainted.

DJO also recommends that each OTS product category be further divided into sub-groupings. These sub-categories, or sub-groupings, could represent families of similar codes that would be reflective of the multiple functionalities of the various products, as well as the multitude of coding, coverage and reimbursement complexities necessary to support providing products to beneficiaries in the CBA. For instance, a select, small number of knee brace codes with products that perform the same clinical function could be grouped together. Rather than submitting a separate bid for each HCPCS code within a product category, the supplier would offer a single bid amount for the sub-grouping. Without such a mechanism, DJO is concerned that most suppliers, even large capacity suppliers that operate on a national basis, might be precluded from bidding.

To effect these changes, DJO asks that the applicable proposed regulations be revised as follows:

I. 42 C.F.R. § 414.412 should be revised so that subsection (c) reads (with proposed language in italics): "Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines that there is good cause to align items differently for a particular competitive bidding program*."

II. 42 C.F.R. § 414.412 should be revised so that subsection (d) reads: "Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program, *unless CMS permits a bid for a sub-category for bidding purposes.*"

III. ENSURE THE INTEGRITY OF BID EVALUATIONS BY REQUIRING UNIFORM FINANCIAL STANDARDS & ACCREDITATION, ALLOWING FOR AN EXTENDED GRACE PERIOD FOR ORTHOTICS SUPPLIERS

[Conditions For Awarding Contracts]

CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. DJO strongly supports CMS's proposal to require suppliers to meet quality and financial standards in order to be awarded bids. This should include the requirements that suppliers be subject to a uniform set of financial standards, regardless of the size or type of organization, and that they meet quality standards and be accredited in order to participate in the program.

For bid evaluation, CMS proposes a three-step process: (1) establish a single composite bid for each supplier for a particular product category; (2) array these composite bids from

lowest to highest; and (3) select a pivotal bid (based on estimated beneficiary demand), with winning bidders being those at or below the pivotal bid.[20] In addition, under proposed 42 C.F.R. 414.414, CMS would require that each supplier meet basic eligibility requirements (such as complying with existing Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. CMS does not clarify at what point in the bid evaluation process it would confirm that such standards have been met.

DJO notes that, as a practical matter, for this initial phase of competitive bidding, a large number of suppliers may be in the process of obtaining accreditation and coming into compliance with the quality standards. To address the initial phase, therefore, CMS proposes to allow a grace period for compliance with the quality standards.[21] DJO applauds CMS's recognition that a grace period is needed to assist many suppliers in becoming accredited, particularly given that the finalized standards have not yet been released. An extended grace period should be afforded to suppliers in industries like orthotics in which accreditation is not currently the norm. Suppliers in such industries lack experience with accreditation, and it will take additional time for them to become accredited. DJO strongly urges CMS to provide an extended grace period for orthotics suppliers.

IV. RECOGNIZE THAT SUPPLIERS ARE ONLY EQUIPPED TO PROVIDE ITEMS FROM THEIR OWN INVENTORIES

[Terms of Contract; Physician Authorization/Treating Practitioner]

DJO asks that CMS revise two of its proposals so that they address practical realities and limitations of the DMEPOS industry. Without the below-discussed changes to the proposed regulations, suppliers may face difficulties operating in a manner that makes good business sense and could be disincentivized from participating in the program. If existing large-capacity suppliers exit the Medicare program, this, of course, would have a devastating impact on beneficiaries' ability to obtain needed items and would jeopardize the success of competitive bidding.

Responsibility for Repairs/Maintenance of Items Furnished By Non-Contract Suppliers

CMS proposes to oblige contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers. In many, if not most, instances, suppliers have no experience in repairing or performing maintenance on items that were supplied by other suppliers and would not be able to perform such work themselves. Contract suppliers would, in effect, be forced to pay for a sub-contractor to perform the service—a result that would impose significant costs on winning suppliers. It is difficult to

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20 *See* 71 Fed. Reg. at 25674-75.

21 *See* 71 Fed. Reg. at 25675.

determine what these costs will be in advance of bid submission and, as a result, short of CMS providing the information as part of the Requests for Bids, there is no way for suppliers to weigh this cost in determining bid prices. Even if CMS is able to offer this information prior to bid submission, the proposal is particularly onerous for manufacturer-suppliers that only carry and sell their own products. Thus, DJO asks that CMS continue to pay for repair and maintenance of DMEPOS items performed by non-contract suppliers, as has been the agency's practice in the past. There is no reason to shift this burden to another supplier, particularly one who is likely to be unequipped to perform the services itself.

DJO suggests that 42 C.F.R. § 414.422(c) be revised to add a new subsection (3) which states: "*Contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the competitive bidding area are exempt from the requirement in paragraph (1) for purposes of items furnished by other suppliers.*"

Physician Authorization of Product Brand

DJO believes that revision is also warranted for proposed 42 C.F.R. § 414.420 to acknowledge business considerations for manufacturer/suppliers. Under this provision, contract suppliers would be required to make a reasonable effort to furnish a physician-specified brand (or mode of delivery). CMS notes that physicians and other treating practitioners could prescribe a particular product brand if they determine that it would avoid an adverse medical outcome for the beneficiary. If a treating practitioner specifies a particular product under these circumstances, the contract supplier would be required to "make a reasonable effort to furnish the particular brand." If the supplier is unable to furnish the designated product, it would need to work with the practitioner to find an alternate item that is appropriate and obtain a revised order.[22]

Manufacturer/suppliers maintain inventories that contain predominantly their own products and could have difficulty furnishing a brand other than their own. DJO believes that the regulation should be revised to make clear that the contract supplier need not be able to offer the item if it is not part of its inventory. This could be accomplished by adding a new subsection (b)(4) to 414.420, stating: "*The contract supplier is not required to furnish the particular brand or mode of delivery itself if such brand or mode of delivery is not in its inventory in order to be deemed to have made a reasonable effort under this paragraph (b).*"

V. REVISE CHANGE IN OWNERSHIP RULES SO THAT THEY ARE

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22 *See* 71 Fed. Reg. at 25684.

CONSISTENT WITH EXISTING REQUIREMENTS FOR DMEPOS SUPPLIERS

[Terms of Contract]

Proposed 42 C.F.R. § 414.422(d) would limit a contract supplier's ability to continue to participate in competitive bidding upon a change in ownership of its business. CMS proposes to require contract suppliers to notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized. CMS would only allow the successor entity to continue to furnish products in the competitive bidding area if (1) there is a need for the successor entity to function as a contractor in order to assure expected demand for a competitively bid item; (2) the successor entity meets all requirements applicable to contract suppliers; (3) the successor entity assumes the contract supplier's contract, including all obligations and liabilities; and (4) the successor entity executes a novation agreement.

This proposal is over-broad and would needlessly penalize business arrangements that may have no impact on the contract supplier's relationship with CMS. Furthermore, it would devalue contract suppliers' businesses. Existing standards—including the Medicare supplier standards and the forthcoming quality standards—already provide sufficient assurances to ensure that high quality services are provided to beneficiaries. This proposed notice requirement would not add to these assurances in any meaningful way.

DJO believes that the proposed regulation should be modified to clarify that the notification obligation and the limitations on continuing as a contract supplier apply only where the contract is being transferred to a new or different legal entity. The test would be the same as currently used to determine whether a new supplier enrollment application is needed under the instructions for Form CMS-855S. In those circumstances in which the legal identity of the contract supplier is not altered, by way of example, there may be no need to obtain the prior approvals. In contrast, where the legal identity of the acquired contract supplier would occur as a result of the change in ownership, CMS may want assurances that the new supplier will be able to meet all obligations of the former supplier and will assume all of its liabilities under the existing contract.

CMS could also borrow (as it has in the past) from the definition of "change of ownership" in the provider context under 42 C.F.R. § 489.18(a). With respect to corporations, by way of example, this regulation provides that:

> The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.[23]

DJO thus suggests adopting this definition in the proposed regulation. This would notify contract suppliers of the types of transactions that would trigger the completion of a new Form

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[23] 42 C.F.R. § 489.18(a)(3).

CMS-855S, as well as the change that would trigger the examination by CMS that a contract supplier can continue to meet the obligations under the existing contract.

In addition, DJO believes that there is no reason to depart from the existing 30-day post-change timeframe provided for suppliers to alert CMS as to changes of information, ownership or control. The current regulations do not require notice to CMS until *after the change has occurred*, and there is no reason why prior notice would be needed in this context. CMS recently re-affirmed this approach in newly finalized supplier enrollment regulations. Under 42 C.F.R. § 424.530, DMEPOS suppliers are required to report changes of information and changes of ownership or control within 30 days of their occurrence.

DJO thus suggests the following revisions to 414.422(d)(1): "A contract supplier must notify CMS in writing *within 30 days of* any change of ownership *(as such term is defined in section 489.18(a)) that would trigger completion of an entire new Form CMS-855S*."

VI. SET PAYMENT AMOUNTS SO THAT THEY REASONABLY REFLECT ACTUAL BIDS

[Determining Single Payment Amounts for Individual Items]

CMS's proposed methodology for setting competitive bidding payment amounts may not reasonably reflect actual bid amounts. Under proposed 42 C.F.R. § 414.416, CMS would use the median of winning suppliers' bids as the payment amount. This approach will by its nature result in a rate that is lower than the bid prices of half of the winning bidders. Many suppliers, including DJO, fear that they will not be able to continue to provide products to beneficiaries in the CBAs if the established rates are far below their bid prices. In order to raise the chances that they will be selected to participate in competitive bidding, suppliers are likely to submit bids at or near their margins. Thus, if CMS sets the payment rates at the median of winning bidders' bid prices, up to half of the winning bidders may consider these rates unacceptable and may not be able to continue to provide products to beneficiaries in those areas.

There are alternative approaches open to CMS that would lead to reasonable payment rates. These include the adjustment factor approach that was used in the demonstration projects, which is discussed in the preamble to the proposed regulations.[24] DJO urges CMS to adopt a methodology that ensures that contract suppliers are not being reimbursed at payment rates below their bid amounts on an overall basis. Contract suppliers should receive payment amounts that are at least as much as their bid prices. Suppliers may be less likely to leave the Medicare program if there is some assurance that payment rates will be sufficient.[25] DJO thus recommends that the median approach not be finalized and that an alternative approach resulting in reasonable payment rates be adopted.

VII. RETAIN COMPETITIVE BIDDING PAYMENT AMOUNTS THROUGHOUT

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24 *See* 71 Fed. Reg. at 25679-80.

25 DJO also suggests that CMS consider re-competing a product category in a CBA if a contract supplier with significant capacity exits the program mid-cycle.

BIDDING CYCLE WHEN MULTIPLE HCPCS CODES ARE MERGED INTO A SINGLE CODE

[Gap-filling]

CMS proposes special payment rules in 42 C.F.R. § 414.426 for competitively bid HCPCS codes that are revised in the middle of a competitive bidding cycle. The Company believes that, for the most part, these proposed rules strike the right balance. However, revision is needed for the proposal addressing the situation in which multiple codes describing similar products are combined into a single code. DJO asks that, in such situations, CMS maintain the status quo for until the contract ends to avoid significant decreases in payment rates that would upset suppliers' expectations as to the amounts they will receive for furnishing items to beneficiaries in the CBAs.

CMS proposes to calculate rates differently based on the nature of the coding change, so that:

- If a single code is split into multiple codes, the supplier would be paid the payment amount for the former code.[26] Therefore, the split into new codes would not impact payment. During the subsequent bidding cycle, suppliers would bid on the new separate and distinct codes.

- For codes for several components that are merged into a single new code, the payment policy would differ depending on whether the former codes described (a) components of a single product or (b) multiple products. If the former codes described components of a single product (scenario (a)), the supplier would be paid a rate equal to the total of the payment amounts under the former codes. If the former codes described multiple products (scenario (b)), the new payment amount would be the average (arithmetic mean) of the former payment amounts weighted by the frequency of payments for the former separate codes. For each of the two scenarios, during the subsequent bidding cycle, suppliers will bid on the new single code.[27]

DJO asks CMS not to finalize scenario (b) in the second point above. This formula could result in significantly different pricing for a product or products in the middle of a bidding cycle. Using the new code would up-end suppliers' expectations as to the payment that they would receive for furnishing products to beneficiaries in the CBA. It could also result in unfair payment changes mid-cycle that would be a disincentive to supplier participation. More significantly, adopting this proposal could cause contract suppliers to exit the program mid-cycle—which, in turn, could result in product supply issues for beneficiaries in the CBAs. If CMS decides to adopt this proposal despite these concerns, the agency should clarify how the

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26 This applies both to the circumstance in which the former code was for a single product and is split into codes for its components and that in which the former code was for two or more similar products and is split up.

27 *See* 71 Fed. Reg. at 25688-89.

weighting would occur (for instance, whether CMS would review payments for all suppliers in all jurisdictions or only contract suppliers in CBAs).

DJO thus suggests that, where multiple codes for similar items are merged to a single new code, CMS continue to use the former codes and payment rates for the remainder of the bidding cycle. The proposal in 42 C.F.R. § 414.426(d) would need to be revised as follows: "If multiple codes for similar items are merged into a single code, *the codes that were competitively bid and the established payment amounts for those codes, with any adjustments provided under § 414.408(b), will remain in effect for the remainder of the competitive bidding program*."

VIII. REFRAIN FROM CREATING AN "ANY WILLING PROVIDER" MODEL IF CMS USES COMPETITIVE BIDDING RATES TO ADJUST PAYMENT AMOUNTS IN NON-COMPETITIVE BIDDING AREAS

[Payment Basis]

In 2009 or subsequent years, CMS proposes to use its statutory authority to adjust payment in other areas based on payment information determined under the competitive bidding program. CMS should implement this authority carefully. DJO asks that CMS provide industry stakeholders another opportunity to comment on how to implement this provision at a later date once CMS develops a particular proposal.

DJO fears that CMS may use this authority in a manner that would move the Part B DMEPOS benefit toward a *de facto* "any willing provider" model in which competitive bidding rates are used nationwide and any supplier that is able to provide services may do so (for reimbursement at those rates). Congress did not intend for competitive bidding to result in such a model. Because competitive bidding rates will be based on bid amounts that are calculated using an assumed increase in volume, suppliers' expectations are different than for non-competitive biding areas. The expectation is that there will be few suppliers in each CBA for competitively bid products and, accordingly, that the winning suppliers can offer lower prices because these prices will be offset by the higher volume of products they will furnish. In non-competitive bidding areas, this increase in volume would not necessarily exist to balance out decline in payment rates. Thus, competitive bidding payment rates do not translate to other areas and should not be applied there. DJO asks CMS to take this into account if it uses competitive bidding rates to set fee schedule amounts.

IX. DO NOT FINALIZE THE PROPOSED REBATE PROGRAM

[Determining Single Payment Amounts For Individual Items]

CMS proposes to permit contract suppliers that submitted bids for an item below the competitive bidding payment amount to provide voluntary rebates to beneficiaries. This rebate would be the difference between the supplier's bid amount and the competitive bidding payment amount for the product. As was evident based on the many PAOC committee members and industry representatives who objected to this proposal at the PAOC meeting, the industry is vehemently opposed to this proposal. DJO shares their concerns that this proposal implicates and may violate the Federal Anti-Kickback Statute (the "AKS") and, for that reason, strongly

urges that proposed 42 C.F.R. § 414.416(c), which describes the rebate program, not be finalized.

The AKS is a criminal prohibition that provides punishment for any person who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."[28] Rebates intended to induce beneficiaries to purchase a particular Medicare-covered item are generally prohibited under the AKS. DJO is concerned that adoption of the rebate program would generate significant confusion in the industry as to what is permissible under the AKS and what continues to be prohibited. DJO asks that the proposed regulation be deleted.

X. PROTECT EXISTING APPEAL RIGHTS

[Administrative or Judicial Review]

Under proposed 42 C.F.R. § 414.424, CMS prohibits appeals on most decisions made regarding competitive bidding, in line with the relevant statutory provision. For instance, decisions as to which suppliers are awarded contracts, the payment amounts established, and selection of items to be competitively bid are all not appealable.[29] DJO is concerned, however, that, as written, the proposed regulation does not make clear that existing rights of beneficiaries and suppliers to appeal denied claims are preserved.

In the preamble to the proposed regulations, CMS acknowledges that existing rights are undisturbed by competitive bidding. DJO requests that this be explicitly stated in the regulation itself so that appeal rights are safeguarded. This could be accomplished by adding the following subsection (c) to 414.424: "*All existing rights to appeal individual claims are unaffected by this provision.*" DJO also believes that the statement in the regulation that "[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart" is vague as written and could benefit from clarification (or should be removed).

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28 42 U.S.C. § 1320a-7b(b)(2).

29 71 Fed. Reg. at 25682.

XI. REVISE THE PROPOSED GAP-FILLING METHODOLOGY REPLACEMENT TO FOLLOW STATUTORILY-REQUIRED PROCEDURES & ENSURE FAIR PRICING

[Gap-filling]

[Gap-filling]

DJO applauds CMS for its recognition of the inherent flaws in the current gap-filling methodology and the agency's decision to replace the current formula with a new methodology that reflects the true prices for new technology. Portions of the proposal in 42 C.F.R. § 414.210(g), however, are so vague as to be unworkable. In addition, the effort to use a functional technology assessment without any procedural safeguards impermissibly circumvents CMS's IR authority. This is particularly troubling given that the IR regulations only recently became final and already are being treated as obsolete. It is essential that any formula adopted here be grounded in both substantive and procedural safeguards and follow a transparent process for establishing reasonable, appropriate fee schedule rates for non-competitively bid products.

At the outset, DJO notes that many in the industry have urged CMS to devote considerable attention to this new regulation and specifically have requested that it be considered separate and apart from the proposed regulations for competitive bidding. DJO reiterates this request here, and asks that CMS postpone publication of a final rule to provide time for suppliers to submit additional comments and/or meet with the agency to discuss alternatives. The additional time is needed to give due consideration in separate comments. By including the proposal in the context of the competitive bidding rulemaking—a rule that CMS officials have publicly recognized is only tangentially related to gap-filling—CMS has created needless timing conflicts. Given the resources that need to be expended to comment fully on the competitive bidding rule, suppliers (and CMS, for that matter, since the same individuals are responsible for both competitive bidding and gap-filling) are being pressed to stretch those limited resources. Both rules are simply too important to risk presentation of rushed comments (and/or rushed review of those comments). DJO, therefore, requests an additional period of 60 days to comment on the gap-filling methodology.

In the absence of additional time, and to meet the current time line, DJO submits the following comments concerning the proposal.

Substantive Criteria

Under the gap-filling proposal, where a new HCPCS code is created and no price information is available from the base period, the fee schedule amount for the code would be calculated by taking into account one or more of the following three data sources: (1) median retail prices (from supplier price lists, manufacturer suggested retail prices, or wholesale prices, plus an appropriate mark-up), (2) existing fee schedule amounts for comparable codes, and/or (3) results of a functional technology assessment ("FTA") of products in the new code. DJO supports the move away from the current gap-filling methodology because it relies on deflation

factors that often result in drastic under-compensation for new products.[30] DJO believes, however, that the proposed criteria lack specificity sufficient to inform stakeholders as to the formula to be used.

A lack of specificity without proper safeguards offers the public inadequate notice of how the formula would be used. Two examples are illustrative: First, the proposal suggests that pricing for comparable codes could be used as a proxy for the rates applicable for the new code. How would CMS determine which codes are "comparable"? Would significant functional and clinical differences in the products categorized in these codes be considered? How would CMS account for and quantify these differences?

Second, CMS proposes to use median retail prices to set pricing. How will CMS identify retail prices and how will the agency weight the prices? Regardless of the source for the prices, DJO suggests that CMS use a *weighted median* so that pricing by outlier suppliers that do not provide a significant volume of items to the Medicare program is not given undue importance in setting pricing.

As to the FTA, the notice states that there were three main areas studied in the FTA conducted in CMS's pilot study: (1) Functional Assessment, which evaluated the device's operations, safety and user documentation relative to the Medicare population; (2) Price Comparison Analysis, which involved a cost analysis comparing the product to similar products or alternative treatment modalities; and (3) Medical Benefit Assessment, which focused on the effectiveness of the product using scientific literature and interviews of providers to determine if the product does what it purports to do. Not only is this vague explanation insufficient information for meaningful comments, the FTA analysis oversteps congressional mandates on when the agency can adjust fee schedule amounts and identify alternative "realistic and equitable" amounts. It is improper for CMS to cast aside Congress's grant of IR authority. Further, CMS should not resort to incorporating a coverage analysis to establish pricing. Here, as well, Congress has proscribed how to evaluate coverage. Simply, CMS cannot exercise powers that contradict Congress's specific language in specific statutory grants of authority.[31]

Pricing should be established using objective criteria that can be applied to all products in the same way. A transparent formula, capable of being reproduced for all products must be used. One approach might be to develop an algorithm with a sequential analysis. The FTA should be discarded all together as inappropriate and already addressed through CMS's IR authority.

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30 Gap-filling uses current pricing information, which is then deflated back to a base period to be in line with statutory payment methodology for DME and then inflated based on statutorily-prescribed update factors. CMS has traditionally used the percentage increase in the CPI-U to deflate current pricing—which can be an inappropriate deflationary factor if it is not in line with price increases (or lack thereof) over time in the industry.

31 *See, e.g., Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984) (holding that "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress"); *see also United States v. Haggar Apparel Co.*, 526 U.S. 380, 393 (1999) (confirming that "rules as to instances not covered by the statute should be parallel, to the extent possible, with the specific cases Congress did address").

Procedural Requirements

In addition to the substantive revisions that are needed, CMS's proposal to use an FTA also suffers from a complete lack of procedural safeguards to ensure that appropriate pricing results. Even though this proposal seeks to achieve the results of a coverage a coverage and IR analysis, it fails completely to offer any of the procedural safeguards of these latter processes. Particularly where, as here, CMS is moving away from its current objective gap-filling methodology to a vague, subjective set of criteria, procedural safeguards are even more critically needed.

As CMS describes in the preamble to the proposed regulations, the two FTAs that have previously been undertaken in its pilot study (the results of which have not been shared with stakeholders) involved evaluation of the device's safety and effectiveness in improving clinical outcomes. Both of these elements are considered in determining whether an item meets the Medicare statute's "reasonable and necessary" standard and will be covered under the Medicare program.[32] It is significant that over the years the coverage process has become more open. To that end, Congress recently mandated that CMS follow a defined process for making NCDs, including providing an opportunity to appeal the decisions.[33] There is now a fulsome appeals process available for aggrieved parties who believe an NCD provision is unreasonable.[34] Similar processes are available for challenges to local coverage determinations.[35] CMS must not and may not circumvent these procedural requirements by folding a coverage decision into the payment calculation process.

Perhaps most importantly, payment adjustments like those being proposed here are *statutorily required to undergo a notice and comment process* as well. Under the IR provisions, CMS must analyze a variety of factors and adjust pricing for an item or service upon a determination that the otherwise applicable payment amount is grossly excessive or grossly deficient, which is defined by its own regulations to include a threshold variance of fifteen

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32 42 U.S.C. § 1395y(a)(1)(A); *see also* Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapt. 15, § 110.1 (stating that the necessity of equipment is determined based on "when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member" and that reasonableness is determined based on considerations such as whether the expense of the equipment would not be clearly disproportionate to the therapeutic benefits that could ordinarily be derived from it).

33 Congress revised the Medicare statute to require CMS to issue a proposed decision on a request for an NCD within 6 months of the request for coverage (9 months for requests that require outside technology assessments or Medicare Coverage Advisory Committee deliberation). There is to be a 30-day public comment period from the date of release of the proposed decision and CMS is required to publish a final decision (including responses to comments received) within 60 days of the conclusion of this comment period. *See* 42 U.S.C. § 1395y(l).

34 NCDs can be reviewed by the HHS Departmental Appeals Board ("DAB"). To determine whether the NCD was reasonable, the DAB will review the record, may permit discovery and taking of evidence if it is lacking information, and may consult with scientific and clinical experts. *See* 42 USC § 1395ff(f)(1).

35 *See* Medicare Program Integrity Manual (CMS Pub. 100-08), Chapt. 13, § 13.13.

percent.[36] Once CMS has determined that a payment amount is grossly excessive or deficient, it may establish a payment amount only by considering certain factors, including pricing information and the resources required to produce the products. There is no reason to use an FTA when the robust IR authority exists. Significantly, CMS may not use its IR authority without first following the required procedural steps:

For payment adjustments of 15%, CMS must provide notice and opportunity to comment by publishing the proposed and finalized payment adjustment in the Federal Register.

For payment adjustments of greater than 15% in a single year, more rigorous reviews and procedures are to be undertaken. As to the procedures, CMS must consult with supplier representatives from the industry likely to be affected by the payment change. Notice of the proposed determination must also be published in the Federal Register, with a 60-day public comment period. The Federal Register Notice with the proposed determination must contain an explanation of the factors and data considered in determining that the payment amount is grossly excessive or deficient, list the proposed payment amount, and describe the factors and data used to set this adjusted rate. CMS is to consider any comments submitted prior to publication of a final determination, and discussion responsive to these comments is to be included in the Federal Register Notice announcing the finalized payment determination.[37]

Here, CMS would give itself authority to use the results of an FTA *at any time* to adjust previously-established prices and without identifying any standards. The agency would need only to determine that the pricing methods that were used resulted in payment amounts that do not reflect the cost of furnishing the product. This aspect of the regulation directly conflicts with and circumvents CMS's IR authority, and DJO strongly opposes finalization of this proposal. FTAs should not be used to determine pricing.

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36 IR authority is implicated only where the overall payment adjustment needed to produce a realistic and equitable payment amount is 15% or more. CMS can make an adjustment of less than 15% in a given year under its IR authority, provided that it has been determined that an overall adjustment of 15% or more is warranted. *See* 42 C.F.R. § 405.502(g); 70 Fed. Reg. 73623, 73626 (Dec. 13, 2005).

37 42 USC § 1395u(b)(8)-(9); 42 C.F.R. § 405.502(g)-(h).

Thank you for your considerable efforts to date in implementing the program and for considering DJO's comments regarding the proposed regulations. Should you have any questions or comments, we can be reached at (202) 637-2200.

Truly yours,

Stuart S. Kurlander
Esther R. Scherb
Of LATHAM & WATKINS LLP

Cc: DJO Corporation
Rebecca L. Spain, Latham & Watkins LLP

Submitter : **Mrs. Wendy Gerger** **Date: 06/30/2006**

Organization : **Mrs. Wendy Gerger**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a Certified Hand Therapist.I have been trained to treat patients with all types of upper extremity injuries.
Therapist are unique from other suppliers of DMEPOS. As a hand therapist,while othoses are an important part of treatment,they are just one part of the overall treatment.I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.
Hand therapists typically treat very acute patients and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course if treatment, changes in stability, edema, inflammation and wound healing that require immediate attention. This regulation could significantly interfere with my abillity to react to these changes, putting the surgeries and patients at risk.
I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process.
Thank you for the opportunity to comment on this proposed regulation.
Sincerely, Wendy Gerger

Submitter : Ms. Sara Hicklin **Date:** 06/30/2006

Organization : WAMES

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-1206-Attach-1.DOC

ATTACHMENT TO # 1206

Centers for Medicare & Medicaid Services
Attn: CMS-1270-P
PO Box 8013
Baltimore MD 21244-8013

Electronically to http://www.cms.hhs.gov/eRulemaking

RE: File CMS-1270-P

The following comments are from WAMES, the Wisconsin Association of Medical Equipment Services. We respectfully submit the following comments:

"Payment Basis"
There is no reference in the proposed rule to the use of the Advanced Beneficiary Notice. The final rule should clarify how ABN use, especially for upgrades to deluxe items, will be incorporated. Additionally, the proposed rule seems in conflict by stating that beneficiaries provided with equipment or supplies by a non-contract supplier in a contract area will no have no financial liability but states in other areas that ABNs will be permitted. If a non-contracted supplier obtains a properly-executed ABN informing the beneficiary that an item will not be covered unless obtained from a contracted supplier, will the limitation on beneficiary liability be waived?

The proposed rule states that bidding providers do not have to factor inflation into submitted bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure provider that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U.

The proposed rule regarding grandfathering poses numerous concerns. What will happen to equipment rented by beneficiaries that disenroll from Medicare Advantage plans and return to traditional Medicare? The proposed rule for oxygen needs to be updated to reflect the changes in oxygen equipment ownership as dictated by the DRA of 2006.

The proposed rule requests comments on the authority to adjust payment in other areas. CMS should include methods of establishing that the bid area is comparable to the area(s) for which they will consider applying the bid fees.

"Competitive Bidding Areas"

The proposal for a separate competitive bidding program for mail order suppliers in 2010 seems unnecessary since mail order suppliers are not excluded from participating in the 2007 and 2009 bids. Mail order may meet the needs of some beneficiaries, but some beneficiaries still prefer to use a local provider and should be able to choose between a mail order supplier and a local supplier.

"Criteria for Item Selection"
The final rule should include the specific measures that will be used to decide the potential savings as a result of competitive bidding.

The inclusion of instructions for the provision of brand-specific equipment is unnecessary. Physicians already have the ability to prescribe brand-name equipment. The provider community bears the burden of explaining equipment functionality to the prescribing community to best meet the needs of the beneficiary.

"Submission of bids under the Competitive Bidding Program"
Capped rental items that can be purchased in the first month should include the K0005 ultra lightweight wheelchair.

"Conditions for Awarding Contracts"
There is no provision in the proposed rule to "rationalize" bids to ensure that there are no unreasonably low bids. There must be some provision in the final rule that discourages submission of very low bids to ensure inclusion as a winning bidder.

Because quality standards apply to all DME providers and not just to those affected by competitive bidding, CMS must complete the process for implementation of quality standards prior to implementation of competitive bidding.

The proposed rule states that in cases where two suppliers are below the pivotal bid there will only be two suppliers designated as winning bidders. If one of the two winners is subsequently eliminated during the 3-year bid contract, either due to failure to meet quality standards, natural disaster, acquisition by a non-qualified supplier, or other means this could create dire access problems for affected beneficiaries.

There is also concern that the proposed rule does not provide any protection for small providers.

"Determining Single Payment Amounts for Individual Items"
Setting the single payment amount at the median of winning bids would mean that nearly one-half of the bidders would have to accept a price below their bid. This method is significantly different that the method used in the demonstration projects and seems contrary to the methodology that Congress had in mind when it authorized competitive bidding. The payment amount should be the pivotal bid.

The rebate proposal seems contrary to statutory prohibition of beneficiary inducements. A rebate program would certainly influence the beneficiary's selection of a provider.

"Administrative or Judicial Review"
While we recognize that the MMA specifically prohibited administrative or judicial review, we strongly object.

"Opportunity for Participation by Small Suppliers"
There is very little actual protection for small suppliers. The allowance of networks in no way makes it easier for small providers to participate, and actually creates a larger burden on the small provider.

"Opportunity for Networks"
The allowance of networks in no way makes it easier for small providers to participate, and actually creates a larger burden on the small provider.

Submitter : Mr. Michael Geldart **Date:** 06/30/2006

Organization : CCS Medical

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1207-Attach-1.DOC

ATTACHMENT TO # 1207

CCS MEDICAL

COMMENTS

CCS Medical submits its comments to the Proposed Rules for the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) issued by the Centers for Medicare & Medicaid Services as 24 CFR Parts 411, 414, and 424.

CCS Medical is a national Medicare Provider of diabetic, respiratory, ostomy, urological, and wound care supplies. CCS Medical serves thousands of Medicare Beneficiaries across the country. CCS Medical, as a member of AAHOMECARE and THE DIABETIC PRODUCT SUPPLIES COALITION (DPSC) represented by Fulbright and Jaworski, provided input into both of these associations' comments. We incorporate by reference the comments to the NPRM submitted by these groups. In addition to the comments by AAHOMECARE and DPSC, we submit these additional comments to emphasize certain areas of specific concern from our organization's perspective.

Timing Concerns

We recognize that the agency has been under tremendous time pressures to issue these rules because of the tight deadlines established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L 108-173) However, 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.

Opportunity to Comment on the Supplier Standards

We urge CMS to 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.

Payment Concerns

Inflation Update

CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. Congress has demonstrated in the past that it will override automatic inflation adjustments. We recommend that CMS address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should allow bidders to include an inflation adjustment in their bids.

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. The NPRM does not clearly indicate how CMS will provide notice to all other suppliers which products are under competitive bid. We request that CMS clearly indicate how it will insure that other supplies in an area can protect themselves against accidentally providing an item that is subject to competitive bidding. We recommend a real time web based system that lists each item along with the zip+4 code that suppliers could access prior to providing the product would greatly assist providers. This system would be updated in real time at least hourly in order to ensure that a provider does not inadvertently provide a service for which it cannot receive payment.

Competitive Bidding Areas

Nationwide or Regional Mail Order Competitive Bidding Program

The NPRM does not define what a Nationwide or Regional Mail Order company is. It is possible for a company to be both a retail face-to-face provider and a mail-order company. Would both sets of rules apply to such a company, or could it choose different definitions in different MSAs? It is also unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, it is conceivable that a nationwide or regional mail order company could be a successful bidder in one or more MSAs in 2007 -2009. The NPRM does not address whether such a bidder could then bid in the 2010 bid. The Proposed Rule also seems to indicate that mail order suppliers would not be able to bid differently in different MSAs, even if the costs of providing the products in various MSAs differ. CMS should clarify this mail

order program and how it will relate to the 2007 and 2009 competitive bidding program.

Alternatively, we suggest CMS create a national supplier designation for which DME companies, mail-order or retail, can apply. If a company is selected as a national supplier, they can provide services regardless of which MSA a beneficiary resides. This selection process should precede the individual MSA selections so that any national supplier who is not selected on the national level still has the ability to apply in all MSAs individually.

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). We urge CMS to confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

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, we recommend that CMS 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.

We strongly urge CMS to publish the items it will include in the initial competitive bidding program in an interim final rule.

CCS MEDICAL

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. However, the chosen contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, and if a physician orders a brand/model the chosen contract suppliers do not carry, the suppliers can choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. These options place the chosen contract suppliers in the position of controlling, or at least significantly influencing what product ends up in the hands of the beneficiary based not on what is in the patient's best interest, but based on how to fill the supply needs of the patient within the confines of the suppliers' access to certain brands.

We point out that not all supplies are alike or are easily interchangeable. Even if, for example, diabetes supplies are purported to have the same clinical benefits, their features and functions vary significantly. In many cases, these differences may be insufficient to allow a prescribing physician to justify the need for one brand over another; however from the beneficiaries' standpoint, these differences may be the difference between testing as prescribed and not testing at all. Medicare beneficiaries are elderly, and many have difficulty adjusting to changes of products that they have used for years. We believe that the NPRM does not adequately protect beneficiaries' access to those products that they currently use.

Product Categories for Bidding Purposes

General Issues

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category 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. Capitated codes should not be allowed at all for purposes of competitive bidding. All pricing should be based on a per units supplied basis.

CCS MEDICAL

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. We urge CMS not to proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited. CMS could place patients at risk by allowing unaccredited suppliers to bid. Unaccredited supplies would have substantially lower costs since they are not expending any resources to meet the requirements of accreditation. Moreover, by allowing unaccredited suppliers to bid, CMS would be endorsing suppliers without any guarantee of quality of the services provided.

Further, the evaluation of the supplier's financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. CMS should consider the following evidence of supplier's financial stability:

- Audited Financials
- Insurance Certificates
- Trade References
- Letters of Credit

We suggest CMS encourage accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published. Moreover, if there is a national supplier designation that is selected first, then those suppliers can maintain services to beneficiaries while CMS delays the MSA selection until all potential candidates are appropriately accredited.

Market and Supplier Capacity

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does 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 that the submitted bids are "rational" and not unreasonably low, is to pay contract suppliers an amount equal to their individual bids. Although we understand that the MMA requires CMS to pay a "single payment amount" and that CMS intends to comply with this requirement, the statutory payment basis is the fee schedule amount or the actual charge, whichever is less. Consistent with the requirement, CMS could calculate a single payment amount equal to the pivotal bid and require winning bidders to submit claims in the amount of their bid – the actual charge – not the single payment amount. This approach also achieves price "transparency" for CMS and beneficiaries.

Terms of Contract

Judicial and Administrative Remedies

CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review or appeals process to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

CMS should provide the same level of due process rights for unsuccessful bidders as exist in other governmental bidding programs.

Submitter : Mr. Robert Bosch

Date: 06/30/2006

Organization : Mary Free Bed Rehabilitation Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1208-Attach-1.RTF

ATTACHMENT TO #1208

Restoring Hope and Freedom
Mary Free Bed
Rehabilitation Hospital 800.528.8989 • www.maryfreebed.com • 235 Wealthy SE • Grand Rapids, MI 49503-5299

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program: Competitive Acquisition for DMEPOS (CMS-1270-P)

Dear Dr. McClellan:

I am writing on behalf of Mary Free Bed Orthotics and Prosthetics, a rehabilitation hospital based orthotics and prosthetics provider service much of West Michigan. Mary Free Bed Rehabilitation Hospital is the major physical rehabilitation facility between Detroit and Chicago and provides a continuum of care from acute to home/community. Our O&P organization provides services to over 10 West Michigan acute care hospitals, as well as Mary Free Bed Rehabilitation Hospital itself, and over 1200 physicians.

My comments primarily will apply to the orthotics and prosthetics aspects of this proposal.

1. <u>The proposal ignores the needs of complex inpatients requiring OTS orthotics.</u>

   Our inpatients are usually of high acuity levels and are being treated in an integrated system of care with significant treatment, cost and time constraints. A third party winning bidder would not be able to function effectively as compared to a hospital-based DMEPOS provider, in fact may not even have privileges for providing services within a hospital. Erosion of performance on the DMEPOS end will increase costs on for general inpatient services.

   <u>Recommendation</u>: Exclude hospital-based DMEPOS providers (providing inpatient, outpatient or clinic services) from requirements to comply with this program.

2. <u>This proposal hands automatic advantage to manufacturers of DMEPOS, at the expense of the patient and traditional providers.</u>

   In O&P, we already have brace manufacturers marketing their OTS products directly to hospitals and physicians, often through stock and bill closets and programs. On a daily basis, our orthotists are required to "fix" adjustment problems and repair issues on patient OTS braces provided by manufacturers who do not have trained orthotists or permanent offices and do not provide follow up and repair services. Manufacturers have advantage because they manufacture the OTS brace or product, and offer "wholesale" what everyone else must offer "retail". We

assume they will bid "wholesale" when everyone else will bid "retail". Hence, the potential unfair advantage that could creates further quality issues.

Recommendation: Exclude manufacturers of OTS orthotics and certain DME from participation in this program.

3. The proposal is not specific. Items to be included, quality standards and pricing methodology are not spelled out.

   Recommendation: Issue an interim final rule and invite public comment once specifics have been defined.

4. The proposal is at risk of awarding bids achieved by limiting brand selection and quality standards. DMEPOS brand characteristics can vary significantly, and sometimes a specific brand is required to meet individual patient needs. The Chinese "knock-off" Mont Blanc pen may look like a Mont Blanc, but will not perform as such. How will CMS control for this issue with so many different products and categories? Or, put another way, how will CMS insure that bidders are all bidding on the same OTS orthotics product?

   Recommendation: This is a significant issue. Consider eliminating OTS orthoses (lower limb, spinal and upper limb) from the program, given that the three policy groups represent only 1.9% of the DMEPOS dollars being targeted.

5. The proposal process discriminates against smaller providers located outside major metropolitan areas. The larger companies with area-wide networks tend to be located in major metropolitan areas. They will gain early experience and information that they will then bring into play in subsequent bid processes in smaller communities where certain providers will just be beginning the process.

   Recommendation: Build into the process a counter balance to larger regional providers by insuring the participation of localized small providers.

6. The proposal may not insure geographic access standards. It is conceivable that winning bidders may not have facilities located within easy access of patients needing items. This could result in transportation or time issues developing within a given MSA.

   Recommendation: Require that final bid award insure that there are bid-winning DMEPOS provider facilities within 25 miles of any point within the MSA.

7. The proposal will require significant resources to prepare bids. Already stretched hospital systems will find it difficult to divert resources to this effort.

   Recommendation: Allow hospital-based DMEPOS programs to participate in the competitive bidding program without submitting bids if they agree to accept the single price determined through the bidding process.

Thank you for the opportunity to comment on this proposal. I am happy to respond to any questions you may have at telephone 616-242-0406, or email bob.bosch@maryfreebed.com.

Sincerely,

Robert Bosch
Chief Operating Officer
Mary Free Bed Orthotics and Prosthetics

Submitter : Peter Thomas **Date:** 06/30/2006

Organization : The Orthotic and Prosthetic Alliance

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment and addendum.

CMS-1270-P-1209-Attach-1.DOC

CMS-1270-P-1209-Attach-2.DOC

ATTACHMENT 1 TO #1209

THE ORTHOTIC AND PROSTHETIC ALLIANCE

1875 Eye Street, NW, 12th Floor
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Phone: 202-349-4261
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June 30, 2006

VIA ELECTRONIC MAIL

Mark 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 21244-1850

Re: Comments on Proposed Rule CMS-1270-P; Competitive Acquisition of Certain DMEPOS Under the Medicare Program

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed regulations governing the competitive acquisition of certain durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") as well as the implementation of quality standards in this important area. We are writing on behalf of the Orthotic and Prosthetic Alliance ("the O&P Alliance"), a recently formed coalition of the four primary organizations representing the field of orthotics and prosthetics ("O&P"). The four organizations include the American Academy of Orthotists and Prosthetists (AAOP), the American Board for Certification in Orthotics and Prosthetics (ABC), the American Orthotic & Prosthetic Association (AOPA), and the National Association for the Advancement of Orthotics and Prosthetics (NAAOP). Together, the O&P Alliance represents the scientific, research, professional, business, and quality improvement aspects of the orthotic and prosthetic field.

As discussed below, the O&P Alliance believes that off-the-shelf ("OTS") orthoses should be exempt from the competitive bidding program since the minimal program savings to be gained by competitive bidding of such services will be offset by the significant administrative burden. However, the O&P Alliance supports the proposed use of quality standards and mandatory accreditation for the provision of all DMEPOS to ensure that Medicare beneficiaries receive the highest quality care possible from the most highly qualified suppliers. It is through this mechanism that we believe CMS will achieve both higher quality and lesser expenditures for OTS orthoses. Also attached is an addendum with additional comments related to competitive bidding that are not specific to orthotics and prosthetics.

I. Quality Standards

The O&P Alliance strongly supports the establishment of quality standards and mandatory accreditation for *all* suppliers of orthotic and prosthetic services and devices. Medicare beneficiaries are entitled to receive quality orthotic and prosthetic care from a supplier with the O&P qualifications to provide such care, regardless of the type of supplier that furnishes the services. For this reason, no supplier should be exempt from Medicare's quality standards and accreditation requirements. To do so would contravene the statutory language of the Medicare Modernization Act, potentially put patients at risk of poor quality care, and subject the Medicare program to the threats (e.g., fraud and abuse, overutilization, poor patient care) that the quality standards requirement was intended to address.

The O&P Alliance believes strongly that the level of complexity and sophistication of the orthotic or prosthetic service being provided to the patient should directly correlate to the quality standards and accreditation requirements. For instance, a supplier that is qualified to provide off-the-shelf orthoses may be completely unqualified to provide the full range of comprehensive orthotic care. This is largely a result of significant changes in recent years in the provision of low-level orthotics, which are now routinely provided in non-traditional supplier settings (i.e., not in orthotic patient care clinics and facilities). The accreditation requirements and quality standards that are yet to be published by CMS must recognize this distinction if the intent of the statute is to be realized.

The O&P Alliance, therefore, requests CMS to require organizations that accredit orthotic and prosthetic suppliers to adopt varying levels of credentials that comport with the complexity and clinical expertise required to provide the wide scope of orthotic and prosthetic care. We have previously submitted to CMS documents stating our collective view that there are four basic levels of orthotic care and the qualifications of suppliers that provide these services and devices must comport with the varying levels. These levels are as follows:

1. *Off-the-Shelf Orthotics:* A prefabricated device sized and/or modified for interim, evaluative or short term use by the patient in accordance with a prescription and which does not require clinical judgment and alteration for appropriate use.

2. *Custom Fitted Device (Low)*: A prefabricated device sized and/or modified for use by the patient in accordance with a prescription and which requires substantial clinical judgment (involving medium Patient Assessment and Formulation of the Treatment Plan and Follow Up Treatment Plan skills) and substantive alteration (involving low Technical Implementation skills) for appropriate use.

3. *Custom Fitted Device (High)*: A prefabricated device sized and/or modified for use by the patient in accordance with a prescription and which requires

substantial clinical judgment (involving high Patient Assessment and Formulation of the Treatment Plan and Follow Up Treatment Plan skills) and substantive alteration (involving medium Technical Implementation skills) for appropriate use.

4. *Custom Fabricated Device*: A device fabricated to comprehensive measurements and/or a mold or patient model for use by a patient in accordance with a prescription and which requires clinical and technical judgment in its design, fabrication and fitting.

It is important to note that the term "prefabricated" is not synonymous with the term "off-the-shelf." There are many orthoses that begin as prefabricated devices or prefabricated portions of devices that require high levels of clinical judgment and technical skills to properly design and fit an appropriate permanent orthosis. The levels suggested above explicitly recognize this distinction.

In the proposed rule, CMS explicitly requests public comment on the issue of identifying which HCPCS L-Codes will be considered to represent "off-the-shelf" orthotics, thereby subjecting those orthoses to competitive bidding. With virtually hundreds of L-codes in the HCPCS system, this is a task that requires an intimate understanding of the L-Code system and the practice of orthotics. Led by AOPA's Coding Committee, the O&P Alliance has already undertaken this formidable task and submitted to CMS on two previous occasions a comprehensive list of L-Codes that are divided into the four categories listed above. We request that CMS strongly consider these recommendations as they are the product of many hours of analysis and discussion by experts in the O&P field.

The fact that CMS has not yet published the final quality standards or the accreditation requirements for DMEPOS has made commenting further on this aspect of the proposed rule very difficult. There are significant unknown factors at this point that will be critical to an efficient system of quality standards and accreditation in the DMEPOS benefit. In our view, CMS's main challenge with the O&P benefit is to strike the proper balance between setting the bar too low (and permitting unqualified suppliers to provide comprehensive O&P services to Medicare beneficiaries) and setting the bar too high (and compromising access to orthotic and prosthetic care, particularly in difficult-to-serve areas of the country).

Because of the importance of these issues, the O&P Alliance requests that CMS publish the accreditation requirements on DMEPOS suppliers as a proposed rule, thereby permitting the public to analyze and comment before final implementation. We believe that mandatory accreditation and quality standards, if properly designed and implemented, are the preferred method of achieving both program savings and higher quality in the Medicare OTS orthotic benefit, rather than a competitive bidding model.

II. Exempt Off-the-Shelf Orthotics from Competitive Bidding Based on Low Potential for Savings (Criteria for Item Selection)

When Congress enacted the Medicare Modernization Act of 2003 (MMA), Pub. Law 108-173, lawmakers granted CMS the authority to exempt certain items from a Medicare competitive bidding program that were not likely to result in significant savings. *See* Section 1847(a)(3)(B) of the Social Security Act. In CMS' discussion of this issue in the Notice of Proposed Rulemaking (NPRM), the agency proposes to "exempt items outright or on an area by area basis using area-specific utilization data." *See* 71 Fed. Reg. 25,670.

We urge CMS to exempt outright all OTS orthotics from the Medicare competitive bidding program on the basis that inclusion of OTS orthotics in a competitive bidding program will not produce significant savings to the Medicare program.

Medicare's own data from the competitive bidding demonstration project in San Antonio, Texas strongly supports this conclusion. The Research Triangle Institute's (RTI) Final Evaluation Report "*Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS*" issued in November 2003 concluded,

> *"We believe that the product category of general orthotics is not as well-suited for competitive bidding as oxygen equipment and supplies, hospital beds and accessories, wheelchairs and accessories and nebulizer drugs. We reach this conclusion primarily on the basis of the relatively low potential for savings in the product category. We estimated that allowed charges on the demonstration items would have totaled only about $200,000 per year in San Antonio in the absence of the demonstration. At this level, even if competitive bidding reduced prices by 20 percent, the change in allowed charges would be relatively small. General orthotics had the fewest bidders of all the product categories included in the demonstration in San Antonio with only 14 suppliers submitting bids; 8 suppliers were selected as demonstration providers." (page 253)*

The actual data from the competitive bidding demonstration related to certain orthotics provides compelling support for our position. For the 23-month period (Feb. 1, 2001 – Dec. 31, 2002) during which competitive bidding for certain orthotics was tested in San Antonio, the Medicare program saved a total of $89,462, or less than $45,000 per year *(page 92 of RTI's Final Report).* Moreover, since the conclusion of the San Antonio demonstration project in 2002, all orthotic and prosthetic services, including OTS orthotics, have been subject to a Medicare payment freeze as mandated by the MMA, effectively reducing reimbursement rates for Medicare OTS orthotics by 7.9 percent as compared to inflation.

In light of this data and because CMS determined through its proposed scoring methodology that San Antonio is one of the ten largest MSAs with the highest potential

for DMEPOS savings (*see* 71 Fed. Reg. 25,666), we believe that other MSAs would likely yield even less savings than the original San Antonio demonstration.

Additionally, Section 1847(a)(1)(B)(ii) of the Social Security Act provides CMS the authority to phase-in competitive bidding "first among the highest cost and highest volume of items or those items that the Secretary determines have the largest savings potential." Once again, OTS orthotics do not meet the underlying conditions of the statute. OTS orthotics are not high-cost or high-volume items nor do OTS orthotics have the largest potential for savings based on the San Antonio demonstration.

Rather, we believe that CMS' focus on the OTS benefit should be aimed at designing, implementing and enforcing effective quality standards and mandatory accreditation requirements to help:

(1) improve the quality of orthotic and prosthetic services delivered to Medicare beneficiaries;
(2) ensure that orthotic and prosthetic suppliers are qualified to provide the level of orthotic and prosthetic care required by the individual patient;
(3) validate that services provided to beneficiaries are medically necessary;
(4) ensure that orthotic and prosthetic services are not miscoded;
(5) reduce unnecessary program expenditures for orthotics and prosthetics; and
(6) reduce opportunities for fraud and abuse in the program.

Again, we believe strongly that implementation and enforcement of effective quality standards and mandatory accreditation requirements is a far better course for CMS to take than competitive bidding of OTS orthotics. Whether or not CMS decides to ultimately include OTS orthotics in competitive bidding programs, we recommend a number of changes to the proposed competitive bidding regulations as detailed below and in the attached Addendum, which lists our more general concerns with the design of the competitive bidding program proposed by CMS.

III. Definition of Minimal Self-Adjustment (Criteria for Item Selection)

We recommend amending the proposed definition of "minimal self-adjustment" that is referenced in the preamble of the proposed rule. The Medicare Modernization Act defines OTS orthotics as:

> "[o]rthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual." MMA, Pub. L. No. 108-173, § 302(b), *codified at* 42 U.S.C. § 1395w-3(a)(2)(C).

The statute does not define what is meant by "minimal self-adjustment" other than this statutory language. The definitions section of the proposed regulation (Section 414.402) is consistent with the statute with regard to the definition of "off-the-shelf orthotics."

However, the preamble to the proposed regulation states that "[w]e are proposing that minimal self-adjustment would mean adjustments that the beneficiary, caretaker for the beneficiary, *or supplier of the device* can perform without the assistance of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification)." [Emphasis added]. Accordingly, pursuant to this definition, OTS orthotics would include orthotics that require adjustments by a supplier (albeit not a certified orthotist).

We believe that the definition of OTS orthotics that appears in the definitions section of the proposed rule should not be modified by the preamble language. The definition of OTS orthotics should not include items that require the services of a supplier. CMS's proposed definition of "minimal self-adjustment" conflicts with the plain-meaning of the statute. The term "self" in "self-adjustment" clearly indicates that the definition of "OTS orthotics" are intended to be orthotics which can be properly adjusted by the beneficiary, without assistance from a supplier. If an orthosis requires the assistance of a supplier, then it cannot be self-adjusted.

Accordingly, we request that CMS clarify that "minimal self-adjustment" means adjustments that the beneficiary or caretaker of the beneficiary can perform – it does not mean adjustments that require the involvement of a supplier. In addition, the definition of OTS orthotics must be established in the context of all levels of orthotic care, as described above.

On a related issue, we applaud CMS for recognizing in the preamble the ABC and BOC as the primary accrediting organizations in the field of orthotics and prosthetics. The field of orthotics and prosthetics is separate and distinct from durable medical equipment and supplies. The accrediting agencies that CMS determines are appropriate for suppliers of orthotics and prosthetics should reflect this distinction. Because of this distinction and the impact that the selected accrediting agencies will have on the quality of O&P care for Medicare beneficiaries, we recommend that CMS incorporate references to ABC and BOC in the regulations themselves, rather than relying on the preamble to establish this important distinction.

IV. New Gap-Filling Methodology

The preamble to the proposed rule discusses the use of three factors in its new method of determining fees for new items and services: (1) functional assessment; (2) price comparison analysis; and (3) medical benefit assessment. *See* 71 Fed. Reg. 25,687, to be codified at 42 C.F.R. § 414.210(g). Our comments and recommendations on these issues are as follows:

- **Functional assessment**—This assessment should only be used to ensure that "like is being compared to like" in determining a fee schedule amount. Any other use of a functional assessment is not appropriate, since it would enter the realm of medical necessity judgments.

- **Price comparison analysis**—This comparison is reasonable if an appropriate range of items are reviewed. However, in the past, we have found that CMS has used a very limited list of items, oftentimes comparing orthoses and prostheses to items and services that are not furnished by certified orthotists and prosthetists, to set HCPCS code fee schedule amounts. Most recently, this has occurred in setting fee schedule amounts for a number of orthoses.

  This is unreasonable and results in fee schedule amounts that may be accurate for devices often furnished by DME suppliers, but not for the services of certified orthotists and prosthetists. This type of fee setting tends to either force Medicare patients to use inexpensive, arguably inappropriate devices when a more appropriate device is both available and appropriate to treat the individual's condition.

- **Medical Benefit Assessment**— We strongly protest the use of medical benefit assessment in relation to fee determinations. Certainly, a determination of medical necessity is required before any device can be paid by the Medicare program, however, this decision must be made separately from the calculation of fee schedule amounts.

  The medical benefit of a device is a coverage decision, not a fee determination. It is inappropriate to use the setting of fee schedule amounts as a backdoor method of determining coverage, which has its own protocols, either through the National Coverage Determination process or through the determination of medical necessity by the PSC medical directors at the Local Coverage Determination level. Historically, coverage, coding and reimbursement have been separate and distinct activities and it must remain so for the system to make fair and equitable judgments regarding new technologies.

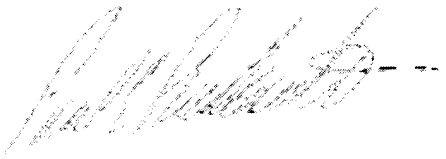
Finally, the O&P Alliance requests that CMS clarify in the final regulations the statement included in the gap-filling discussion that states, "*We can use the technology assessment process at any time to adjust prices on or after January 1, 2007 that were previously established using the gap-filling methodology if it is determined that those pricing methods resulted in payments amounts that do not reflect the cost of furnishing the item.*" 71 Fed. Reg. 25,688. We request clarification as to whether this statement is referring to the Medicare inherent reasonableness methodology of altering fee schedule amounts, or to some other process?

If you have any questions regarding the above comments or our more general comments on competitive bidding reflected in the attached Addendum, please feel free to contact our Washington counsel, Peter W. Thomas, at (202) 466-6550.

Sincerely,

Mark D. DeHarde
President
National Association for the Advancement of Orthotics and Prosthetics

Walter L. Racette, CPO
President
American Orthotic & Prosthetic Association



Paul E. Prusakowski, CPO, FAAOP
President
American Academy of Orthotists and Prosthetists

Jeffrey J. Yakovich, CO
President
American Board for Certification in Orthotics in Prosthetics

ATTACHMENT 2 TO #1209

Addendum

Additional Comments of the O&P Alliance to the Proposed Rule Regarding Competitive Acquisition of DMEPOS; CMS-1270-P

The following comments are offered by the O&P Alliance on CMS's Proposed Rule for Competitive Acquisition of Durable Medical Equipment, Orthotics, Prosthetics, and Supplies. These comments relate to the general concerns of the O&P community with respect to Medicare competitive bidding of DMEPOS and not with the more specific concerned of the orthotic and prosthetic field outlined in our primary comments.

I. Opportunity for Participation by Small Suppliers/Opportunity for Networks

Section 1847(b)(6)(D) of the Act states that "[i]n developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall 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." We believe that the proposed competitive bidding system strongly favors large providers with the ability to cover large service areas, provide all of the products in various categories, and use economies of scale to underbid smaller suppliers. The final regulations must include further measures to ensure that small suppliers have the opportunity to meaningfully participate in serving the needs of Medicare beneficiaries in competitive bidding areas.

The O&P Alliance recommends that CMS require a minimum percentage of small suppliers in each competitive bidding area ("CBA"). For example, CMS could establish a rule that required in each CBA at least fifty percent of the suppliers who receive a contract to be small suppliers (the definition of small supplier may be based on either FTEs or annual revenue). CMS may employ a number of means to ensure that CBAs include minimum percentages of small suppliers, such as: (1) creating CBAs that are reasonably sized in order to allow small suppliers to participate (since small suppliers often will be unable to furnish services to a large CBA); (2) allowing small suppliers to bid for "carve out" areas of CBAs; or (3) awarding contracts to the small suppliers with the lowest bids that exceed the pivotal bid (until the minimum percentage threshold is met). We believe that requiring CMS to contract with a minimum percentage of small suppliers is necessary to effectuate Congress's unequivocal mandate that small suppliers are included within the competitive bidding program.

Furthermore, we do not believe that the proposal for suppliers to form supplier networks serves as a meaningful method to ensure participation by small suppliers. We question whether any such network is permissible under federal antitrust laws. While antitrust laws permit provider networks, such networks are based on the so-called "messenger model" and do not permit suppliers to reach a mutual consensus on pricing.

In contrast, CMS's proposed model requires suppliers who are marketplace competitors to agree on proposed prices for all items within a competitive bidding product category. If CMS believes that its proposed network model is permissible under federal antitrust laws, we request that the agency publish any internal legal analyses supporting this position. Furthermore, if CMS believes that its supplier network option is

permissible under the antitrust principle of "implied repeal" (in which there is an irreconcilable conflict between a federal regulatory scheme and antitrust laws), then we request that CMS clarify this in the final regulation. *See, e.g., National Gerimedical Hospital and Gerontology Center v. Blue Cross of Kansas*, 452 U.S. 278, 101 S. Ct. 2415 (1981). Otherwise, we believe that the proposed network model does not pose a viable solution for ensuring that small suppliers can participate in the competitive bidding program because of the risk that such a network violates federal antitrust law.

II. Beneficiary Access to Non-contract Suppliers

The proposed rule generally does not permit beneficiaries to access non-contract suppliers within a CBA (as grandfathering is not available to O&P). While we recognize that CMS has adopted this policy to ensure program cost savings, we believe it is imperative for CMS to permit beneficiaries to obtain services from a non-contract supplier. This is necessary for quality assurance purposes and to ensure that beneficiaries continue to have access to unique or particularly high-quality services from longstanding Medicare suppliers. As discussed below, this can be done in a fashion that ensures that Medicare receives its full program savings and which provides incentives for suppliers to seek contract-supplier status.

We recommend that CMS permit beneficiary's to access non-contract suppliers if:

(1) the beneficiary pays 20% of the competitive bidding amount for the item;
(2) the beneficiary also pays the difference between the competitive bidding amount and the lesser of the Medicare fee schedule or the supplier's usual charge;
(3) the supplier provides, and the beneficiary signs, a notice indicating the lower payment rate available at a contract supplier.

This methodology ensures that the Medicare program obtains its program savings (since the program would only pay 80% of the competitive bidding amount, as it would had the beneficiary received services from a contract supplier). It provides a strong incentive to the beneficiary to use contract suppliers (since the beneficiary will have clear notice that the coinsurance payment rate will be lower at such suppliers). It preserves beneficiary choice, without unduly penalizing beneficiaries for using non-contract suppliers. Finally, it provides an incentive to suppliers to submit bids (because, due to increased coinsurance amounts, it can be expected that beneficiaries would mostly utilize contract suppliers).

The following example illustrates how Medicare and the beneficiary would pay for non-contract services in a CBA. Supplier A is a non-contract supplier who charges $120 for an item. The Medicare fee schedule amount is $100, and the competitive bidding payment for the item is $80. If the beneficiary chooses to go to Supplier A, Medicare will pay the supplier 80% of the competitive bidding amount, or $64. The beneficiary will be responsible for 20% of the competitive bidding amount ($16), plus the difference between the competitive bidding payment amount and the lesser of the fee schedule payment or supplier charge ($20). Supplier A also must provide a notice to the beneficiary that the beneficiary's coinsurance at a contract supplier would be $16 rather than $36.

Accordingly, in this example Medicare pays the same amount as if the beneficiary went to a contract supplier ($64), the noncontract supplier receives its usual payment amount ($64 from Medicare, and $36 from the beneficiary), and the beneficiary retains a choice of suppliers. There remains a strong incentive for the beneficiary to use a contract supplier (since the beneficiary would have paid $16 rather than $36). An added benefit of this methodology for Medicare is that it provides an additional incentive for suppliers to offer lower bids (since a contract supplier can only expect to gain significant additional market share if the difference between the competitive bidding amount and the fee schedule amount provides sufficient incentive to beneficiaries). The O&P Alliance views this as the ultimate quality assurance mechanism, as beneficiaries would be able to "vote with their feet" and access the provider of choice if the contract supplier or suppliers were not meeting their needs.

III. Geographic Access to Suppliers

The proposed rule does not include any provision to ensure adequate geographic distribution of suppliers within a CBA in order to maintain access for beneficiaries. For example, CBAs potentially may be as large as an entire MSA (possibly even including some adjacent counties), and under the proposed selection process, all contract suppliers may be located in one portion of the CBA. This will make it difficult for beneficiaries to obtain medically necessary services (especially in large urban areas where beneficiaries may have limited means of transportation).

The O&P Alliance recommends that CMS ensure adequate geographic access to contract suppliers by creating relatively small CBAs (with multiple CBAs in each chosen MSA). Doing so ensures that beneficiaries will not be forced to travel across large cities in order to obtain Medicare services.

IV. Use of Median Bid

CMS has proposed to pay contract suppliers the median of the winning bids. This means that, for any given HCPCS code subject to competitive bidding, half of the contract suppliers in a CBA will be paid less than their bid amount. We believe that this policy significantly discourages suppliers from participating in the competitive bidding program. It is our view that quality suppliers may be unlikely to become contract suppliers if they will be reimbursed at less than their proposed bid amount. Furthermore, this system may lead to a high level of supplier attrition in the competitive bidding program. Suppliers who drop out of the program will not be easily replaced since the potential replacements are suppliers who will be paid the same amount but who submitted even higher bids.

We recognize that CMS believes that the median bid methodology is necessary to ensure program savings. However, we believe that this methodology is a fundamental flaw in the competitive bidding program. We believe that the program will be placed in jeopardy due to lack of supplier participation under this model, or will lead to a substantial deterioration in quality due to this attempt to maximize program savings.

We recommend that CMS use the highest selected bid. While CMS states in the preamble to the proposed rule that it disfavors this approach, we request that the agency reconsider. The use of the highest bid provides an equitable result (because it ensures that no supplier is required to accept less than the supplier's bid amount). It will ensure sufficient supplier participation in the program (because suppliers are more likely to bid and remain in the program if they are paid at least their bid amount). Finally, it is a valid representation of the market payment rate (the process will still weed out disproportionately high prices because composite bids above the pivotal bid will not be selected).

V. Use of Rebates

The O&P Alliance opposes CMS's proposal to allow contract suppliers to offer rebates to Medicare beneficiaries. First, we believe that such rebates constitute illegal "kickbacks" under federal fraud and abuse laws. While the proposed rule states that the collection of coinsurance and the provision of rebates must be separate transactions, in practice we expect that collection of coinsurance and the use of rebates will be reduced to a single transaction. Furthermore, while the proposed rule prohibits advertising of rebates, word-of-mouth advertising is inevitable.

Accordingly, the rebate system will become nothing more than the routine waiver or reduction of coinsurance. The Office of Inspector General has made clear on numerous occasions that such a practice represents an impermissible kickback, potentially interfering with clinical judgment and leading to overutilization. *See, e.g.,* 59 Fed. Reg. 31,157 (Dec. 19, 1994). The routine waiver or reduction of coinsurance is illegal in traditional fee-for-service Medicare, and we believe the same should be true for Part B competitive bidding.

Second, the proposed rebate system will lead to a decrease in professionalism and quality of care. Suppliers of DMEPOS should be expected to provide high quality professional care. Patients should choose suppliers (and physicians should refer to suppliers) based on a supplier's record of providing quality medical services. Medicare certainly would not expect a beneficiary to choose a physician based on whether a coinsurance rebate is available. The use of rebates leads to patients instead choosing suppliers based solely on the availability of discounts, rather than quality of care. This could lead to decreased patient outcomes.

We do not see any merit to the proposed use of rebates. Accordingly, we request that CMS withdraw this proposal.

VI. Miscellaneous Provisions

In addition to the above mentioned provisions, the O&P Alliance makes the following recommendations:

- ***Authority to Adjust Payments in Other Areas (414.408)*** – CMS should not use the competitive bidding program to adjust payment rates outside of

competitive bidding areas – such a payment adjustment does not take into account a variety of factors (*e.g.*, differences in wage indexes, differences among suppliers, the inability of small suppliers to provide services based on bids of large, more streamlined suppliers).

- ***Furnishing Items to Beneficiaries Whose Permanent Residence is Outside a CBA (§ 414.408)*** – A beneficiary from outside of the CBA should not be required to use a contract supplier. This requirement will lead to beneficiary confusion when traveling. This provision should be eliminated or should only apply to beneficiaries who have resided in the CBA for three or more months.
- ***Requirement to Obtain Competitively Bid Items from a Contract Supplier (§ 414.408)*** – We do not believe it is appropriate to set the payment for suppliers outside of a beneficiary's CBA at the competitive bidding amount for that CBA. The suppliers outside of the CBA will not have agreed to participate in the competitive bidding program, and may be unable to offer services at the competitive bidding amount (due to differences in wage indexes or an inability to match the price of a potentially much larger supplier). We recommend that Medicare pay the supplier its normal Medicare payment amount (*e.g.*, lesser of fee schedule or charge). The beneficiary will have an incentive to obtain DMEPOS from the competitive bidding area because of lower coinsurance amounts.
- ***Conditions for Awarding Contracts (§ 414.414)*** – We recommend a grace period of at least six months for suppliers to obtain accreditation.
- ***Composite Bids (§ 414.414)*** – We recommend that the composite bid should be weighted by utilization rather than payment amount, since this will result in a more accurate composite bid (otherwise "big ticket" items that are rarely purchased can be underbid to artificially deflate the overall composite bid).
- ***Terms of Contracts (§ 414.422)*** – A contract supplier should not be required to furnish services to a Medicare beneficiary. The supplier may be operating beyond capacity and unable to reasonably service the beneficiary. The supplier may not believe that the requested orthosis is appropriate for the patient, despite the physician order. In fact, the regulation does not even require a physician order; it simply states that the supplier must respond to beneficiary "requests." Since there will be more than one supplier per CBA, there is no need to prohibit suppliers from turning away beneficiaries.
- ***Information Collection from the Supplier (Misc.)*** –The O&P Alliance requests that CMS clarify what is meant by "information on product integrity," "information on business integrity," and "customer service protocol." Orthotic clinics are more like physicians offices than retail environments and, therefore, "customer service" is not accurate terminology.
- ***Beneficiary Education (Misc.)*** – The proposed rule's preamble states that "[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 ...." 71 Fed. Reg. 25,684. We disagree with this statement. It is unproven that competitive bidding will increase the quality of products. In fact, the O&P Alliance believes that a system based on the lowest bidder has the potential to impact quality in a very detrimental way. CMS should be vigilant in monitoring quality as the competitive bidding system is implemented and not assume before this system is underway that quality will be improved.

Submitter : **Mr. Juan Izquierdo** **Date: 06/30/2006**

Organization : **Mr. Juan Izquierdo**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Education and Outreach

Education and Outreach

As both an enforcer of civil rights law and a major purchaser of health care services, the Federal government has a pivotal role in ensuring culturally competent health care services. Title VI of the Civil Rights Act of 1964 mandates that no person in the United States shall, on ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

Organizations and programs have multiple, competing responsibilities to comply with Federal, state and local regulations for the delivery of health services. The Bureau of Primary Health Care, in its Policy Information Notice 98-23 (8/17/98), acknowledges that: "Health centers serve culturally and linguistically diverse communities and many serve multiple cultures within one center. Although race and ethnicity are often thought to be dominant elements of culture, health centers should embrace a broader definition to include language, gender, socioeconomic status, housing status and regional differences. Organizational behavior, practices, attitudes and policies across all health center functions must respect and respond to the cultural diversity of communities and clients served. Health centers should develop systems that ensure participation of the diverse cultures in their community, including participation of persons with limited English-speaking ability, in programs offered by the health center. Health centers should also hire culturally and linguistically appropriate staff."

It would behoove CMS to exclude, until 2009, or once further experience has been accumulated and cultural competency been accounted for, to exclude culturally diverse MSAs such as Miami and Puerto Rico from competitive bidding. Doing so would allow for CMS time to ramp up logistics associated with the start-up of this new and complex program. For example, this would allow CMS time and experience to provide beneficiaries with materials, information, and administrative guidance to beneficiaries who are culturally distinct and diverse in language, customs, and
community.

CMS-1270-P-1210-Attach-1.DOC

CMS-1270-P-1210-Attach-2.DOC

ATTACHMENT 1 TO #1210

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ATTACHMENT 2 TO #1210

As both an enforcer of civil rights law and a major purchaser of health care services, the Federal government has a pivotal role in ensuring culturally competent health care services. Title VI of the Civil Rights Act of 1964 mandates that no person in the United States shall, on ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

Organizations and programs have multiple, competing responsibilities to comply with Federal, state and local regulations for the delivery of health services. The Bureau of Primary Health Care, in its Policy Information Notice 98-23 (8/17/98), acknowledges that: "*Health centers serve culturally and linguistically diverse communities and many serve multiple cultures within one center. Although race and ethnicity are often thought to be dominant elements of culture, health centers should embrace a broader definition to include language, gender, socioeconomic status, housing status and regional differences. Organizational behavior, practices, attitudes and policies across all health center functions must respect and respond to the cultural diversity of communities and clients served. Health centers should develop systems that ensure participation of the diverse cultures in their community, including participation of persons with limited English-speaking ability, in programs offered by the health center. Health centers should also hire culturally and linguistically appropriate staff.*"

It would behoove CMS to exclude, until 2009, or once further experience has been accumulated and cultural competency been accounted for, to exclude culturally diverse MSAs such as Miami and Puerto Rico from competitive bidding. Doing so would allow for CMS time to ramp up logistics associated with the start-up of this new and complex program. For example, this would allow CMS time and experience to provide beneficiaries with materials, information, and administrative guidance to beneficiaries who are culturally distinct and diverse in language, customs, and community.

Submitter : Mr. Timothy Zipp **Date:** 06/30/2006

Organization : The SCOOTER Store

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1211-Attach-1.DOC

ATTACHMENT TO #1211

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW.
Washington, DC 20201

June 30, 2006

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule [71 Federal Register 25654-25703 (May 1, 2006)]

Dear Dr. McClellan:

On behalf of the The SCOOTER Store (TSS), the nation's leading provider of Power Mobility Devices (PMD), we respectfully submit the following comments concerning the Notice of Proposed Rule Making entitled, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues* (herein referred to as the NPRM) published in the Federal Register on March 1, 2006. 71 Fed Reg 25654-25703.

TSS understands that the Centers for Medicare and Medicaid Services (CMS) has a daunting task implementing this program; however, we strongly recommend that the agency immediately implement Quality Standards, including Accreditation requirements, as directed by 42 U.S.C. §1395m(a)(20). Since April of 2003, when employees of TSS were the first to report the fraud situation in Harris County, Texas, TSS, along with most of the Power Mobility Device (PMD) industry, has been pushing CMS to develop such standards for all suppliers not just those participating in the Competitive Acquisition Program.

We are concerned that CMS will not mandate the increased standards for all suppliers when competitive bidding is implemented in 2007. In fact, the NPRM indicates that CMS will delay the accreditation process, a critical fraud prevention method, and allow suppliers to be reimbursed without accreditation, even inside of the winning bidder pool of suppliers. *See* 71 Fed Reg 25659. It appears that CMS's only goal is to drive down price for certain items of DME. We challenge CMS to not allow this to occur.

Second to our main concern is the fact that this is not a National Competitive Bidding program. It is closer to a city by city bid process designed solely to lower prices. The original intent of the program was to allow the marketplace to set its price and not CMS, however, CMS is tainting this process by forcing suppliers to submit prices less than the current allowables, then taking the median price, and ultimately only paying 80% of that amount. This system only favors very large suppliers with bidding expertise, economies of scale, and abilities to survive lost bids by having diversity in payor sources and geographic areas served.

We currently do not support the competitive bidding program, as written, because of the issues listed above and discussed in detail below. However, we realize this is a statutory requirement and therefore must share our opinions through the comment process. We hope that our comments can help lead to higher quality standards and accreditation requirements designed to fight fraud and increase standards within this industry.

Very truly yours,

Tim Zipp
Senior Vice President
Compliance
The SCOOTER Store

I. General Comments

Supplier Standards and Accreditation must be required for ALL suppliers of DMEPOS
The NPRM states, in part, that "All suppliers of DMEPOS and other items to which section 1834(a) (20) of the Act applies will be required to meet the quality standards established under that section. Finally, section 1847(b)(2)(A)(i) of the Act requires an entity (a DMEPOS supplier) to meet the quality standards specified by the Secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program." 71 Fed Reg 25658 However, CMS has inexplicably proposed that the accreditation program be phased in, thereby allowing non-accredited suppliers to be awarded c ontracts in Competitive Bidding Areas ("CBA"). 71 Fed Reg 25659

Quality standards and accreditation becomes a way for CMS to keep fraudulent and sub-standard suppliers from gaining access to Medicare Beneficiaries and federal healthcare dollars. CMS should not allow non-accredited suppliers to participate in the Medicare program in or out of CBAs. TSS recommends that CMS designate Approved Accrediting Entities immediately to allow not only bidding suppliers, but rather all suppliers, to become accredited prior to the implementation of the Competitive Bidding Program.

II. Comments Regarding "Payment Basis" – Proposed Section 414.408

A. Payment Adjustment to Account for Inflation – Proposed Section 414.408(b)

The NPRM states that the competitive bid price will be updated by the CPI-U and this "will obviate the need for the supplier to consider inflation in the cost of business when submitting its bids." 71 Fed Reg 25664. While we appreciate this provision, it leaves suppliers at risk to future changes that may further "freeze" pricing. CMS should ensure that price updates are received in the MSAs under contract. This can be adjusted in future rounds of bidding, but it must be made clear at the time that the bids are submitted. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

B. Beneficiary Switch to Contract Suppliers

The NPRM states that a beneficiary may choose to transfer their capped rental or oxygen equipment to a contracted supplier at any time during their rental cycle. 71 Fed Reg 25662. Contract suppliers will be required to furnish these items regardless of the rental months remaining on the equipment. While CMS expects suppliers to include this possibility as part of their bid price, we maintain that it is impossible for suppliers to predict the rate at which beneficiaries will transfer or in which month in the cycle they will transfer. Contracted suppliers should be able to provide needed equipment and re-start the capped rental cycle again under the new pricing model since there is no way to predict the cost associated with assuming another supplier's rental contract. Suppliers should be compensated when accepting beneficiaries with less than full rental periods remaining, as suppliers are required to provide service in such circumstances.

The NPRM states that no bid will be accepted if it is higher than the current fee schedule amount for an item. 71 Fed Reg 25678. This mandated ceiling on the bid price eliminates the opportunity for the marketplace to determine the price and reduces this program to nothing more than a price reduction exercise. If this is the intent of the program, CMS already has inherent reasonableness authority to change prices, provided the agency validates its actions.

C. Authority to Adjust Payment in Other Areas

The NPRM states that CMS can use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside of the competitive bidding area. 71 Fed. Reg. 25664. CMS should not be able to apply competitive bid prices to non-bid areas as different economies of scale, demographic densities, delivery costs, etc. exist in different regions of the country. Suppliers bidding for a specific CBA will estimate their costs, and therefore their bid price is solely based on servicing the specific CBA.

Because the NPRM does not allow contracted suppliers to refuse to service or provide equipment in these areas, it puts winning bidders at financial risk to be required to sell and service DMEPOS in areas to which they had not previously agreed or included in bid price. CMS should not adjust payments in these areas unless it does so at the next round of bidding. That will allow bidders to decide if they want to be required to service that area and then account for that in their submission.

III. Comments Regarding Competitive Bidding Areas

A. Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that for 2007 and 2009 the competitive acquisition areas will be established ***in*** an MSA. 42 U.S.C. § 1395w-3(a)(1)(B)(i). The areas ***adjoining*** a CBA should not be subject to the bid price. They should be properly bid, or excluded from the CBA.

B. Proposed Methodology for MSA Selection – Proposed Section 414.410

CMS proposed to use a factor of "suppliers per beneficiary" when determining how to rank which MSAs to choose. 71 Fed. Reg. 25666. Will CMS only calculate suppliers with physical locations inside of the CBA area or will it base its number of suppliers on those who have billed Medicare claims for DMEPOS for some time period? Medicare is allowing suppliers to bid who can service the area and not necessarily have a location inside the CBA. Therefore, it would only make sense that Medicare "count" all suppliers who have submitted Medicare DMEPOS bills in the past year to use in determining he number of "suppliers per beneficiary".

IV. Criteria for Item Selection

The NPRM requires suppliers to submit bids for individual items included in a "product category" for which contracts are awarded. 71 Fed Reg 25672. Based on the tables provided by CMS, it appears that all wheelchairs, POVs, and power wheelchairs may be bid in some type of

"product category". Suppliers would be required to submit bids for all three products and related accessories as opposed to choosing which single items they may want to attempt to participate in the bidding process. We recommend that CMS publish RFBs for single items and any components accompanying them. Such a proposal would be more user friendly for small suppliers and better represent the marketplace.

A. Potential for Savings

The NPRM will choose items for competitive bidding based upon the potential for savings, and CMS includes a list of factors that it may use to determine potential savings. 71 Fed Reg 25671. We believe, however, that CMS should explain and clarify the specific criteria or standards they will use when assessing potential savings. It needs to be made clear what methodology CMS will use to objectively identify products to be included in the first round of bidding.

B. Coding Issues and Item Selection

CMS proposes a methodology for item selection based upon historical data, 71 Fed Reg 25670, and does not take into account recent and forthcoming changes that will significantly affect utilization. Upcoming changes for PMDs to the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. As a result there will be no historical data to support decisions based upon price or utilization. We recommend that CMS not include PMDs in the initial 10 CBAs as there will be no data on which to support which items to include. Moreover, there will be very little experience on which suppliers can base their cost estimates, utilization rates, and bid prices as these will be changing with new codes, prices, and coverage policy.

V. Comments Regarding "Submission of Bids Under the Competitive Bidding Program" – Proposed Section 414.412

Physicians

The NPRM allows suppliers located outside of a competitive bidding area to submit bids and participate in the competitive bidding program for that area if they do business in the CBA and are able to service the beneficiaries residing within the CBA. 71 Fed Reg 25672. We would amend the proposal to only include those accredited suppliers with the capability to service the CBA and that capability must be proven by existing utilization and delivery patterns in the MSA.

VI. Comments Regarding "Conditions for Awarding Contracts" – Proposed Section 414.414

A. Quality Standards and Accreditation Proposed 414.414(c)

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process, thus allowing an undisclosed amount of time for such suppliers to become accredited. 71 Fed Reg 25675. This process will allow sub-standard suppliers to taint the bid pool and manipulate the bid price. This is detrimental to the integrity of the program as it allows companies with different cost structures the opportunity to bid for the

same items and then leave the Medicare program if they cannot live up to the standards. At the same time, accredited winning suppliers subject to the same price will not be allowed to refuse to serve beneficiaries in that CBA.

O***nly*** accredited suppliers should be eligible to bid. 42 U.S.C. § 1395w-3(b)(2)(A). CMS should not proceed with competitive bidding if it will not mandate that suppliers receive accreditation prior to submitting a bid.

Because CMS has delayed the quality standards and delayed choosing the entities that will actually accredit suppliers, it will enable non-accredited suppliers to participate in the bidding process. This is contrary to the will of Congress and an inexplicable action by CMS to delay the one real initiative that will effectively stop fraud and abuse. We again urge CMS to not allow this to occur.

B. Financial Information – Proposed Section 414.414(d)

The NPRM states that as CMS develops the "methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process." 71 Fed Reg 25675. It is important to evaluate a supplier's financial stability before the bid prices are arrayed and the pivotal bid is selected. Failure to do this would taint the bid pool. It should be made clear in the regulation and application process exactly how this information will be used. Further, CMS must, at a minimum, clearly define and publish what ratios are needed to qualify, who decides what constitutes adequate insurance documentation and coverage, and what score qualifies a company to have a positive credit history.

We further recommend that all suppliers be required to submit financial reports which have been reviewed by an outside, independent accounting firm or CPA so there is some validation of the report. Companies who have audited financial statements and use GAAP should be given greater priority because their information conforms to general accounting principles and has passed review by external parties. The standards establishing how the collected information will include or exclude suppliers from this process should be made public.

C. Eligibility -- Proposed Section 414.414(b)

1. Introduction and Overview

We have a number of concerns regarding (1) the "eligibility" criteria set forth in proposed regulation 414.414(b), (2) the "Draft" "Medicare DMEPOS Competitive Bidding Program" Application form ("Application Form"), and (3) the review criteria for assessing "Change in Ownership" under proposed rule 414.422(d). Overall, although they are intended to assist the agency in making the same sort of "responsibility" determination that are common to virtually all federal procurements, the proposed criteria and standards are so broad, ambiguous, undefined, and internally inconsistent that they will (i) pose serious hardships for any Durable Medical Device ("DME") supplier that tries to comply, (ii) require the creation of substantial databases and administrative systems to track required information, (iii) create numerous situations where

information wholly irrelevant to the responsibility of a supplier might be considered in some arbitrary manner to favor or exclude a particular entity, and (iv) expose applicants unnecessarily to sanction for noncompliance or erroneous statements based upon an inability to gather all the required information. This is all the more of a concern considering that proposed section 414.424(a) would deny all administrative and / or judicial review of contract awards.

2. General Concerns

As a basic premise, CMS seeks to accomplish through the sui generis Medicare DMEPOS Competitive Bidding Program ("CBP") the same goals and results as those that the Department of Health and Human Services and other federal agencies seek to accomplish when they utilize the Federal Acquisition System to procure a product or service for themselves – *i.e.*, to obtain on a timely basis the best value product or service that it can, while maintaining the public's trust and fulfilling public policy. Compare FAR 1.102(a) ("The vision for the Federal Acquisition System is to deliver on a timely basis the best value product or service to the customer, while maintaining the public's trust and fulfilling public policy objectives.") with *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS and Other Issues,* 71 FR 25654, 25657 (May 1, 2006) ("Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost. . . ."). In short, the CBP is no more or less than a federal procurement program to acquire goods and services, except that the users will not be government personnel but Medicare and Medicaid beneficiaries.

It is quite likely that the government procures under the simplified acquisition procedures applicable to "commercial items" authorized under of the Federal Acquisition Regulation ("FAR"), see FAR Part 12 (Commercial Items), the very same products as to which CMS now seeks to create a unique procurement system wholly outside of the established procurement system. Considering that the existing procurement procedures and requirements for commercial items already operate successfully in achieving the goals to which the Federal Acquisition System and the CBP both aspire, one must question why CMS endeavors to recreate from scratch a wholly new system. The mere fact that the purchases are to be used by Medicare and Medicaid beneficiaries rather than federal employees or patients in military hospitals certainly affords no valid basis for an independent program. Nor, considering the speed with which commercial item procurements can be accomplished under the FAR, is the need to ramp up quickly a basis for such an approach. The pitfalls inherent in trying to create a "new" system are highlighted by the faulty standards through which it proposes to assess the business integrity of prospective suppliers.

Those who are to administer the CBP, like those who for many years have administered the Federal Acquisition System, presumably will seek to ensure that suppliers are "responsible" in the sense that they are technically and financially qualified to supply a quality product in sufficient quantity to meet contract demands. They also will seek to ensure that prospective contractors possess sufficient business integrity so that the government will feel comfortable in entering into a business arrangement with them. To that end the FAR, after substantial consideration of alternatives over the years, now contains a well accepted representation and certifications clause that addresses those criminal and civil matters within the previous three

years that reasonably might be considered substantively and temporally relevant to the government's consideration of a prospective contractor's business integrity. FAR 52.209-5.[1] In

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[1] FAR Section 52.209-5 (Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters (Dec 2001)) provides as follows:

(a) (1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals—

(A) Are / are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have / have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are / are not presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.

(ii) The Offeror has / has not, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principals," for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

addition, that provision explains that adverse information will not necessarily bar a prospective contractor from contract award and, more importantly, assures them that they need not establish special record keeping procedures and databases to comply with the certification requirement. FAR 52.209-5(d). Notably, the current FAR provision reflects a substantial retreat from a much broader set of representations and certifications – that inquired into a broad array of civil and administrative actions involving the prospective contractor and others associated with the entity – that was briefly promulgated during 2001 and then quickly and withdrawn as unduly burdensome and unmanageable. See Federal Acquisition Case ("FAC") 97-21, 65 FR 80,255 (Dec 20, 2000), effective Jan 19, 2001, stayed FAC 97-24, 66 FR 17,753 (Apr. 3, 2001), corrected 66 FR 18,735 (Apr. 11, 2001, finalized with changes FAC 2001-03, 66 FR 66,984 (Dec 27, 2001)). CMS is now erroneously heading down the same road the federal government rejected some years ago for its own direct procurements.

Instead of adopting the tried, tested, and relatively effective representations and certifications language contained in section 52.209-5 of the FAR, without advancing any substantive reason or basis -- other than that it possesses the authority to ignore the FAR -- CMS strikes out on its own to create anew a set of criteria to supposedly assess applicant business integrity, as reflected in proposed section 414.414 and the associated Application Form. In doing so, it demands an extraordinarily burdensome, intrusive, contradictory, and unmanageable set of certifications and disclosures with which few if any entities could hope to comply. It will leave applicants potentially subject to exclusion or sanctions for noncompliance based upon certification and disclosures criteria that are wholly irrelevant to whether a potential supplier is responsible from a business integrity standpoint. Moreover, the situation is exacerbated when one considers that CMS purports to bar ***any*** judicial or administrative review of its contract award decisions. See proposed section 414.424 (discussed below). Such a system does not suggest one focused upon the benefits of competition and ensuring business integrity but rather a system where unnecessary and irrelevant information is amassed and whose unregulated use will lead to mistakes, arbitrary action, and favoritism in contract awards that will go unrevealed by exposure to the sunlight of review that is a critical aspect of virtually every other procurement in the Federal Acquisition System.

3. Specific Comments Regarding "Eligibility"-- Proposed Section 414.414(b)

At a specific level, section 414.414(b) contains numerous defects and ought to be thoroughly rewritten along the lines of existing FAR language. It provides as follows:

> Each bidding supplier must –
>
> (i) Certify in its bid that it, its high level employees, chief corporate officers, members of its board of directors, its affiliated companies, and its subcontractors are not now and was not sanctioned by any governmental agency or accreditation or licensing organization, or

(ii) Disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

71 FR at 25,700

First, it is unclear in both subsections as to whom "high level employees" refers. In a large company this might include hundreds of persons. It might involve persons who have nothing to do with the procurement. For example, it might include all plant supervisory personnel over whom few if any entities require or maintain records of this sort. There is no way to know from the language whom is covered. Similar confusion arises to somewhat of a lesser degree regarding "Chief corporate officers." Which officers are included and which are not included?

Second, it is unclear to whom "affiliated companies" refers. This could include just parent and direct subsidiaries. Or, depending on how one defines "affiliation", it could include a vast array of entities which have little if anything to do with the procurement at issue. In a large corporation, it could include scores of entities most, if not all, of which operate relatively independently of the entity seeking the contract.

Third, it is unclear what entities are to be included as "subcontractors." Are only proposed subcontractors for the prospective contract included? Are second tier subcontractors included? Are the subcontractor disclosures to extend only to those involving the subcontractor entity or to its high level employees, directors, chief corporate officers, affiliated entities, and its own subcontractors? It is unclear how a contractor is to obtain the required information from "subcontractors" and how it is to verify the information. It also is unclear what happens if a subcontractor refuses to furnish the information or only furnishes a part of the requested information. In this regard, what CMS demands, without reason or justification, goes well beyond what the government requires of federal contractors regarding contracting with commercial item and most other subcontractors without affording the government as much protection as does the pertinent FAR provision for a like situation. FAR 52.209-6.[2]

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[2] SAR 52.209-6 (Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment.) (Jan 2005) provides as follows:

(a) The Government suspends or debars Contractors to protect the Government's interests. The Contractor shall not enter into any subcontract in excess of $25,000 with a Contractor that is debarred, suspended, or proposed for debarment unless there is a compelling reason to do so.

(b) The Contractor shall require each proposed first-tier subcontractor, whose subcontract will exceed $25,000, to disclose to the Contractor, in writing, whether as of the time of award of the subcontract, the subcontractor, or its principals, is or is not debarred, suspended, or proposed for debarment by the Federal Government.

(c) A corporate officer or a designee of the Contractor shall notify the Contracting Officer, in writing, before entering into a subcontract with a party that is debarred, suspended, or proposed for debarment (see FAR 9.404 for information on the Excluded Parties List System). The notice must include the following:

Fourth, in subparagraph 414.414(b)(2)(i), besides the grammatical issue of "was" versus the presumably intended "were", there is no limitation on what is meant to be included by "sanctioned by any governmental agency or accreditation or licensing organization." The preamble, whose text is not included in the regulation, offers no clarification or limitation in stating that "[s]anctions would include, but are not limited to, debarment from any Federal program, sanctions issued by the Office of Inspector General, or sanctions issued at the State or local level." This is no definition at all! This could include everything from a Labor Department or EPA sanction regarding a division of a large cooperation that has no tie at all to the proposed contract, to a speeding ticket issued to a company employee, to a citation issued by the county to a company CFO for an unleashed dog or improperly planted tree that violates some historical use regulation. Moreover, it is temporally unrestricted. Although the FAR only requires an entity to report back for three years at most, see FAR 52.209-5(a)(1), CMS would have applicants go back to the dawn of time. Such a broad sweeping requirement will pose unjustifiable burdens on an applicant.

Fifth, as a practical matter, it would be virtually impossible, except perhaps for a very small company with no affiliations, to make the certification required by subsection 414.414(b)(2)(i) because the affiant would not know whether he or she was subjecting the company to sanctions for noncompliance. Considering the severity of potential sanctions, and the lack of an appeal, the certification option is no option at all.

Sixth, the alternative of trying to comply with subsection 414.414(b)(2)(ii) is equally unattainable at least for all but the smallest of companies. Besides the challenges discussed above regarding the definitions of high-level employees, chief corporate officers, affiliated companies, and subcontractors, as discussed above, one has no way of knowing what to disclose in terms of "[d]isclos[ing] information about any prior or current legal actions, sanctions, or debarments by any Federal, State, or local program, . . ." Even if one had some idea of how far back one was required to go in addressing this issue, one likely would not have the means to go about collecting (much less verifying) such information from employees, affiliates, subcontractors or even various divisions of a company. Besides all of the federal, sate, and local government matters that are theoretically covered by this provision, it also appears to cover every administrative or judicial action that was ever brought against or by the company, its personnel, its affiliates and its subcontractors. As the government realized during 2001 when it

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(1) The name of the subcontractor.

(2) The Contractor's knowledge of the reasons for the subcontractor being in the Excluded Parties List System.

(3) The compelling reason(s) for doing business with the subcontractor notwithstanding its inclusion in the Excluded Parties List System.

(4) The systems and procedures the Contractor has established to ensure that it is fully protecting the Government's interests when dealing with such subcontractor in view of the specific basis for the party's debarment, suspension, or proposed debarment.

proposed substantially less draconian disclosure requirements for addition to the FAR 52.205-9, such requirements would require applicants to develop huge database collections and infrastructures to locate and track the enormous quantity of essentially irrelevant but potentially responsive information that might need to be disclosed. CMS, realistically, must establish reasonable substantive and temporal limitations on what is to be disclosed.

In this regard, a significant issue is what standards CMS would propose to apply to the information that is submitted. What CMS official or implementation contractor is capable of properly assessing the significance regarding a potential supplier's business integrity based on a local ordinance violation (or a failure to disclose such a matter), or a state sanction for a noise abatement, or a Fair Labor Standards Act sanction for a minor infraction, or an EPA regulatory violation, or a state or federal sanction based upon violations of regulations governing the length of time a tractor trailer operator may dive in one day, or an IRS or state tax authority sanction imposed because an accountant made an error, or the relative significance of a sanction issued 10, 5 or two years ago. The potential for inadvertent error, abuse, or arbitrary action to favor of or exclude an entity based upon a review of the types of material encompassed by the proposed regulation is far too high for this regulation to stand unaltered. As we noted above, during 2001, the federal government rapidly retreated from far less onerous disclosure requirements in considering appropriate representations and certifications to ensure it had the necessary information to assess business integrity. There is no justifiable reason for CMS to cast its net for information any broader than the criteria it applies under the FAR when procuring goods for itself that are like those encompassed under this program. It too, should retreat to bounds no greater than those set forth in FAR 52.209-5.

4. Medicare DMEPOS Competitive Bidding Program Application

CMS has issued a proposed Medicare DMEPOS Competitive Bidding Program Application form ("Application Form") in association with the proposed regulation. OMB No. 0938-xxxx (Form CMS-10169A (xx/xx). With respect to certifications and disclosures of information, it is rife with inconsistencies and ambiguities vis-à-vis the proposed regulation and generally sweeps far too broadly to be justifiable as drafted..

First, proposed section 414.414(b)(2) provides that contractors are to be afforded an alternative between providing a certification and disclosing various past matters. Putting aside the fact that the regulatory alternative is in effect illusory, no such alternative is afforded on the Application Form. Rather, Section D of the Application requires offerors to make the following certification:

> Neither I, nor the owner, director, officer or employee of the (Supplier) or other organizations on whose behalf I am signing this certification statement, or any contractor retained by the company of any of the aforementioned persons, currently is subject to sanctions under the Medicare or Medicaid program, or disbarred, suspended or excluded under any other Federal agency or program, or otherwise prohibited from providing services to CMS or other Federal agencies.

Application at 6. In addition, the Application Form requires applicants to disclose the following array of information:

> Please provide a brief explanation of any past or pending, if known, investigations, legal actions, or matters subject to arbitration involving the applicant, subcontractors, and any entities under legal arrangement (including parent firm). Information provided must include: 1) circumstances; 2) status (pending or closed); and 3) if closed, details concerning any resolution and any monetary damages.

Application at 5. This dual requirement directly conflicts with the supposed alternative set forth in section 414.414(b)(2). The Application Form needs to be reconciled with the regulation in this regard and as discussed further below.

Second, with respect to the certification, it is substantially at variance with the scope of the certification set forth in section 414.414(b)(2). Although somewhat more narrowly focused as to the type of matters to which one must certify – and more closely aligned with what one finds under the FAR – the expansion of the certification to "owners," "employees" (as compared with "high level employees") "officers" (as compared with "chief corporate officers") and to "any contractor retained by the company of (sic) any of the aforementioned persons" creates a wholly different and far broader universe of persons from whom information theoretically must be obtained The certificate, as drafted, includes every shareholder and employee of a company that could number in the thousands or more. Considering that as constructed, it now covers the janitor and a shareholder with but ten shares out of a million shares, and the contracted accounting shop, fuel oil company, and temp agency for the entity. It would be virtually impossible for a middle-sized or larger company to gather the information to make such a certification or to have any confidence that it had not exposed itself to the substantial penalties set forth in the Application Form for an erroneous statement. Such a broad certification is not required for federal procurements under the FAR and there is no justifiable reason why such a broad request is warranted here. Again, as we explained above, CMS should simply adopt the certification set forth in section 52.209-5 of the FAR for this purpose.

Third, the disclosure requirement, besides also being at variance with the disclosure set forth in section 414.414(b)(2), also mandates disclosure of information on a far broader scale than the regulation in other respects. The Application Form requires disclosure of "investigations" without defining what is covered, which could include a host of minor local, state, or federal matters with absolutely no bearing on the integrity of the prospective contractor. Similarly, "legal actions" and matters "subject to arbitration" could encompass an enormous array of matters that have nothing to do with a company's integrity or responsibility. Lastly, the requirement to make disclosures regarding "any entities under legal arrangement (including parent firm)" is ambiguous as to what it covers and potentially extends to any entity that has a minor contract, or minor ownership interest in the applicant. Again, there is no basis for requesting information of this breadth particularly where it finds no support in the proposed regulation or otherwise.

Once again, much of the information being gleaned here would appear to have little or no bearing upon the integrity or other aspects of applicant's responsibility. Moreover, there appears to be no standard by which such information is to be analyzed or weighed. Nor is there any provision for an applicant to be informed of and to address matters that may be of concern to CMS. Thus, as we explained above, the certifications and disclosures under these provisions, besides conflicting with what the regulations require and constituting a further unreasonable collection burden, also pose serious threats for confusion, erroneous submissions, and misuse of the data to favor or exclude an applicant on some arbitrary basis. Accordingly, in conjunction with revising and limiting the scope of section 414.414(b)(2), CMS should harmonize and similarly limit the scope of the certification and disclosure requirements on the Application.

D. Market Demand and Supplier Capacity – Proposed Section 414.414(e)

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers needed to service all the expected beneficiaries in an MSA. 71 Fed Reg 25675. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. CMS's recommendations, however, do not include methods to keep unreasonable bids from being considered. When suppliers are asked to submit their capacity, they should be able to assume that they will only be required to supply the volume of product included in their bid. However, the regulation also stipulates that they are not permitted to refuse to provide or service a beneficiary. Unreasonable bids not only improperly affect the bid pool, they may also contribute to financial hardship for the supplier who is asked to increase capacity to fully service the market demand.

We recommend the bid consideration process protect against this type of behavior. CMS should consider eliminating outlier bids or include strategies employed in the previous pilot bidding programs. These included adjustments to the single price or accepting more than one bid price.

CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. A number of circumstances, such as a natural disaster or other calamity, could create unanticipated access problems for beneficiaries in the MSA. The ability of CMS to predict the demand in a marketplace with any precision will doubtless have an error factor and lead to incorrect conclusions. This would also eliminate the need to amend the process during the 3-year term as contracted suppliers exit the market for various reasons.

E. Determining the Single Payment Amounts for Individual Items – Proposed Section 414.416

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." 71 Fed Reg 25679. This methodology will result in 50% of the winning bidders receiving reimbursement that is less than their submitted bid. Further, suppliers may not refuse to provide equipment or servicing to these beneficiaries. Some suppliers will thus be subject to reimbursement lower than they were willing to accept and a quantity of demand greater than they agreed to provide. This methodology is significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects.

We recommend CMS set the payment at the pivotal bid price, which is the highest priced bid to adequately meet the market demand. This was the method used effectively in the earlier demonstration projects.

F. Rebate Program – Proposed Section 414.416(c)

The NPRM proposes that any supplier that submitted a bid lower than the single payment amount may choose to offer that difference as a "rebate" to all beneficiaries in the CBA. 71 Fed Reg 25680. CMS should immediately remove the rebate program from the proposed regulation. There were no supporting opinions offered for this provision at the recent PAOC meeting. Further, it will be difficult to police this provision or enforce the prohibitions against discussing, marketing or using the rebate information with customers and referral sources. This provision could be a violation of the Anti Kickback Statute, and it could open the program to improper inducements and provides no clear way to monitor the infractions.

VII. Comments Regarding "Terms of Contracts" – Proposed Section 414.422

A. Furnishing of Items – Proposed Section 414.422(c)

CMS should clarify the relationship between the volume of product a supplier submits with its bid and the requirement to provide product and service to any beneficiary covered in the CBA. CMS must clarify when a supplier can refuse to provide service and if providers will be required to provide beyond their bid quantity.

B. Repair or Replacement of Equipment

CMS must clarify when a supplier can refuse to serve a beneficiary. It is clear with Oxygen and Sleep products that if a patient has the correct test score or completed sleep exam they will qualify, and therefore should receive, the prescribed product and treatment. However, with a Power Mobility Device (PMD), the supplier relies upon the physician's evaluation, prescription, and documentation to decide if this patient should or should not receive a PMD. The system CMS has set up through the recent Final rule on PMDs puts the supplier in the role of deciding if the physician has documented the beneficiary's condition well enough to be served by a supplier. The NPRM, however, indicates that any time a patient receives a written order from his/her physician, the supplier would be breaching their contract with CMS if they chose not to follow such order. CMS must clarify the specific circumstances when a contracted supplier can refuse to serve patients and the specific circumstances that would justify a supplier not complying with a physician written order inside of the Competitive Bidding Program.

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area and to repair or replace beneficiary owned equipment subject to the competitive bidding program. 71 Fed Reg 25681. As highlighted above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. Winning bidders should be reimbursed for the service and replacement products they provide. If there are

warranties to be honored on previously rented or purchased equipment, the cost of service must be borne by the supplier who received reimbursement for the unit that failed. This should be the one exception where a non-winning bidder is allowed to provide equipment in a CBA. However, they would not be allowed to bill Medicare, as they are replacing parts or entire units still covered under warranty.

C. Change of Ownership – Proposed Section 414.422(d)

We are concerned with what is unsaid in the text of subsection 414.422(d), but included in the preamble, regarding "Change in Ownership." In the text of the regulation, one of the conditions is that a successor contractor must meet "all requirements applicable to contract suppliers for the applicable competitive bidding program." 71 FR at 25,702. In the preamble, however, CMS asserts that it will assess, among other things, a company's "compliance status with government programs before we determine that a supplier can qualify as a contract supplier." 71 FR at 25,681. Besides facing all of the challenges we address in the context of section 414.414, above, CMS does not define what it means by the quoted phrase. It, too, is unbounded as to what will be considered and affords no indication as to how CMS intends to acquire this information, who is qualified to assess the collected information, and whether and if so how the application would be afforded the opportunity to comment regarding adverse information. As such, the regulation, particularly as explained in the preamble, affords another example of where abuse or error could lead to favoritism, the disqualification of an entity, or the imposition of sanctions against an entity for improper or unsubstantiated reasons all without there being any opportunity to seek redress. Accordingly, it is necessary for CMS to clarify what it means by this reference in the context of section 414.422.

Suppliers cannot be prohibited from selling their businesses; CMS cannot unreasonably withhold its approval of a change of ownership and CMS should not deny winning supplier status to new owners on the basis that its capacity is not necessary within the competitive bidding area.

CMS should approve a change of ownership if the new entity meets the applicable quality standards, a ccreditation r equirements, and f ully adheres to other requirements of c ompetitive bidding, including the terms of the original contract.

VIII. Comments Regarding "Opportunity for Participation by Small Suppliers"

The NPRM states that the needs of small businesses will be considered when determining what the applicable financial standards will be. 71 Fed Reg 25682. We contend that all suppliers awarded bids must adhere to the same standards. Each supplier must fully comply with accreditation requirements, supplier quality standard requirements, and financial standards to ensure the integrity of the Medicare program and ensure that each Medicare beneficiary receives proper care.

IX. Comments Regarding "Opportunity for Networks" – Proposed Section 414.418

The NPRM will allow small businesses to form networks, for bidding purposes, in order to increase the strength and competitiveness of their bids. 71 Fed Reg 25683. We do not oppose this provision allowing for networks as long as the guidelines are set forth by CMS which explain how these entities will operate. For instance; if they are legal entities, which entity will bill claims? How will these entities bill claims or be audited? If action is needed to be taken against one network member but not all, how would other members continue with the contract, or would the entire network be liable for one company's violations?

X. Comments Regarding "Quality Standards and Accreditation for Suppliers of DMEPOS"

We reiterate the need within the PMD industry for CMS to implement quality standards and accreditation. This competitive bidding process must not be an excuse to allow CMS to not implement the one tool that is an effective fraud deterrent.

XI. Comments Regarding "Establishing Payment Amounts for New DMEPOS (Gap-Filling)" – Proposed Section 414.210(g)

Changes to Gap filling should be placed in its own comment format and not included as part of this regulation. We agree with CMS that the use of deflation and inflation factors has always been flawed and a new system needs to be recommended and then formalized. 71 Fed Reg 25687. However, to be able to properly comment, CMS would need to develop a specific proposal upon which stakeholders can then respond.

XII. Comments Regarding "Administrative or Judicial Review" – Proposed Section 414.424

CMS proposes in section 414.424 that there is to be "no administrative or judicial review under this subpart of the following: . . . (2) awarding of contracts." Section 414.424(a), 71 FR at 25,702. In the preamble, CMS asserts that the Act bars such review. 71 FR at 25,683.

We are greatly concerned and strongly object to any suggestion that CMS intends to conduct itself, or through implementing contractors, what are likely to be multi-million dollar procurements without any opportunity for administrative or judicial oversight of the process. The fact is that the CBP is a procurement program by which CMS seeks to acquire the same types of commercial items that it acquires for itself pursuant to the FAR. Considering the number of procurements that are set aside each year by the General Accountability Office ("GAO") and the United States Court of Federal Claims based upon government error, it is inconceivable that CMS would even suggest such a secret and insulated process. That is a recipe for arbitrary and erroneous awards, if not a direct invitation for the perpetration of fraud. CMS should clarify that all contract awards and invitations to participate will be subject to the traditional review of procurements conducted by the government.

Regardless of whether it possesses the right to ignore the FAR and avoid judicial or administrative oversight, prudence and the obligation to maintain some sense of integrity in the procurement process that it is developing requires that CMS open the process up to protest review. The failure to do so invites disaster.

XIII. 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. Regardless of the timeline, we again implore CMS to publish the quality standards and require mandatory accreditation as soon as possible and prior to the introduction of competitive bidding.

XIV. Conclusion

We urge CMS to follow the lead of Congress by implementing Quality Standards and mandatory Accreditation immediately. We implore CMS to take their time in the implementation of Competitive Bidding. At the very least, we ask CMS to consider the provisions of the Hobson-Tanner bill which has over 120 sponsors currently, when considering changes to this regulation. Among other provisions, the bill would:

- Protect patients by requiring that "competitive bidding" not begin until quality standards are in place;
- Exempt smaller, rural areas (Metropolitan Statistical Areas with populations under 500,000);
- Allow all qualified providers to participate at the selected award price;
- Restore the rights of participating providers to administrative and judicial review;
- Exempt items and services unless savings of at least 10 percent can be demonstrated compared to the fee schedule in effect January 1, 2006;
- Protect beneficiary access to care by requiring CMS to conduct a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care;

Submitter : **Date: 06/30/2006**

Organization : **National Orthotic Manufacturers Association**

Category : **Device Industry**

Issue Areas/Comments

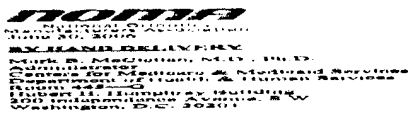
GENERAL

GENERAL

Attachment

CMS-1270-P-1212-Attach-1.PDF

ATTACHMENT TO # 1212



June 30, 2006

BY HAND DELIVERY

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

Dear Administrator McClellan:

The National Orthotic Manufacturers Association (NOMA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding the above-referenced proposed regulations, which establish the Medicare Part B DMEPOS Competitive Bidding Program.[1] As a trade association of manufacturers of therapeutic and rehabilitation products for individuals suffering from musculoskeletal diseases or injuries, including a variety of orthoses, NOMA is particularly concerned with the impact of the proposed regulations on beneficiaries' access to orthotic products. NOMA members include a number of manufacturers who are also Medicare Part B orthotic suppliers, including Orthofix/Breg, EBI/Biomet, and DJO Incorporated, each of which expects to participate in this new program. Other members manufacture orthotic products only and want to ensure that beneficiaries are able to obtain needed orthoses from the suppliers with whom they work.

NOMA urges CMS to refrain from competitively bidding orthotic products for the initial phase of the program. Under competitive bidding, Medicare will pay for DMEPOS items used by beneficiaries in the home based on bid amounts submitted by suppliers in competitive bidding areas (CBAs). It is therefore essential that suppliers be able to bid accurately and for CMS to be able to evaluate those bids accurately as well. Because of the large number of orthotic products and the many codes describing them, there is significant variation in the industry as to which codes are used to bill particular products. NOMA fears that, unless and until sufficient clarity as to coding is provided, orthotic suppliers will be unable to determine an appropriate bid for each HCPCS code. Similarly, it will be difficult, if not impossible, for the agency to evaluate these bid submissions properly. This will likely result in competitive bidding payment amounts for

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1 71 Fed. Reg. 25654 (May 1, 2006).

orthotics that are entirely irrational.

NOMA is also deeply concerned that the proposed definition of off-the-shelf (OTS) orthotics is overbroad and uses an inappropriate benchmark (*i.e.*, involvement of a certified orthotist) to determine whether a product may be competitively bid. Most critically, the proposed definition contradicts both the statutory definition of OTS orthotics and existing Federal law specifying which practitioners are qualified to perform fitting and adjustment services for certain orthotic products. CMS should not and must not finalize its proposal and should instead adopt the statutory definition.

Summary of NOMA's Recommendations

Below we provide recommendations for revisions to the proposals (with CMS comment areas noted in brackets):

(1) *OTS orthotics should be defined as required by the Medicare statute.* [Criteria for Item Selection]

(2) *CMS should ensure that suppliers with sufficient capacity can participate in the program, regardless of whether they are physically located in the CBA.* [Submission of Bids Under the Competitive Bidding Program]

(3) *If CMS includes OTS orthotics in the initial phase of the program, existing SADMERC policy groups should be used to categorize competitively bid products and CMS should allow single bids to be made on sub-groupings of orthotic products.* [Submission of Bids Under the Competitive Bidding Program]

(4) *CMS should evaluate each bidding supplier's compliance with financial and quality standards and accreditation status, allowing for an extended grace period for suppliers in industries, such as orthotics, in which accreditation is not the norm.* As urged in NOMA's comments on the draft quality standards (which were submitted under separate cover in fall of 2005), CMS should focus on the quality of the products furnished to beneficiaries. These standards must be in place prior to the launch of competitive bidding and, more critically, CMS must give suppliers time to come into compliance and become accredited. [Conditions for Awarding Contracts]

(5) *CMS should ensure that competitive bidding payment amounts reasonably reflect actual bids.* [Determining Single Payment Amounts for Individual Items]

1. Define OTS Orthotics As Required By the Medicare Statute

[Criteria For Item Selection]

OTS orthotics are among the types of DMEPOS products that may be competitively bid under the statutory provisions for the competitive bidding program.[2] CMS's proposed definition of OTS orthotics would dramatically and impermissibly expand upon the statutory definition so that it includes all orthotics that do not require assistance of a certified orthotist. CMS should not

[2] 42 U.S.C. § 1395w-3(a)(2)(C).

and must not depart from the statutory definition in this manner. The proposal is particularly troublesome because it would also contravene an existing statutory provision governing Medicare payment for certain custom-fabricated orthotics. NOMA registers its strong objections to this proposal with this comment letter. We believe that CMS must implement the definition in line with the criteria already provided by Congress. To determine whether a product is off-the-shelf, the congressional approach uses task-related criteria, such as whether and what level of self-adjustment is needed to fit the product to the patient. Tying the definition of OTS orthotics to an amorphous standard—involvement of a certified orthotist—as CMS proposes to do here does not bring clarity to which products should be included. There is no Federal definition of certified orthotist, nor of the orthotist's scope of practice. At the state level, such definitions either do not exist at all or vary widely between states. Thus, the proposal does not bring CMS closer to a process that will lead to an appropriate list of products that are off-the-shelf as defined by the statute. NOMA strongly urges that CMS implement the clearly stated statutory definition in its regulation and not try to add words that change the original meaning and intent of the statute. We would be pleased to work with CMS to help determine which HCPCS codes describe OTS products under that definition and which of those, if any, should be competitively bid.

CMS Must Abide By Existing Medicare Requirements Regarding Qualified Practitioners

The Medicare statute defines OTS orthotics as those that "require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual."[3] Proposed 42 C.F.R § 414.402 uses this language. However, in the discussions in the Notice of Proposed Rulemaking, CMS significantly expands upon and departs from this language. There, the agency hinges the definition of OTS orthotics on whether adjustments requiring the expertise of a certified orthotist would be needed to fit the product to the patient. Specifically, the agency proposes to define OTS orthotics as those that both: (1) can be adjusted by a beneficiary, caretaker, or orthotic supplier without the assistance of an orthotist certified by the American Board for Certification in Orthotics and Prosthetics, Inc. ("ABC") or the Board for Orthotist/Prosthetist Certification ("BOC"); and (2) do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual, which, CMS states, are activities that can only be performed by certified orthotists.[4]

NOMA strongly urges CMS not to finalize this sub-regulatory definition. We believe that it is inconsistent with existing orthotics payment provisions in the Medicare statute (the Qualified Practitioner Rule).[5] The Medicare statute already identifies a list of practitioners

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3 *See* 42 U.S.C. § 1395w-3(a)(2)(C).

4 71 Fed. Reg. at 25669-70.

5 There are special Medicare payment rules for certain custom-fabricated orthotics, which include a definition of "qualified practitioners" that possess expertise to furnish such products to beneficiaries. Under these rules, Medicare payment for an item on a list of certain custom-fabricated orthotics is only to be made if it is (1) furnished by a qualified practitioner; and (2) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the HHS Secretary determines appropriate. "Qualified practitioner" is defined to include physicians, qualified physical and occupational therapists, licensed orthotists (in states requiring orthotist licensure), and other individuals who are specially trained or educated in the area and certified by ABC, BOC or other approved credentialing programs (in states

qualified to furnish certain custom-fabricated orthotic products to beneficiaries. This list includes physicians and qualified physical and occupational therapists, in addition to certified orthotists. CMS is not at liberty to cherry-pick from this list and define OTS orthotics as those not requiring involvement of a certified orthotist. Congress has already determined which practitioners possess the expertise to furnish orthotic fitting and adjustment services for certain orthotic products.

Fundamental principles of statutory interpretation require that "effect must be given, if possible, to every word, clause and sentence of a statute," and that "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.[6] The Qualified Practitioner Rule clearly designates several types of practitioners (not just ABC- or BOC-certified orthotists) as qualified to trim, bend, mold, assemble, or customize certain orthotics to fit them to an individual. Furthermore, although the particular sub-set of custom-fabricated orthotics to which the Qualified Practitioner Rule applies has yet to be established, the statute clearly excludes OTS orthotics and thus serves as congressional recognition that these practitioners are capable of performing services for non-OTS orthotics. In light of this statutory language, CMS may not include only ABC- and BOC-certified orthotists as practitioners with the expertise to fit non-OTS orthotics.[7] Finally, we note that CMS is required by statute to promulgate regulations to implement the Qualified Practitioner Rule. It is improper to circumvent this process by partially implementing the Rule through the competitive bidding regulations.

CMS's Definition of OTS Orthotics Must Not Exceed the Congressional Mandate

NOMA has yet another significant concern with the proposed definition of OTS orthotics: it exceeds the congressional mandate as to which products are to be included in competitive bidding. The statutory definition specifically demarcates which orthotics may be competitively bid by limiting it to products that do not require much, if any, adjustment in order to be used appropriately and that do not require fitting and adjustment expertise in order to be fit to the patient. CMS's proposed definition linking OTS orthotics to the work of a certified orthotist would dramatically *expand* the list of products that are considered OTS and that are subject to competitive bidding. Such an approach may also result in quality of care issues for Medicare beneficiaries. This is because products furnished through the competitive bidding process that require more than minimal self-adjustment may result in a poor fit, product ineffectiveness or even potential injury.

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without orthotist licensure requirements). *See* 42 U.S.C. § 1395m(h)(1)(F) (as added by Section 427 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA")).

6 NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:06, 181-86 (6th ed. 2000); *See also Washington Hosp. Center v. Bowen,* 795 F.2d 139 (D.C. Cir. 1986) (concluding that, in order to fulfill "our obligation to construe a statute so as 'to give effect, if possible, to every word Congress uses,'" it must strike down the Secretary's regulation requiring hospitals to wait until completion of the cost year before appealing prospective payment amounts to the Provider Reimbursement Review Board because the regulation ignored the provision of the Medicare statute permitting such appeals prior to filing a cost report).

7 The Qualified Practitioner Rule is only intended only to require involvement of qualified practitioners for a small sub-set of custom-fabricated orthotics. For purposes of the competitive bidding definition of OTS orthotics, CMS should recognize that it serves as Congress' recognition that other practitioners have the experience to adjust and fit non-OTS orthotics.

CMS's proposal would set aside the task-related criteria used to define OTS orthotics in the statute (*i.e.*, minimal self-adjustment for appropriate use and no expertise in trimming, bending, molding, assembling, or customizing to fit to the individual) and replace them with an entirely different criterion—the need for a certified orthotist's involvement. The landmark U.S. Supreme Court case concerning agency interpretation of congressional language explicitly precludes agencies from exceeding congressional mandates, as would the proposal here. In that case, the court stated: "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[8] Hinging the determination as to whether an item is off-the-shelf on involvement of a certified orthotist is different from and inconsistent with basing the determination on whether certain tasks must be performed. The stark difference in these criteria is evidenced by the fact that CMS's proposal would result in a much broader list of orthotic products being competitively bid than Congress intended. Furthermore, if Congress had intended to use the need for an orthotists as the determinative factor, it would have done so. The Qualified Provider Rule illustrates that Congress does not shy away from referring to the need for practitioner expertise when it is appropriate.

NOMA urges CMS not to finalize its proposal in the text of the Notice of Proposed Rulemaking. Instead, we recommend that CMS adopt the proposed regulation because it closely mirrors the statutory language. If, despite these serious misgivings, CMS does seek to enhance the definition, the agency must recognize all other practitioners with expertise to provide orthotic products who are currently recognized under Federal law. Under this alternate approach, any orthotic that requires the assistance of a qualified practitioner (as defined under the Qualified Provider Rule) would not be considered OTS.

In addition, NOMA strongly encourages CMS to consult stakeholders as to which orthotics codes should be considered off-the-shelf for purposes of competitive bidding. We would be pleased to provide a list of OTS orthotics to the agency for its consideration upon request.

2. Finalize Proposal Not to Require Suppliers to be Physically Located in CBAs

[Submission of Bids Under the Competitive Bidding Program]

NOMA applauds CMS for its recognition that a supplier need not be physically located in a CBA in order to service it well. Location is not a precise gauge for a supplier's capability to provide orthotic products to beneficiaries a given CBA. Several NOMA members are large capacity suppliers that provide a significant volume of orthotic products to beneficiaries. NOMA asserts that such large capacity suppliers are essential to the success of competitive bidding; without them, there will likely be a shortage or total lack of certain competitively bid items in the CBAs.

Many large capacity suppliers, including NOMA members, offer services nationwide, but

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[8] *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984); *see also* NORMAN J. SINGER, STATUTES AND STATUTORY CONSTRUCTION, § 46:01, 121-22 (6th ed. 2000) (stating that "[t]here is no safer nor better settled canon of interpretation that that when language is clear and unambiguous it must be held to mean what it plainly expresses").

operate through central headquarters. NOMA members who function as Medicare suppliers use centralized operations (at which billing, patient contact, complaint and other matters are addressed), with sales representatives operating in locations throughout the country. Often, based on a prescription, orthotic products are shipped from the manufacturing plant or headquarters of a supplier to a patient's home or to a physician's office, the location at which they are provided to the patient. Under this longstanding physician's office model, the supplier does not maintain physical locations in all 50 states, but still ably serves locations across the country.

CMS has long recognized through its Medicare supplier standards that suppliers are not and need not be physically located in every state or region. Under the Medicare statute, all suppliers furnishing medical equipment and supplies to beneficiaries must comply with supplier standards in order to obtain a supplier number. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[9] Through Medicare Supplier Standard #7, CMS implements this requirement and recognizes that some suppliers will be operating in various geographic areas but that they can be organized using a centralized location.[10] NOMA believes that centralized operations are beneficial in that they can enhance and streamline suppliers' interactions with Medicare contractors and enable them to provide consistent, high quality services to beneficiaries.

NOMA supports CMS's proposal to use a supplier's past business to beneficiaries in the CBA (as well as any detailed business plan for expansion) to gauge whether a supplier is willing and able to serve beneficiaries in the CBA. We believe that the draft Form B (Bidding Sheet) is an appropriate method for collecting this information.[11] On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if they plan to expand their business during the contract term.[12] These are accurate measures of supplier capacity, and NOMA therefore asks that the proposal be finalized as written.

3. Use Existing SADMERC Policy Groups For Competitive Bidding Product Categories and Allow Single Bids To Be Made on Sub-Groupings of Orthotic Products

[Submission of Bids Under the Competitive Bidding Program]

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9 42 U.S.C. § 1395m(j).

10 *See* 42 C.F.R. § 424.57(c)(7). Supplier Standard #7 states that a supplier must certify that it: "Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location."

11 71 Fed. Reg. at 25676.

12 *See* http://www.cms.hhs.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterbyDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS063052.

As stated above, NOMA believes that OTS orthotics should be excluded from the initial phase of competitive bidding until the logistical difficulties concerning the orthotics code-set can be resolved. There are a significant number of HCPCS codes and considerable variation in the industry as to how the codes are interpreted. Perhaps more critically, most suppliers are unlikely to have a product for each code. The NOMA members that serve as Medicare suppliers are among the largest suppliers of orthotic products in the U.S., and even they believe that they may not have a product for each code in a policy group. If, despite these concerns, CMS decides to proceed with inclusion of OTS products in 2007, NOMA recommends that existing SADMERC policy groups be used to categorize competitively bid products. Furthermore, we suggest that CMS permit suppliers to submit single bids on sub-groupings of orthotic products within the product categories.

CMS proposes to group products into product categories (defined as groups of similar items used in the treatment of a related medical condition) for purposes of competitive bidding. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category, with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[13] Existing SADMERC policy groups are the logical choice for the product categories for competitive bidding. Some of the SADMERC policy groups for orthotics classify HCPCS codes according to the medical policy to which they belong (*e.g.*, knee-ankle-foot orthoses), making them rational groupings from a clinical perspective. Other policy groups for orthotics reflect different areas of the body for which the products may be used (*e.g.*, lumbar-sacral orthoses and thoracic-lumbar-sacral orthoses). These groupings provide ready categories, with sound clinical bases and with which both CMS and suppliers are familiar, for use in competitive bidding.

NOMA further suggests that CMS divide each OTS product category into sub-groupings that represent families of similar codes that would be reflective of the multiple functionalities of the various products, as well as the multitude of coding, coverage and reimbursement complexities necessary to support providing products to beneficiaries in the CBA. As an illustration, select, small number ankle brace codes with the same clinical function could be grouped together. Rather than submitting a separate bid for each HCPCS code within such a product category, the supplier would offer a single bid amount for this sub-grouping which would be reflective of the costs needed to support providing products in this sub-grouping to beneficiaries in the CBA. This approach would ensure that existing suppliers, that may not have products to fit the full panoply of codes, can participate in the program.

Two changes need to be made to the proposed regulations to adopt NOMA's recommendation. First, proposed 42 C.F.R. § 414.412 would need to be revised so that subsection (c) reads (with proposed language in italics):

> Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the

[13] 71 Fed. Reg. at 25672-73.

request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines that there is good cause to align items differently for a particular competitive bidding program*.

Second, proposed 42 C.F.R. § 414.412 would need to be revised so that subsection (d) reads:

> Suppliers must submit a separate bid for every item included in each product category that they are seeking to furnish under a competitive bidding program, *unless CMS permits a bid for a sub-category for bidding purposes.*

4. Evaluate Bidding Suppliers' Compliance with Financial and Quality Standards and Accreditation Status, Allowing For an Extended Grace Period for Orthotics Suppliers

[Conditions For Awarding Contracts]

NOMA has been a longstanding advocate for stringent quality standards for DMEPOS suppliers, and we submitted lengthy comments regarding the proposed standards in fall of 2005. Maintaining quality while achieving savings for the Medicare fisc is the primary goal of competitive bidding. NOMA applauds CMS for proposing that suppliers be required to meet basic eligibility requirements (*e.g.*, Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards eligibility requirements in order to participate in competitive bidding.

NOMA strongly believes that the best indicator that a product is of high quality is the certification and compliance status of the product's manufacturer. NOMA therefore supports CMS's proposal in the draft quality standards to include manufacturer compliance with mandatory FDA good manufacturing practices and ISO standards as a benchmark to ensure quality products are provided to Medicare beneficiaries.[14] NOMA strongly believes that the quality standards must be finalized and implemented prior to the launch of competitive bidding, as is planned. Most critically, CMS must give suppliers sufficient time to develop the policies and procedures needed to comply with the standards and become accredited.

As a practical matter, for this initial phase of competitive bidding, a large number of suppliers may be in the process of obtaining accreditation and coming into compliance with the quality standards. We believe that CMS's proposal to permit a grace period for compliance with the quality standards is an appropriate compromise for the initial phase of the program.[15] In particular, an extended grace period should be afforded to suppliers in industries like orthotics in which accreditation is not currently the norm. Suppliers in such industries lack experience with accreditation, and it will take additional time for them to become accredited. A grace period is also essential for these entities as they will need to come into compliance with the final quality

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[14] All NOMA members are FDA registered, are compliant with FDA good manufacturing practices and, significantly, are ISO certified.

[15] *See* 71 Fed. Reg. at 25675.

standards that have not yet been released. NOMA strongly supports an extended grace period for orthotics suppliers.

5. Ensure That Competitive Bidding Payment Amounts Reasonably Reflect Actual Bids

[Determining Single Payment Amounts for Individual Items]

NOMA recommends that CMS adopt the competitive bidding payment methodology used in the demonstration programs, in lieu of the formula proposed, for setting payment rates for competitively bid items. We are concerned that the proposed formula may not reasonably reflect actual bid amounts. CMS proposes to use the median of winning suppliers' bids as the payment amount—an approach that will always result in a rate that is lower than the bid prices of half of the winning bidders. There is a risk that, if payment rates are far below bid prices, suppliers may not be able to continue to service beneficiaries in the CBAs. In order to raise the chances that they will be selected to participate in competitive bidding, suppliers are likely to submit bids at or near their margins. Thus, if CMS sets the payment rates at the median of winning bidders' bid prices, up to half of the winning bidders may consider these rates unacceptable and may not be able to continue to provide products to beneficiaries in those areas.

The adjustment factor approach used in the demonstration projects does not suffer from this flaw and would lead to reasonable payment rates.[16] As CMS describes it in the Notice of Proposed Rulemaking, under this approach, CMS would calculate payment rates by adjusting each winning supplier's overall bids for a product category up to the pivotal bid, thereby ensuring that the overall payment amount that contract suppliers receive is at least as much as their bid prices. The advantage of this approach is that suppliers may be less likely to leave the Medicare program because it provides assurances that payment rates will be at least adequate. We therefore ask that this formula be used instead of the median approach proposed.

Thank you for your attention to these comments. Should you have any questions regarding NOMA's positions or concerns, we can be reached through our outside health care regulatory counsel, Stuart Kurlander of Latham & Watkins LLP, at (202) 637-2169, or me at (469) 742-2840.

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[16] *See* 71 Fed. Reg. at 25679-80.

Truly yours,

Rhonda Fellows/RB

Rhonda Fellows
President
National Orthotic Manufacturers Association

Cc: NOMA Members

Submitter : Mrs. Phyllis Peterson **Date:** 06/30/2006

Organization : Ocoee Physical Therapy, Inc.

Category : Physical Therapist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The bidding process seems to just put everything up for grabs...Forget quality, forget needs, forget what might be best. I'm a PT, CHT and basically evaluate daily as I treat patients, specifically traumatic hand patients. Conditions both improve or deteriate rapidly and frequently require adjustments or complete changes in splinting. Therapists must respond immediately to change in status if recovery is to maximized. I have no problem with Medicare setting a realistic price for a prefabricated item assuming I can obtain it for that amount. We have always past our ordered items on to patients at cost plus shipping. I am not looking to have another stream of income. I'm looking to provide care to my patients that is needed and appropriate. I can't tell you the number of times that patients have tried to obtain the 'right devices' on their own at DMEPOS places and have ended up with braces or orthosis that do not fit or were detrimental to their progress because all of the disease elements were not considered. It becomes more expensive in the end. Please reconsider another option. This one is not without problems and from the therapeutic stand point, is not practical. I see bracing and splinting as being quite different from wheelchair items and such. Maybe the durable medical equipment should be broken down into categories. Thanks for considering my thoughts.

Submitter : **Dr. Susan Love** **Date: 06/30/2006**

Organization : **Dr. Susan Love**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

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).

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. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Susan G. Love, DPM

Submitter : **Date: 06/30/2006**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Proposed Methodology in for selecting the 10 MSAs for 2007

I would like to comment specifically on the methodology that is being used for selecting the initial MSA s that will commence in 2007. I am provider in the Miami/Fort Lauderdale MSA that is under consideration. Much like the cities, New York, Chicago, and Los Angeles, that have been excluded from the initial rollout of the DRA, the Miami/Fort Lauderdale MSA should also be excluded due to unique obstacles relevant in the demographic area that will prevent a smooth and difficult implementation, especially without the prior knowledge and understanding gathered from initial implementation in other MSA s first. These obstacles include:

1.) The prevalence of Natural disasters such as Hurricanes, which could turn into a logistical nightmare and place an undue burden of Fire and Police, should contracted suppliers is directly affected.
2.) Cultural Competency. The majority of the demographic population has English as their second language, thus placing an unnecessary burden on CMS to provide materials that will clearly explain the DRA.
3.) The prevalence of snow birds in the beneficiary population. Specifically Medicare enrollees the travel back and forth from South Florida to areas in the North especially New York and Chicago where NPRM will not exist. Will CMS reimburse two different fees two various providers and how will that effect the 36 month cap.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

I feel that is extremely vital and imperative that only qualified suppliers be allowed to submit bids in their respective MSA. Qualified meaning accreditation status must be approved prior to being allowed to submit a bid. CMS must have systems in place that will allow them to fully evaluate and ensure that all necessary qualifications (such as those stated on page 107) have been met by providers submitting bids. An example demonstrating the importance of having only qualified suppliers bid is a similar project that was attempted for Florida Medicaid in 2002. The state of Florida in 2002 performed a competitive bidding proposal for certain durable medical equipment for the Medicaid program. The state did not have systems in place to ensure that only qualified suppliers bid, thus granting the intent to award to a supplier(who also happen to be the lowest price bidder by a large margin) who did not meet the baseline standards. Thus the original award was revoked and caused a delay in implementation. The delay eventually led to a complete collapse of the project and large waste of taxpayer money and time. So as you can see are factual precedents demonstrating the importance of ensuring that CMS have systems in place to ensure only qualified suppliers meeting the necessary criteria before being allowed to bid. This failed project also demonstrated the importance of not allowing information from unqualified bidders in calculating the single payment amount(the winning bid amount). In my previous example of the 2002 Florida Medicaid project, the original winning provider whom later did not meet the minimum quality standards, was also the lowest bidder by a large margin. The lowball bid offered by the disqualified provider was not realistic and thus exaggerated the potential savings. Low ball bidders are only concerned in the bidding process with price. And that type of motivation in a health care arena will lead to possible dire results such as death or a lower quality of life for those already vulnerable. In order to realistically meet those low prices, services and quality must be reduced. Thus outlier bids should also be eliminated when arriving at the single payment amount.

Terms of Contracts

Terms of Contracts

I feel that is extremely vital and imperative that only qualified suppliers be allowed to submit bids in their respective MSA. Qualified meaning accreditation status must be approved prior to being allowed to submit a bid. CMS must have systems in place that will allow them to fully evaluate and ensure that all necessary qualifications, such as those stated in Terms of Contract Section 6.Information Collection from Supplier have been met by providers submitting bids. An example demonstrating the importance of having only qualified suppliers bid is a similar project that was attempted for Florida Medicaid in 2002. The state of Florida in 2002 performed a competitive bidding proposal for certain durable medical equipment for the Medicaid program. The state did not have systems in place to ensure that only qualified suppliers bid, thus granting the intent to award to a supplier(who also happen to be the lowest price bidder by a large margin) who did not meet the baseline standards. Thus the original award was revoked and caused a delay in implementation. The delay eventually led to a complete collapse of the project and large waste of taxpayer money and time. So as you can see are factual precedents demonstrating the importance of ensuring that CMS have systems in place to ensure only qualified suppliers meeting the necessary criteria before being allowed to bid. This failed project also demonstrated the importance of not allowing information from unqualified bidders in calculating the single payment amount(the winning bid amount). In my previous example of the 2002 Florida Medicaid project, the original winning provider whom later did not meet the minimum quality standards, was also the lowest bidder by a large margin. The lowball bid offered by the disqualified provider was not realistic and thus exaggerated the potential savings. Low ball bidders are only concerned in the bidding process with price. And that type of motivation in a health care arena will lead to possible dire results such as death or a lower quality of life for those already vulnerable. In order to realistically meet those low prices, services and quality must be reduced. Thus outlier bids should also be eliminated when arriving at the single payment amount.

Submitter : Mr. Chris Kane **Date:** 06/30/2006

Organization : Pacific Pulmonary Services

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1216-Attach-1.PDF

ATTACHMENT TO #1216

Pacific Pulmonary Services

June 30, 2006

By Electronic Submission

Department of Health and Human Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Sirs and Mesdames;

Pacific Pulmonary Services/Med Mart (Pacific Pulmonary Services) is pleased to provide the following comments in response to the Notice of Proposed Rule Making ("NPRM") published by the Centers for Medicare and Medicaid Services (CMS) in the Federal Register on May 1, 2006 (CMS-1270-P)[1].

Pacific Pulmonary Services (PPS) is a home oxygen, oxygen equipment, and inhalation medication pharmacy DMEPOS provider with more than twelve years' experience in providing the Medicare program and its beneficiaries with superior products and personal in-home services. The company serves many thousands of Medicare beneficiaries from over one hundred and twenty local field service centers located in fifteen states. Its DMEPOS service centers are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Pacific Pulmonary Services has adopted the practice standards promulgated by JCAHO since 1994 and has established best practice guidelines consistent with those respected by the wider health care community. These practice standards are focused on improving patient outcomes and are implemented to ensure the timely delivery of goods and services for self-administration by the chronically ill in the home setting.

The majority of the Medicare beneficiaries that we serve suffer from either chronic obstructive pulmonary disease (COPD), which is the fourth leading cause of death in the United States, or congestive heart failure (CHF). Providing oxygen, oxygen equipment, and quality patient care in the home setting to patients who suffer from COPD is the primary means of controlling and alleviating the debilitating symptoms of this chronic disease in cost-effective manner.

[1] "Proposed Rules," Federal Register, Vol. 71, No. 83; Monday, May 1, 2006, 25654–25704 [06–3982].

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Summary of Key Points:

Pacific Pulmonary Services respectfully requests that CMS consider the following comments before finalizing the proposed rule for competitive acquisition provisions of Section 1847(2) (A) of the Social Security Act:

Pricing & Capacity

- Single Payment Pricing Methodology: Adopt and implement the pricing methodology that was tested and proven effective in the three demonstration rounds which established the single payment amount at the level of the pivotal bidder's composite bid.

- Supplier Capacity: To protect beneficiary access, develop and implement a methodology that independently verifies a supplier's ability to meet or exceed the supplier's self-determined capacity levels within a Competitive Bid Area (CBA), or multiple CBAs, *in advance of accepting a supplier's bid for any DMEPOS product category*. This methodology, at minimum, should incorporate a financial means test, as described below under *Financial Standards.*

- Market Demand: To protect beneficiary access, assume market demand of at least one hundred and ten percent (110%) for each of the initial 10 CBAs in 2007 to protect against disruption to beneficiary access caused by industry consolidation, supplier business failures and / or natural disasters.

- Rebate Proposal: Withdraw the ill-advised rebate program proposal, which is contrary to all established CMS and OIG guidance relating to financial interactions with Medicare beneficiaries and poses significant risks of inducing beneficiaries to select a provider solely on the basis of financial considerations, is difficult for CMS to oversee, and will likely spawn beneficiary-driven fraud that will increase program costs.

- Authority to Apply CBA Single Payment Levels to Other Areas: CMS' authority to extend competitive acquisition single payment levels beyond a defined CBA in lieu of applying inherently reasonable pricing should, if used at all, be accompanied by the same protocols and procedures as are used to ensure beneficiary access and fair pricing as in the final rule, *Medicare Program: Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other than Physician Services).*

- Gap-Filling Methodology: In lieu of applying the current gap-filling methodology, we suggest CMS's authority to create or adjust payment determinations for new or current HCPC codes be limited to the provisions under the final rule, *Medicare Program: Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other than Physician Services).*

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Standards & Accreditation

- Supplier Standards: PPS supports the implementation of quality standards for DMEPOS and recommends that CMS require documented compliance with all DMEPOS quality standards *as a prerequisite for participation* under the competitive acquisition provision of section 1847(a)(2)(A) of the Social Security Act.

- Accreditation: CMS should require that DMEPOS suppliers be accredited by, and in good standing with, a recognized independent accreditation organization such as JCAHO, Accreditation Commission for Health Care (ACHC), and the Community Health Accreditation Program (CHAP). *in advance of any participation* under the competitive acquisition provision of section 1847(a)(2) (A) of the Social Security Act

- Financial Standards: Establish financial standards requiring supplier bidders to provide unqualified, annual audited financial statements and to demonstrate a level of capitalization commensurate with the scope of their bid.

Geography & Implementation

- Identification of the Initial Ten MSAs in 2007: CMS should publish the initial ten MSAs for 2007 in conjunction with the methodology and supporting beneficiary census and utilization data employed to determine the MSAs in the form of an interim final rule in 2006 to allow for proper supplier and provider notice and comment.

- Implementation of Initial Ten MSAs in 2007: CMS should consider a staged implementation of the competitive acquisition program in the initial ten MSAs to ensure participating suppliers are accredited and in full compliance with the DMEPOS quality standards in advance of participation in the bidding process.

Product Requirements

- Product Categories: CMS should publish the DMEPOS items it intends to include in the initial ten markets in 2007 as well as clearly defined categories by HCPCS codes in the form of an interim final rule in 2006 to allow for proper supplier notice and comment.

- Product Category Definitions: In light of its requirement that suppliers bid on all of the HCPCS codes contained in a product category, CMS should define the product categories narrowly to ensure they reflect same or similar HCPCS codes grouped on the basis of function, cost of acquisition and cost of service.

- Physician Authorization / Treating Practitioner Brand Prescribing: CMS should withdraw its proposal to require that suppliers allow physicians and medical practitioners

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to prescribe a specific brand of DMEPOS equipment to facilitate cost savings through volume buying and inventory efficiency, and to reduce costs normally associated with direct-to-consumer pull through advertising of more expensive brands.

Contracts

- Beneficiary Transfer & Equipment Replacement: To ameliorate the impact of the transfer of equipment ownership provisions contained in the Deficit Reduction Act of 2005 (DRA) on contract suppliers, CMS should initiate a new period of continuous use whenever a beneficiary transitions to new a contracted supplier.

- Equipment Repair: CMS should delineate separate contract bid amounts for equipment that has transitioned ownership from the supplier to the patient. These bid amounts should be separate and discrete from the repair or replacement of provider-owned equipment.

- Change of Ownership: PPS supports CMS's proposed requirement that a successor entity must be in full compliance with all the requirements of the competitive acquisition and relevant government programs prior to merging with or acquiring a contract supplier's business. However, we question CMS's authority to determine whether there is a need for the successor entity as a contract supplier and the requirement that the successor entity is legally liable for non-fulfilled obligations of the original contract supplier.

A. Pacific Pulmonary Services General Comment Regarding The NPRM for DMEPOS Competitive Acquisition.

The information contained in the NPRM for DMEPOS competitive acquisition is incomplete and cannot serve as the basis for comprehensive notice and comment by DMEPOS suppliers seeking to participate in the development and implementation of the competitive acquisition program. CMS should address the missing or incomplete program specifications in the form of a complete interim final rule with a full sixty day notice and comment period prior to issuing a final rule for the competitive acquisition program in 2006.

Specifically, the NPRM fails to address the following fundamental program details:

- Interaction of the competitive acquisition program and DMEPOS provisions contained in the Deficit Reduction Act of 2005.
- Supplier accreditation requirements, timing and interaction with supplier quality standards.
- Impact and costs associated with final supplier quality standards.
- Initial 10 MSAs that will comprise the Competitive Bid Areas (CBAs) in 2007.
- Defined product categories and product weighting.

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At this time, suppliers are limited to providing notice and comment solely on individual elements of the program, unfairly handicapping our ability to understand the composition and function of the competitive acquisition program as a whole and its interaction with other service modalities. At minimum, CMS should issue a comprehensive interim final rule for the competitive acquisition program in 2006 that is inclusive of all germane program details, complete with a full sixty day notice and comment period, to allow for effective stakeholder understanding and input prior to implementation of the program.

B. Pacific Pulmonary Services Comments on Specific Program Recommendations.

Section II H: Determining Single Payment Amounts for Individual Items. CMS proposes applying a new methodology to set the single payment amount that would use the median of the contract suppliers' bids at or below the pivotal bid for a given CBA. This is a departure from the methodology that was applied in the demonstration markets in Polk County, Florida and San Antonio, Texas from 1999-2002. This untested method for calculating the single payment amount is flawed and will result in a number of potentially fatal market distortions that are inconsistent with the intent of the competitive acquisition program. Specifically, applying this methodology will result, by definition, in 50% of the winning suppliers participating at a single payment level lower than their "best price" bid, a result wholly inconsistent with the anticipated outcome of any truly competitive bidding process. In addition to discouraging providers from providing a meaningful and realistic "best price" bid, the method fails to provide safeguards against irrationally low bids by suppliers that are unable to serve the entire market at the bid price. The outcome is an artificial payment level, resulting in inaccurately high or low single payment levels that do not optimize the competitive process, and/or needless and preventable market disruption.

PPS recommends that CMS should adopt and implement for the competitive acquisition program the pricing methodology that was tested and proven effective in the three demonstration rounds that established the single payment amount at the level of the pivotal bidder's composite bid. This method resulted in significant program savings, competitive market pricing and supplier capacity rationalization while protecting against unsustainable bidding activity.

Section II G. 4a: Market Demand and Supplier Capacity. Market Demand: PPS endorses CMS' proposed methodology to determine the expected market demand by examining two years of trended, monthly beneficiary claims utilization data in conjunction with estimates on the growth of new fee-for-service Medicare enrollees coming into a competitive bidding area. We expect that this method will result in reasonably accurate, objective estimates of current and future market demand in the majority of CBAs. However, we urge that CMS exercise considerable caution in attempting to "fine-tune" the balance between the estimated market demand and estimated supplier capacity, particularly since there are inadequate safeguards in the NPRM to validate a supplier's self-determined capacity to serve a CBA. To protect against an outcome that mismatches market demand and supplier capacity, CMS should assume market

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demand of at least one hundred and ten percent (110%) for each of the initial 10 CBAs in 2007. Such a provision would help mitigate disruptions resulting from unanticipated events such as supplier business failures, miscalculations in the initial bid process and/or natural disasters and ensure that timely and convenient beneficiary access to DMEPOS is maintained.

Section II G. 4a: Market Demand and Supplier Capacity. Supplier Capacity: As stated above, CMS should protect against a supplier's inadvertent or intentional overstatement of its capacity to serve a CBA so that there is no harmful and unsustainably low distortion of both the number of "winning" suppliers needed to meet the calculated market demand in a CBA and the single payment amount. CMS should develop and implement a more robust methodology to independently verify a supplier's ability to meet or exceed their self-determined capacity levels within a CBA before accepting a supplier's bid for any DMEPOS product category. This methodology should at a minimum incorporate an objective financial means test, as described in detail below under *Financial Standards.*

Section II G. 2: Rebate Proposal. PPS respectfully suggests that CMS's proposal to permit suppliers to pay cash rebates to beneficiaries is ill conceived and should be eliminated. There are few tenets more firmly entrenched in Medicare law than the concept that a Medicare beneficiary should not be personally enriched when the government is required to pay for a health care service, yet this is essentially the result of the proposed rebate.

Potentially abusive beneficiary-level inducements having the potential for increasing utilization or "steering" prescribers or beneficiaries to a particular product have long been proscribed by CMS and by the Office of the Inspector General ("OIG"). Consider, for example, the August 2002 Special Advisory Bulletin, *Offering Gifts and Inducements to Beneficiaries,* advising providers that:

> *Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services.*

Consistent with this advice, OIG advisory opinions have prohibited co-payment subsidies for drugs out of concern that prescribers and beneficiaries will 'steer' utilization to the product that reduces the beneficiary's financial burden,[2] and suppliers are precluded from offering life-saving bicycle helmets to beneficiary hemophiliac children,[3] even when it is undisputed that helmets reduce the chance of an intracranial bleed and thus reduce overall program costs. Moreover, recent guidance from CMS and the OIG regarding pharmaceutical patient assistance programs under Medicare Part D seeks to eliminate any direct or indirect incentive to

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2 See, OIG Advisory Opinion 02-13.

3 See, OIG Advisory Opinion 02-14.

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beneficiaries that could potentially increase costs to the program, could steer beneficiaries to a particular supplier, or is potentially anticompetitive.[4]

It is difficult to imagine any supplier-to-beneficiary rebate program that fails to increase costs to Medicare, steer utilization to particular products and suppliers, and result in behavior that is anticompetitive, or all of the above. One need only consider the effect that direct to consumer rebates and coupon programs have on drug utilization in order to imagine the long-term impact of cash rebates to beneficiaries for DMEPOS, even if the rebates are not pre-advertised. Under the proposed rebate program, beneficiaries have a conspicuous financial incentive to over utilize certain DMEPOS, particularly where the rebate exceeds the amount of the co-payment or the beneficiary qualifies for a hardship waiver. "Use more lancets, supplement your Social Security income" scarcely seems to be the message Congress intended to send with competitive bidding, yet it is the logical result of the proposed program. Even where the beneficiary makes a co-payment that is greater than the rebate, the program will have perverse incentives such as lesser out of pocket cost for a more expensive DMEPOS item having a rebate, when compared with a less expensive counterpart for which the beneficiary will not receive a rebate. As soon as these perverse incentives are realized by physicians and beneficiary advocates – and they will be -- utilization in that CBA will be driven toward the items that are more expensive for the program, but less expensive for the beneficiary. Further, for DMEPOS supplies that are sold by retailers that do not typically provide capped rental equipment or in-home service, the rebate proposal will also have the effect of allowing retail store DMEPOS suppliers to "cherry pick" that portion of the DMEPOS business that is least costly to provide, driving up the costs of providing full-line services without any comparable savings to the program.

We respectfully submit that the rebate proposal presents a stunning departure from Congress's goal of achieving savings for the Medicare Trust. The costs of administering the rebate program and processing thousands of monthly rebate checks in small amounts to numerous beneficiaries are staggering for the supplier and will directly or indirectly be passed through to the program. In addition, CMS's task of monitoring potentially fraudulent or abusive pricing anomalies is also extensive. While we appreciate that CMS desires to capture the benefits of an 'underbid' single payment amount, we respectfully recommend that any added benefits passed through to beneficiaries be strictly limited to specifically-bid extra healthcare services (similar to the extra services that Medicare HMO plans may offer to beneficiaries) or to the statutory exception for 'remuneration' under the antikickback law, e.g., preventive health care benefits within the meaning of §1128A(i)(6) or similar health care screening designed to reduce future program costs. *See,* 42 C.F.R. 1003.101.

Section II C. 5: Authority to Adjust Payments in Other Areas. Under 1834(a)(1)(F)(ii), found at section 302 of the MMA, CMS is permitted to use payment information obtained from the competitive bidding process to adjust payments for products that

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[4] See, Special Advisory Bulletin, *Patient Assistance Programs for Medicare Part D Enrollees,* November 2005.

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are dispensed outside of the CBA in lieu of its authority to adjust pricing under the final rule, *Medicare Program: Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other than Physician Services)*. CMS has requested comments on the potential use of the single payment pricing from CBA, including comments on whether adjustments will be on a local, regional or national level.

We respectfully submit that meaningful comments cannot be provided until the single payment amounts are known, and respectfully submit that CMS should call for comments on this closer to the planned implementation date. As a general rule, we suggest that there may be wide variations in service costs between highly urban MSAs that are not included in the CBA, and that it would be highly unlikely that any such determination should be made on a national level. It would also be appropriate for CMS to investigate pricing in each regional market using the same or similar pricing mechanisms as are required for adjustments under the final rule on inherent reasonableness.

Section II R: Establishing Payment Amounts for New DMEPOS (Gap-Filling). In the NPRM, CMS suggests a new gap-filling methodology to establish appropriate payment amounts for new HCPCS codes and DMEPOS products. The new methodology proposes that CMS will direct unnamed external contractors to assess new DMEPOS technologies and determine if they have the potential to provide new or superior technical, clinical and or price / value benefits to beneficiaries versus currently available DMEPOS equipment.

PPS is concerned that the new methodology described by CMS is too vague for proper notice and comment. In its current form, the specific assessment criteria are unknown, resulting in the potential application of arbitrary or qualitative judgments in the assessments performed by the external contractors. In addition, there are no provisions delineated for stakeholder notice and comment in the assessment process. Therefore, we recommend that in lieu of applying the current gap-filling methodology, CMS's authority to create or adjust payment determinations for new or current HCPC codes be limited to the provisions under the final rule, *Medicare Program: Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other than Physician Services)*.

Section II G. 1: Quality Standards and Accreditation. Quality Standards: Pacific Pulmonary Services supports CMS' efforts to establish and implement meaningful quality standards for DMEPOS suppliers in the Medicare program, including suppliers seeking contract status in the CBAs. We expect this new requirement, if applied and enforced in a consistent fashion, to result in an improvement in the overall quality and value of the services DMEPOS suppliers provide to Medicare program and its beneficiaries.

However, as stated above in our general comments, PPS observes that updated quality standards were not issued for review and final comment by all impacted stakeholders prior to the closing of the notice and comment period for this NPRM. Interplay between the new quality standards, the existing 21 supplier standards, accreditation requirements and the implementation of rules defining the DRA provisions remains undefined. As a result, we do not have the

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opportunity to make meaningful observations and comments regarding the interstitial nature of these changes. We therefore recommend that CMS issue the revised quality standards and requisite program clarifications as a component of a comprehensive interim final rule with a sixty day notice and comment period in advance of any further program implementation in 2006.

Section II G. 1: Quality Standards and Accreditation. Accreditation: Pacific Pulmonary Services recommends that CMS enforce and expand the accreditation requirement imposed under the MMA which states that quality standards and accreditation must be fully implemented in any MSA subject to competitive acquisition before the bidding begins. We encourage CMS to require that all providers must be accredited prior to any participation whatsoever in the bidding process, further bolstering the requirement in the MMA that providers be accredited only prior to billing the Medicare program. Requiring accreditation in advance of any supplier participation will address the key findings contained in the September 2005 GAO report[5] which states, "National Supplier Clearinghouse (NSC) efforts to verify compliance with the 21 standards are insufficient because of weaknesses in two screening procedures – checking state licensure and conducting on-site inspections"

By requiring suppliers to achieve accreditation in advance of any program participation, CMS will benefit from the additional comprehensive oversight and on-site verification services provided by the authorized accrediting bodies, thereby eliminating the opportunity for waste, fraud and abuse by non-compliant suppliers in the competitive acquisition program.

In addition, if CMS proceeds with the proposed grace period, it risks allowing providers to participate in the bidding process with little or no understanding of the additional financial costs and operational burdens incurred in achieving and maintaining accreditation, resulting in faulty, unsustainable bid amounts. It is likely these faulty bids would be considered in the determination of the pivotal bid and single payment amount in a CBA, thereby distorting the bid process. In lieu of the proposed grace period, CMS should delay the implementation of the competitive acquisition program to provide willing and interested suppliers the opportunity to become accredited.

It is our understanding that the independent accrediting bodies such as JCAHO have been preparing their organizations to accommodate a rapid increase in the number of DMEPOS suppliers who will require accreditation surveys in advance of the implementation of the competitive acquisition program in 2007. We encourage CMS to verify that their preparations are sufficient, and to identify the criteria it will use to select the accrediting bodies immediately. Doing so will address the concerns of those suppliers who argue that the timing for supplier accreditation be delayed beyond the implementation of the competitive acquisition program.

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[5] United States General Accountability Office (GAO), Report to the Chairman, Committee on Finance. U.S. Senate, *"More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers"* GAO-05-656.

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Section II G. 3: Financial Standards. Pacific Pulmonary Services supports CMS' recommendation to require specific financial information to evaluate a supplier's fitness and ability to meet or exceed their self-determined composite bid price and market service capacity. At a minimum, CMS should review a supplier's general financial condition, credit history, insurance documentation, business capacity and line of credit to verify in advance that the supplier has the net worth and solvency necessary to successfully fulfill the contract.

In addition to the proposed financial management standards, PPS recommends CMS establish a more stringent requirement. We suggest that a DMEPOS supplier demonstrate capitalization or financial resources sufficient to provide equipment and service commensurate with the beneficiary volume commitment in all competitive bid product categories, and that this information be incorporated in the supplier's bid so that CMS has the information and evaluates it before accepting the bid. One simple method would be to require a supplier demonstrate financial solvency at their proposed "best price" bid using their historical capacity before any bid for (or assumption of) increased capacity to serve a CBA would be considered. If the supplier was not solvent on a proforma basis, they would be required to present a credible plan to reduce expenses without affecting quality of service; otherwise any proforma revenue loss would drop to their bottom line, thereby disqualifying them from the bid process.

Section II D. 1a: MSAs for 2007. Pacific Pulmonary Services recommends that: CMS publish the initial ten MSAs for 2007 in conjunction with the methodology and supporting beneficiary census and utilization data employed to determine the MSAs in the form of an interim final rule in 2006 to allow for proper supplier and provider notice and comment.

Implementation of Initial 10 MSAs in 2007: Given CMS' own estimates that the implementation of the competitive acquisition program is likely to begin in October of 2007, CMS should consider a staged implementation of the competitive acquisition program in the initial ten MSAs so that participating suppliers are accredited and in full compliance with the new DMEPOS quality standards before participating in the bidding process. Incremental implementation would have the added benefit of allowing CMS to more readily identify and remedy unanticipated issues as they materialize, thereby preventing unforeseen problems from being compounded in frequency and severity across multiple CBAs.

Section II F. 3: Product Categories for Bidding Purposes. The NPRM is silent on the composition and contents of the product categories that CMS intends to include in the initial ten CBAs. We believe CMS should publish the DMEPOS items it intends to include in these initial ten CBAs in 2007 as well as clearly defined HCPCS-code level product categories in the form of an interim final rule in 2006 to allow for proper supplier notice and comment on this important aspect of the program.

Product Category Definitions: In light of the requirement that suppliers bid on all of the HCPCS codes contained in a product category, product categories should be narrowly defined to ensure they reflect same or similar HCPCS codes and are grouped on the basis of function, cost of acquisition and cost of service.

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In the proposed rule, CMS proposes to define the term "product category" as *"a group of similar items used in the treatment of a medical condition,"* and states, *"the use of product categories will allow Medicare beneficiaries to receive all of their related products from one supplier, which will minimize disruption to the beneficiary."*

PPS supports CMS' goal of maximizing the efficiency and value of Medicare DMEPOS expenditures and reducing beneficiary disruption through the use of product categories as an organizing principle for competitive acquisition. However, we urge CMS to use caution when defining product categories, and to refrain from describing a product category too broadly. For example, an expansive product category such as *"Oxygen Equipment and Related Supplies"* is likely to contain both stationary oxygen concentrators and liquid oxygen systems. While this may appear logical on the surface, the grouping is in fact incompatible with accurate bidding because of the wildly divergent costs of acquisition, beneficiary support and service and equipment maintenance involved in the different modalities. A grouping of seemingly similar items with different cost components will have the unanticipated and wholly undesirable effect of producing inaccurate bids, and potentially escalating bid pricing for an entire product category, despite product weighting.

Section II F. 3: Physician Authorization / Treating Practitioner. Brand Specific Requirements: PPS strongly suggests that CMS reconsider allowing physicians and medical practitioners to prescribe a specific brand or type of DMEPOS equipment. The proposal may encourage the marketing of more expensive products directly to physicians and beneficiaries knowing that they will be provided without regard to cost to the program, essentially depriving the competitive bidding program of a critical cost control 'gatekeeper.' Furthermore, to a great extent, the provision is redundant with existing practice and policy. Physicians and treating practitioners have always been free to prescribe precise specifications for DMEPOS equipment, and they do so when they deem it necessary. To permit them to call the brand, however, is a costly added burden that produces no comparable benefit. Suppliers will no longer be able to take advantage of discounts available for consolidating purchases with a single manufacturer, and will have to maintain a huge inventory of brand differentiated, but functionally equivalent, DMEPOS equipment. The resulting incremental inventory cost will be passed through in the form of increases in the composite "best bid" price of suppliers who participate in the competitive acquisition program, thereby needlessly reducing potential program savings.

Section II I. 3: Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding. Beneficiary Transfer & Equipment Replacement: The NPRM proposes that contract suppliers be required to furnish, service and replace all DMEPOS products and related services in a product category to beneficiaries within a CBA regardless of the number of rental months remaining on the equipment. In addition, it proposes that a beneficiary may transfer from one supplier to another at any time. With regards to the forced ownership provisions contained in the Deficit Reduction Act of 2005 (DRA), CMS proposes that providers incorporate the cost of servicing and supporting beneficiaries near or beyond the payment cap on their equipment rental periods into their contract bid "best price" calculations. We respectfully

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suggest that it is not possible to estimate the potential cost impact of such activity. Suppliers have no means of estimating the volume of, or frequency with which beneficiaries may choose to transition from one supplier to another within the CBAs. In addition, due to a lack of access to the common working file, DMEPOS suppliers are unable to determine when a beneficiary initiated service for any particular DMEPOS item or service. The interaction of the two laws obviously produces a service gap. An oxygen patient who moves from one area to another at 37 months will have exhausted his lifetime oxygen benefit under 'capped rental', but not his need for service. Under the current proposal, suppliers would be forced to provide equipment and services to beneficiaries for which they may receive partial, or no payment whatsoever. This requirement places an unfair cost burden on all contract suppliers within a CBA. To preserve the ability for beneficiaries to transfer to a contract supplier of their choosing, while accommodating the true impact of the ownership provisions contained in the Deficit Reduction Act of 2005, CMS should initiate a new period of continuous use whenever a beneficiary transitions to new a contracted supplier.

Section II I. 3: Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding. Equipment Repair: CMS should delineate separate contract bid amounts for equipment that has transitioned ownership from the supplier to the patient. These bid amounts should be separate and discrete from the repair or replacement of provider-owned equipment. In this context, we note that the title transfer provisions under the DRA voids the manufacturer's warranty for most equipment, requiring that Medicare now bear repair expense that was formerly borne by the equipment manufacturer.

Section II I. 7: Change in Ownership. PPS supports CMS's proposed requirement that a successor entity must be in full compliance with all the requirements of the competitive acquisition and relevant government programs prior to merging with or acquiring a contract supplier's business. However, we question CMS's authority to determine by means of market capacity estimation if there is a need for the successor entity as a contract supplier, as a change of ownership of a contract supplier does not, in any fashion, impact the external market demand or capacity for DMEPOS products and services. We respectfully suggest CMS withdraw this proposed requirement. In addition, we respectfully submit that CMS lacks the authority to dictate the legal terms of merger by requiring that the successor entity assume legal liability for the non-fulfillment of any obligations of the original contract supplier.

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SUMMARY.

Pacific Pulmonary Services is thankful for the opportunity to provide the above comments in response to the Notice of Proposed Rule Making ("NPRM") published by the Centers for Medicare and Medicaid Services (CMS) in the Federal Register on May 1, 2006 (CMS-1270-P)[6]. CMS has shown in its proposed rule a willingness to work with industry to develop a set of payment policies that will balance the need to preserve access with the need to ensure that the Medicare program receives value for the items and services that it purchases under the competitive acquisition program. We thank CMS for the spirit with which it has approached this crucial component of the MMA implementation challenge. Although significant additional policy decisions must be made by CMS in order to protect access while ensuring the success of program implementation efforts in 2007 and beyond, we are optimistic that CMS will continue to work collaboratively with industry throughout this process and we stand ready to assist CMS in this important effort.

Yours sincerely,

Chris Kane
Vice President of Government Affairs

CC: Leslie Norwalk, Esq.

Herb Kuhn

[6] "Proposed Rules," Federal Register, Vol. 71, No. 83; Monday, May 1, 2006, 25654–25704 [06–3982].

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Submitter : **Mr. Thomas Kascak** **Date: 06/30/2006**

Organization : **Integrated Rehab Services**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See below (or attachment version)

6-30-2006

Dear CMS:

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS, CMS-1270 P

I am writing on behalf of my many compromised patients in need of timely care. I urge CMS to revise proposed legislation in a way to enable physical therapists to continue current, timely, and patient-oriented decision-making/care provisions regarding the application of orthotics within their total patient plan-of-care.

I am a Physical Therapist specializing in Hand Therapy as a Certified Hand Therapist (CHT). As a CHT, I required 5 years of experience and passing a national certification exam. Once a therapist becomes a CHT, continuing-education requirements are mandated and must be met each 5 years. I have over 30 years experience in hand therapy, hundreds of hours of continuing education, and I teach in a Doctoral Program for Physical Therapy.

I recognize the custom splinting we (as therapists) provide will likely be exempt from this ruling, however, the situation is more complex than a dichotomous stock or custom application. We incorporate professional judgment and deductive reasoning based on our specialized knowledge and each individual patient s needs. Patients often need a stock component along with custom items. Success in the patient s comprehensive program depends on correct application of each item. Timeliness providing care is crucial to recovery. Their status changes weekly post-op and post-injury and decisions/treatment applications must be promptly made regarding their tissue management. (As I tell my patients, Mother Nature makes the rules we must follow regarding how their tissue behaves & not the therapist or doctor. We are there to help them move or remain stationary at the correct times to get the most out of their healing.) It is not a timely or reasonable consideration for proper patient care to hold up treatment issues while an outside DME vendor is located. Patients are often impaired for mobility by age and health factors. They are further compromised by their extremity injury, in negotiating their daily routines. Making them travel more when they are dependent on others for attending appointments is counterproductive.

Splinting (Orthotics) are part of a patient s care. We have the expertise to apply that component of a patient s program, right when it is needed. Whether it is upper extremity as in my case, or lower extremity or spinal care in the case of other therapists and their clientele, professional judgment and timely application we provide make for better patient care.

Thank you for your consideration of these perspectives.

Respectfully,

Thomas Kascak, MBA, PT, CHT
Director, Sacred Heart University Sports Medicine and Rehabilitation Center
Fairfield, CT

Submitter : Mr. Timothy Zipp **Date:** 06/30/2006

Organization : The SCOOTER Store

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1218-Attach-1.RTF

ATTACHMENT TO #1218

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW.
Washington, DC 20201

June 30, 2006

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule [71 Federal Register 25654-25703 (May 1, 2006)]

Dear Dr. McClellan:

On behalf of the The SCOOTER Store (TSS), the nation's leading provider of Power Mobility Devices (PMD), we respectfully submit the following comments concerning the Notice of Proposed Rule Making entitled, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues* (herein referred to as the NPRM) published in the Federal Register on March 1, 2006. 71 Fed Reg 25654-25703.

TSS understands that the Centers for Medicare and Medicaid Services (CMS) has a daunting task implementing this program; however, we strongly recommend that the agency immediately implement Quality Standards, including Accreditation requirements, as directed by 42 U.S.C. §1395m(a)(20). Since April of 2003, when employees of TSS were the first to report the fraud situation in Harris County, Texas, TSS, along with most of the Power Mobility Device (PMD) industry, has been pushing CMS to develop such standards for all suppliers not just those participating in the Competitive Acquisition Program.

We are concerned that CMS will not mandate the increased standards for all suppliers when competitive bidding is implemented in 2007. In fact, the NPRM indicates that CMS will delay the accreditation process, a critical fraud prevention method, and allow suppliers to be reimbursed without accreditation, even inside of the winning bidder pool of suppliers. *See* 71 Fed Reg 25659. It appears that CMS's only goal is to drive down price for certain items of DME. We challenge CMS to not allow this to occur.

Second to our main concern is the fact that this is not a National Competitive Bidding program. It is closer to a city by city bid process designed solely to lower prices. The original intent of the program was to allow the marketplace to set its price and not CMS, however, CMS is tainting this process by forcing suppliers to submit prices less than the current allowables, then taking the median price, and ultimately only paying 80% of that amount. This system only favors very large suppliers with bidding expertise, economies of scale, and abilities to survive lost bids by having diversity in payor sources and geographic areas served.

We currently do not support the competitive bidding program, as written, because of the issues listed above and discussed in detail below. However, we realize this is a statutory requirement and therefore must share our opinions through the comment process. We hope that our comments can help lead to higher quality standards and accreditation requirements designed to fight fraud and increase standards within this industry.

Very truly yours,

Tim Zipp
Senior Vice President
Compliance
The SCOOTER Store

I. General Comments

Supplier Standards and Accreditation must be required for ALL suppliers of DMEPOS
The NPRM states, in part, that "All suppliers of DMEPOS and other items to which section 1834(a) (20) of the Act applies will be required to meet the quality standards established under that section. Finally, section 1847(b)(2)(A)(i) of the Act requires an entity (a DMEPOS supplier) to meet the quality standards specified by the Secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive Bidding Program." 71 Fed Reg 25658 However, CMS has inexplicably proposed that the accreditation program be phased in, thereby allowing non-accredited suppliers to be awarded c ontracts in Competitive Bidding Areas ("CBA"). 71 Fed Reg 25659

Quality standards and accreditation becomes a way for CMS to keep fraudulent and sub-standard suppliers from gaining access to Medicare Beneficiaries and federal healthcare dollars. CMS should not allow non-accredited suppliers to participate in the Medicare program in or out of CBAs. TSS recommends that CMS designate Approved Accrediting Entities immediately to allow not only bidding suppliers, but rather all suppliers, to become accredited prior to the implementation of the Competitive Bidding Program.

II. Comments Regarding "Payment Basis" – Proposed Section 414.408

A. Payment Adjustment to Account for Inflation – Proposed Section 414.408(b)

The NPRM states that the competitive bid price will be updated by the CPI-U and this "will obviate the need for the supplier to consider inflation in the cost of business when submitting its bids." 71 Fed Reg 25664. While we appreciate this provision, it leaves suppliers at risk to future changes that may further "freeze" pricing. CMS should ensure that price updates are received in the MSAs under contract. This can be adjusted in future rounds of bidding, but it must be made clear at the time that the bids are submitted. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

B. Beneficiary Switch to Contract Suppliers

The NPRM states that a beneficiary may choose to transfer their capped rental or oxygen equipment to a contracted supplier at any time during their rental cycle. 71 Fed Reg 25662. Contract suppliers will be required to furnish these items regardless of the rental months remaining on the equipment. While CMS expects suppliers to include this possibility as part of their bid price, we maintain that it is impossible for suppliers to predict the rate at which beneficiaries will transfer or in which month in the cycle they will transfer. Contracted suppliers should be able to provide needed equipment and re-start the capped rental cycle again under the new pricing model since there is no way to predict the cost associated with assuming another supplier's rental contract. Suppliers should be compensated when accepting beneficiaries with less than full rental periods remaining, as suppliers are required to provide service in such circumstances.

The NPRM states that no bid will be accepted if it is higher than the current fee schedule amount for an item. 71 Fed Reg 25678. This mandated ceiling on the bid price eliminates the opportunity for the marketplace to determine the price and reduces this program to nothing more than a price reduction exercise. If this is the intent of the program, CMS already has inherent reasonableness authority to change prices, provided the agency validates its actions.

C. Authority to Adjust Payment in Other Areas

The NPRM states that CMS can use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside of the competitive bidding area. 71 Fed. Reg. 25664. CMS should not be able to apply competitive bid prices to non-bid areas as different economies of scale, demographic densities, delivery costs, etc. exist in different regions of the country. Suppliers bidding for a specific CBA will estimate their costs, and therefore their bid price is solely based on servicing the specific CBA.

Because the NPRM does not allow contracted suppliers to refuse to service or provide equipment in these areas, it puts winning bidders at financial risk to be required to sell and service DMEPOS in areas to which they had not previously agreed or included in bid price. CMS should not adjust payments in these areas unless it does so at the next round of bidding. That will allow bidders to decide if they want to be required to service that area and then account for that in their submission.

III. Comments Regarding Competitive Bidding Areas

A. Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that for 2007 and 2009 the competitive acquisition areas will be established ***in*** an MSA. 42 U.S.C. § 1395w-3(a)(1)(B)(i). The areas ***adjoining*** a CBA should not be subject to the bid price. They should be properly bid, or excluded from the CBA.

B. Proposed Methodology for MSA Selection – Proposed Section 414.410

CMS proposed to use a factor of "suppliers per beneficiary" when determining how to rank which MSAs to choose. 71 Fed. Reg. 25666. Will CMS only calculate suppliers with physical locations inside of the CBA area or will it base its number of suppliers on those who have billed Medicare claims for DMEPOS for some time period? Medicare is allowing suppliers to bid who can service the area and not necessarily have a location inside the CBA. Therefore, it would only make sense that Medicare "count" all suppliers who have submitted Medicare DMEPOS bills in the past year to use in determining he number of "suppliers per beneficiary".

IV. Criteria for Item Selection

The NPRM requires suppliers to submit bids for individual items included in a "product category" for which contracts are awarded. 71 Fed Reg 25672. Based on the tables provided by CMS, it appears that all wheelchairs, POVs, and power wheelchairs may be bid in some type of

"product category". Suppliers would be required to submit bids for all three products and related accessories as opposed to choosing which single items they may want to attempt to participate in the bidding process. We recommend that CMS publish RFBs for single items and any components accompanying them. Such a proposal would be more user friendly for small suppliers and better represent the marketplace.

A. Potential for Savings

The NPRM will choose items for competitive bidding based upon the potential for savings, and CMS includes a list of factors that it may use to determine potential savings. 71 Fed Reg 25671. We believe, however, that CMS should explain and clarify the specific criteria or standards they will use when assessing potential savings. It needs to be made clear what methodology CMS will use to objectively identify products to be included in the first round of bidding.

B. Coding Issues and Item Selection

CMS proposes a methodology for item selection based upon historical data, 71 Fed Reg 25670, and does not take into account recent and forthcoming changes that will significantly affect utilization. Upcoming changes for PMDs to the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. As a result there will be no historical data to support decisions based upon price or utilization. We recommend that CMS not include PMDs in the initial 10 CBAs as there will be no data on which to support which items to include. Moreover, there will be very little experience on which suppliers can base their cost estimates, utilization rates, and bid prices as these will be changing with new codes, prices, and coverage policy.

V. Comments Regarding "Submission of Bids Under the Competitive Bidding Program" – Proposed Section 414.412

Physicians

The NPRM allows suppliers located outside of a competitive bidding area to submit bids and participate in the competitive bidding program for that area if they do business in the CBA and are able to service the beneficiaries residing within the CBA. 71 Fed Reg 25672. We would amend the proposal to only include those accredited suppliers with the capability to service the CBA and that capability must be proven by existing utilization and delivery patterns in the MSA.

VI. Comments Regarding "Conditions for Awarding Contracts" – Proposed Section 414.414

A. Quality Standards and Accreditation Proposed 414.414(c)

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process, thus allowing an undisclosed amount of time for such suppliers to become accredited. 71 Fed Reg 25675. This process will allow sub-standard suppliers to taint the bid pool and manipulate the bid price. This is detrimental to the integrity of the program as it allows companies with different cost structures the opportunity to bid for the

same items and then leave the Medicare program if they cannot live up to the standards. At the same time, accredited winning suppliers subject to the same price will not be allowed to refuse to serve beneficiaries in that CBA.

O***nly*** accredited suppliers should be eligible to bid. 42 U.S.C. § 1395w-3(b)(2)(A). CMS should not proceed with competitive bidding if it will not mandate that suppliers receive accreditation prior to submitting a bid.

Because CMS has delayed the quality standards and delayed choosing the entities that will actually accredit suppliers, it will enable non-accredited suppliers to participate in the bidding process. This is contrary to the will of Congress and an inexplicable action by CMS to delay the one real initiative that will effectively stop fraud and abuse. We again urge CMS to not allow this to occur.

B. Financial Information – Proposed Section 414.414(d)

The NPRM states that as CMS develops the "methodology for financial standards, we will further consider which individual measures should be required so that we can obtain as much information as possible while minimizing the burden on bidding suppliers and the bid evaluation process." 71 Fed Reg 25675. It is important to evaluate a supplier's financial stability before the bid prices are arrayed and the pivotal bid is selected. Failure to do this would taint the bid pool. It should be made clear in the regulation and application process exactly how this information will be used. Further, CMS must, at a minimum, clearly define and publish what ratios are needed to qualify, who decides what constitutes adequate insurance documentation and coverage, and what score qualifies a company to have a positive credit history.

We further recommend that all suppliers be required to submit financial reports which have been reviewed by an outside, independent accounting firm or CPA so there is some validation of the report. Companies who have audited financial statements and use GAAP should be given greater priority because their information conforms to general accounting principles and has passed review by external parties. The standards establishing how the collected information will include or exclude suppliers from this process should be made public.

C. Eligibility -- Proposed Section 414.414(b)

1. Introduction and Overview

We have a number of concerns regarding (1) the "eligibility" criteria set forth in proposed regulation 414.414(b), (2) the "Draft" "Medicare DMEPOS Competitive Bidding Program" Application form ("Application Form"), a nd (3) the review c riteria for a ssessing "Change in Ownership" under proposed rule 414.422(d). Overall, although they are intended to assist the agency in making the same sort of "responsibility" determination that are common to virtually all federal procurements, the proposed criteria and standards are so broad, ambiguous, undefined, and internally inconsistent that they will (i) pose serious hardships for any Durable Medical Device ("DME") supplier that tries to comply, (ii) require the creation of substantial databases and administrative systems to track required information, (iii) create numerous situations where

information wholly irrelevant to the responsibility of a supplier might be considered in some arbitrary manner to favor or exclude a particular entity, and (iv) expose applicants unnecessarily to sanction for noncompliance or erroneous statements based upon an inability to gather all the required information. This is all the more of a concern considering that proposed section 414.424(a) would deny all administrative and / or judicial review of contract awards.

2. General Concerns

As a basic premise, CMS seeks to accomplish through the sui generis Medicare DMEPOS Competitive Bidding Program ("CBP") the same goals and results as those that the Department of Health and Human Services and other federal agencies seek to accomplish when they utilize the Federal Acquisition System to procure a product or service for themselves – *i.e.*, to obtain on a timely basis the best value product or service that it can, while maintaining the public's trust and fulfilling public policy. Compare FAR 1.102(a) ("The vision for the Federal Acquisition System is to deliver on a timely basis the best value product or service to the customer, while maintaining the public's trust and fulfilling public policy objectives.") with *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS and Other Issues,* 71 FR 25654, 25657 (May 1, 2006) ("Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost. . . ."). In short, the CBP is no more or less than a federal procurement program to acquire goods and services, except that the users will not be government personnel but Medicare and Medicaid beneficiaries.

It is quite likely that the government procures under the simplified acquisition procedures applicable to "commercial items" authorized under of the Federal Acquisition Regulation ("FAR"), see FAR Part 12 (Commercial Items), the very same products as to which CMS now seeks to create a unique procurement system wholly outside of the established procurement system. Considering that the existing procurement procedures and requirements for commercial items already operate successfully in achieving the goals to which the Federal Acquisition System and the CBP both aspire, one must question why CMS endeavors to recreate from scratch a wholly new system. The mere fact that the purchases are to be used by Medicare and Medicaid beneficiaries rather than federal employees or patients in military hospitals certainly affords no valid basis for an independent program. Nor, considering the speed with which commercial item procurements can be accomplished under the FAR, is the need to ramp up quickly a basis for such an approach. The pitfalls inherent in trying to create a "new" system are highlighted by the faulty standards through which it proposes to assess the business integrity of prospective suppliers.

Those who are to administer the CBP, like those who for many years have administered the Federal Acquisition System, presumably will seek to ensure that suppliers are "responsible" in the sense that they are technically and financially qualified to supply a quality product in sufficient quantity to meet contract demands. They also will seek to ensure that prospective contractors possess sufficient business integrity so that the government will feel comfortable in entering into a business arrangement with them. To that end the FAR, after substantial consideration of alternatives over the years, now contains a well accepted representation and certifications clause that addresses those criminal and civil matters within the previous three

years that reasonably might be considered substantively and temporally relevant to the government's consideration of a prospective contractor's business integrity. FAR 52.209-5.[1] In

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[1] FAR Section 52.209-5 (Certification Regarding Debarment, Suspension, Proposed Debarment, and Other Responsibility Matters (Dec 2001)) provides as follows:

(a) (1) The Offeror certifies, to the best of its knowledge and belief, that—

(i) The Offeror and/or any of its Principals—

(A) Are / are not presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have / have not, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are / are not presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision.

(ii) The Offeror has / has not, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principals," for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a subsidiary, division, or business segment, and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

addition, that provision explains that adverse information will not necessarily bar a prospective contractor from contract award and, more importantly, assures them that they need not establish special record keeping procedures and databases to comply with the certification requirement. FAR 52.209-5(d). Notably, the current FAR provision reflects a substantial retreat from a much broader set of representations and certifications – that inquired into a broad array of civil and administrative actions involving the prospective contractor and others associated with the entity – that was briefly promulgated during 2001 and then quickly and withdrawn as unduly burdensome and unmanageable. See Federal Acquisition Case ("FAC") 97-21, 65 FR 80,255 (Dec 20, 2000), effective Jan 19, 2001, stayed FAC 97-24, 66 FR 17,753 (Apr. 3, 2001), corrected 66 FR 18,735 (Apr. 11, 2001, finalized with changes FAC 2001-03, 66 FR 66,984 (Dec 27, 2001)). CMS is now erroneously heading down the same road the federal government rejected some years ago for its own direct procurements.

Instead of adopting the tried, tested, and relatively effective representations and certifications language contained in section 52.209-5 of the FAR, without advancing any substantive reason or basis -- other than that it possesses the authority to ignore the FAR -- CMS strikes out on its own to create anew a set of criteria to supposedly assess applicant business integrity, as reflected in proposed section 414.414 and the associated Application Form. In doing so, it demands an extraordinarily burdensome, intrusive, contradictory, and unmanageable set of certifications and disclosures with which few if any entities could hope to comply. It will leave applicants potentially subject to exclusion or sanctions for noncompliance based upon certification and disclosures criteria that are wholly irrelevant to whether a potential supplier is responsible from a business integrity standpoint. Moreover, the situation is exacerbated when one considers that CMS purports to bar ***any*** judicial or administrative review of its contract award decisions. See proposed section 414.424 (discussed below). Such a system does not suggest one focused upon the benefits of competition and ensuring business integrity but rather a system where unnecessary and irrelevant information is amassed and whose unregulated use will lead to mistakes, arbitrary action, and favoritism in contract awards that will go unrevealed by exposure to the sunlight of review that is a critical aspect of virtually every other procurement in the Federal Acquisition System.

3. Specific Comments Regarding "Eligibility"-- Proposed Section 414.414(b)

At a specific level, section 414.414(b) contains numerous defects and ought to be thoroughly rewritten along the lines of existing FAR language. It provides as follows:

> Each bidding supplier must –
>
> (i) Certify in its bid that it, its high level employees, chief corporate officers, members of its board of directors, its affiliated companies, and its subcontractors are not now and was not sanctioned by any governmental agency or accreditation or licensing organization, or

(ii) Disclose information about any prior or current legal actions, sanctions, or debarments by any Federal, State or local program, including actions against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, and subcontractors.

71 FR at 25,700

First, it is unclear in both subsections as to whom "high level employees" refers. In a large company this might include hundreds of persons. It might involve persons who have nothing to do with the procurement. For example, it might include all plant supervisory personnel over whom few if any entities require or maintain records of this sort. There is no way to know from the language whom is covered. Similar confusion arises to somewhat of a lesser degree regarding "Chief corporate officers." Which officers are included and which are not included?

Second, it is unclear to whom "affiliated companies" refers. This could include just parent and direct subsidiaries. Or, depending on how one defines "affiliation", it could include a vast array of entities which have little if anything to do with the procurement at issue. In a large corporation, it could include scores of entities most, if not all, of which operate relatively independently of the entity seeking the contract.

Third, it is unclear what entities are to be included as "subcontractors." Are only proposed subcontractors for the prospective contract included? Are second tier subcontractors included? Are the subcontractor disclosures to extend only to those involving the subcontractor entity or to its high level employees, directors, chief corporate officers, affiliated entities, and its own subcontractors? It is unclear how a contractor is to obtain the required information from "subcontractors" and how it is to verify the information. It also is unclear what happens if a subcontractor refuses to furnish the information or only furnishes a part of the requested information. In this regard, what CMS demands, without reason or justification, goes well beyond what the government requires of federal contractors regarding contracting with commercial item and most other subcontractors without affording the government as much protection as does the pertinent FAR provision for a like situation. FAR 52.209-6.[2]

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[2] SAR 52.209-6 (Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment.) (Jan 2005) provides as follows:

(a) The Government suspends or debars Contractors to protect the Government's interests. The Contractor shall not enter into any subcontract in excess of $25,000 with a Contractor that is debarred, suspended, or proposed for debarment unless there is a compelling reason to do so.

(b) The Contractor shall require each proposed first-tier subcontractor, whose subcontract will exceed $25,000, to disclose to the Contractor, in writing, whether as of the time of award of the subcontract, the subcontractor, or its principals, is or is not debarred, suspended, or proposed for debarment by the Federal Government.

(c) A corporate officer or a designee of the Contractor shall notify the Contracting Officer, in writing, before entering into a subcontract with a party that is debarred, suspended, or proposed for debarment (see FAR 9.404 for information on the Excluded Parties List System). The notice must include the following:

Fourth, in subparagraph 414.414(b)(2)(i), besides the grammatical issue of "was" versus the presumably intended "were", there is no limitation on what is meant to be included by "sanctioned by any governmental agency or accreditation or licensing organization." The preamble, whose text is not included in the regulation, offers no clarification or limitation in stating that "[s]anctions would include, but are not limited to, debarment from any Federal program, sanctions issued by the Office of Inspector General, or sanctions issued at the State or local level." This is no definition at all! This could include everything from a Labor Department or EPA sanction regarding a division of a large cooperation that has no tie at all to the proposed contract, to a speeding ticket issued to a company employee, to a citation issued by the county to a company CFO for an unleashed dog or improperly planted tree that violates some historical use regulation. Moreover, it is temporally unrestricted. Although the FAR only requires an entity to report back for three years at most, see FAR 52.209-5(a)(1), CMS would have applicants go back to the dawn of time. Such a broad sweeping requirement will pose unjustifiable burdens on an applicant.

Fifth, as a practical matter, it would be virtually impossible, except perhaps for a very small company with no affiliations, to make the certification required by subsection 414.414(b)(2)(i) because the affiant would not know whether he or she was subjecting the company to sanctions for noncompliance. Considering the severity of potential sanctions, and the lack of an appeal, the certification option is no option at all.

Sixth, the alternative of trying to comply with subsection 414.414(b)(2)(ii) is equally unattainable at least for all but the smallest of companies. Besides the challenges discussed above regarding the definitions of high-level employees, chief corporate officers, affiliated companies, and subcontractors, as discussed above, one has no way of knowing what to disclose in terms of "[d]isclos[ing] information about any prior or current legal actions, sanctions, or debarments by any Federal, State, or local program, . . ." Even if one had some idea of how far back one was required to go in addressing this issue, one likely would not have the means to go about collecting (much less verifying) such information from employees, affiliates, subcontractors or even various divisions of a company. Besides all of the federal, sate, and local government matters that are theoretically covered by this provision, it also appears to cover every administrative or judicial action that was ever brought against or by the company, its personnel, its affiliates and its subcontractors. As the government realized during 2001 when it

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(1) The name of the subcontractor.

(2) The Contractor's knowledge of the reasons for the subcontractor being in the Excluded Parties List System.

(3) The compelling reason(s) for doing business with the subcontractor notwithstanding its inclusion in the Excluded Parties List System.

(4) The systems and procedures the Contractor has established to ensure that it is fully protecting the Government's interests when dealing with such subcontractor in view of the specific basis for the party's debarment, suspension, or proposed debarment.

proposed substantially less draconian disclosure requirements for addition to the FAR 52.205-9, such requirements would require applicants to develop huge database collections and infrastructures to locate and track the enormous quantity of essentially irrelevant but potentially responsive information that might need to be disclosed. CMS, realistically, must establish reasonable substantive and temporal limitations on what is to be disclosed.

In this regard, a significant issue is what standards CMS would propose to apply to the information that is submitted. What CMS official or implementation contractor is capable of properly assessing the significance regarding a potential supplier's business integrity based on a local ordinance violation (or a failure to disclose such a matter), or a state sanction for a noise abatement, or a Fair Labor Standards Act sanction for a minor infraction, or an EPA regulatory violation, or a state or federal sanction based upon violations of regulations governing the length of time a tractor trailer operator may dive in one day, or an IRS or state tax authority sanction imposed because an accountant made an error, or the relative significance of a sanction issued 10, 5 or two years ago. The potential for inadvertent error, abuse, or arbitrary action to favor of or exclude an entity based upon a review of the types of material encompassed by the proposed regulation is far too high for this regulation to stand unaltered. As we noted above, during 2001, the federal government rapidly retreated from far less onerous disclosure requirements in considering appropriate representations and certifications to ensure it had the necessary information to assess business integrity. There is no justifiable reason for CMS to cast its net for information any broader than the criteria it applies under the FAR when procuring goods for itself that are like those encompassed under this program. It too, should retreat to bounds no greater than those set forth in FAR 52.209-5.

4. Medicare DMEPOS Competitive Bidding Program Application

CMS has issued a proposed Medicare DMEPOS Competitive Bidding Program Application form ("Application Form") in association with the proposed regulation. OMB No. 0938-xxxx (Form CMS-10169A (xx/xx). With respect to certifications and disclosures of information, it is rife with inconsistencies and ambiguities vis-à-vis the proposed regulation and generally sweeps far too broadly to be justifiable as drafted..

First, proposed section 414.414(b)(2) provides that contractors are to be afforded an alternative between providing a certification and disclosing various past matters. Putting aside the fact that the regulatory alternative is in effect illusory, no such alternative is afforded on the Application Form. Rather, Section D of the Application requires offerors to make the following certification:

> Neither I, nor the owner, director, officer or employee of the (Supplier) or other organizations on whose behalf I am signing this certification statement, or any contractor retained by the company of any of the aforementioned persons, currently is subject to sanctions under the Medicare or Medicaid program, or disbarred, suspended or excluded under any other Federal agency or program, or otherwise prohibited from providing services to CMS or other Federal agencies.

Application at 6. In addition, the Application Form requires applicants to disclose the following array of information:

> Please provide a brief explanation of any past or pending, if known, investigations, legal actions, or matters subject to arbitration involving the applicant, subcontractors, and any entities under legal arrangement (including parent firm). Information provided must include: 1) circumstances; 2) status (pending or closed); and 3) if closed, details concerning any resolution and any monetary damages.

Application at 5. This dual requirement directly conflicts with the supposed alternative set forth in section 414.414(b)(2). The Application Form needs to be reconciled with the regulation in this regard and as discussed further below.

Second, with respect to the certification, it is substantially at variance with the scope of the certification set forth in section 414.414(b)(2). Although somewhat more narrowly focused as to the type of matters to which one must certify – and more closely aligned with what one finds under the FAR – the expansion of the certification to "owners," "employees" (as compared with "high level employees") "officers" (as compared with "chief corporate officers") and to "any contractor retained by the company of (sic) any of the aforementioned persons" creates a wholly different and far broader universe of persons from whom information theoretically must be obtained The certificate, as drafted, includes every shareholder and employee of a company that could number in the thousands or more. Considering that as constructed, it now covers the janitor and a shareholder with but ten shares out of a million shares, and the contracted accounting shop, fuel oil company, and temp agency for the entity. It would be virtually impossible for a middle-sized or larger company to gather the information to make such a certification or to have any confidence that it had not exposed itself to the substantial penalties set forth in the Application Form for an erroneous statement. Such a broad certification is not required for federal procurements under the FAR and there is no justifiable reason why such a broad request is warranted here. Again, as we explained above, CMS should simply adopt the certification set forth in section 52.209-5 of the FAR for this purpose.

Third, the disclosure requirement, besides also being at variance with the disclosure set forth in section 414.414(b)(2), also mandates disclosure of information on a far broader scale than the regulation in other respects. The Application Form requires disclosure of "investigations" without defining what is covered, which could include a host of minor local, state, or federal matters with absolutely no bearing on the integrity of the prospective contractor. Similarly, "legal actions" and matters "subject to arbitration" could encompass an enormous array of matters that have nothing to do with a company's integrity or responsibility. Lastly, the requirement to make disclosures regarding "any entities under legal arrangement (including parent firm)" is ambiguous as to what it covers and potentially extends to any entity that has a minor contract, or minor ownership interest in the applicant. Again, there is no basis for requesting information of this breadth particularly where it finds no support in the proposed regulation or otherwise.

Once again, much of the information being gleaned here would appear to have little or no bearing upon the integrity or other aspects of applicant's responsibility. Moreover, there appears to be no standard by which such information is to be analyzed or weighed. Nor is there any provision for an applicant to be informed of and to address matters that may be of concern to CMS. Thus, as we explained above, the certifications and disclosures under these provisions, besides conflicting with what the regulations require and constituting a further unreasonable collection burden, also pose serious threats for confusion, erroneous submissions, and misuse of the data to favor or exclude an applicant on some arbitrary basis. Accordingly, in conjunction with revising and limiting the scope of section 414.414(b)(2), CMS should harmonize and similarly limit the scope of the certification and disclosure requirements on the Application.

D. Market Demand and Supplier Capacity – Proposed Section 414.414(e)

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers needed to service all the expected beneficiaries in an MSA. 71 Fed Reg 25675. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. CMS's recommendations, however, do not include methods to keep unreasonable bids from being considered. When suppliers are asked to submit their capacity, they should be able to assume that they will only be required to supply the volume of product included in their bid. However, the regulation also stipulates that they are not permitted to refuse to provide or service a beneficiary. Unreasonable bids not only improperly affect the bid pool, they may also contribute to financial hardship for the supplier who is asked to increase capacity to fully service the market demand.

We recommend the bid consideration process protect against this type of behavior. CMS should consider eliminating outlier bids or include strategies employed in the previous pilot bidding programs. These included adjustments to the single price or accepting more than one bid price.

CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. A number of circumstances, such as a natural disaster or other calamity, could create unanticipated access problems for beneficiaries in the MSA. The ability of CMS to predict the demand in a marketplace with any precision will doubtless have an error factor and lead to incorrect conclusions. This would also eliminate the need to amend the process during the 3-year term as contracted suppliers exit the market for various reasons.

E. Determining the Single Payment Amounts for Individual Items – Proposed Section 414.416

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." 71 Fed Reg 25679. This methodology will result in 50% of the winning bidders receiving reimbursement that is less than their submitted bid. Further, suppliers may not refuse to provide equipment or servicing to these beneficiaries. Some suppliers will thus be subject to reimbursement lower than they were willing to accept and a quantity of demand greater than they agreed to provide. This methodology is significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects.

We recommend CMS set the payment at the pivotal bid price, which is the highest priced bid to adequately meet the market demand. This was the method used effectively in the earlier demonstration projects.

F. Rebate Program – Proposed Section 414.416(c)

The NPRM proposes that any supplier that submitted a bid lower than the single payment amount may choose to offer that difference as a "rebate" to all beneficiaries in the CBA. 71 Fed Reg 25680. CMS should immediately remove the rebate program from the proposed regulation. There were no supporting opinions offered for this provision at the recent PAOC meeting. Further, it will be difficult to police this provision or enforce the prohibitions against discussing, marketing or using the rebate information with customers and referral sources. This provision could be a violation of the Anti Kickback Statute, and it could open the program to improper inducements and provides no clear way to monitor the infractions.

VII. Comments Regarding "Terms of Contracts" – Proposed Section 414.422

A. Furnishing of Items – Proposed Section 414.422(c)

CMS should clarify the relationship between the volume of product a supplier submits with its bid and the requirement to provide product and service to any beneficiary covered in the CBA. CMS must clarify when a supplier can refuse to provide service and if providers will be required to provide beyond their bid quantity.

B. Repair or Replacement of Equipment

CMS must clarify when a supplier can refuse to serve a beneficiary. It is clear with Oxygen and Sleep products that if a patient has the correct test score or completed sleep exam they will qualify, and therefore should receive, the prescribed product and treatment. However, with a Power Mobility Device (PMD), the supplier relies upon the physician's evaluation, prescription, and documentation to decide if this patient should or should not receive a PMD. The system CMS has set up through the recent Final rule on PMDs puts the supplier in the role of deciding if the physician has documented the beneficiary's condition well enough to be served by a supplier. The NPRM, however, indicates that any time a patient receives a written order from his/her physician, the supplier would be breaching their contract with CMS if they chose not to follow such order. CMS must clarify the specific circumstances when a contracted supplier can refuse to serve patients and the specific circumstances that would justify a supplier not complying with a physician written order inside of the Competitive Bidding Program.

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area and to repair or replace beneficiary owned equipment subject to the competitive bidding program. 71 Fed Reg 25681. As highlighted above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. Winning bidders should be reimbursed for the service and replacement products they provide. If there are

warranties to be honored on previously rented or purchased equipment, the cost of service must be borne by the supplier who received reimbursement for the unit that failed. This should be the one exception where a non-winning bidder is allowed to provide equipment in a CBA. However, they would not be allowed to bill Medicare, as they are replacing parts or entire units still covered under warranty.

C. Change of Ownership – Proposed Section 414.422(d)

We are concerned with what is unsaid in the text of subsection 414.422(d), but included in the preamble, regarding "Change in Ownership." In the text of the regulation, one of the conditions is that a successor contractor must meet "all requirements applicable to contract suppliers for the applicable competitive bidding program." 71 FR at 25,702. In the preamble, however, CMS asserts that it will assess, among other things, a company's "compliance status with government programs before we determine that a supplier can qualify as a contract supplier." 71 FR at 25,681. Besides facing all of the challenges we address in the context of section 414.414, above, CMS does not define what it means by the quoted phrase. It, too, is unbounded as to what will be considered and affords no indication as to how CMS intends to acquire this information, who is qualified to assess the collected information, and whether and if so how the application would be afforded the opportunity to comment regarding adverse information. As such, the regulation, particularly as explained in the preamble, affords another example of where abuse or error could lead to favoritism, the disqualification of an entity, or the imposition of sanctions against an entity for improper or unsubstantiated reasons all without there being any opportunity to seek redress. Accordingly, it is necessary for CMS to clarify what it means by this reference in the context of section 414.422.

Suppliers cannot be prohibited from selling their businesses; CMS cannot unreasonably withhold its approval of a change of ownership and CMS should not deny winning supplier status to new owners on the basis that its capacity is not necessary within the competitive bidding area.

CMS should approve a change of ownership if the new entity meets the applicable quality standards, a ccreditation r equirements, and f ully adheres to other requirements of c ompetitive bidding, including the terms of the original contract.

VIII. Comments Regarding "Opportunity for Participation by Small Suppliers"

The NPRM states that the needs of small businesses will be considered when determining what the applicable financial standards will be. 71 Fed Reg 25682. We contend that all suppliers awarded bids must adhere to the same standards. Each supplier must fully comply with accreditation requirements, supplier quality standard requirements, and financial standards to ensure the integrity of the Medicare program and ensure that each Medicare beneficiary receives proper care.

IX. Comments Regarding "Opportunity for Networks" – Proposed Section 414.418

The NPRM will allow small businesses to form networks, for bidding purposes, in order to increase the strength and competitiveness of their bids. 71 Fed Reg 25683. We do not oppose this provision allowing for networks as long as the guidelines are set forth by CMS which explain how these entities will operate. For instance; if they are legal entities, which entity will bill claims? How will these entities bill claims or be audited? If action is needed to be taken against one network member but not all, how would other members continue with the contract, or would the entire network be liable for one company's violations?

X. Comments Regarding "Quality Standards and Accreditation for Suppliers of DMEPOS"

We reiterate the need within the PMD industry for CMS to implement quality standards and accreditation. This competitive bidding process must not be an excuse to allow CMS to not implement the one tool that is an effective fraud deterrent.

XI. Comments Regarding "Establishing Payment Amounts for New DMEPOS (Gap-Filling)" – Proposed Section 414.210(g)

Changes to Gap filling should be placed in its own comment format and not included as part of this regulation. We agree with CMS that the use of deflation and inflation factors has always been flawed and a new system needs to be recommended and then formalized. 71 Fed Reg 25687. However, to be able to properly comment, CMS would need to develop a specific proposal upon which stakeholders can then respond.

XII. Comments Regarding "Administrative or Judicial Review" – Proposed Section 414.424

CMS proposes in section 414.424 that there is to be "no administrative or judicial review under this subpart of the following: . . . (2) awarding of contracts." Section 414.424(a), 71 FR at 25,702. In the preamble, CMS asserts that the Act bars such review. 71 FR at 25,683.

We are greatly concerned and strongly object to any suggestion that CMS intends to conduct itself, or through implementing contractors, what are likely to be multi-million dollar procurements without any opportunity for administrative or judicial oversight of the process. The fact is that the CBP is a procurement program by which CMS seeks to acquire the same types of commercial items that it acquires for itself pursuant to the FAR. Considering the number of procurements that are set aside each year by the General Accountability Office ("GAO") and the United States Court of Federal Claims based upon government error, it is inconceivable that CMS would even suggest such a secret and insulated process. That is a recipe for arbitrary and erroneous awards, if not a direct invitation for the perpetration of fraud. CMS should clarify that all contract awards and invitations to participate will be subject to the traditional review of procurements conducted by the government.

Regardless of whether it possesses the right to ignore the FAR and avoid judicial or administrative oversight, prudence and the obligation to maintain some sense of integrity in the procurement process that it is developing requires that CMS open the process up to protest review. The failure to do so invites disaster.

XIII. 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. Regardless of the timeline, we again implore CMS to publish the quality standards and require mandatory accreditation as soon as possible and prior to the introduction of competitive bidding.

XIV. Conclusion

We urge CMS to follow the lead of Congress by implementing Quality Standards and mandatory Accreditation immediately. We implore CMS to take their time in the implementation of Competitive Bidding. At the very least, we ask CMS to consider the provisions of the Hobson-Tanner bill which has over 120 sponsors currently, when considering changes to this regulation. Among other provisions, the bill would:

- Protect patients by requiring that "competitive bidding" not begin until quality standards are in place;
- Exempt smaller, rural areas (Metropolitan Statistical Areas with populations under 500,000);
- Allow all qualified providers to participate at the selected award price;
- Restore the rights of participating providers to administrative and judicial review;
- Exempt items and services unless savings of at least 10 percent can be demonstrated compared to the fee schedule in effect January 1, 2006;
- Protect beneficiary access to care by requiring CMS to conduct a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care;

Submitter : **Mrs. Connie Lane** **Date: 06/30/2006**

Organization : **Hand and Physical Rehab**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It Concerns:
Position: Request that Medicare revise the proposed regulation to allow physical and occupational therapists to continue supplying orthoses to beneficiaries in their care without additional constraints.

I am a physical therapist who has specialized in upper extremity disorders for the last 24 years. I am also a certified hand therpist which required five years experience and at least 4000 hours in upper extremity patient treatment befor passing the certification exam.

Over the years, we have had patients with insurance plans which cover DME products only with contracted suppliers, similar to your proposed legislation.

The problems I have seen with this type of arrangement are as follows: 1) the supplier stocks only one type of splint per area for all types of disorders. As an example, a cock-up wrist splint is used for carpal tunnel syndrome but will be of no value for treatment of wrist/thumb tendonits(Dequervain's disease) or thumb arthritis which is a very common problem in the Medicare age group. 2)Specific splints may be ordered from distributors but it may be weeks before patients get the prescribed item. 3)Splints are fitted by untrained staff which sometimes results in in ill-fitting splints which only complicates the medical problem. Devices should as joint jacks which are used after injury for flexion contractures require adjustment and instruction in use. Futhermore adjustments are necessary are the condtion changes. The suppliers are not trained to do this.

Thanks for your consideration.

Connie PT, CHT

Submitter :

Date: 06/30/2006

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

On page 21 CMS describes that section 187(b)(2)(A)(i) of the act requires an entity to meet the quality standards specified by the secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive bidding program and on page 24 CMS states CMS will phase in the accreditation process and require accreditation organizations to prioritize their surveys to accredit suppliers in the selected MSAa and competitive bidding areas. This issue needs to be addressed for three problematic reasons:

1. There will be suppliers who will delay accreditation until they find out if they win the bid or not.

2. It is impossible for suppliers who are not accredited to know the true cost of maintaining accreditation; therefore their bid price will be incorrect and cause additional burdens on the system including artificially low bids and possible bankruptcy.

3. There will be a significant amount of suppliers who will win the bid without accreditation and will fail the accreditation process.

I would suggest making accreditation mandatory in the 10 selected MSAs before issuing the RFB and then giving suppliers sufficient time to become accredited. Accreditation should then be a mandatory condition before submitting a bid and before awarding a contract.

CMS-1270-P-1220-Attach-1.DOC

ATTACHMENT TO #1220

Conditions for awarding Contracts

On page 21 CMS describes that *"section 187(b)(2)(A)(i) of the act requires an entity to meet the quality standards specified by the secretary under section 1834(a)(20) of the Act before being awarded a contract under the Medicare DMEPOS Competitive bidding program"* and on page 24 CMS states *"CMS will phase in the accreditation process and require accreditation organizations to prioritize their surveys to accredit suppliers in the selected MSAa and competitive bidding areas."* This issue needs to be addressed for three problematic reasons:

1. There will be suppliers who will delay accreditation until they find out if they win the bid or not.

2. It is impossible for suppliers who are not accredited to know the true cost of maintaining accreditation; therefore their bid price will be incorrect and cause additional burdens on the system including artificially low bids and possible bankruptcy.

3. There will be a significant amount of suppliers who will win the bid without accreditation and will fail the accreditation process.

I would suggest making accreditation mandatory in the 10 selected MSAs before issuing the RFB and then giving suppliers sufficient time to become accredited. Accreditation should then be a mandatory condition before submitting a bid and before awarding a contract.

Submitter : Mr. Larry Crum **Date:** 06/30/2006

Organization : Pharmaco, Inc. (Home Medical Equipment)

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Ours is a small DME company that has been serving its customers for 25 years. Competitive bidding as can be interpreted from the proposed rules will probably put us out of business. We can not gain the same purchasing prices as larger companies. We serve a fairly small geographic area of Maryland providing a wide array of equipment and supplies but not all items. We are an accredited company through JCAHO that provides quality services and truly cares about the customers we serve. As is usually the case, it will be our customers who will suffer the most from these changes. There is still so much that is unknown about this process and the time constraints to put together a bid will be severe. We do not have the luxury of a large corporate structure that will be able to reallocate resources to get the work done. The selection of products and defining the MSA's effected are still unanswered questions with time winding down. It will be sad and difficult for us if we complete our silver anniversary and never get to participate beyond. Even if we are lucky enough to participate, it is unclear whether we will be able to survive on rates below the current medicare allowable. With limited purchasing power to gain discounted prices and the rising fuel and labor costs, it seems improbable. As a parent of a muliply handicapped child, I know the benefit of dealing with reputable companies who work with the client to provide the necessary services in a timely manner.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

As a small supplier who serves in a suburban and semi- rural area, we have provided services for the last twenty four years and are now in our twenty-fifth. It has been difficult to celebrate our silver anniversary as we are faced with the possibility of not seeing a 26th. Small suppliers have many obstacles to overcome to achieve even a small profit. We don't have the benefit of large amounts of money to obtain volume discounts for our products. We also don't have large volumes to be able to specialize in one or two specialized product lines. We must sell a variety of supplies and equipment to be able to cover our expenses. Under the proposed competitive bidding rules, I have interpreted it to say that we must be able to cover the entire MSA. That will be an almost impossible challenge for any small company. There is lots of discussion about forming networks. Although that seems like a plausible idea, there are many limitations in implementation. Not the least of which is how much of the Shrinking reimbursement dollar will each entity receive. There will be legal fees and others which cost money that many will not be able to afford. It seems that the little guy is being put into a position for elimination. There are a lot small suppliers who cover a lot of territory and provide a lot of quality services. Big companies filling that gap are going to have a difficult time. Please don't implement a system which punishes or elimates the small businessman or woman.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

As a JCAHO accreditated supplier, we have been providing quality services for many years. However, CMS has now come up with another set of expansive standards that are too detailed and directive. Furthermore, we do not know if JCAHO accreditation is going be acceptable under the new regulations. The accreditation is not free. We pay a significant price,not to mention the tremendous number of hours required in staff time which is borne by our companies. My company is on a schedule to have an onsite review in early 2007. Will we then have to pay for participation with a differnt accrediting body based on decisions that still have not been made, or maybe just not announced? I believe that any reputable supplier would agree that there are quality standards that should be met, but that the effort should not be so onerous that we can not meet primary needs of our companies.

Submitter :

Date: 06/30/2006

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

Payment Basis

Payment Basis

The grandfathering of non-contracted suppliers will cause several problems but it has an easy solution of simply reimbursing contracted suppliers for the work they have done. On page 105 you state In order to ensure beneficiary access to competitively bid items that are rented, we are proposing that the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. This is particularly important in those cases where a supplier or noncontract supplier does not elect to ontinue furnishing the item in accordance with the grandfathering provisions discussed in section II.C.3. Suppliers must factor the cost of furnishing items in these situations onto their bids This statement is completely unreasonable and inappropriate. Problems with this approach and grandfathering include:

1. Grandfathered suppliers will refuse to service equipment with in the last few months of rental because they no longer of any financial incentive. This will put an unjust financial burden on winning providers to pick up any slack.

2. Grandfathered suppliers will pick up the equipment a month before it is capitated putting an unjust burden on winning providers.

3. Non-grandfathered suppliers will immediately pick up their equipment leaving beneficiaries at risk and contracted suppliers with an unreasonable financial loss.

4. Predicting how many grandfathered or non-grandfathered suppliers will pick up their equipment before the cap date is unfeasible and can not be factored into any bid.

5. Forcing contracted suppliers to deliver and setup new equipment, free of charge or at a loss, when a grandfathered or non-grandfathered supplier pulls out is unjust, irresponsible, and un-American.

A simple solution to this problem would be as follows:

If a non-contracted provider picks up their equipment that is a capped rental item before the cap date and a winning provider is forced to replace that item before it is capititated, it should be considered a break in service and a new rental period should commence once the contracted provider places his new equipment in the patients home. This is the policy all private insurance companies currently practice. This was also the policy that was in acted for hurricane victims that were displaced and a new provider had to deliver the new equipment to the beneficiary even though it had already been capped or was in the process of being capped.

CMS-1270-P-1222-Attach-1.DOC

CMS-1270-P-1222-Attach-2.DOC

ATTACHMENT 1 TO # 1222

Payment Basis

Grandfathering:

The grandfathering of non-contracted suppliers will cause several problems but it has an easy solution of simply reimbursing contracted suppliers for the work they have done. On page 105 you state *"In order to ensure beneficiary access to competitively bid items that are rented, we are proposing that the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. This is particularly important in those cases where a supplier or noncontract supplier does not elect to ontinue furnishing the item in accordance with the grandfathering provisions discussed in section II.C.3. Suppliers must factor the cost of furnishing items in these situations onto their bids"* This statement is completely unreasonable and inappropriate. Problems with this approach and grandfathering include:

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ATTACHMENT 2 TO #1222

Payment Basis

Grandfathering:

The grandfathering of non-contracted suppliers will cause several problems but it has an easy solution of simply reimbursing contracted suppliers for the work they have done. On page 105 you state *"In order to ensure beneficiary access to competitively bid items that are rented, we are proposing that the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. This is particularly important in those cases where a supplier or noncontract supplier does not elect to ontinue furnishing the item in accordance with the grandfathering provisions discussed in section II.C.3. Suppliers must factor the cost of furnishing items in these situations onto their bids"* This statement is completely unreasonable and inappropriate. Problems with this approach and grandfathering include:

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Submitter : Richard Brockman **Date:** 06/30/2006

Organization : Alabama Nursing Home Association

Category : Health Care Provider/Association

Issue Areas/Comments

Issue

Issue

I am writing this on behalf of the Alabama Nursing Home Association, representing over 95% of Alabama's 240 plus nursing facilities. We believe that this rule should be delayed until further study is made on the manner in which services to residents in skilled nursing facilities will be affected. Many nursing facilities are certfied as Medicare durable medical equipment providers for items such as enteral feedings, infusion pumps, urological supplies, oxygen and wound care items. This permits these facilities to always have a ready supply of DME items on hand for times when a resident's condition changes at night or on a weekend or the item is needed immediately. We believe that the rationale for the proposed rule to require competitve bids for DME overlooked this important access and immediate need situation.

In addition, those nursing facilities that contract with third-parties for these DME items, will no longer be able to find the DME provider who can provide immediate delivery of these supplies that could mean the difference in care.

Thus, we urge that the immplemntation of the proposed rule be delayed until these important issues are resolved.

Submitter :

Date: 06/30/2006

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

When attempting to submit a comment on this form prior to this page under the initial necessay fields such as zip code, country, and category, under category there is no specific listing for Durable Medial Equipment Providers. I feel this is misleading and confusing and preventing suppliers to submit comments electronically.

Submitter : Kathy Sircovitch **Date:** 06/30/2006

Organization : AtHome Medical

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter :

Date: 06/30/2006

Organization : **American Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1226-Attach-1.DOC

ATTACHMENT TO #1226

American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

June 30, 2006

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

Re: CMS-1270-P

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule implementing a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Act) directs the Department of Health and Human Services (HHS) to revise the payment system for certain DMEPOS equipment under Medicare. In the future, suppliers located in a competitive acquisition area will be required to submit bids for each type of DMEPOS they supply to Medicare beneficiaries. Only those suppliers who submit a bid and contract with the Centers for Medicare and Medicaid Services (CMS) will be allowed to continue billing Medicare Part B for these items. The competitive bidding program will dramatically affect who can supply DMEPOS equipment to Medicare beneficiaries. Therefore, the program is of significant interest to the Association and our pharmacist members, many of whom supply some form of DMEPOS equipment to their patients.

APhA has a number of concerns with the competitive bidding program as currently proposed. Our concerns include the Agency's failure to implement safeguards to protect existing relationships between Medicare beneficiaries and providers, the fact that the program does not provide small DMEPOS suppliers with sufficient opportunity to participate as required by law, the development of a program that appears to consider cost savings more than quality care, and the negative impact the program will have on patient access to DMEPOS if implemented as proposed.

2215 Constitution Avenue, NW • Washington, DC 20037-2985 • 202 628-4410 • Fax: 202 783-2351
www.aphanet.org • www.pharmacist.com

COMPETITIVE BIDDING AREA

Establishing Competitive Bidding Areas

The Act provides CMS with the authority to exempt rural areas and areas with low population density within urban areas that are not competitive from the competitive bidding program.[1] According to the proposed rule, CMS intends to use this authority to exempt areas with a history of low utilization of DMEPOS items and allowed charges, areas with a low number of suppliers, and areas with a low number of Medicare-fee-for service beneficiaries. APhA supports the Agency's proposal to exempt the aforementioned areas.

Nationwide or Regional Mail Order Competitive Bidding Program

The preamble of the proposed regulation includes a discussion of a nationwide or regional competitive bidding program for diabetic testing supplies. According to the preamble, CMS intends to create a national or regional competitive bidding area that would allow beneficiaries to obtain supplies through mail service. The mail service program would be available to beneficiaries who elect to obtain these supplies through the mail. APhA appreciates that the mail service program would be one option for beneficiaries; beneficiaries would also have the option to continue obtaining their diabetic supplies from their provider of choice.

However, we have significant concerns with a second mail service proposal included in the preamble. The preamble continues to state that CMS is considering an alternative proposal that would require beneficiaries to obtain replacement of all supplies such as glucose testing strips and lancets from a mail service supplier. APhA strongly objects to this alternative proposal. This proposal would limit beneficiaries' choice of DMEPOS provider and severely restrict beneficiaries' access to needed items and supplies. Limiting beneficiaries' access to mandatory mail service is not appropriate for diabetic testing equipment or any other type of DMEPOS.

Many patients appreciate and benefit from the opportunity to interact face-to-face with their DMEPOS provider. This interaction is especially valuable for the elderly and disabled Medicare population. Medicare beneficiaries often require face-to-face demonstrations on how to use or maintain DMEPOS equipment. Even items such as glucose testing strips, which may be viewed as a "simple" DME supply by the Agency, can present a challenge to certain Medicare beneficiaries. For example, beneficiaries may need assistance programming their glucose monitor to accept the testing strips or require assistance replacing the monitor's battery and reprogramming the machine. This type of service would be difficult, if not impossible, to conduct through the mail. Mandatory mail service will also not work for beneficiaries who are hesitant to place orders by phone or do not have access to the Internet, and submitting order forms by mail may cause unnecessary delays to items that beneficiaries need convenient and frequent access to. Beneficiaries must have the option of obtaining their DMEPOS supplies from their provider of choice.

If the Agency decides to create a national or regional mail service program, APhA also recommends that CMS include a program oversight provision related to replacement procedures. CMS must prohibit suppliers from automatically refilling and sending replacement supplies without receiving a refill request from the patient. It is our understanding that some mail service suppliers engage in this practice now.

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[1] PL 108-173 Sec. 302(b)(1)

This could lead to increased risk of fraud and abuse and may unnecessarily increase costs to the Medicare program and beneficiaries.

Again, beneficiaries must not be forced to use one provider over another. Beneficiary choice of provider must be preserved in any new program.

CRITERIA FOR ITEM SELECTION

DMEPOS Items Included in the Program

The new competitive acquisition program will include ten categories of different DMEPOS equipment in the first year of the program. According to the proposed rule, CMS has not yet identified the specific categories that will be included; however, the Agency is looking at categories with the highest cost and highest volume or those with the largest savings potential. Many of the DMEPOS items mentioned throughout the preamble include common supplies such as glucose testing strips and lancets – supplies that beneficiaries need convenient and frequent access to. A sound competitive bidding program would build from the experience of the competitive bidding demonstration projects. Thus, the competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies or other commonly provided items that were not tested through the San Antonio, TX, or Polk County, FL, competitive bidding demonstration projects. If the Agency wants to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be more economically provided by a central supplier.

SUBMISSION OF BIDS UNDER THE COMPETITIVE BIDDING PROGRAM

Product Categories for Bidding Purposes

According to the preamble, CMS has not yet finalized the bidding process for the competitive acquisition program. However, the Agency intends to allow suppliers to submit bids only for the product category or categories they want to furnish instead of requiring suppliers to bid on every DMEPOS item included in the competitive bidding program in their area. APhA supports this provision. Suppliers should have the option to bid only on those DMEPOS items they wish to supply under the program.

APhA is, however, concerned that bids must include all costs related to the furnishing of each item such as delivery, set-up, training, and proper maintenance for rental items. Suppliers will not be able to determine all of the costs associated with providing an item of DMEPOS to a beneficiary until the quality standards for DMEPOS suppliers are finalized. Based on the draft quality standards, which were released last fall, DMEPOS suppliers will be required to meet specific requirements related to delivery/set-up, beneficiary education/training, follow-up, and other beneficiary services.[2] Until suppliers know what will be required, it will be impossible for them to accurately submit a bid that takes all of these costs into consideration. To address this problem, the quality standards must be finalized and released prior to the start of the competitive bidding process.

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[2] Abt Associates Inc./Centers for Medicare & Medicaid Services. Draft of Proposed Recommendations: Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Items and Services. September 26, 2005.

CONDITIONS FOR AWARDING CONTRACTS

Quality Standards and Accreditation
Under the Act, all DMEPOS suppliers must meet quality standards and obtain accreditation from an approved accreditation organization in order to bill for DMEPOS equipment under Medicare Part B.

Suppliers must go through an accreditation process to qualify as a supplier under the competitive bidding program. APhA appreciates the Agency's proposal to allow suppliers with a current valid accreditation to be considered grandfathered if the accreditation was granted by an organization designated acceptable by CMS. It is our understanding that CMS has not yet named the accreditation bodies that qualify for grandfathered status. We request that CMS announce the names of those accreditation organizations immediately to allow suppliers to determine whether or not they must initiate the new accreditation process. The Agency should also announce the approved accrediting organizations for the new accreditation process, as well as provide detailed information on that process.

It is essential that CMS finalize and release the quality standards prior to the start of the competitive bidding process. Suppliers must have sufficient opportunity to review the standards, work towards compliance, and initiate the accreditation process before the competitive bidding process begins. The cost of these efforts by suppliers must be known to submit a well-informed bid for participation.

Determine the Pivotal Bid
Under the proposed rule, CMS will select multiple suppliers to provide DMEPOS in each competitive bidding area. The Agency will select each supplier based in part on the supplier's bid; only those bids that meet or are less than the pivotal bid will be selected. CMS intends to set the pivotal bid at the point where the Agency estimates it will have a sufficient number of suppliers to meet projected demand and provide beneficiaries with "adequate access" to these items. APhA requests that the Agency clarify how it will define "adequate access". Preserving access to a beneficiary's choice of provider and easy accessibility to local providers was a cornerstone of the Act that created the competitive bidding program. Congress clearly worked to ensure that beneficiaries can continue to access the provider of their choice. CMS must follow Congress' intent and ensure that beneficiaries have convenient access to DMEPOS items, and wherever possible, can continue to maintain established relationships with current providers. This will require the Agency to set the pivotal bid at a level that allows maximum supplier participation while still meeting CMS' goal to reduce overall Medicare expenditures for DMEPOS.

DETERMINING SINGLE PAYMENT AMOUNTS FOR INDIVIDUAL ITEMS

Setting Single Payment Amounts for Individual Items
After the pivotal bid is established, the Agency is required to determine a single payment amount for each item of DMEPOS in a competitive bidding area based on the bids submitted and accepted. According to the proposed rule, CMS intends to use the median bid submitted by suppliers as the single payment amount. APhA is concerned that using the median bid will set an artificially low payment rate that many small suppliers 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.

In some cases, the single payment amount may actually be higher than the current reimbursement rate for an item. There may be items for which the current reimbursement rate does not or will not cover a supplier's cost to acquire and provide the item to beneficiaries. For example, supplier costs may increase due to additional beneficiary services that must be provided in order to comply with the DMEPOS quality standards and accreditation process. CMS must recognize this possibility and consider setting the single payment amount at a level higher than the current reimbursement rate. The Agency has the authority to do this under the Act. The Act directs CMS that the "total amounts" paid in a competitive bidding area should be less than the "total amounts" that would be paid if the competitive bidding was not in operation. Because Congress is looking for a reduction in overall or total expenditures – not each individual item – CMS has the flexibility to raise reimbursement for individual items of DMEPOS as appropriate.

The Agency must also periodically examine the payment rate as it compares to supplier acquisition costs. While we appreciate CMS' intent 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. Suppliers would be required to continue providing the product at the single payment rate even if the reimbursement rate is significantly less than their acquisition cost. Suppliers will not be able to continue providing DMEPOS supplies in this situation. CMS must make provisions to increase the payment amount during the year if acquisition costs change.

Rebate Program

The preamble includes a discussion of a potential rebate program under the competitive bidding program. If implemented as proposed, suppliers who submit a bid less than the single payment amount would have the option of providing the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid and the single payment amount. APhA has significant concerns with the rebate program proposal. Although CMS would be paying all suppliers the same reimbursement rate, large suppliers could use the rebate program to drive beneficiaries to them. Not only would the rebate program give large suppliers an unfair competitive advantage, it may also violate the federal Anti-kickback Statute and the Beneficiary Inducement Statute. We strongly discourage the Agency from creating a rebate program.

If the Agency allows suppliers to provide rebates, both the supplier and CMS should be prohibited from advertising the rebates to beneficiaries, prescribers, or other referral sources.

OPPORTUNITY FOR PARTICIPATION BY SMALL SUPPLIERS

Protection of Small Suppliers

The Act requires CMS to "take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program."[3] However, in the proposed rule, CMS does little to ensure that small suppliers can participate in the competitive bidding program. The Agency believes that selecting multiple winners in each competitive bidding area and conducting separate bidding competitions for each product category are sufficient to ensure that small suppliers have appropriate opportunity to compete in the program. APhA disagrees with this assessment. CMS

[3] PL 108-173 Sec. 302(b)(1)

must do more to ensure that small suppliers – which include the majority of pharmacy-based suppliers – can participate in the competitive bidding program.

APhA requests that the Agency revise the final rule to allow small suppliers to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas with large suppliers. We also urge the Agency to revise the contracting process under this program. After CMS establishes the single payment amount for each item of DMEPOS, any supplier willing to accept that payment amount should be allowed to join the competitive bidding program as a contracted supplier.

Taking these steps is necessary to allow small suppliers to participate in the program, preserve beneficiaries' convenient access to DMEPOS supplies, and maintain established provider/patient relationships. Without this additional action, CMS will have not met the intent of the small suppliers provision.

QUALITY STANDARDS AND ACCREDITATION FOR SUPPLIES OF DMEPOS

Quality Standards

APhA reiterates our earlier comments under "Conditions for Awarding Contracts" that CMS must publish the final quality standards before the competitive bidding process begins. Suppliers must have sufficient time to review the quality standards, determine their ability to meet them, revise business and clinical practices and procedures as necessary, and begin the accreditation process if appropriate.

Although the Act provides CMS with the authority to implement the competitive bidding program before the quality standards are released, it would not be in the Agency's, beneficiaries', or suppliers' best interest to do so. As previously mentioned, the final quality standards must be available before a supplier can determine their total costs associated with supplying a DMEPOS item to a beneficiary; before a supplier can initiate the accreditation process; and before a supplier can obtain a Medicare Part B number under the new program requirements. Congress now recognizes this provision as a flaw in the Act. Congress has recognized that the quality standards must be released before the competitive bidding program takes effect and legislation was recently introduced to revise this provision of the Act.[4]

If CMS plans to implement the competitive bidding program by opening the first round of bidding in 2006, the Agency must release the final quality standards immediately.

Accreditation Process

The preamble to the proposed rule includes a discussion on the requirements an accreditation organization must meet in order to receive CMS approval to serve as an accrediting body for the competitive bidding program. While we appreciate the opportunity to review and comment on the application process for an accreditation organization to obtain CMS approval, we are concerned that the Agency has not yet moved further with designating approved accreditation organizations. As with the quality standards, DMEPOS suppliers need detailed information on the accreditation process before they can decide whether or not to submit a bid under the competitive bidding program. Suppliers not only

[4] HR 3559: Medicare Durable Medical Equipment Access Act of 2005. Introduced July 28, 2005 by Rep. David Hobson. This legislation would not allow HHS to award contracts under the competitive bidding program unless the quality standards have been implemented.

need to know who the approved accreditation organizations are – and whether or not their current accreditation is acceptable – but also what the accreditation process entails. Again, we ask CMS to announce the names of those accreditation organizations and provide additional information on the accreditation process before the final rule to implement this program is released.

REGULATORY IMPACT ANALYSIS

Effect on Beneficiaries

According to the regulatory impact analysis, CMS does not anticipate any negative effects on beneficiaries. While the Agency acknowledges that there will be a decrease in choice of suppliers, CMS "assumes that there will be no negative impact on beneficiary access".[5] APhA disagrees with this statement. The Agency does not provide any data or meaningful assurances that beneficiary access to DMEPOS items will be protected. This is particularly concerning since some access issues were identified in the Polk County, FL, competitive bidding demonstration project.[6] As discussed above, CMS must take steps to ensure that beneficiaries have convenient access to DMEPOS items and can continue to use the provider of their choice.

Effect on Suppliers

CMS acknowledges that the competitive bidding program will have a significant impact on DMEPOS suppliers. APhA strongly agrees with this assessment. The competitive bidding program will fundamentally alter who can supply DMEPOS items and services to Medicare beneficiaries. We anticipate that a large number of pharmacy-based DMEPOS suppliers will no longer be able to serve their Medicare patients under this program if it is implemented as currently proposed. According to the Agency's own estimates, in 2007 there will be approximately 18,383 suppliers who provide DMEPOS items subject to the competitive bidding program. Of these 18,383, CMS anticipates that it will contract with less than half – only 8,272; 10,111 suppliers will no longer be able to seek reimbursement from Medicare.[7] This may force suppliers to discontinue providing these products and services to Medicare beneficiaries at an estimated revenue loss of $275 million in 2008 alone.[8] Unfortunately, as the number of accredited DMEPOS suppliers decrease, so will beneficiary access.

Consider for example the effects a reduction in pharmacy suppliers would have on diabetic patients. There are 20.8 million diabetic patients in the United States.[9] Many of these patients obtain diabetic supplies such as glucose monitors, lancets, testing strips, and calibration chips from a community pharmacy. If a beneficiary's pharmacy stops providing DMEPOS equipment to Medicare beneficiaries, the beneficiary will be forced to obtain their necessary diabetic testing supplies from another source. This will compromise many beneficiaries, especially those in rural areas who may be forced to travel significant distances to find a supplier who contracts with the Agency under the competitive bidding program. It will also fragment their diabetes care as beneficiaries will obtain the medications to manage their condition from their local pharmacy and their testing supplies from another source. Decreasing beneficiary access to DMEPOS equipment and fragmenting patient care is clearly not what Congress intended.

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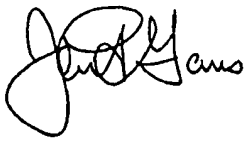
[5] 71 FR at 25,693.
[6] Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. Tommy Thompson, Secretary of Health and Human Services. 2004; Pages 7-8.
[7] 71 FR at 25,694.
[8] Ibid.
[9] American Diabetes Association.

In closing, APhA urges the Agency to revise the final regulation to ensure that beneficiaries can continue to access quality DMEPOS services from the provider of their choice. As discussed in our comments, CMS can protect existing patient/provider relationships by not forcing beneficiaries to use one provider over another, allowing small suppliers to designate smaller markets, and allowing any supplier willing to accept the single payment amount to join the competitive bidding program as a contracted supplier. These changes are necessary to meet the intent of the Act – ensuring access to quality DMEPOS items, providing patient choice, and protecting small suppliers' ability to participate. Additionally, the Agency should limit the competitive bidding program to those unique products that could be more economically provided by a central supply. CMS must also finalize and release the quality standards and name the accreditation organizations before the competitive bidding process begins. Without these revisions, many suppliers will be forced to discontinue serving Medicare beneficiaries and access to necessary DMEPOS equipment and services will decrease.

As the Agency reviews comments and works to modify the competitive bidding program, APhA recommends that the dialogue between the Agency, health care providers, and DMEPOS suppliers – including pharmacies – continue.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan K. Bishop, Director, Federal Regulatory Affairs, at 202-429-7538 or SBishop@APhAnet.org, or Susan C. Winckler, Vice President, Policy & Communications and Staff Counsel, at 202-429-7533 or SWinckler@APhAnet.org, with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Susan C. Winckler, RPh, Esq, Vice President, Policy & Communications and Staff Counsel
Susan K. Bishop, MA, Director, Federal Regulatory Affairs

Submitter :

Date: 06/30/2006

Organization :

Category : Health Care Provider/Association

Issue Areas/Comments

Payment Basis

Payment Basis

CMS has incorrectly evaluated and analyzed its policy on oxygen equipment and supplies. Oxygen equipment is a life sustaining device and must be taken seriously. There is no room for error for it is not a simple commodity like a cane or walker. It is life support.

On pages 37&38 For items requiring frequent and substantial servicing, as well as oxygen and oxygen equipment, we are proposing that a grandfather supplier may continue these items to beneficiaries in accordance with existing rental agreements or supply arrangements. Since rental payments are not calculated based on or limited to the purchase fee for that item as is the case for other rented DME items, we do not believe that it is not reasonable to continue paying the fee schedule amounts for these items and that payment at the competitively determined rates will comport with an overarching goal of competitive bidding to achieve savings for the Medicare program. In addition, unlike oxygen equipment the payment amounts made for capped rental items and inexpensive or routinely purchased items are limited to the approximate purchase fee for the item

The Deficit Reduction Act includes a cap on Medicare rental of oxygen equipment at 36 months, then transfers title to the beneficiary. As of January 1, 2006 all oxygen equipment therefore could be possibly capped at 36 months and is limited to the fee for that item. Since this new oxygen policy was obviously not taken into account into this RFB, I would suggest further study by CMS, as to the appropriateness of bidding out oxygen equipment and supplies before any implementation and ultimately excluding it from the bid process. Or a more simple solution would be repeal Onerous Medicare 36-month Rent-to-Own Oxygen Equipment Provision.

CMS-1270-P-1227-Attach-1.DOC

ATTACHMENT TO #1227

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Submitter : **Mr. JIM GREATOREX** **Date: 06/30/2006**

Organization : **BLACK BEAR MEDICAL**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

sEE aTTACHMENT

CMS-1270-P-1228-Attach-1.DOC

ATTACHMENT TO #1228

BLACK BEAR MEDICAL
275 MARGINAL WAY
PORTLAND ME 04101
207-871-0008

BLACK BEAR MEDICAL
1113 STILLWATER AVE
BANGOR ME 04401
207-989-9849

COMMENTS REGARDING PROPOSED COMPETEIVE BIDDING POLICY

I am writing you regarding some comments we have regarding proposed Competitive Bidding Policy. I'm Jim Greatorex, president of Black Bear Medical, with offices in Portland and Bangor Maine. Each office has it's own provider number. I'm also President of NEMED, New England Medical Equipment Dealers Association.

My first issue is that we strongly feel that high-end rehab mobility equipment should be exempt from bidding. To provide this equipment requires a lot of individual attention, and trial and error and creativity on behalf of the provider and client and clinical people involved with each case. The ability to provide appropriate cost efficient equipment to maximize the health and function of the end user would be greatly diminished if the product were competitively bid. I feel that CMS has the tools already in place to save money on power mobility products with new codes and pricing, and to bid the high end very labor intensive custom product would most certainly result in poor outcomes and accessibility to appropriate product to the end user.

I'm also very concerned about accreditation. Our company is presently in process of working towards accreditation, and it's a huge undertaking for a small business to get through. We absolutely must have adequate time to achieve this goal, and we don't even have the quality standards in place yet. It takes most companies 9 months to a year minimum, to take this process from A-Z, so please, to be fair allow adequate time for this process, and then you can only take bids from accredited providers. How can one properly bid,

if one does not have the experience of operating a business that's accredited, which is more costly.

Allowing rebates for providers who bid under the median bid cannot happen. This will clearly be an inducement, and that has been illegal right up until now. Also, the median bid price should be the price paid to all providers. Without one price per HCPC code, mass confusion will be the case.

I'm also concerned that CMS is only going to take bids that will only cover 100% of capacity of expected need. What happens when someone overestimates his or her capacity, or someone goes out of business, Will there be any provider's left who can provide at bid price. This is a dangerous strategy that could easily leave the beneficiary struggling to get their prescriptions filled.

I can understand CMS wanting to save money on healthcare, but I don't understand why they feel the need to devastate our industry with this concept. Please be aware that the small provider is the one who is there in the community and meeting the needs of the community and customers is first for them and they are not beholden to the needs and of there stockholders. What happens to the Medicaid's of this country who rely on the small provider to provide the small ancillary products that the big national can't or won't because of profitability. If you wipe half of us out, that supply chain will go away.

Also please be aware that during times of natural disaster, such as Katrina, that the big national companies closed up shop, the small independents, overcame many obstacles to still provide needed services to their clients.

I also am concerned about not allowing the bid to be transferred in the event a business is sold. This concept has already devalued DME business's, this rule would take what little value is left, and make our business worthless.

Lastly, please realize that increasing our overhead, and reducing our reimbursement will conclude in less service to the end user, and low quality products for the consumer.

I can be reached at 207-871-0008
Thank-you

Jim Greatorex
President

Submitter : Ms. CAROLINA PEREIRA **Date:** 06/30/2006

Organization : ARROW RESPIRATORY CARE

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

---1)SMALL COMPANIES -THE SMALL COMPNAIES WHO ACTUALLY CARE ABOUT CUSTOMER CARE ARE GOING TO SUFFER, FORCING PATIENTS TO STAY WITH A COMPANY WHO REGULATES HOW MANY TANKS OF OXYGEN A PATIENT SHOULD HAVE PER MONTH AND NOT HOW MANY THEY NEED.
----2)WE AS A SMALL COMPANY HAVE INCREASED OUR PATIENT FLOW BY PATIENTS WHO PICK US BECAUSE WE ARE LOCAL, AND CARING INSTEAD OF STAYING WITH THE BIGGER COMPANIES WHO THEY NEVER EVER GET HUMAN INTERACTION WITH.

----3)BID ON ALL PRODUCT CATERGORIES- SUPPLIERS ARE ABLE TO BID AT ONE ITEM FOR EXAMPLE WHEELCHAIRS, AND GET THE WINNING BID. WHAT HAPPENS WHEN THE PATIENTS GETS THE WHEELCHAIS BUT NEEDS DIFFERENT SEATING THIS IS GOING TO FORCE THE PATIENT TO GO THROUGH MUPLTIPLE PROVIDERS TO GET MEDICALLY NECESSARY ITEMS.

----4)CMS HAS NO AUTHORITY TO EXTEND COMPETITIVE BIDDING AREAS OUTSIDE AN MSA IN 2007 AND 2009. THE MMA CLEARLY STATES THAT THE COMPETITIVE AQUISITION AREAS WILL BE ESTABLISHED IN AN MSA. CMS MUST IDENTIFY THE MSAS IN WHICH IT WILL COMMENCE COMPETITIVE BIDDING IN 2007 IN AN INTERIM FINAL RULE. CMS SHOULD ALSO SCHEDULE A MEETING OF THE PAOC AFTER IT IDENTIFIES THE MSAS.

----5)BENEFICIARIES- WE PROVIDERS WOULD LIKE THE DATA IN WHICH THE BENEFICIARIES ARE AGREEING TO BE PUSHED TO USE ONE PROVIDER FOR A CERTAIN ITEM. ARE THEY HAPPY TO HAVE ONE CHOICE. PLEASE INFORM US WHERE WE CAN OBTAIN THE SURVEYS COMPLETED BY THE BENEFICIARIES. OR DO THEY NOT HAVE A CHOICE?

----6)CMS SHOULD PHASE IN THE FIRST 10 MSA'S, THIS WILL ALLOW CMS TO IDENTIFY AND CORRECT PROBLEMS BEFORE THE PROBLEMS BECOME WIDESPREAD.

----7)SEPARATE BIDDING AREA- WHY DOES MEDICARE PROPOSE A SEPARATE BIDDING PROGRAM FOR MAIL ORDER SUPPLIERS IN 2010, THEY ARE NOT EXCLUDED FROM PARTICIPATING IN COMPETITIVE BIDDING IN 2007 AND 2009. A SEPARATE PROGRAM FOR THEM IN 2010 IS JUST A WASTE OF THE MONIES YOU ARE TRYING TO SAVE.
MAIL ORDER- WHAT IS THE DEFINITION OF MAIL ORDER , MANY OF US SUPPLIERS PROVIDE SOME ITEMS TO BENEFICIARIES VIA MAIL ORDER YET WE ALSO PROVIDE THEM RETAIL OR DELIVERY TOTHEIR HOMES. SO WHO WOULD QUALIFY FOR MAIL ORDER BIDDING COMPETITION.

----8)THE OVERALL PATIENT ACCESS TO CARE AND SERVICES WILL NOT BE MET IF THE PATIENTS THMSELVES ARE NOT GIVEN CHOICES.

Submitter : Mr. Jeremy Ramage **Date:** 06/30/2006

Organization : Good Samaritan Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1230-Attach-1.TXT

ATTACHMENT TO #1230

To Whom It May Concern:

This letter is written on behalf of the Physical Therapists/Occupational Therapists working at Good Samaritan Hospital in Cincinnati, OH in response to the proposed CMS rules changes regarding DMEOS and the CAP process.

Our facility is a large urban hospital that provides acute care rehab, acute inpatient rehab, and outpatient therapy services to the Greater Cincinnati community. Many of our patients include Medicare beneficiaries and in reviewing the proposed rules, we foresee a potentially negative impact to our patients in several ways.

It is important to understand the way in which Physical Therapists/Occupational Therapists at our facility, and we believe the profession at large, utilize DMEOS. In the acute care setting in particular, P.T.s/O.T.s are required to utilize their skills to evaluate a patient's equipment needs at discharge. Often this includes equipment such as assistive devices for ambulation (crutches, walkers, canes, etc.) that make return home safe, particularly for those patients that have limited assistance from family/friends. The patient is sure to get the **most appropriate** DME for their personal needs because a licensed Physical Therapist is deciding what DME is medically needed, not an equipment salesman at a store who may or may not have adequate training. This includes the opportunity to collaborate with the physician regarding such factors as weight bearing status that could affect choice of equipment. We use one vendor that supplies our stock most often, and a price list for our stocked equipment is made available upon request. The patient is informed that they have the option to purchase from another vendor. The patients appreciate this option, but generally prefer to purchase the equipment they have practiced on and that is readily available at D/C. As therapists, we also think the ability to train a patient on the very equipment they are to take home is the safest, most reassuring option. Under the proposed rule, a vendor that wins the bid to be a Medicare supplier may not be able to supply our stockroom and we will be forced to just recommend the type of equipment to go pick up. It is vital that CMS ensure enough suppliers are awarded bids in any given MSA to assure competitive incentive to provide this service, as many clinics/hospitals use this system. There may also be supply limitations for vendors if there are only a small number of approved suppliers in each MSA. Under this scenario, the patient may or may not end up with the proper DME!

Another concern involves equipment options. Our therapists enjoy the ability to choose an outside vendor (and sometimes do) when the equipment available by our in-house vendor is inadequate for that patient's needs. Sometimes, this results in a vendor representative from an outside company delivering the desired equipment directly to the hospital. They reliably provide this service because the incentive is there to provide optimal service from a competitive standpoint. Also, we routinely receive inservices (as do many facilities) from various DME vendors so the therapists can keep up to date on what equipment is available. While the price might be better to Medicare, the convenience and more importantly, the safety of our patients would be put at risk. Do the proposed quality control standards include the supplier proving they have the full breadth of products available within a certain category? We could not find any such standard but it is unlikely this could ever be expected because there are many, many products from different companies of the same general type but with small differences. For example,

there is a difference between the standard walker width from the company Drive versus the width of the standard walker from Invacare. This could affect a therapist's recommendation based on a patient's girth, or the width of their doorways. The wrong choice could result in an "adverse medical outcome," such as a fall. Another example that comes to mind is that there are many different wheelchair models offered under each K Level. A chair that is heavier or with poorer maneuverability than another brand in the same K category could result in the long term "adverse medical outcome" of an overuse injury to the shoulders. We feel strongly that this limit in choice will undercut our goal to provide optimum care to our Medicare patients. This problem would be especially acute if only one supplier was available in a given region, as there would be no incentive to offer a wide variety of products within a specific equipment category. Perhaps an exceptions process could be put in place that allows using outside vendors for equipment if sufficiently shown to be of an advantage to a particular patient over that available through the Medicare supplier(s).

As for the portions of the rule pertaining to off the shelf orthotics, there are additional concerns. Our facility provides off the shelf orthotics such as pre-fabricated AFOs. While this type of equipment is not on par with Custom Fabricated AFOs supplied by certified prosthetists/orthotists, they can require the type of adjustments mentioned in the rule such as "trimming, bending, molding" and other adjustments such as adding supportive straps. The proposed CMS quality standard that defines "Custom fitted low" and "Custom fitted high" orthotics appears to address these type of adjustments. Not only are these adjustments necessary at times, they are within a Physical Therapist's scope of care and training. For example even the simplest AFO can cause a pressure area at a bony prominence. Often this can be remedied by an easy but skilled trim or flare by the treating Physical Therapist. This is in contrast with the rule's apparent assumption that only certified orthotist/prosthetists can perform these tasks. Therefore, we would argue that at least some off the shelf orthotics provided under the care of a Physical Therapist should be eligible for exemption from the CAP. At the very least, it seems difficult to define any "off the shelf" orthotic as not requiring expertise because one truly doesn't know what will be required until the orthotic is issued. There are simply too many variables that could affect how well the item fits and how much if any, adjustment is needed.

In closing, we respectfully appreciate the efforts of CMS to control spiraling costs. There are some admirable qualities to the proposed process but there seems to be some disadvantages that should be considered before the final rule is drafted. As trained professionals, we think it should be recognized that even with "off the shelf" equipment, there is an evaluative process that occurs beyond the order from a physician. Whether P.T. or O.T., our patients deserve to have us serve them in a way that takes advantage of our extensive and ongoing training.

Sincerely,

The Rehabilitation Team of Good Samaritan Hospital
Cincinnati, OH
513-872-2481

Submitter : **Date: 06/30/2006**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Payment Basis

Payment Basis

The allowance of a rebate is fundamentally wrong and will only lead to enticements and fraud as well as confusion to benficiaries. This should not have any place in a federally mandated program that continually stresses against the possibility of any form of kickbacks

Submitter : Mr. David Fiorini **Date:** 06/30/2006

Organization : PA Association of Medical Suppliers

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1232-Attach-1.DOC

ATTACHMENT TO #1232

June 30, 2006

Via Electronic Transmission

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1270-P
7500 Security Boulevard
Baltimore, MD 21224

Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment

Dear Dr. McClellan:

The Pennsylvania Association of Medical Suppliers (PAMS) appreciates the opportunity to submit comments relative to the proposed rule for competitive acquisition for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS).

PAMS is a state association compromised primarily of 163 durable medical equipment providers (DME) and manufacturers located throughout Pennsylvania and Delaware. Seventy percent of our membership is considered small businesses. Our members deliver home medical equipment including, but not limited to, respiratory, rehab/assistive technology, and home infusion therapy products and services to the patient's home, residence or custodial care facility.

PAMS is also a member of the American Association of Homecare (AAHomecare) and we fully endorse the comments submitted by AAHomecare. We would like to stress the following issues.

Timeline 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.

From the operational prospective of our businesses, we need to plan and budget for staff, inventory, vehicles, Information Technology, and communications just to name a few items. In an effort to assure that the transition to Competitive Acquisition (CA) is not wrought with problems, we are suggesting that CMS establish an implementation timeline that identifies the critical steps leading-up to competitive acquisition. We urge CMS to consider the operational aspects of our businesses and adopt realistic timelines. The remaining steps include:

The Pennsylvania Association of Medical Suppliers
1000 Bent Creek Boulevard, Ste. 10 · Mechanicsburg, PA 17050
(717) 795-9684 · Fax (717) 795-9685 · www.pamsonline.org

- Publication of the supplier standards
- Selection and announcement of the CBIC including detailed bid scoring criteria
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSA

Payment Basis

Inflation Update

The proposal states that providers do not have to factor inflation into their bids because the competitive bid price will be updated annually by the CPI-U.

- Providers need assurances in the bid process that the CPI-U will not be overridden by other legislation or regulation.
- If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Medicare Advantage

The NPRM does not address the impact of competitive acquisition on Medicare Advantage (MA) patients who leave their plan to reenter traditional Medicare.

- These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier.
- What rules will apply to this patient population under competitive acquisition? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program?

Recommendation: Patients moving from an MA plan to traditional Medicare should be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers

The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive acquisition area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids.

- Suppliers will be unable to include these additional costs into their bids because of detail lack of knowledge on what the beneficiaries may decide.
- Providers would need access to detailed information to assure that they bill properly. Access to the Common Working File would assist in resolving this issue.

Recommendation: There should be a defined time frame that the transition can occur. All transitioning patients start a new rental period.

Bid Prices

CMS states that suppliers may not submit bids higher than the current fee schedule amount for an item.

- This establishes an artificial ceiling on the bids and does not allow for appropriate payment considerations for items that are not currently reimbursed at competitive fees.
- This further complicates acquisition considerations for the provider. It may require the provider to bid at a higher rate on other products in the group.

Recommendation: Remove the restrictive language in the final rule. Allow the appropriate pricing to be considered for each product.

DRA implications for Capped Rental to Oxygen Patients

The DRA further complicates the Competitive Acquisition process. Several issue need to be addressed surrounding ownership, grandfathering and repairs.

- Will forced ownership be required for Capped Rentals and Oxygen equipment?
- With the breadth of products available in the market place providers may lack expertise in trouble shooting and repairing the product owned by the patient.
- 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?
- DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive acquisition. Providers cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements.

Recommendation (s): 1.CMS should publish an interim final rule before it publishes the final rule on competitive acquisition. 2. To ensure quality patient care, CMS should consider the ramifications of forced ownership and the requirement that the winning bidders must service and repair all patient owned equipment.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive acquisition program, to use the payment information obtained through competitive acquisition to adjust the payment amounts for those items in areas outside the competitive acquisition area.

- The authority for the DME, 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 acquisition 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 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 acquisition. Consequently, the authority to use information derived from a competitive acquisition 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 from competitive acquisition 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.

- It is illogical that CMS would consider utilizing prices from a competitive bid area with some volume expectations to a non competitive bid area that does not have like markets or volume expectations.

Limitation on Beneficiary Liability

We understand that Medicare will not cover DMEPOS items subject to competitive acquisition furnished to a beneficiary in a competitive acquisition 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. Does this restrict the beneficiary's freedom of choice to pay for a product or have repairs done if they chose to pay for the service?
- Other portions of the NPRM specifically state that ABNs will be permitted under a competitive acquisition program, and the MMA requires that CMS continue to allow suppliers to use ABNs.

Recommendation(s): 1.CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier. 2. Allow providers to use an ABN, thus giving the freedom of choice to the beneficiary.

Competitive Bidding Areas

Staggered Implementation
The NPRM is silent on whether CMS will commence competitive acquisition in 10 MSAs at the same time, or stagger the initial implementation of competitive acquisition beginning in 2007.
Recommendation: We recommend that CMS phase-in the first 10 MSAs. This will allow CMS and its contractors to identify and correct problems as competitive acquisition commences.

Nationwide or Regional Mail Order Competitive Bidding Program
It is unclear why CMS proposes a separate competitive acquisition program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive acquisition during 2007 and 2009, a separate program for them in 2010 would be unnecessary.

When CMS has provided a greater level of detail, we would appropriately comment on the need for this provision.

Competitive Bidding Area
We question CMS's authority to extend competitive acquisition outside an identified MSA in 2007 and 2009.

- The MMA clearly states that the competitive acquisition areas will be established in an MSA.
- CMS must identify the MSAs in which it will commence competitive acquisition in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding
CMS identifies three categories of items that are subject to competitive acquisition 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 acquisition 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 acquisition 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 competitive acquisition for a product category? When referencing the allowed charges is this billed or paid dollars?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category? Is this billed or paid dollars?
- 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? Will these studies cross disciplines? e.g. hospital admissions, Home Health visits, emergency room visits.

Product Categories for Bidding Purposes

General Issues

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category 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.

Issues for Clarification and Correction

The true meaning and explanation of product categories was not clear in the NPRM. Is it to be by product type or HCPCS code?

- CMS must define products categories narrowly to make sure that they are consistent and representative of the products that a supplier might actually furnish. By example, a broad category for wheelchairs or power wheelchairs will not work.
- Power wheelchair codes are in the process of being revised and have been in that process for several years due to their complexity. It makes them inappropriate for use in a competitive acquisition model.
- Complex Rehab wheelchairs are predominantly custom-configured to the individual. These complex pieces of equipment are inappropriate for use in a competitive acquisition model.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Therefore there may be valid codes in place by 2008 in the "wheelchair" product category that do not exist during the bid process.
- The final rule should be changed so that a provider who bids on the category of manual wheelchairs will not be required to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space.
- CMS should ensure that the process accounts for narrow product categories so that providers may submit proposals for products and services that they currently have expertise in providing.

Skilled Nursing Facilities and Physicians

CMS proposes that only skilled nursing facilities (SNFs) and physicians selected as contract suppliers would be eligible to provide DMEPOS in a competitive biding area. Physicians and SNFs can limit their services to their own residents or patients and would not be required to service all beneficiaries in an MSA. In contrast, DMEPOS suppliers awarded contracts, cannot refuse to serve any beneficiary. This means that contract suppliers would be required to accept beneficiaries regardless of the costs the supplier may have to absorb (e.g., assuming a caped rental in the 10th rental month) whereas SNFs and physicians could limit their service costs. Including SNFs and physicians in the same competition with DMEPOS suppliers will distort the bid evaluation and selection of the pivotal bid because SNFs and physicians will have significantly lower costs to operate under the acquisition program. We recommend that CMS conduct separate competitions for those items that will be furnished by SNFs or physicians such as enteral nutrition, equipment and supplies.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

- CMS needs to identify the criteria it will use to select accrediting bodies before the final rule is published. There is no benefit in waiting. This has been discussed and positive options provide by the PAOC.

- We support an aggressive accreditation campaign to assure that providers in any MSA with a competitive acquisition program who which to participate are able to be accredited before the bid solicitations are published.

- The "pivotal" bid methodology outlined in the NPRM does not include any mechanism to ensure that there are no unreasonably low bids. The proposed methodology will allow and almost encourages suppliers with small individual capacity to submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

- CMS must eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. A key term used often at the last PAOC meeting was sustainability. Winning suppliers who can not actually afford to stay in business with a low winning bid ultimately do nothing for the beneficiary.

- Another phrase used often at the last PAOC meeting was the minimalist approach to the number of winning suppliers to provide minimum capacity requirements in the competitive acquisition area. There are limitless natural-occurring events that could create unanticipated access problems for beneficiaries in the MSA. CMS should consider other variables beyond capacity that may affect the selection of winning bidders.

- Artificially limiting bids by disqualifying bids above the current fee schedule amount for an item is not truly "competitive" based on market prices. Use the methodology proven in the demonstrations that focused on 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.

- As defined in the NPRM, the Single Payment Amount for "winning suppliers" 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 acquisition area due to a higher level of capacity. It does not make any sense that Congress had this expectation in mind when it authorized competitive acquisition under the MMA. CMS should set the payment amount at the pivotal bid level as defined in the NPRM.

- CMS should remove the Rebate Program from the rule. There is a statutory prohibition on beneficiary inducements that prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. As discussed and described at the last PAOC meeting, the rebate program proposed in the NPRM is problematic and it does not fit any of the statutory exceptions.

- Once again, it was clearly and loudly discussed at the last PAOC meeting that CMS should be driving beneficiaries to HIGH QUALITY SUPPLIERS and instead the NPRM seems to be focusing on LOWEST COST SUPPLIERS.

Recommendation: CMS should withdraw the rebate proposal. We believe that this constitutes an inducement and as such a violation of the Anti-Kickback statute.

Terms of Contract

Issues for Clarification and Correction

We support a recommendation that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires.

The repair of patient owned equipment should be treated as a separately bid item on the RFB and CMS should solicit bids for the repair of patient owned equipment.

CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

CMS cannot unreasonably withhold its approval of a change of ownership of a winning supplier and should not deny winning supplier status to new owners on the basis that its capacity is not necessary within the competitive acquisition area.

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS should expand this to allow greater participation by small suppliers with a small supplier set asides in at least some MSAs.

CMS' proposal for allowing networks is void of any of the practical details for implementation. If this is to be a viable option, substance needs to be placed around it or else it is of no value.

Conclusion
PAMS appreciates the opportunity to submit these comments. The Competitive Acquisition rule has sweeping impacts on the industry and more importantly, on the patients served. The plan must be logical and implemented in a manner that can be successful.

I remain available to discuss in further detail.

Respectfully submitted,

David N. Fiorini

David N. Fiorini
Executive Director
PAMS

Submitter : Dr. Samuel Masket **Date:** 06/30/2006

Organization : Amer. Society of Cataract and Refractive Surgery

Category : Health Care Professional or Association

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

See attachment

CMS-1270-P-1233-Attach-1.DOC

ATTACHMENT TO # 1233

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 Dr. McClellan:

On behalf of over 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care, the American Society of Cataract and Refractive Surgery (ASCRS) would appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) 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). ASCRS members perform the vast majority of the more than 2 million cataract procedures performed annually in the United States and are very concerned with certain aspects of this proposal. Although we generally support and endorse the comments filed by the American Medical Association, ASCRS submits these comments to focus on the issues of most concern to its members.

As mandated by the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003, CMS is proposing to establish the Medicare DMEPOS Competitive Bidding Program, whereby physicians who supply DMEPOS items must submit bids and be awarded contracts in order to furnish the items included in the competitive bidding program. In addition, CMS is proposing to establish and implement quality standards for DMEPOS suppliers of certain items, including consumer service standards. These standards will be applied by CMS-selected independent accreditation organizations. In the rule, the agency explains that the need for quality standards stems from fraudulent and abusive activities by DMEPOS suppliers of certain DMEPOS items identified by the Department of Health and Human Services Office of Inspector General (OIG).

While ASCRS appreciates CMS' efforts to provide more oversight of DMEPOS suppliers and to combat the fraudulent and abusive activities by some of these entities, we are concerned that the proposed rule does not consider the possibility of making any exceptions from the quality standards and accreditation requirements for those DMEPOS

suppliers who pose no risk of program or patient abuse. Even if CMS believes it does not have the statutory authority to make blanket exceptions, it certainly has the discretion to make some accommodations in the quality standards for these suppliers. In the absence of an exception or special accommodations, we are concerned that the proposal will drive ophthalmologists out of the business of supplying post-cataract eyewear and, therefore, inadvertently impose an undue burden on patients, primarily those who are elderly and/or have limited ability. It is precisely these patients who benefit the most from the convenience of being able to purchase their post-cataract eyeglasses or contact lenses directly from their ophthalmologist.

We believe including ophthalmologists who act as DMEPOS suppliers for purposes of furnishing their post-cataract patients with the one pair of post-cataract eyeglasses or contact lenses covered by the Medicare program is unnecessary and does not fulfill the programs' primary objectives. **Therefore, we request that the agency exempt ophthalmologists who act as DMEPOS suppliers for purposes of dispensing their post-cataract patients with the one pair of conventional eyeglasses or contacts lenses covered by Medicare from any quality standards or accreditation requirements. At a minimum, special accommodations should be made for these suppliers to reduce the regulatory burden of complying with quality standards. We also strongly endorse the AMA's position that these standards should be issued through notice and comment rulemaking proceedings, rather than through program memoranda.**

We ask the agency to consider our concerns outlined below as the final regulations on the DMEPOS quality standards and accreditation activities are crafted.

Quality Standards and Accreditation for Suppliers of DMEPOS

As the agency is aware, many ophthalmologists act as DMEPOS suppliers for purposes of dispensing post-cataract eyewear to their Medicare patients. They do this to provide a valuable and convenient service to their Medicare patient, particularly those who have difficulty getting from place to place.

In 1998, CMS included post-cataract eyeglasses and contact lenses in their definition of designated health services (DHS) for purposes of the proposed regulations addressing physician self-referrals, collectively referred to as the "Stark II regs." ASCRS, along with the rest of the ophthalmic community, adamantly opposed the inclusion of post-cataract eyewear in the definition of DHS because Medicare coverage is limited to one pair of conventional eyeglasses or contact lenses after each medically necessary cataract surgery and includes fixed fee limits that do not vary with the expense of the eyewear. Therefore, the dispending of these products poses no risk of program or patient abuse.

This same argument was made by Representative Pete Stark in a letter to the agency, then the Health Care Financing Administration (HCFA) on March 9, 1998, where he urged that the one pair of eyeglasses or contact lenses following cataract surgery, "be exempted from coverage under the [Stark II] regulations." **Congress never intended for Stark II to apply to post-cataract eyeglasses or contact lenses because they understood the limited nature of this service under Medicare.** Rep. Stark further stated that

"[i]ncluding lenses and glasses in the law creates a hassle which achieves no good purpose and can be an inconvenience to patients."

The agency agreed; concluding that eyeglasses and contact lenses should be not be included as designated health services for purposes of Stark II. In the Stark II final regulations, published in the *Federal Register* on January 4, 2001, the Department of Health and Human Services (HHS) excluded eyeglasses and contact lenses, as shown below:

> *"[E]yeglasses and contact lenses should be excluded from the reach of section 1877 of the Act for purposes of Medicare referrals. The Medicare coverage of these items is unique in that it is limited to one pair of either item after each cataract surgery and is available to any patient who has had this surgery. In that respect, the coverage is similar to the coverage of preventive screening services that are subject to frequency limits, as discussed earlier in this section. In addition, the Medicare-approved amount of payment does not vary based on the expense of a particular pair of glasses or contact lenses. Medicare pays fixed amounts for eyeglasses and contact lenses that are single focal, and fixed amounts for eyeglasses and contact lenses that are bifocal. In sum, we see little opportunity or incentive for a physician to either under or overutilize these items in the Medicare program. Accordingly, we are creating a new exception under the authority in section 1877(b)(4) of the Act for eyeglasses and contact lenses after cataract surgery. Like other section 1877(b)(4) exceptions, the new exception is subject to there being no violation of the anti-kickback statute or any billing or claims submission law or regulation."*

As CMS explains in this proposed rule,

> *"Suppliers of DMEPOS must comply with the quality standards in order to furnish any item for which payment is made under Part B, and to receive and retain a provider or supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. Section 1834(a)(20)(D) of the Act requires us to apply these quality standards to suppliers of the following items for which we deem the standards to be appropriate:*
>
> - *Covered items, as that term is defined in section 1834(a)(13), for which payment may be made under section 1834(a);*
> - *Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4); and*
> - *Items described in section 1842(s)(2) of the Act, which include medical supplies, home dialysis supplies and equipment, therapeutic shoes, parenteral and enteral nutrients, equipment, and supplies, electromyogram devices, salivation devices, blood products, and transfusion medicine."*

The rule further explains that;

> *"Even with the implementation of the enrollment standards at § 424.57, we believe there has not been sufficient oversight of suppliers of DMEPOS and other items related to the quality and provision of their products. The Department of Health and Human Services, Office of Inspector General (OIG), has conducted several investigations of suppliers of DMEPOS and other items to determine the legitimacy of their businesses and has uncovered many examples of fraud and abuse. Examples of the types of fraud and abuse that were discovered include--*
>
> - *Billing for services not performed;*
> - *Billing for a more expensive service than was rendered;*
> - *Billing separately for several services that should be combined into one billing;*
> - *Billing twice for the same service;*
> - *Billing for more expensive equipment or supplies than were used;*
> - *Offering or receiving kickbacks (that is, offering or accepting something in return for services);*
> - *Offering or accepting a bribe to use a particular service or company;*
> - *Providing unnecessary services; and*
> - *Submitting false cost reports."*

Again, while we appreciate CMS' efforts to the combat fraudulent and abusive activities, we believe that ophthalmologists who act as DMEPOS suppliers for purposes of dispensing their Medicare patients with post-cataract eyewear should not be required to meet any quality or accreditation standards, because there is no documented history of this supplier type engaging in any fraudulent activity that poses a risk to the Medicare program or Medicare patients. Because of the frequency and payment limits that apply in this area, there is simply no incentive or ability for ophthalmologists to overcharge or over-prescribe post-cataract eyewear. Thus, applying quality standards and accreditation requirements to these "suppliers" will not accomplish the goals set forth by Congress in establishing or CMS in implementing these standards.

In addition, we believe including ophthalmologists who act as DMEPOS suppliers to provide their Medicare patients with post-cataract eyewear is inconsistent with the agency's previous pledge to take a common-sense approach to preventing potentially abusive behaviors by Medicare providers. ASCRS finds that the agency's proposal to require ophthalmologists who serve as DMEPOS suppliers to dispense post-cataract eyewear to their Medicare patients to meet quality standards that address:

- administration;
- financial management;
- human resource management;
- beneficiary services;
- performance management;
- environment and safety;

- beneficiary rights/ethics;
- and information management

to be a, unnecessary, unwarranted and undue regulatory burden.

Ophthalmologists who dispense post-cataract eyewear to their Medicare patients are providing a valuable and convenient service and including them in this requirement is hardly in the best interest of Medicare patients. By requiring ophthalmologists to meet quality standards and seek accreditation by a CMS-approved accreditation organization, the agency would inadvertently create a significant hassle for its beneficiaries, particularly those beneficiaries who are elderly and have limited mobility.

Ophthalmologists typically supply post-cataract eyewear as a convenience to their patients. Because of the payment limits, this is not a profitable enterprise for physicians. Should ophthalmologists who typically dispense post-cataract eyewear to their Medicare patients not be exempt from this unnecessary requirement, they may be compelled to preclude their optical shops from providing post-cataract eyewear to their Medicare patients to avoid this unnecessary and unwarranted regulatory burden. We are concerned that this would inflict a significant hardship on Medicare's cataract patients because obtaining eyewear from their ophthalmologists' on-site or nearby optical shop is typically the most convenient option.

Again, ophthalmologists provide a valuable and convenient service to their Medicare patients, and including them would pose a significant inconvenience. Since ophthalmologists have no ability under the current system to overutilize or overcharge for post-cataract eyewear, and there is no documented history of abusive practices with respect to ophthalmologists dispensing post-cataract eyeglasses and contacts to Medicare patients, we maintain this requirement is unnecessary and unwarranted.

*****

Therefore, ASCRS requests that the agency exempt ophthalmologists, who act as DMEPOS suppliers for the purpose of dispensing post-cataract eyeglasses and contact lenses to their Medicare patients, from any requirement to meet certain quality standards and seek accreditation by a CMS-approved accreditation organization. At a minimum, any standards that are established should have minimal quality requirements for these suppliers. Should you have any comments or questions, please contact Emily L. Graham, CCS-P, CPC, ASCRS' Manger of Regulatory Affairs at 703-383-5725 or egraham@ascrs.org.

Sincerely,

Samuel Masket, MD
President, ASCRS

Submitter : Mr. Steven Brill **Date:** 06/30/2006

Organization : Bioworks, Inc

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am the owner of a small business in the Midwest providing orthotics, both off the shelf and custom, as well as some Musculoskeletal DME such as CPM Machines and E-Stim. I am an ABC Certified and State Licensed Orthotist. Our company also employs another Certified/Licensed Orthotist as well as a Certified/Licensed Pedorthist. We went through the rigorous process to obtain the status of an Accredited Facility. After reviewing the CMS draft concerning Competitive Bidding I am forwarding the following comments.

(1) Our profession fits a wide variety of orthotic products. Some require significant skill and expertise to fit such as custom fabricated and custom fit products, and some products that routinely don t require a great amount of expertise such as cock-up wrist splints or lace-up ankle braces. Although many of these products are normally fairly easy to fit, there are consistently exceptions such as how to address fluctuating edema, skin breakdown, neuropathy or skin allergies that require the expertise of a licensed professional. It s not unusual for me to become involved in fitting or establishing alternative products for what an outsider would consider a simple product. My understanding is that the San Antonio pilot achieved low cost saving in the orthotics arena. I propose eliminating these products from Competitive Bidding process.

(2) As a local provider we are held to a very high standard by the Orthopedic practices that refer patients to us. Their reputation is in part based upon the service we provide. As a business we have multiple locations near the physicians and the patients we serve. Our hours of operation are such that, if physicians are seeing patients, then we are available to fit orthotic products. If a patient cannot come to one of our offices, we see them at their residence even for the most inexpensive product. Although we seek value in the products we fit, we seldom are buying the least expensive product and are very conscious of quality, durability and comfort. I m very concerned that the Competitive Bidding process will favor providers that are not currently doing business in the area. Although they meet the minimum standard set forth by CMS, they will be able to gain business on a basis of cost only and will not have to meet the difficult standard that we have had to meet to be able to grow and sustain business in this area. Product quality and patient care and convenience will surely suffer with the proposed process. I would recommend to CMS that they not accept proposals from businesses unless they are currently legitimately operating in the specific MSA.

(3) Many patients of custom orthosis can be extremely complicated and difficult. Many patients who walk through our doors have conditions so complex that it will be difficult to break even financially. We gladly accept these patients with the understanding that overall our business is profitable. Taking away some of the OTS products will make it increasingly difficult to provide the more at risk part of the Medicare population with the orthotic products they require. I believe if this process cuts too deeply, Medicare will lose capacity to handle Custom Orthotics/Prosthetics. Lowering our reimbursement on products will adversely affect our ability to compete, but eliminating these products all together could make the situation much worse for providers and beneficiaries alike. I propose allowing accredited businesses the ability to provide product at the Medicare approved price.

(4) I think increased credentialing and quality standards will reduce fraud and abuse in Orthotics/DME. I believe up-coding and over-utilization due to kick-backs and improper Contractual Joint Ventures is costing Medicare, Medicaid and private insurances tremendous amounts of money. I believe more money would be saved by stepping up enforcement and increasing standards than by limiting the choices of Medicare participants.

Steven M. Brill

Submitter : Ms. Ann-Marie Lynch **Date:** 06/30/2006

Organization : AdvaMed

Category : Device Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Conditions for Awarding Contracts

Conditions for Awarding Contracts

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Criteria for Item Selection

Criteria for Item Selection

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Education and Outreach

Education and Outreach

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

GENERAL

GENERAL

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Gap-filling

Gap-filling

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

See Attachment. Our comment letter addresses a number of issues contained in the Proposed Rule.

CMS-1270-P-1235-Attach-1.PDF

ATTACHMENT TO # 1235

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AdvaMed
Advanced Medical Technology Association

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery
Direct: 202 434 7203
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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,

/s/
Ann-Marie Lynch
Executive Vice President

Submitter : **Date: 06/30/2006**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

CMS has proposed to exclude from consideration, for competitive bidding until 2009, the three largest MSAs in terms population, as well as any MSA that is geographically located in an area served by two DMERCs. This response by CMS to gain experience with the program, before implementing it in these particular MSAs which would be logistically difficult for them, has merit.

CMS must also propose to exclude MSAs which are located in disaster areas or high potential natural disaster areas. These MSAs include the gulf coast, the south eastern seaboard of the United States and Puerto Rico. Competitively bidding these areas for medical equipment and life support systems would pose an obvious threat to national security. As we have seen in previous natural disasters medical equipment suppliers are called upon during these times to quickly discharge patients to the home to make room for new and existing waiting patients and to relieve the burden of the overwhelmed fire and police departments on saving beneficiary lives who can not get oxygen or other life support equipment because the original medical equipment company has been destroyed by the natural disaster. Including these MSAs would create a logistical nightmare for CMS if a natural Disaster hits.

In summary, CMS should exclude these high probability areas of natural disaster prone areas until 2009 and consult with both FEMA and the Department of Homeland Security before implementing competitive bidding in these areas.

CMS-1270-P-1236-Attach-1.DOC

Competitive Bidding areas

CMS has proposed to exclude from consideration, for competitive bidding until 2009, the three largest MSAs in terms population, as well as any MSA that is geographically located in an area served by two DMERCs. This response by CMS to gain experience with the program, before implementing it in these particular MSAs which would be logistically difficult for them, has merit.

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In summary, CMS should exclude these high probability areas of natural disaster prone areas until 2009 and consult with both FEMA and the Department of Homeland Security before implementing competitive bidding in these areas.

Submitter : **Date: 06/30/2006**

Organization :

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

I am against the implemetation of a competitive bidding program, because it will severly reduce and curtail technologicl research into health care products that will ultimately benefit the quality of life for those requiring special health care assistance as well as possibly reducing hospital admissions. Manufacturers will not be inclined to put new products in the market if they know providers will have no reason to provide costlier alternatives irregardless of the increased benefit it will have on the patient. Because of reduced competition, providers will put out the lowest priced product and not make consumers aware of alternatives.

Submitter : Mr. Jeremy Ramage **Date:** 06/30/2006

Organization : Good Samaritan Hospital

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1238-Attach-1.TXT

ATTACHMENT TO #1238

To Whom It May Concern:

This letter is written on behalf of the Physical Therapists/Occupational Therapists working at Good Samaritan Hospital in Cincinnati, OH in response to the proposed CMS rules changes regarding DMEOS and the CAP process.

Our facility is a large urban hospital that provides acute care rehab, acute inpatient rehab, and outpatient therapy services to the Greater Cincinnati community. Many of our patients include Medicare beneficiaries and in reviewing the proposed rules, we foresee a potentially negative impact to our patients in several ways.

It is important to understand the way in which Physical Therapists/Occupational Therapists at our facility, and we believe the profession at large, utilize DMEOS. In the acute care setting in particular, P.T.s/O.T.s are required to utilize their skills to evaluate a patient's equipment needs at discharge. Often this includes equipment such as assistive devices for ambulation (crutches, walkers, canes, etc.) that make return home safe, particularly for those patients that have limited assistance from family/friends. The patient is sure to get the **most appropriate** DME for their personal needs because a licensed Physical Therapist is deciding what DME is medically needed, not an equipment salesman at a store who may or may not have adequate training. This includes the opportunity to collaborate with the physician regarding such factors as weight bearing status that could affect choice of equipment. We use one vendor that supplies our stock most often, and a price list for our stocked equipment is made available upon request. The patient is informed that they have the option to purchase from another vendor. The patients appreciate this option, but generally prefer to purchase the equipment they have practiced on and that is readily available at D/C. As therapists, we also think the ability to train a patient on the very equipment they are to take home is the safest, most reassuring option. Under the proposed rule, a vendor that wins the bid to be a Medicare supplier may not be able to supply our stockroom and we will be forced to just recommend the type of equipment to go pick up. It is vital that CMS ensure enough suppliers are awarded bids in any given MSA to assure competitive incentive to provide this service, as many clinics/hospitals use this system. There may also be supply limitations for vendors if there are only a small number of approved suppliers in each MSA. Under this scenario, the patient may or may not end up with the proper DME!

Another concern involves equipment options. Our therapists enjoy the ability to choose an outside vendor (and sometimes do) when the equipment available by our in-house vendor is inadequate for that patient's needs. Sometimes, this results in a vendor representative from an outside company delivering the desired equipment directly to the hospital. They reliably provide this service because the incentive is there to provide optimal service from a competitive standpoint. Also, we routinely receive inservices (as do many facilities) from various DME vendors so the therapists can keep up to date on what equipment is available. While the price might be better to Medicare, the convenience and more importantly, the safety of our patients would be put at risk. Do the proposed quality control standards include the supplier proving they have the full breadth of products available within a certain category? We could not find any such standard but it is unlikely this could ever be expected because there are many, many products from different companies of the same general type but with small differences. For example, there is a difference between the standard walker width from the company Drive versus

the width of the standard walker from Invacare. This could affect a therapist's recommendation based on a patient's girth, or the width of their doorways. The wrong choice could result in an "adverse medical outcome," such as a fall. Another example that comes to mind is that there are many different wheelchair models offered under each K Level. A chair that is heavier or with poorer maneuverability than another brand in the same K category could result in the long term "adverse medical outcome" of an overuse injury to the shoulders. We feel strongly that this limit in choice will undercut our goal to provide optimum care to our Medicare patients. This problem would be especially acute if only one supplier was available in a given region, as there would be no incentive to offer a wide variety of products within a specific equipment category. Perhaps an exceptions process could be put in place that allows using outside vendors for equipment if sufficiently shown to be of an advantage to a particular patient over that available through the Medicare supplier(s).

As for the portions of the rule pertaining to off the shelf orthotics, there are additional concerns. Our facility provides off the shelf orthotics such as pre-fabricated AFOs. While this type of equipment is not on par with Custom Fabricated AFOs supplied by certified prosthetists/orthotists, they can require the type of adjustments mentioned in the rule such as "trimming, bending, molding" and other adjustments such as adding supportive straps. The proposed CMS quality standard that defines "Custom fitted low" and "Custom fitted high" orthotics appears to address these type of adjustments. Not only are these adjustments necessary at times, they are within a Physical Therapist's scope of care and training. For example even the simplest AFO can cause a pressure area at a bony prominence. Often this can be remedied by an easy but skilled trim or flare by the treating Physical Therapist. This is in contrast with the rule's apparent assumption that only certified orthotist/prosthetists can perform these tasks. Therefore, we would argue that at least some off the shelf orthotics provided under the care of a Physical Therapist should be eligible for exemption from the CAP. At the very least, it seems difficult to define any "off the shelf" orthotic as not requiring expertise because one truly doesn't know what will be required until the orthotic is issued. There are simply too many variables that could affect how well the item fits and how much if any, adjustment is needed.

In closing, we respectfully appreciate the efforts of CMS to control spiraling costs. There are some admirable qualities to the proposed process but there seems to be some disadvantages that should be considered before the final rule is drafted. As trained professionals, we think it should be recognized that even with "off the shelf" equipment, there is an evaluative process that occurs beyond the order from a physician. Whether P.T. or O.T., our patients deserve to have us serve them in a way that takes advantage of our extensive and ongoing training.

Sincerely,

The Rehabilitation Team of Good Samaritan Hospital
Cincinnati, OH
513-872-2481

Submitter : Mrs. nancy cannon **Date:** 06/30/2006

Organization : ASHT

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Date: 06/30/2006**

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

Education and Outreach

Education and Outreach

If DME companies are allowed to bid on just specific hcpc codes Paitients will inventibly be confused on how to call for repairs or supllies due to multiple providers in the home. I am concerned on the burden this will cause on both the beneficiary and the referal source.
For example, if an 89 year old women being discharged from the hospital who needs a walker, motorized wheelchair, hospital bed, oxygen, commode, and urological supplies. If bidding is done by hcpcs code or groups of hcpc codes how are referral sources such as doctor office or hospital discharge planner going to know where to order for a patient who needs multiple items? My sugesstion would be to allow a winning provider cross over Hcpc codes or groups of hcpcs if he has not one the particular hcpc group but has won one of the hcpcs codes needed by the patient and is willing to except the medicare bid price.

Submitter : Mrs. Cortney McDowell **Date:** 06/30/2006

Organization : Health Aid of Ohio

Category : Other Health Care Provider

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

After careful review of the pilot program and the goals of competitive bidding, my biggest concern is that there are no quality standards for providers. Homecare's goal is to provide good, quality care to keep recipients safe and healthy in the room. By lowering the bar and providing only the cheapest care in the home environment, it is clear that quality will be compromised. The care of respiratory clients is of a huge concern. Medicare seems to be addressing the tiniest portion of their budget - the portion that aims to keep costs low. The administrative costs alone must be staggering. Instead, lower reimbursement and only allow good, quality providers to become Medicare providers.

Submitter : **Mrs. Rita Hostak** **Date: 06/30/2006**

Organization : **Sunrise Medical**

Category : **Private Industry**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 30, 2006

Department of Health and Human Services
Attn: CMS-12-70-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Sunrise Medical is pleased to have this opportunity to submit the following comments in response to the Centers for Medicare and Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) for Competitive acquisition for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and other issues. Sunrise Medical is a large manufacturer of durable medical equipment. We feel it is important to establish our belief that efforts to reduce costs, if not balanced with a desire to preserve or improve the clinical outcome of Medicare beneficiaries, will result in less quality care for Medicare beneficiaries. Moreover, unless great care is taken in the development of the competitive bidding program, manufacturers will be forced to focus solely on cost reduction efforts as opposed to investing in technological advancements aimed at improving people s lives and better clinical outcomes.

General Comments
Sunrise Medical acknowledges that CMS and its contractors have given extensive consideration to the many proposals within this NPRM. However, we remain concerned that many critical areas of the competitive bidding program still need to be developed. Sunrise encourages CMS to provide ample opportunity for stakeholder involvement and comment.

While Sunrise acknowledges the intent for a competitive bidding program is to provide savings for the Medicare program, we also believe that Congress intended for consideration to be given to clinical outcome for Medicare beneficiaries. Therefore, we recommend that CMS accept the recommendations of PAOC committee members and presenters during the February 2006 PAOC meeting to exempt complex rehab and assistive technology devices from competitive bidding. We believe that all products that require a comprehensive technology assessment by a supplier as well as those devices that must be fitted, configured, adjusted or programmed to meet the specific and unique needs of an individual are not appropriate for competitive bidding.
II. Provisions of the Proposed Regulation

C. Payment Basis (' 414.408) (a)
In this section, CMS proposes that a beneficiary could choose, at any time, to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer. Sunrise Medical finds this requirement to be especially problematic and unreasonable. Sunrise Medical believes that product costs, service and delivery costs as well as paperwork associated with documentation and billing are too high for a supplier to accept any amount below a full (13 months) rental period. Sunrise Medical recommends that CMS must start the rental period over if beneficiaries are transferring to a contract supplier and payment is under capped rental. Sunrise Medical believes it would be impossible for suppliers to accurately estimate their financial loss in these situations. Therefore, suppliers cannot accurately account for this loss in a bid amount.

5. Authority to Adjust Payments in Other Areas 414.408 (c) (P.43)
Sunrise Medical understands that the Secretary has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program and to use the payment information determined under that competitive bidding program to adjust payment amounts for the same DMEPOS in areas not included in the competitive bidding program. CMS is proposing to use this authority but provides no detailed methodology for doing so. Sunrise Medical recommends that CMS issue a separate Interim Final Rule addressing payment issues that have broad implications outside of the competitive bidding program. It is critical for the industry to have specific proposals on which to develop commentary and be allowed ample time to develop substantive

CMS-1270-P-1242-Attach-1.PDF

ATTACHMENT TO # 1242

June 30, 2006

Department of Health and Human Services
Attn: CMS-12-70-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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General Comments

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6. Requirement to Obtain Competitively Bid Items from a Contract Supplier (§414.408(f))

The NPRM states that if the area the beneficiary is visiting is not a competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, the supplier would be paid at the rate of the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. Sunrise Medical believes this proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. While Sunrise Medical recognizes that this is the current Medicare policy, the maximum fee schedule difference from one State to another is 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. Sunrise Medical recommends that CMS continue to pay the fee schedule amount that corresponds with the beneficiary's permanent residence when beneficiaries travel outside their competitive bid area.

D. Competitive Bid Areas

Proposed Methodology for MSA selection for 2007 and 2009 Competitive Bidding Programs (§ 414.410)

In this section, CMS proposes to use a formula-driven methodology for selecting MSAs for competitive bidding in 2007 and 2009. CMS proposes to score the MSAs based on combined rankings of DMEPOS allowed charges per FFS beneficiary and the number of DMEPOS suppliers per beneficiary receiving DMEPOS items in CY 2004, with equal weight being given to each factor. CMS further states that the number of suppliers would be based on suppliers with at least $10,000 in allowed charges attributed to them for DMEPOS items furnished in the MSA in CY 2004. Sunrise Medical believes it is important for CMS to understand the number of DMEPOS suppliers that provide the specific items targeted for a specific MSA. Sunrise Medical believes that the proposed dollar amount is too low. In addition, the $10,000 threshold may be too small for some items of DME. For higher cost items, $10,000 would not indicate an adequate level of experience with a product to appropriately meet the needs of Medicare beneficiaries. Sunrise Medical suggests that CMS look at total allowed charges and allowed charges for the items being bid. In addition, we recommend that CMS set an appropriate dollar threshold for each product category that would demonstrate that the supplier has adequate experience with product category before counting that supplier for MSA selection purposes.

CMS also proposes, in a situation where more than one MSA receives the same score, to use the total DMEPOS allowed charges for items that CMS has the authority to include in competitive bidding in each MSA as the tiebreaker. Sunrise Medical suggests instead that CMS should consider the FFS charges for the items proposed for bidding in each MSA and the total number of accredited suppliers in each MSA to break ties.

Sunrise Medical agrees with CMS' proposal to exclude the three largest MSAs from inclusion in a competitive bidding until 2009. However, CMS indicates that an alternative is being considered that would establish a CBA that may include portions of one or more of these MSAs. Sunrise Medical understands the desire to phase-in portions of the extremely large MSAs. However, Sunrise Medical recommends that CMS not consider bidding portions of these complex MSAs in 2007.

Sunrise Medical agrees with CMS' proposal to have at least one CBA in each DMERC region. It is critical for each region to gain experience in competitive bidding. This will allow CMS to monitor each DMERC's performance to ensure that any issues are identified and rectified before larger scale competitive bidding is implemented. The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time or stagger the initial implementation of competitive bidding in 2007. Sunrise Medical recommends that CMS phase-in the first 10 MSAs. We suggest beginning with one MSA in each DMERC region and then phase-in the remaining 6 MSAs. A staggered implementation would allow CMS to identify and address problems as competitive bidding commences and avoid widespread problems.

1. b. MSAs for 2009

CMS proposes to use the same criteria to score MSAs for 2009 as would be used for 2007. However, the proposal also indicates that CMS is considering an option that would modify the rankings based on allowed DMEPOS charges per beneficiary so that it focuses on charges in each MSA for items that experienced the largest payment reduction or savings under the initial round of competitive bidding in 2007. Sunrise Medical recommends that CMS not modify the criteria for 2009. There are many differences that may impact costs in various MSA. Focusing in on those items that provided the highest savings in the first round may not be indicative of future savings in round two of the same

area, much less round one in a new area. Sunrise Medical recommends using the same criteria in 2009.

E. Criteria for Item Selection

Section 1847(a)(1)(B)(ii) of the Act gives CMS the authority to phase in competitive bidding "first among the highest cost and highest volume items of those items that the Secretary determines have the largest savings potential. In addition, section 1847(a)(3)(B) of the Act grants the authority to exempt items for which the application of competitive bidding is not likely to result in significant savings. Based on these provisions, CMS proposes to exempt items outright or on an area-by-area basis using area-specific utilization data. Sunrise Medical believes it is critical for CMS to truly understand costs associated with certain product groups in addition to the actual product cost. Moreover, Sunrise strongly encourages CMS to consider any negative clinical outcome as well as the potential to increase other healthcare cost when determining which products to include in any competitive bidding program.

Sunrise Medical believes that CMS should establish a savings threshold including on-going administrative costs to access the appropriateness of competitive bidding for each product category. Sunrise Medical further recommends that in order to determine whether a product group should be competitively bid, CMS use a consistent threshold of 10% net savings after adjusting to include administrative costs associated with the on-going support of the competitive bidding program.

In addition, Sunrise Medical believes any attempt to competitively bid complex rehab and assistive technology devices would result in a negative impact on the clinical outcome for the beneficiary. CMS, then HCFA, included K0004 high strength lightweight manual wheelchairs in the competitive bidding demonstration in San Antonio, TX. CMS had proposed including K0005 Ultra-lightweight Manual Wheelchairs also, but after receiving comments from the industry, CMS decided to exclude this category of products. Therefore, K0004 coded products are the closest CMS has come to demonstrating the impact of competitively bidding items that are uniquely prescribed for an individual. While K0004 coded products are not all equally configurable, we did glean some important information about the clinical impact for beneficiaries based on the San Antonio demonstration project.

In the November 2003 Final Evaluation Report, Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, page 181, section 4.5 Wheelchairs and Accessories evaluates the impact of competitively bidding this class of wheelchairs. The report states that "referral agents raised a number of issues about wheelchairs". Further, the reports states," Referral agents also found that the prescriptions needed to be very detailed to ensure that beneficiaries got the required product" and "prior to the demonstration, referral agents used suppliers who would provide wheelchairs with removable arms and adjustable leg rests as standard equipment. After the demonstration, they found that some suppliers stopped providing this equipment in every case, opting to do so only if these features were specifically ordered". The report also indicated a change in the service/delivery model for these wheelchairs. Some referrals noted that, prior to the demonstration, suppliers usually either had a physical therapist on staff or the wheelchair would be delivered by someone who was familiar with the product and how to measure its fit. When the wheelchair was delivered, the supplier delivering the chair would have the beneficiary sit in the chair and check the fit. However, during the demonstration, referrals reported examples of wheelchairs being delivered and left folded with no attempt to check fit; delivery staff being unknowledgeable about the products being provided or how to adjust or check for proper fit; and even that one supplier's policy was to deliver an 18" wheelchair to all patients and then replace it if a different size was required. Sunrise Medical does not believe that the same degree of measuring, fitting and adjustment is needed for all manual wheelchairs. In fact, standard products are only available in limited sizes and with little to no adjustability. However, as one considers the products moving up the spectrum of manual wheelchairs, those that are available in more sizes/configurations and are adjustable to meet the functional needs of the patient require a more labor-intensive evaluation on the part of the supplier and in collaboration with a clinician/physician to ensure that product solutions meet the medical needs and anticipated needs of the beneficiary. The rehab company must employ trained and knowledgeable staff to perform the technology evaluations, fittings and adjustments as well as technicians to repair and service complex technologies. We recognize that many of the issues identified could be mollified by developing specific supplier standards for complex rehab and assistive technology. Sunrise Medical provided comments regarding the draft supplier standards that encourage CMS to create specific standards for Complex Rehab and Assistive technology. We believe this will ensure that all Medicare beneficiaries will be better served. Actually, CMS may find that the Medicare program will experience savings by

using only suppliers that are qualified to provide this level of technology. This savings would result from the beneficiary receiving a comprehensive evaluation of their technology needs which would facilitate appropriate product selection up front as opposed to beneficiaries finding that the products they have been provided do not meet their functional needs, or the progressive nature of their disease was not taken into consideration in the initial evaluation.

In addition to exempting rehab and assistive technology devices from competitive bidding, Sunrise Medical recommends that CMS exclude all manual and power wheelchair and accessory codes from the 2007 round of competitive bidding. This would allow time for CMS to implement new HCPCS codes for power and manual wheelchairs, gain accurate utilization data and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. Sunrise Medical recognizes that power wheelchairs are high in utilization and cost. However, we also believe that significant savings will result from the vast changes in coverage and conditions for payment that have occurred in this product category over the last year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

Sunrise Medical also recommends that CMS exclude wheelchair cushions, adaptive seating and positioning products and speech generating devices. Clients in need of complex rehab or assistive technology typically require a complete system to meet their functional and medical needs. A complete system means various pieces of equipment, each meeting a specific medical or functional need, have been determined to be compatible technologies.

F. Submission of Bids Under the Competitive Bidding Program (proposed §414.412)

3. Product categories for bidding purposes

In this section, CMS indicates, "We believe that the use of product categories will allow Medicare beneficiaries to receive all of their related products (for example, hospital beds and accessories) from one supplier, which will minimize disruption to the beneficiary". Sunrise Medical does not believe this would be appropriate in cases where some codes within a policy group may be inappropriate for

competitive bidding while the HCPCS codes for the accessories are the same for each base code. While Sunrise Medical believes these issues reflect inadequacies in the HCPCS code set, there is not time to address this issue. Sunrise Medical believes any contract supplier for competitive bidding would be able to provide accessories even if they were not competitively bid. If necessary, CMS could require suppliers to provide all needed accessories for base products under competitive bidding. This would meet the stated goal of minimizing disruption for the beneficiary while allowing non-contract suppliers to bill for the accessories needed for non-bid items.

4. Bidding Requirements (§414.408)

d. Capped rental items

CMS proposes that the lump sum purchase option in §441.229(d) for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program. Sunrise Medical agrees with this proposal, but again recommends that power wheelchairs not be included in the 2007 round of bidding and that utilization and price data be analyzed to determine which if any should be included in 2009. Complex rehab and assistive technology should be exempt.

G. Conditions for Awarding Contracts

1. Quality Standards and Accreditation (proposed §414.414(c))

CMS proposes a grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid. Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure 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.

CMS further states in the NPRM that if a supplier fails to successfully attain accreditation, CMS will suspend or terminate the supplier contract. We believe this concern supports the need to require that a supplier be accredited before submitting a bid. It is imperative that CMS not include any price in calculating the single payment amount unless it was submitted by an accredited supplier. Suppliers that have actually been through the accreditation process will inherently have a better understanding

of the costs associated with accreditation. It is critical that the final single payment amount be reflective of precise and informed bids.

4. Evaluation of Bids (proposed §414.414(e))

a. Market Demand and Supplier Capacity

CMS proposes to compare expected capacity and Medicare volume to determine how many suppliers would be needed in an area. Sunrise Medical recommends that CMS consider using 130% of anticipated Medicare volume as the threshold for the number of suppliers needed in an area. We believe 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. Sunrise Medical also recommends that CMS should not count the projected capacity of suppliers that do not have a proven track record of providing a bid item for purposes of determining the pivotal bid. Additionally, suppliers should be capped at 120% of their past 12 months of billing history for purposes of determining the pivotal bid.

c. Determine the Pivotal Bid

Sunrise Medical recommends using 130 % of anticipated demand. In addition, when determining the pivotal bid, capacity of suppliers that have not previously provided the bid items should not be included. In addition, a maximum of 120% of a supplier's previous 12 months billing for the bid items should be added to achieve the pivotal bid. This would in no way limit a supplier's ability to grow their actual market share if they become a contract supplier in a competitive bidding program.

d. Assurance of Savings (proposed §414.414(f))

Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in competitive bidding areas are expected to be less than the total amounts that would otherwise be paid. 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. Sunrise Medical acknowledges 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 of the RFB in our opinion artificially restricts bidding. Sunrise Medical believes that CMS should allow suppliers to bid based on the true costs associated with each bid item. We believe this would provide CMS more accurate information by which to accurately determine potential savings. Sunrise Medical believes that concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. Sunrise Medical believes that the use of payment to control utilization is inappropriate. Medicare beneficiaries must have adequate access to appropriate equipment that will meet their medical needs.

f. Selection of New Suppliers After Bidding (proposed §414.414(h))

CMS proposes to select only as many suppliers as necessary to meet projected demand. However, CMS further suggests that if a supplier falls out of compliance with any of the requirements identified in the regulation and in the bidding contract, it may be necessary to suspend or terminate their contract. This could result in unmet demand. In these situations, CMS proposes to contact remaining contract suppliers to see if they could absorb the demand. If an unmet demand remains, CMS proposes then to refer to the list of suppliers that submitted a bid for that product category in that round of competitive bidding areas, use the list of composite bids that they arrayed in lowest to highest, and proceed to the next supplier on the list. Sunrise Medical believes this process would result in a single payment amount being developed using bids from suppliers that do not meet Medicare's standards. In addition, Sunrise Medical recommends that CMS establish a timeframe in which a supplier will be allowed to correct issues that have caused them to be out of compliance with the current requirements.

H. Determining Single Payment Amounts for Individual Items (proposed §414.416)

b. Setting Single Payment Amounts for Individual Items (proposed §414.416(b))

CMS proposes to determine the single payment amounts for individual items by using the median of the supplier bids that are at or below the pivotal bid for each individual item within each product category. Sunrise Medical believes that no supplier should be paid less than their bid amount. It is also important that CMS analyze deviations amount bid amounts to determine whether these deviations may indicate extremely high or extremely low bid prices. CMS must ensure that

inappropriate bids do not influence the single payment amount. It is critical to ensure that the price ultimately established in a CBA for each item is adequate to ensure that beneficiaries receive quality products and services and to provide market stability in that CBA.

c. Rebate Program (proposed §414.416(c))

In the NPRM, CMS proposes 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. CMS proposes that the rebate be voluntary but that contract suppliers cannot implement on a case by case basis. Contract suppliers would also be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribing health care professionals. However, CMS proposes to publish a list of contract suppliers denoting those that offer rebates.

Sunrise Medical strongly disagrees with the offering of rebates even when not advertised by the supplier. We believe these types of arrangements violate anti-kickback laws. We further believe that having a program like this sanctioned by CMS in its competitive bidding program would encourage similar offerings outside of this program. Sunrise Medical respectfully recommends that CMS not include a rebate program within the competitive bidding program.

I. Terms of Contracts (proposed §414.422)

1. Terms and Conditions of Contracts

CMS proposes "non-discrimination against beneficiaries in a competitive bidding area", so that all beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier would provide to other customers. Given that payment for the same HCPCS code can vary from payer to payer, Sunrise Medical believes that competitive bidding will by necessity limit the devices available to Medicare beneficiaries. We do not feel it is appropriate for CMS to mandate that access be limited to individuals outside the Medicare program. Suppliers should be allowed to provide higher levels of technology when higher reimbursement is available. Sunrise Medical does not see this as discrimination but simply free trade.

3. Repairs and Replacements of Patient Owned Items Subject to Competitive Bidding (proposed §414.422(c))

Sunrise Medical believes that this proposal is problematic for many reasons. In many situations suppliers actually lose money when repairing patient owned equipment under Medicare reimbursement. This is due to the low fee schedule amount associated with repairs and the need for replacement parts HCPCS codes. Therefore, requiring that contract suppliers repair all patient owned equipment inside an MSA is a disadvantage for those suppliers.

In addition, contract suppliers may not have access to the parts necessary to repair equipment sold by another supplier. Suppliers do not all carry the same brand of equipment. Also, some manufacturers desire to limit access to their products to those suppliers with sufficient knowledge to properly service, repair and otherwise support their products. To require that contract suppliers be able to service all patient owned equipment would require manufacturers to open accounts with suppliers that they may feel do not meet their requirements.

4. Furnishing Items to Beneficiaries Whose Permanent Residence is Within a CBA

CMS is proposing that a supplier must agree to accept a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. In light of changes to capped rental payment pursuant to the deficit reduction act of 2005, this provision is extremely onerous. As already stated earlier in these comments, Sunrise Medical recommends that CMS must start the rental period over if beneficiaries are transferring to a contract supplier and payment is under capped rental. Sunrise Medical believes it would be impossible for suppliers to accurately estimate their financial loss in these situations. Therefore, suppliers cannot accurately account for this type of loss in a bid amount.

7. Change in Ownership (proposed §414.422(d))

CMS proposes that contract suppliers must notify CMS in writing 60 days prior to any changes of ownership, mergers or acquisitions being finalized. CMS states they have the discretion to allow a successor entity after a merger with or acquisition of a contract supplier to function as contract supplier when, among other things, there is a need for the successor entity as a contractor to ensure

Medicare's capacity to meet expected beneficiary demand for a competitive bid item. Sunrise Medical recommends that as long as the successor company meets all other requirements and is willing to assume the contract supplier's contract, including all contract obligations and liabilities that may occur after the awarding of the contract to the previous supplier, CMS should allow the successor company to function as a contract supplier.

K. Opportunity for Participation by Small Suppliers

Section 1847(b)(6)(D) of the MMA requires CMS to take appropriate steps to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Under the current proposal, the only possibility a small supplier has of participating is by submitting one of the lowest bid prices. The fact that capacity is a key element in the selection process, if small suppliers don't under-bid suppliers with higher capacity they have very little hope of being included in the Program. In order to better ensure participation by small suppliers, Sunrise Medical recommends that any supplier that bids within 105% of the pivotal bid should be allowed to participate if they are willing to accept the payment amount and meet all other requirements.

M. Education and Outreach

2. Beneficiary Education

Sunrise Medical recognizes that being involved with beneficiary education allows suppliers to develop relationships with beneficiaries and to market their services. However, Sunrise Medical believes that CMS must hold educational sessions for suppliers to ensure there is some level of consistency in the way beneficiaries are educated and the information they are provided. In addition, Sunrise Medical recommends CMS provide materials that can be used by suppliers to effectively educate beneficiaries regarding the Competitive Bidding Program. In addition, CMS should not depend solely on suppliers or the CMS website to educate Medicare beneficiaries. Sunrise Medical recommends that CMS hold multiple town hall meetings in each CBA to ensure that beneficiaries and referral sources are knowledgeable about the competitive bidding program.

O. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids

CMS proposes to allow physicians and other treating practitioners to request a specific item, brand, or mode of delivery. When this occurs, contract suppliers would be required to furnish that item or mode of delivery, assist the beneficiary in finding another contract supplier in the 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.

For many items of DME there are not sufficient differences between products to justify specifying a particular brand. This however is not the case for many manual and power wheelchairs, seating systems, speech generating devices, CPAP and other respiratory therapy devices. In situations where patients require a specific device, access must be maintained. Sunrise Medical believes that due to the level of specificity that goes into selecting the appropriate technology that will meet the individual needs of a beneficiary that this proposal is insufficient to ensure appropriate access. Clinical evaluations and technology assessments routinely result in brand specific recommendations. This in fact is part of what makes competitive bidding of this technology problematic. Sunrise Medical feels that this proposal by CMS falls short of ensuring access to appropriate technology for those in need of complex rehab or assistive technology devices.

HCPCS Codes

CMS proposes not to require suppliers to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. The current code set is inadequate and therefore only requiring suppliers to supply an item that meets the descriptor of the code will not adequately meet the needs of Medicare beneficiaries.

The current coding system categorizes items into very general codes and in many cases does not recognize clinical application differences. In these cases the items are designed for a similar use, but because of the anatomical anomalies, functional limitations, compliance issues etc., beneficiaries must have access to a specific device within a code. Unfortunately, due to differences in design, product cost and other factors, the costs associated with the devices are fundamentally different.

While focused and aggressive efforts are occurring that will hopefully develop more appropriate code sets, the current HCPCS code set is grossly inadequate to support competitive bidding for some code sets.

R. Establishing Payment Amounts for New DMEPOS Items (Gap-filling) (proposed §414.210(g))

Sunrise Medical applauds CMS' recognition of the inadequacies of the gap-filling methodology. The gap-filling formula has become more and more problematic due to fee schedule freezes mandated by congress. In addition, the problem is intensified by the growing trend toward testing requirements and SADMERC code verification of products to HCPCS codes. Sunrise Medical further agrees with CMS that "there is an inherent responsibility to pay enough for beneficial new technologies to ensure the beneficiary access to care, while also being a prudent payer".

CMS proposes to discontinue the practice of deflating supplier prices and manufacturers' suggested retail prices to the fee schedule base period. When fee schedule amounts are established based on pricing information, prices in effect at the time the fee schedule amounts are established would be used.

CMS further proposes in some situations to use the functional technology assessment process in part or in whole as another method for establishing payment amounts for new items. Based on the results of the technology assessment, the fee schedule amounts would be established using fee schedule amounts for items determined to be compatible to the new item or an amount determined to be appropriate for the new item based on the cost comparison. CMS also proposes to use the technology assessment process at any time to adjust prices on or after January 1, 2007 that were previously established using the gap-filling methodology if it is determined that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

It is important to note that the IR methodology established by Congress requires CMS to make a determination that using the "standard rules for calculating payment" results in a payment amount

that is inherently reasonable. Congress directed the Secretary to identify the factors that it would use to determine that a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. In determining whether a payment amount is inherently reasonable, and in establishing a new payment amount, CMS or its contractors must use "valid and reliable data" that meets specific criteria applicable to the data collection and analysis. 42 C. F. R. §405.502 (g). Importantly, the IR methodology contains specific procedural safeguards that apply to any determination to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, one factor CMS must consider is the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates." §1842b (8) (C).

Sunrise Medical recommends that CMS identify the factors it would consider in deciding to initiate a technology assessment. Sunrise Medical further recommends that CMS allow participation in the technology assessment by interested stakeholders. Additionally, Sunrise Medical recommends that CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support their opinion.

This proposal has broad sweeping impact on the Medicare program, not only the competitive bidding program. The competitive bidding program proposals and the proposal regarding establishing payment for DME both inside and outside of the competitive bidding program should be two separate rules. Sixty days does not provide enough time to develop substantive comments for both of these significant issues. As such, Sunrise Medical recommends that CMS initiate a separate rulemaking proceeding to solely address changes to the pricing methodology for DME.

Adjustments to competitively bid payment amounts to reflect changes in the HCPCS codes- §414.426.
CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occur 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. Further, CMS proposes that contract suppliers must furnish the items in accordance with the new codes.

Sunrise Medical disagrees with this proposal. The reasons that CMS would determine that new HCPCS are needed is when there are differences in technology, clinical application and pricing. In these situations, it is inappropriate to expect suppliers to provide these products at the price of the single payment amount of the single code. Sunrise Medical recommends, that in the event a single HCPCS code is divided into two or more separate codes during a bidding cycle, CMS should re-bid the codes in the new code set which are appropriate for competitive bidding.

Summary Statement

Sunrise Medical strongly recommends that CMS consider exempting items that if included in a competitive bidding program could negatively impact the clinical outcome of Medicare beneficiaries. Sunrise Medical also recommends that CMS initiate separate rulemaking processes for decisions that will impact the Medicare program outside of competitive bidding such as those related to the establishment of payment for new technology or re-pricing revised codes. Moreover, it is critical that CMS continue to seek stakeholder feedback regarding supplier standards. Finally, CMS must ensure that all stakeholders are adequately educated regarding all rules and processes that relate to the competitive bidding program. We appreciate this opportunity to provide our comments.

CMS-1270-P-1243 **Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**

Submitter : Mrs. Lisa Sokol

Date & Time: 06/30/2006

Organization : Innovatix

Category : Private Industry

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

see attachment

GENERAL

GENERAL

see attachment

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

see attachment

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

see attachment

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

see attachment

CMS-1270-P-1243-Attach-1.DOC

CMS-1270-P-1243-Attach-1.DOC

CMS-1270-P-1243-Attach-1.DOC

CMS-1270-P-1243-Attach-1.DOC

CMS-1270-P-1243-Attach-1.DOC

ATTACHMENT TO #1243

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June 30, 2006

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Administrator
Centers for Medicare & Medicaid Services
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Mail Stop C4-26-05
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RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues (71 F.R. 25654)

Dear Administrator McClellan,

Innovatix, LLC is pleased to offer comments on 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). Innovatix provides high quality group purchasing and consultative services to a national membership base of alternate care and non acute care institutional providers. Innovatix programs provide services to patients in: Home Infusion, Extended Care, Long Term Care (dispensing pharmacy), Retail and Mail Order Pharmacy, Extended Care providers of DMEPOS supplies, and select medical oncologist segments.

Innovatix and its members are directly impacted by this proposed regulation. We have a number of concerns and comments regarding the proposed rule. Our specific comments and concerns are provided below.

1. Delay Implementation of National Competitive Bidding

A. Quality Standards

A key component of the competitive bidding proposal involves the application of quality standards for all DMEPOS suppliers, including DMEPOS suppliers that participate in the competitive bidding program. The proposed rule also contains a provision requiring accreditation. CMS approved accrediting organizations will be applying the quality standards for all DMEPOS suppliers, including DMEPOS suppliers that will be participating in the competitive bidding program. The proposed rule makes it clear that the quality standards are an integral part of the

regulatory plan to implement the competitive bidding program and will have an enormous impact on the competitive bidding process.

DMEPOS suppliers will have to comply with the quality standards in order to furnish any item for which payment is made under Medicare Part B, as well as to obtain a provider or supplier billing number used to submit claims for reimbursement. However, CMS has not finalized the quality standards. They have only been issued in draft form on September 23, 2005 with the public comment period ending November 28, 2005.

Until the final quality standards are released, interested parties will be unable to provide meaningful, comprehensive comments that address the program requirements that will be applied by CMS to DMEPOS competitive bidding. The proposed rule is not sufficiently descriptive of the quality standards and the competitive bidding program under consideration. Therefore, interested parties, including Innovatix, are not able to offer informed criticism and comment on the proposed rule in accordance with the Administrative Procedures Act. In addition, **CMS's description of the competitive bidding proposal is incomplete without a thorough discussion of these requirements**.

The quality standards are a significant component to the competitive bidding process for DMEPOS, and as such, we request that the comment period for the competitive bidding proposal be extended to ninety (90) days after the publication of the final DMEPOS supplier quality standards.

B. Financial standards

Since the financial standards are not detailed, it is not possible to provide detailed comments. However, small suppliers that are not financially troubled must be reasonably able to comply with the financial standards implemented by CMS without having to incur the undue cost.

More importantly, satisfaction of the financial standards is a precondition to bidding. If the financial standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the financial standards are not restrictive enough, unsound suppliers may be awarded contracts. These suppliers may not be able to supply beneficiaries at the single payment amount, resulting in impaired access. CMS' failure to specify financial standards leaves both beneficiaries and suppliers vulnerable, **and CMS should specify financial standards so interested parties can comment prior to the effectiveness of the Proposed Rule.**

C. Time Frame

In addition to extending the comment period until after the publication of the final DMEPOS Quality Standards, the implementation of competitive acquisition should be delayed as much as permitted by § 1847(a)(1) of the SSA. The original CMS timeline was to have the competitive bidding proposed rule published in the Spring of 2005. The timeline set forth a comment period of summer 2005. The final rule was to be published in the Spring of 2006. This timeline allowed the supplier community to have from Spring 2006 through the end of 2006 to make arrangements for the implementation of the competitive bidding regulation. However, the delays in the development of the competitive bidding proposal show that the issues are complex and their resolution difficult. The fact that the development of the quality standards and the proposed rule has taken at least one year longer than originally contemplated by CMS shows that it is unrealistic to expect the final rule to be published and all of the implementation steps to be accomplished in any reasonable manner by early 2007. The statute's requirements do not state that implementation is required to take place at or near the beginning of 2007. It merely states that the requirements of the statute will be satisfied if competitive bidding is implemented in 2007.

Innovatix believes that CMS needs to take the time to carefully implement competitive bidding or beneficiaries will be negatively impacted. As such, it is our belief that CMS has the authority to begin the competitive bidding process at or near the end of 2007 and not at the beginning of 2007 as is indicated in the proposed rule. **Implementation of the competitive bidding proposal toward the end of 2007 is more consistent with CMS' original timetable in terms of time allocated to tasks, and will afford a much greater opportunity for the program to achieve its objectives without adversely impacting beneficiaries.**

D. Issuance of Interim Final Rule

The proposed rule leaves a lot of very important, detailed information to be determined in the final rule including the products and codes to be included, the quality standards, the particular MSA's impacted, and how CMS will determine the number of suppliers necessary in a bid area just to name a few. In addition, it appears that although small suppliers are supposed to be afforded the same abilities to provide products under a competitive bid program, the CMS proposed rule will impact small businesses negatively. As such, **Innovatix believes that CMS should issue an interim final rule with comments, so that interested parties can submit additional comments before this regulation is implemented.**

2. Single Payment amount

Innovatix is very concerned about the methodology that CMS has proposed regarding the payment amount and feels that it is seriously flawed. The methodology goes against the very program that CMS is trying to implement. CMS is asking companies to provide the lowest bid for providing certain DMEPOS products. Then CMS is going to award the contract to certain companies, yet they will be lowering the bid amount to a median amount rather than the amount that the company believes is the lowest price they can afford to provide the product. This methodology simply does not work.

There is no assurance that all suppliers who bid at or below the pivotal bid will be able to furnish the chosen items at a payment amount equal to the median of the bids equal to or lower than the pivotal bid. The pivotal bid, moreover, is the bid just sufficient to meet demand. If the supplier bidding the pivotal bid is not able to provide the items at the median in the proposed rule, the demand will not be met and access will be impaired. This method is different than that used in the demonstration project.

CMS has also indicated that if the demand will not be met, they will select additional suppliers. However, their discussion regarding the selection of additional suppliers will not address the problem because the suppliers added after the bid process must still accept the single payment amount. These suppliers will have the same issues: if the suppliers that bid between the median and the pivotal bid submitted the best bids they could make, then they will not be able to furnish the supplies at the median, which is lower than the amounts they bid. To the extent such suppliers are not able to meet projected demand, it is not reasonable to expect that more responsible suppliers will be able to provide the items at the artificially depressed single payment amount.

The methodology for determining the single payment amount as set forth in the proposed rule is seriously flawed and will have an adverse impact on beneficiary access to needed items, especially in undefined HCPCS codes. In order to assure beneficiary access, **Innovatix suggests that CMS utilize the pivotal bid to be the payment amount rather than the median between the pivotal bid and the low bid.**

3. Adjustment of payment amounts in other areas

Innovatix strongly believes that it is not appropriate to use payment amounts determined in one competitive bidding MSA to make inherent reasonableness adjustments to payment amounts in other areas. CMS seems

to suggest that the competitive bided price for a specific good or service in one MSA provides adequate data to adjust the allowable for the same item in another area. This is completely contrary with historically accepted practices that recognize the uniqueness of each distinct geographic area based on such factors as cost of living and available work force to list just a few.

Moreover, as stated in the proposed rule, the MSAs chosen in the first two phases will be the largest MSAs. The remaining areas will likely be rural and less densely populated. Therefore, single payment amounts established for large MSAs on the basis of competitive bidding will have no relation to appropriate payment amounts in areas outside of those MSAs.

Innovatix believes that it is not reasonable to use the competitive bid amounts in one MSA to make inherent "reasonableness" adjustments to payment amounts outside of the competitively bid MSAs.

4. Item and product selection

Under the competitive bidding program, CMS will have the authority to determine which items should be subject to competitive bidding. Innovatix urges CMS to limit the items and product categories subject to competitive bidding as the program is largely untested. By minimizing the number of items subject to competitive bidding, adverse impacts on beneficiaries may be avoided. Until a critical analysis of the items included in certain HCPCS codes is completed, competitive bidding should be limited to a product group or groups that include only codes or items that are truly generic and clinically equivalent. **We urge CMS to provide a list of the items that they plan to include in the competitive bidding program prior to implementation and allow interested parties an opportunity to provide public comment.**

The goal of competitive bidding must be to reasonably reduce program and beneficiary costs while maintaining or enhancing quality and access. The selection by current Health Care Procedure Code System (HCPCS) codes will adversely impact the quality of care for beneficiaries. 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 statute does not state that items

have to be selected by HCPCS codes – rather the statute refers only to the competitive bidding of DMEPOS items. Many current HCPCS codes include items of widely different cost, technology and clinical application.

The use of HCPCS codes that include items of widely varying cost and clinical application will adversely affect the quality of care for the beneficiaries. The use of such codes will result in a race to the bottom by suppliers, and diminish beneficiary access to medically necessary, higher cost or higher technology items that are included in HCPCS codes together with inexpensive items that may not be appropriate. Once contracts are awarded to suppliers, the suppliers will have a significant incentive to furnish the lowest cost item within the code, unless a different item is specifically prescribed by the physician. 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. We are very concerned about this possibility.

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.

As stated above, Innovatix believes the initial set of products should be limited to a product group or groups that include only codes or items that are truly generic and clinically equivalent. We urge CMS to provide a list of the items that they plan to include in the competitive bidding program prior to implementation (in an interim final rule) and allow interested parties an opportunity to provide public comment.

5. Grandfathered Items

Innovatix believes that CMS does not have the legal authority to change a material term in a contractual agreement. Section § 1847(a)(4) of the Act provides that CMS "shall establish a **process** by which rental agreements for the covered items … may be continued notwithstanding this section." . A "process" is an administrative mechanism or methodology for continuation of the agreements, not an authorization to unilaterally modify agreements. The price term of an agreement is not a minor detail, but one of the central terms of an agreement. The Act plainly requires that agreements be continued notwithstanding competitive bidding. It does not state that the agreements may be continued as adjusted by competitive bidding. The provision permitting an agreement to continue except for the price raises significant constitutional

questions. The due process clause of the Fifth Amendment precludes the Federal government from unilaterally changing terms of agreements, yet this is exactly what CMS is proposing to do.

The terms of a contract encompass many aspects including the products and services that will be offered, how the products will be delivered and value added services that all account for the ultimate price of the contract. To have CMS unilaterally say that the price of the contract has to be changed to reflect the competitive bid price, does not take into account the services that are included in the contract. **CMS should adhere to the plain language and meaning of the Act and provide for the continuation of agreements under § 1847(a)(4) without modification of the price.**

6. Allowing SNFs to Continue to Provide Needed Items to Their Residents

Innovatix strongly believes that products and supplies that are covered and provided to Medicare beneficiaries who are in long term care facilities should be exempt from these rules for a number of reasons.

First, it is our belief that the law was never intended to apply to institutional purchasers and that the phrase "items or services" means those that are purchased directly by individuals and not by institutions on behalf of individuals. There is nothing to suggest that Congress intended to undermine institutional purchasing power. To the contrary, the language makes clear that the competitive bidding law was designed to give individual beneficiaries similar, although not identical, purchasing leverage as enjoyed by institutional purchasers.

In addition, **the language in the Social Security Act (SSA) supports the notion that CMS intended to apply to items and services purchased by individuals and not by institutions.** Specifically, Section 1847(b)(2)(A)(iv) requires "access of individuals to a choice of multiple suppliers in the area.". In addition, Section 1847(b)(4)(A) states that 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." Finally, SSA § 1847(b)(8) states that the "Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program." All of these provisions focus on the individual rather than the

institution and make no sense in the context of purchases by long term care facilities on behalf of beneficiaries.

Furthermore, **patients in nursing homes typically have a higher acuity level than those treated at home**. Therefore, it is not in the best interest of beneficiaries for the facility to be forced into accepting a supplier that has prevailed in the bid process by bidding low margins, while betting on high volume and low service. Such a supplier may have little experience in the care of patients in long-term care facilities. Further, such a supplier will have little incentive to provide appropriate services and interaction with the facility's clinical staff, because this will adversely impact already low margins, and could cost more than the single payment amount established through competitive bidding.

Moreover, in implementing the Part D benefit, CMS has recognized that quality and price requirements for covered benefits must be different for those patients who are institutionalized within a long term care facility. The same argument applies to Part B covered products and supplies offered to patients within long-term care facilities. The competitive bidding law requires competition regarding the price and quality of the services provided. However, with respect to long-term care facility patients, additional costs are incurred that are not generally incurred for beneficiaries outside of the long-term care facility setting such as the costs of 24/7 standby capacity. In the competitive bidding scenario, these types of costs and qualifications are not necessary for the broader population.

Long term care facilities have been facing reimbursement cuts from most public payers, while bearing the additional administrative burden of implementing new programs, such as the new Medicare prescription drug benefit. Under the proposed regulation, facilities will have to invest more resources to prepare for the competitive bidding process. **We argue that long term care facilities should not be treated like the other DMEPOS suppliers**. First, they only provide DMEPOS items and services to their residents; second, this limited scope and the realities of working with a frail, institutionalized population do not allow long term care facilities to achieve the same cost savings as a larger supplier in the community, creating an a priori disadvantage for these facilities in the competitive bidding process.

Finally, Innovatix fears that there will be disruption of service to beneficiaries if a long term care facility utilizes one provider for Part A and another that was chosen under the competitive bid program for Part B. This potential **disruption in service could create serious quality and access problems to beneficiaries in long term care facilities.**

For all of the reasons stated above, **Innovatix strongly urges CMS to allow long term care facilities in competitive bidding areas to continue to provide items and supplies to their residents without having to participate in the competitive bidding process; reimbursement would be based on current pricing mechanisms or the single payment amount established through competitive bidding.**

7. Any Willing Provider

The proposed rule states that if a supplier fails to bid or fails to win the bid, that they are no longer permitted to provide and bill for the items in the competitive bid area. In the regulatory analysis, CMS has determined that 54% of suppliers will no longer be in business as a result of the competitive bidding program. It is likely that a majority of these suppliers will be small businesses. To allow small suppliers a greater opportunity for participation, CMS should allow any qualified supplier to provide DMEPOS if the provider is willing to accept the payment amount determined under the competitive bidding process. Additionally, these small suppliers should not have to participate in the costly and time-consuming bidding process if they are willing to accept this payment amount.

If suppliers are willing to adhere to the quality standards, become accredited and accept the competitive bid price in a particular MSA, they should be allowed to participate. This program is intended to save money, not to put legitimate suppliers out of business or restrict patient access to quality goods and services. As such, **Innovatix strongly recommends that CMS allow for any willing providers to participate so long as they meet the accreditation and quality standards.**

Additionally, under the Proposed Rule, only a sufficient number of suppliers need be selected to meet demand, and CMS states that in some cases this could mean only two suppliers. CMS however does not specify what is a sufficient number. Nor does CMS fully explain what would happen if the contract suppliers that are chosen drop out of the program. What will this do to access and quality? Innovatix is very concerned about this section of the Proposed Rule. The Act requires that awards be made in each competitive bid area for each product category to "multiple" suppliers. Multiple is not reasonably construed to mean two.

Again, Innovatix strongly believes that CMS should allow any willing provider to provide products and services to the Medicare population. CMS should not make

up numbers to satisfy what CMS believes to be the appropriate number to satisfy the demand.

8. Small Business

Innovatix believes that the Proposed Rule does not adequately protect small suppliers. Section 1847(b)(6)(D) of the Medicare Modernization Act (MMA) requires CMS to take steps to ensure that small suppliers of items have an opportunity to be considered for participation in the competitive bidding program. While the MMA requires some balancing of program savings through the competitive acquisition of DMEPOS with the protection of small suppliers, the Proposed Rule provides no effective method of leveling the competitive playing field so that small suppliers are not disproportionately disadvantaged. While the Proposed Rule seems to make it clear that small suppliers are given the "opportunity to bid", there is no requirement in the proposed rule that allows small suppliers to actually "win a bid". This seems to be contrary not only in the intent of the law, but the specific provisions contained within.

Further, the "Opportunity for Networks" proposed by CMS actually creates an additional challenge for small suppliers who will already be hard-pressed to handle the inherent burdens of competitive bidding. The building of a network is no easy feat. It must be done with great caution and with even greater legal oversight as it raises serious anti-trust issues. In addition, we believe that what the Proposed Rule contemplates appears to be a horizontal market allocation agreement, which is illegal per se under antitrust law. Assuming that a network can be constructed to meet the scrutiny of the Department of Justice (DOJ) and the Federal Trade Commission (FTC), the majority of small businesses will not be able to bear the additional expense of network-building.

Again, assuming that a network can be constructed to meet the scrutiny of the DOJ and the FTC, there is nothing that would protect those small suppliers in the network from legal action from those who are not in the network or who are not permitted to join the network. So while **CMS is encouraging the formation of networks that are questionable under the anti-trust laws to begin with, there are additional legal burdens that they may encounter as a result of the building of these networks.**

To address this inadequacy within the Proposed Rule, we once again recommend that CMS consider allowing any willing and qualified supplier to provide DMEPOS whereby payment is subject to the single payment amount determined through the competitive bidding process.

Conclusion

Thank you for your consideration of these comments. Innovatix welcomes the opportunity to work with CMS to resolve the issues contained in this document. Please feel free to contact us with any questions that you may have.

Sincerely,

Lisa Sokol
Vice President
Communications and Public Relations

Submitter : **Diane Abbott** **Date: 06/30/2006**

Organization : **BJC Home Medical Equipment**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

The bidding timeline established by CMS is behind a year at best. Beginning in 2007, 10 of the largest metropolitan statistical areas (MSAs) are to be phased in to the competitive bidding program. Since the concept of competitive bidding is new to CMS, bidding in MSAs in 2007 should be staggered to allow CMS to identify problems that occur in the competitive bid areas and correct them before they become widespread.

At this time, the Quality Standards necessary to bid are still unknown. It is difficult, if not impossible, to provide meaningful comments to the proposed competitive bidding rule without knowledge of what standards CMS will require for bid participants. Although accreditation is one of the requirements of the Quality Standards, the acceptable accrediting entities have not been named. These accreditation bodies may then have to establish new standards under their accreditation requirements. In addition, only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. Without the identification of the Quality Standards and the accrediting bodies, providers cannot be reasonably expected to analyze the cost of servicing beneficiaries in order to make an informed bid.

CMS should not restrict bids to only those that are beneath the current Medicare fee schedule. Providers are just now analyzing the effects of capped rental and oxygen reimbursement changes on their businesses. Combine that with unknown Quality Standards and unselected accreditation bodies, providers are struggling to determine what their true cost of doing business will be. In addition, the proposed CMS rules suggest that providers will need to deliver brand specific equipment if so ordered by the physician. Providers often establish relationships with manufacturers for certain products. These relationships assist not only in determining the acquisition cost of the equipment but often extend to a guarantee of availability of product, shipping time, maintenance and repair, etc. It is costly in both time and money for a provider to have to search for a specific product, establish the necessary financial arrangement to purchase the product and schedule special shipping to the provider s warehouse. This will cause unnecessary delay in providing the equipment to the beneficiary. Also, many manufacturers establish distributorships in a given geographical region which could exclude a provider from accessing that product.

Another unknown burden to the competitive bidding providers is the cost of grandfathering in capped rental items previously furnished by providers who were not awarded the Medicare bid. These providers can chose not to continue to service their Medicare beneficiaries under the competitive bid rates, and some of these providers are predicted to even close their businesses. The affected beneficiaries will need to transition to the providers who have been awarded the bid for whatever months of reimbursement is remaining in the capped rental cycle for that equipment. This could be as little as a month or two of reimbursement for a brand new item placed in service for that beneficiary by the new provider. All of these unknowns could result in potential informed bids that realistically would exceed the current fee schedules.

CMS needs to reexamine their proposed rules in regard to implementation dates as well as processes for selection and transition. The Quality Standards and accreditation bodies should be determined by CMS with adequate time allowed for stakeholder comments before beginning any phase of competitive bidding. Otherwise CMS will undoubtedly incur unnecessary costs and time losses in implementing a plan that in theory is supposed to save Medicare dollars.

Diane Abbott
Director
BJC Home Medical Equipment
1935 Beltway
St Louis, MO 63114
(314) 953-2128
dxa5398@bjc.org

Submitter : Mr. Marc Heflin **Date:** 06/30/2006

Organization : Bird and Bear Medical

Category : Other Health Care Provider

Issue Areas/Comments

Payment Basis

Payment Basis

What impact will the 36 month cap on oxygen have on O2 patients and providers if they wish to transfer from a provider who is either participating or non-participating but "grandfathered" company to a participating provider? Under CMS-1270-P we are required to accept them which is fine until they want to switch at month 32 or some other month that will not allow a provider to recoup upfront cost...much less actually make a profit.(gasp!) Will that capped period start over or atleast allow the provider taking the patient an additional amount of months to absorb that cost?

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Would it not be in the best interest of the beneficiary to allow all qualified providers who submit bids be allowed to participate at the "accepted" bid amount? It certainly gives the physician/patient more options which will encourage real competition as it relates to service.

Also just wanting to clarify that you have to be "qualified" in order to even submit a bid.

Submitter : paula patton **Date:** 06/30/2006

Organization : paula patton

Category : Other Health Care Professional

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

If the quality standards are not in place prior to bidding,
service will not be the same therefore the cost of providing the service will be different.

Submitter : **Dr. Robert Scott Steinberg, DPM** **Date: 06/30/2006**

Organization : **Dr. Robert Scott Steinberg, DPM**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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).

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. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals and determine that a walking boot is necessary for immobilization of the injured foot with associated edema. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall might occur, which could result in other additional injuries.

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 to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Robert Scott Steinberg, DPM
4158 Portage Lane
Hoffman Estates, IL 60192
847-650-3668

Submitter : **Mrs. Lisa Sokol** **Date: 06/30/2006**

Organization : **Innovatix**

Category : **Private Industry**

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

see attachment

GENERAL

GENERAL

see attachment

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

see attachment

Payment Basis

Payment Basis

see attachment

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

see attachment

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

see attachment

CMS-1270-P-1248-Attach-1.DOC

ATTACHMENT TO #1248

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June 30, 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

RE: Proposed Rule on Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS) and Other Issues (71 F.R. 25654)

Dear Administrator McClellan,

Innovatix, LLC is pleased to offer comments on 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). Innovatix provides high quality group purchasing and consultative services to a national membership base of alternate care and non acute care institutional providers. Innovatix programs provide services to patients in: Home Infusion, Extended Care, Long Term Care (dispensing pharmacy), Retail and Mail Order Pharmacy, Extended Care providers of DMEPOS supplies, and select medical oncologist segments.

Innovatix and its members are directly impacted by this proposed regulation. We have a number of concerns and comments regarding the proposed rule. Our specific comments and concerns are provided below.

1. Delay Implementation of National Competitive Bidding

A. Quality Standards

A key component of the competitive bidding proposal involves the application of quality standards for all DMEPOS suppliers, including DMEPOS suppliers that participate in the competitive bidding program. The proposed rule also contains a provision requiring accreditation. CMS approved accrediting organizations will be applying the quality standards for all DMEPOS suppliers, including DMEPOS suppliers that will be participating in the competitive bidding program. The proposed rule makes it clear that the quality standards are an integral part of the

regulatory plan to implement the competitive bidding program and will have an enormous impact on the competitive bidding process.

DMEPOS suppliers will have to comply with the quality standards in order to furnish any item for which payment is made under Medicare Part B, as well as to obtain a provider or supplier billing number used to submit claims for reimbursement. However, CMS has not finalized the quality standards. They have only been issued in draft form on September 23, 2005 with the public comment period ending November 28, 2005.

Until the final quality standards are released, interested parties will be unable to provide meaningful, comprehensive comments that address the program requirements that will be applied by CMS to DMEPOS competitive bidding. The proposed rule is not sufficiently descriptive of the quality standards and the competitive bidding program under consideration. Therefore, interested parties, including Innovatix, are not able to offer informed criticism and comment on the proposed rule in accordance with the Administrative Procedures Act. In addition, **CMS's description of the competitive bidding proposal is incomplete without a thorough discussion of these requirements**.

The quality standards are a significant component to the competitive bidding process for DMEPOS, and as such, we request that the comment period for the competitive bidding proposal be extended to ninety (90) days after the publication of the final DMEPOS supplier quality standards.

B. Financial standards

Since the financial standards are not detailed, it is not possible to provide detailed comments. However, small suppliers that are not financially troubled must be reasonably able to comply with the financial standards implemented by CMS without having to incur the undue cost.

More importantly, satisfaction of the financial standards is a precondition to bidding. If the financial standards are too restrictive, fewer suppliers will be able to participate in the bid process, diminishing beneficiary choice and potentially adversely affecting the single payment amount. If the financial standards are not restrictive enough, unsound suppliers may be awarded contracts. These suppliers may not be able to supply beneficiaries at the single payment amount, resulting in impaired access. CMS' failure to specify financial standards leaves both beneficiaries and suppliers vulnerable, **and CMS should specify financial standards so interested parties can comment prior to the effectiveness of the Proposed Rule.**

C. Time Frame

In addition to extending the comment period until after the publication of the final DMEPOS Quality Standards, the implementation of competitive acquisition should be delayed as much as permitted by § 1847(a)(1) of the SSA. The original CMS timeline was to have the competitive bidding proposed rule published in the Spring of 2005. The timeline set forth a comment period of summer 2005. The final rule was to be published in the Spring of 2006. This timeline allowed the supplier community to have from Spring 2006 through the end of 2006 to make arrangements for the implementation of the competitive bidding regulation. However, the delays in the development of the competitive bidding proposal show that the issues are complex and their resolution difficult. The fact that the development of the quality standards and the proposed rule has taken at least one year longer than originally contemplated by CMS shows that it is unrealistic to expect the final rule to be published and all of the implementation steps to be accomplished in any reasonable manner by early 2007. The statute's requirements do not state that implementation is required to take place at or near the beginning of 2007. It merely states that the requirements of the statute will be satisfied if competitive bidding is implemented in 2007.

Innovatix believes that CMS needs to take the time to carefully implement competitive bidding or beneficiaries will be negatively impacted. As such, it is our belief that CMS has the authority to begin the competitive bidding process at or near the end of 2007 and not at the beginning of 2007 as is indicated in the proposed rule. **Implementation of the competitive bidding proposal toward the end of 2007 is more consistent with CMS' original timetable in terms of time allocated to tasks, and will afford a much greater opportunity for the program to achieve its objectives without adversely impacting beneficiaries.**

D. Issuance of Interim Final Rule

The proposed rule leaves a lot of very important, detailed information to be determined in the final rule including the products and codes to be included, the quality standards, the particular MSA's impacted, and how CMS will determine the number of suppliers necessary in a bid area just to name a few. In addition, it appears that although small suppliers are supposed to be afforded the same abilities to provide products under a competitive bid program, the CMS proposed rule will impact small businesses negatively. As such, **Innovatix believes that CMS should issue an interim final rule with comments, so that interested parties can submit additional comments before this regulation is implemented.**

2. Single Payment amount

Innovatix is very concerned about the methodology that CMS has proposed regarding the payment amount and feels that it is seriously flawed. The methodology goes against the very program that CMS is trying to implement. CMS is asking companies to provide the lowest bid for providing certain DMEPOS products. Then CMS is going to award the contract to certain companies, yet they will be lowering the bid amount to a median amount rather than the amount that the company believes is the lowest price they can afford to provide the product. This methodology simply does not work.

There is no assurance that all suppliers who bid at or below the pivotal bid will be able to furnish the chosen items at a payment amount equal to the median of the bids equal to or lower than the pivotal bid. The pivotal bid, moreover, is the bid just sufficient to meet demand. If the supplier bidding the pivotal bid is not able to provide the items at the median in the proposed rule, the demand will not be met and access will be impaired. This method is different than that used in the demonstration project.

CMS has also indicated that if the demand will not be met, they will select additional suppliers. However, their discussion regarding the selection of additional suppliers will not address the problem because the suppliers added after the bid process must still accept the single payment amount. These suppliers will have the same issues: if the suppliers that bid between the median and the pivotal bid submitted the best bids they could make, then they will not be able to furnish the supplies at the median, which is lower than the amounts they bid. To the extent such suppliers are not able to meet projected demand, it is not reasonable to expect that more responsible suppliers will be able to provide the items at the artificially depressed single payment amount.

The methodology for determining the single payment amount as set forth in the proposed rule is seriously flawed and will have an adverse impact on beneficiary access to needed items, especially in undefined HCPCS codes. In order to assure beneficiary access, **Innovatix suggests that CMS utilize the pivotal bid to be the payment amount rather than the median between the pivotal bid and the low bid.**

3. Adjustment of payment amounts in other areas

Innovatix strongly believes that it is not appropriate to use payment amounts determined in one competitive bidding MSA to make inherent reasonableness adjustments to payment amounts in other areas. CMS seems

to suggest that the competitive bided price for a specific good or service in one MSA provides adequate data to adjust the allowable for the same item in another area. This is completely contrary with historically accepted practices that recognize the uniqueness of each distinct geographic area based on such factors as cost of living and available work force to list just a few.

Moreover, as stated in the proposed rule, the MSAs chosen in the first two phases will be the largest MSAs. The remaining areas will likely be rural and less densely populated. Therefore, single payment amounts established for large MSAs on the basis of competitive bidding will have no relation to appropriate payment amounts in areas outside of those MSAs.

Innovatix believes that it is not reasonable to use the competitive bid amounts in one MSA to make inherent "reasonableness" adjustments to payment amounts outside of the competitively bid MSAs.

4. Item and product selection

Under the competitive bidding program, CMS will have the authority to determine which items should be subject to competitive bidding. Innovatix urges CMS to limit the items and product categories subject to competitive bidding as the program is largely untested. By minimizing the number of items subject to competitive bidding, adverse impacts on beneficiaries may be avoided. Until a critical analysis of the items included in certain HCPCS codes is completed, competitive bidding should be limited to a product group or groups that include only codes or items that are truly generic and clinically equivalent. **We urge CMS to provide a list of the items that they plan to include in the competitive bidding program prior to implementation and allow interested parties an opportunity to provide public comment.**

The goal of competitive bidding must be to reasonably reduce program and beneficiary costs while maintaining or enhancing quality and access. The selection by current Health Care Procedure Code System (HCPCS) codes will adversely impact the quality of care for beneficiaries. 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 statute does not state that items

have to be selected by HCPCS codes – rather the statute refers only to the competitive bidding of DMEPOS items. Many current HCPCS codes include items of widely different cost, technology and clinical application.

The use of HCPCS codes that include items of widely varying cost and clinical application will adversely affect the quality of care for the beneficiaries. The use of such codes will result in a race to the bottom by suppliers, and diminish beneficiary access to medically necessary, higher cost or higher technology items that are included in HCPCS codes together with inexpensive items that may not be appropriate. Once contracts are awarded to suppliers, the suppliers will have a significant incentive to furnish the lowest cost item within the code, unless a different item is specifically prescribed by the physician. 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. We are very concerned about this possibility.

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.

As stated above, Innovatix believes the initial set of products should be limited to a product group or groups that include only codes or items that are truly generic and clinically equivalent. We urge CMS to provide a list of the items that they plan to include in the competitive bidding program prior to implementation (in an interim final rule) and allow interested parties an opportunity to provide public comment.

5. Grandfathered Items

Innovatix believes that CMS does not have the legal authority to change a material term in a contractual agreement. Section § 1847(a)(4) of the Act provides that CMS "shall establish a **process** by which rental agreements for the covered items … may be continued notwithstanding this section." . A "process" is an administrative mechanism or methodology for continuation of the agreements, not an authorization to unilaterally modify agreements. The price term of an agreement is not a minor detail, but one of the central terms of an agreement. The Act plainly requires that agreements be continued notwithstanding competitive bidding. It does not state that the agreements may be continued as adjusted by competitive bidding. The provision permitting an agreement to continue except for the price raises significant constitutional

questions. The due process clause of the Fifth Amendment precludes the Federal government from unilaterally changing terms of agreements, yet this is exactly what CMS is proposing to do.

The terms of a contract encompass many aspects including the products and services that will be offered, how the products will be delivered and value added services that all account for the ultimate price of the contract. To have CMS unilaterally say that the price of the contract has to be changed to reflect the competitive bid price, does not take into account the services that are included in the contract. **CMS should adhere to the plain language and meaning of the Act and provide for the continuation of agreements under § 1847(a)(4) without modification of the price.**

6. Allowing SNFs to Continue to Provide Needed Items to Their Residents

Innovatix strongly believes that products and supplies that are covered and provided to Medicare beneficiaries who are in long term care facilities should be exempt from these rules for a number of reasons.

First, it is our belief that the law was never intended to apply to institutional purchasers and that the phrase "items or services" means those that are purchased directly by individuals and not by institutions on behalf of individuals. There is nothing to suggest that Congress intended to undermine institutional purchasing power. To the contrary, the language makes clear that the competitive bidding law was designed to give individual beneficiaries similar, although not identical, purchasing leverage as enjoyed by institutional purchasers.

In addition, **the language in the Social Security Act (SSA) supports the notion that CMS intended to apply to items and services purchased by individuals and not by institutions.** Specifically, Section 1847(b)(2)(A)(iv) requires "access of individuals to a choice of multiple suppliers in the area.". In addition, Section 1847(b)(4)(A) states that 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." Finally, SSA § 1847(b)(8) states that the "Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program." All of these provisions focus on the individual rather than the

institution and make no sense in the context of purchases by long term care facilities on behalf of beneficiaries.

Furthermore, **patients in nursing homes typically have a higher acuity level than those treated at home**. Therefore, it is not in the best interest of beneficiaries for the facility to be forced into accepting a supplier that has prevailed in the bid process by bidding low margins, while betting on high volume and low service. Such a supplier may have little experience in the care of patients in long-term care facilities. Further, such a supplier will have little incentive to provide appropriate services and interaction with the facility's clinical staff, because this will adversely impact already low margins, and could cost more than the single payment amount established through competitive bidding.

Moreover, in implementing the Part D benefit, CMS has recognized that quality and price requirements for covered benefits must be different for those patients who are institutionalized within a long term care facility. The same argument applies to Part B covered products and supplies offered to patients within long-term care facilities. The competitive bidding law requires competition regarding the price and quality of the services provided. However, with respect to long-term care facility patients, additional costs are incurred that are not generally incurred for beneficiaries outside of the long-term care facility setting such as the costs of 24/7 standby capacity. In the competitive bidding scenario, these types of costs and qualifications are not necessary for the broader population.

Long term care facilities have been facing reimbursement cuts from most public payers, while bearing the additional administrative burden of implementing new programs, such as the new Medicare prescription drug benefit. Under the proposed regulation, facilities will have to invest more resources to prepare for the competitive bidding process. **We argue that long term care facilities should not be treated like the other DMEPOS suppliers**. First, they only provide DMEPOS items and services to their residents; second, this limited scope and the realities of working with a frail, institutionalized population do not allow long term care facilities to achieve the same cost savings as a larger supplier in the community, creating an a priori disadvantage for these facilities in the competitive bidding process.

Finally, Innovatix fears that there will be disruption of service to beneficiaries if a long term care facility utilizes one provider for Part A and another that was chosen under the competitive bid program for Part B. This potential **disruption in service could create serious quality and access problems to beneficiaries in long term care facilities.**

For all of the reasons stated above, **Innovatix strongly urges CMS to allow long term care facilities in competitive bidding areas to continue to provide items and supplies to their residents without having to participate in the competitive bidding process; reimbursement would be based on current pricing mechanisms or the single payment amount established through competitive bidding.**

7. Any Willing Provider

The proposed rule states that if a supplier fails to bid or fails to win the bid, that they are no longer permitted to provide and bill for the items in the competitive bid area. In the regulatory analysis, CMS has determined that 54% of suppliers will no longer be in business as a result of the competitive bidding program. It is likely that a majority of these suppliers will be small businesses. To allow small suppliers a greater opportunity for participation, CMS should allow any qualified supplier to provide DMEPOS if the provider is willing to accept the payment amount determined under the competitive bidding process. Additionally, these small suppliers should not have to participate in the costly and time-consuming bidding process if they are willing to accept this payment amount.

If suppliers are willing to adhere to the quality standards, become accredited and accept the competitive bid price in a particular MSA, they should be allowed to participate. This program is intended to save money, not to put legitimate suppliers out of business or restrict patient access to quality goods and services. As such, **Innovatix strongly recommends that CMS allow for any willing providers to participate so long as they meet the accreditation and quality standards.**

Additionally, under the Proposed Rule, only a sufficient number of suppliers need be selected to meet demand, and CMS states that in some cases this could mean only two suppliers. CMS however does not specify what is a sufficient number. Nor does CMS fully explain what would happen if the contract suppliers that are chosen drop out of the program. What will this do to access and quality? Innovatix is very concerned about this section of the Proposed Rule. The Act requires that awards be made in each competitive bid area for each product category to "multiple" suppliers. Multiple is not reasonably construed to mean two.

Again, Innovatix strongly believes that CMS should allow any willing provider to provide products and services to the Medicare population. CMS should not make

up numbers to satisfy what CMS believes to be the appropriate number to satisfy the demand.

8. Small Business

Innovatix believes that the Proposed Rule does not adequately protect small suppliers. Section 1847(b)(6)(D) of the Medicare Modernization Act (MMA) requires CMS to take steps to ensure that small suppliers of items have an opportunity to be considered for participation in the competitive bidding program. While the MMA requires some balancing of program savings through the competitive acquisition of DMEPOS with the protection of small suppliers, the Proposed Rule provides no effective method of leveling the competitive playing field so that small suppliers are not disproportionately disadvantaged. While the Proposed Rule seems to make it clear that small suppliers are given the "opportunity to bid", there is no requirement in the proposed rule that allows small suppliers to actually "win a bid". This seems to be contrary not only in the intent of the law, but the specific provisions contained within.

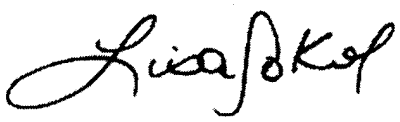
Further, the "Opportunity for Networks" proposed by CMS actually creates an additional challenge for small suppliers who will already be hard-pressed to handle the inherent burdens of competitive bidding.

To address this inadequacy within the Proposed Rule, we once again recommend that CMS consider allowing any willing and qualified supplier to provide DMEPOS whereby payment is subject to the single payment amount determined through the competitive bidding process.

Conclusion

Thank you for your consideration of these comments. Innovatix welcomes the opportunity to work with CMS to resolve the issues contained in this document. Please feel free to contact us with any questions that you may have.

Sincerely,



Lisa Sokol
Vice President
Communications and Public Relations

Submitter : **Dr. Charles Cavicchio** **Date: 06/30/2006**

Organization : **Dr. Charles Cavicchio**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,
Charles M. Cavicchio, DPM
RI CAC Representative

Submitter : Ms. Lori Corey **Date:** 06/30/2006

Organization : Oxygen One, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1250-Attach-1.PDF

ATTACHMENT TO #1250

Oxygen One, Inc.
The Home Respiratory & Sleep Specialists

1900 Pewaukee Road • Suite F
Waukesha, WI 53188•2447
1.888.OXYGEN.1 (699.4361)
262.521.2202 • Fax: 262.521.2249

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Delivered Via Electronic Mail: http://www.cms.hhs.gov/eRulemaking

Re: (File Code CMS-1270-P) Notice of Proposed Rule Making entitled "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues"

Dear Dr. McClellan:

We are writing to thank you for the opportunity to comment on the Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS and Other Issues Proposed Rule (CMS 1270-P) that was released on 5/1/06 for public comment. Our attached comments reflect the concerns expressed by the American Association of Homecare as well as specifically address the issues that relate to our company and the future ability to provide service to Medicare beneficiaries. We firmly believe our comments reflect a quality yet cost effective approach to providing healthcare to those who suffer from lung and/or cardiac disease.

Oxygen One, Inc. is a family owned, home respiratory specialist serving over 1500 patients per day in Southeastern Wisconsin. In business for six years and Accredited by JCAHO for both Home Medical Equipment and Clinical Respiratory Services, we bring dedicated care to the patient in their home at a far reduced cost than that of any institution.

We would be happy to provide further comments on or assist in the development of the Competitive Acquisition Program or the adopting of another such model relating to pricing. If you have any questions as to the comments please do not hesitate to contact us. We can best be reached Monday-Friday 8:30 -5:00 Central Time at 1-888-699-4361 or by email at the addresses listed below.

Thank you again for the opportunity and the consideration you will take on our comments.

Sincerely,

Lori Corey
lori@oxygenone.com
Financial Director

Jill Spellman RRT
jillrrt@oxygenone.com
President

Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS and Other Issues Proposed Rule (CMS 1270-P)

1. 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. 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. This is another reason for a delay in planned implementation.

   - *Delay of implementation date until ALL details can be clearly outlined and participation criteria fully developed would significantly reduce costly errors.*

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 regulation; 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. It is expected 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.

- *As a quality provider in Southeastern Wisconsin that is currently accredited by the Joint Commission we do not believe that any company that is not already accredited should be given the option of bidding. Will companies that wait to become accredited until it is mandatory really provide quality care and service or merely scramble to pass a survey that will allow them to participate in the Competitive Bidding process? This process would detract from the companies that have chosen voluntarily to undergo the rigorous accreditation process because they believe it is the right thing to do!*

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.

   - *This process must be clearly defined to allow for all companies to be reviewed equally and fairly regardless of size. It must also define a process to insure that it does not allow for providers to severely under bid prices to secure a larger market share.*

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.

   - *Bids should be allowed to be reflective of the true cost of doing business whether that means higher or lower than the current fee schedule. We believe that the cost can be all over the board with out any rationale and must be looked at thoroughly to determine which prices are simply overstated/understated and what prices truly reflect what the market is doing.*

7. "Conditions for Awarding Contracts"- Do Not Make It Harder For Providers To Sell Their Businesses. (proposed §414.414(e)) 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. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement, that contracted supplier and its new ownership should retain its contract.

- *We believe that CMS should restrict the larger companies from not bidding but then buying their way into the business thru acquisition which is what occurred in the demonstration projects.*

8. "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.

9. "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.

   - *A clear plan must be in place for the beneficiaries that reside in more than one location (one area that is being bid and one area that is not in the bid) or for beneficiaries that require services from the competitive bid products and other equipment or services that is not in the bid. Patients will have a difficult time if they do not know who to go to for what and pricing as well.*

10. "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.

    - *We must have the rules clearly defined that can be clearly communicated to the patient what the impact of owning the equipment will be – what the service and maintenance expectation of them will be. The patient needs this information long before any policy or bid is put in place.*
    - *As a respiratory specialist we believe a true cost study would give information to truly and accurately price products for reimbursement.*

11. "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.

- *A rebate provision is just a poor idea no matter how you look at it. It has no purpose and should be removed.*

12. "Determining Single Payment Amounts for Individual Items"- Provide More Details On The "Composite Bid" Calculation. The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should provide suppliers with the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

13. "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.

- *I do not believe that companies outside of a geographic area should have the ability to bid. I believe that you must have been in the area prior to the bid process in order to be considered. It should not be open to any mail order company that can ship a wheelchair or nebulizer via ups. This is not quality patient care no matter who accredited that company.*

14. "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.

- *See item 6*

15. "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.

16. "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 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".

17. "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 payors, 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.

18. "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.

19. "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.

- *As a small provider that currently services 4 counties in Southeastern Wisconsin it would be difficult for the full MSA. We need to have some ability to bid within service areas to be able to maintain quality patient care.*

20. "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.

- *See item 6*

21. "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.

- *The current rates do not adequately cover the actual cost of repair or replacement of most items.*

22. "Terms of Contract"- Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment. (proposed §414.422(c))

23. "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.

- *We need to be able to choose what equipment will be supplied as Medicare covered and what will not. Not all products can be supplied to a Medicare patient as covered as our cost far exceeds the current reimbursement fee schedule.*

24. "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.

- *We support a new rental period beginning should a patient choose to switch companies. This supports the patients freedom to choose and allows providers to continue to compete on* ***service*** *a non-reimbursed extra.*

25. "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.

- *There are currently no safe guards in place to ensure that small suppliers will be able to compete let alone other measures that ensure they will not such as having to service the entire MSA.*

26. "Opportunity for Networks"- Clarify Network Regulations. (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?

27. "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 through other means.

28. "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 allowable amount that corresponds with the beneficiary's permanent residence for up to five months.

- *In addition to payment how do the months apply to rental caps.*

29. "Payment Basis"- Provide Details On How Pricing Will Be Used After January 1, 2009. CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to use the payment information determined under that competitive bidding programs to adjust payments amount for the same DMEPOS in areas not included in the competitive bidding program. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

30. "Gap-filling"- Different Alternatives To Gap Filling Must Be Used. (proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the gap filling pricing methodology. The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process.

31. "Gap-filling"- Develop More Equitable System To Price HCPCs Changes. CMS 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. This is not equitable solution and a more appropriate procedure must be developed.

Submitter : **Marsha Lawrence** **Date: 06/30/2006**

Organization : **Handworx**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-1251-Attach-1.DOC

CMS-1270-P-1251-Attach-2.RTF

ATTACHMENT 1 TO #1251

Sample Letter

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Marsha Lawrence, and I am a physical therapist specializing in the treatment of upper extremity disorders.) I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working at Truman Medical Center in Kansas City , MO and in my own private practice and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its

possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, 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. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Marsha Lawrence PT CHT

ATTACHMENT 2 TO #1251

Sample Letter

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Marsha Lawrence, and I am a physical therapist specializing in the treatment of upper extremity disorders.) I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working at Truman Medical Center in Kansas City , MO and in my own private practice and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for?

Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, 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. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Marsha Lawrence PT CHT

Submitter : Ms. Carol Gilligan **Date:** 06/30/2006

Organization : Health Aid of Ohio, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

I am concerned about this because there are many areas that need clarified. I don't want to move into this era before we understand the impact on the providers and the patient. The Quality Standards are not defined. CMS' movement to bring providers of HME services to a uniform level of care is important but the defined standards are needed. The implementation of the DRA will impact the bidding process for a provider. We as providers need to understand more about this impact. Again, patient care is going to be the most notable area of concern. HME services include services that are life sustaining and those services must be provided consistently, correctly and efficiently. The focus must be on the level of care of the service not on when to change the provider when the patient moves locations. Just an example of needing some time to discuss the impact to providers and to patients.

Submitter : **Mr. Patrick Hanna** **Date: 06/30/2006**

Organization : **B&K Home Medical Services**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Ms. Sheba Wilburn** **Date: 06/30/2006**

Organization : **Wheelchair Sales & Services (WS&S Medical)**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment...

CMS-1270-P-1254-Attach-1.DOC

CMS-1270-P-1254-Attach-2.PDF

ATTACHMENT 1 TO #1254

WS&S MEDICAL

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

Submitter : **Alan Carpenter** **Date: 06/30/2006**

Organization : **Foster Drug Co., Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I do not believe that competitive bidding is the best way to provide professional services to these patients. This will cut out many small businesses, therefore decreasing availability and convenience for many patients (especially in rural areas).

Submitter : Mr. John Carpenter **Date:** 06/30/2006

Organization : Foster Drug Co., Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Competitive bidding is NOT the way to proceed in this area. As always, you should continue to set the pricing on DME items and then let each organization decide if participation is in the best interest of their business.

Submitter : **Ms. Leslie Boone** **Date: 06/30/2006**

Organization : **Ms. Leslie Boone**

Category : **Occupational Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Facts are for the Government to make patients travel to various places for healthcare concerning one injury it not PEOPLE focused, time effective, cost effective as well as greatly decreases the Patient's quality of care. When swelling changes orthoses or splints have to be readjusted. Also, depending on Patient compliance splints need numerous readjustments. As for liablity if I didn't make a splint why would I then be the one to adjust for someone else who really is not the 'expert' for hand orthosis/splints. A hand therapist, like my self, has the 'expertise' for COMPREHENSIVE health care concerning what is best for the patient. If the cost to Medicare for this equipment is so high than why not put caps on the equipment---not the quality of care you are providing to hard working individuals who have now earned their healthcare. Please don't skimp the elderly. Hopefully one day I will be 'elderly' too and want the best care provided. (Being older and driving around town or even to varioius towns (rural areas) would be very taxing). Hope you reconsider these issues. Please try to think of someone you love and the hardship you will be putting on them. If you don't understand the full effects please just call a hand therapist/hand doctor--see if there is a patient will to talk to you and tell them what type of service they received and how it would be different if you implement these changes.

Submitter : **Miss. Sheila Flaherty** **Date: 06/30/2006**

Organization : **Charlotte Orthopedic Clinic**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am an Occupational Therapist and Certified Hand Therapist. I am very concerned about the adverse impact the 'Proposed Rule for Competitive Acquisition of Certain DMEPOS' CMS-1270-P will have on quality patient care and patient functional outcomes. There is a marked difference between my work as a Certified Hand Therapist and other DMEPOS suppliers. As a provider with specialty training and expertise in the disease process of Upper Extremity Disorders, I consider not only the mechanics of the device, but also the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs etc. A beneficiary's needs are thoroughly evaluated to determine the appropriate orthosis for her/his use. In many cases, a specific brand may be the only one that would appropriatly 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. As a result, it is not guaranteed that a beneficiary will be able to find a specific orthosis in their local area, potentially limiting beneficiary access to a critical orthosis. Ultimately, this could result in harm to the patient, causing greater disability and long term dysfunction. Delays in the supply of an orthosis will interfere with clinical reasoning and patient treatment. Many of the patients I treat are in an acute state. This necessitates frequent changes in their orthosis to adapt to their rapidly changing condition (e.g. inflammation, instability, pain etc). In order to assure patient safety, it is critical that I am able to respond to that need immediately. Finally, I believe that there would be a very small profit margin in UE off-the-shelf orthosis. I am hopeful that Medicare will consider all of the aformentioned concerns I have as a Certified Hand Therapist. I believe our Medicare beneficiary's continue to deserve a quality level of care that maximizes their function and preserves their independence. Thank you very much for your consideration of my concerns. Sheila Flaherty, OTR/L, CHT

Submitter : Mrs. Victoria NAmihas **Date:** 06/30/2006

Organization : ASHT- CMS 1270 p

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

With regard to CMS-1270-P, Request that Medicare revise proposed regulatory to establish a process that will enable therapists to continue to supplu upper extremity orthoses to beneficiaries in their care without additional constraints.

Submitter : **Dr. Rhonda Turner** **Date: 06/30/2006**

Organization : **The Prosthetic Center**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1260-Attach-1.DOC

ATTACHMENT TO #1260

Dr Rhonda F Turner
BOCPO, CMF
The Prosthetic Center
3000 Richmond Avenue, Suite 100
Houston Texas 77098

June 30, 2006

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

http://www.cms.hhs.gov/eRulemaking.

RE: Comments on Proposed Rule CMS-1270-P

Dear Dr. McClellan:

I would like to include several points in the comment on Proposed Rule CMS 1270-P. I am an independent, BOC certified orthotic and prosthetic practitioner as well as an ABC certified mastectomy fitter. I am an owner of one full service O & P facilities and mastectomy facilities two states.

Regarding Quality Standards

H. Quality Standards for Suppliers of (DMEPOS)

CMS-1270-P Section 302(a)(1) of the MMA added section 1834(a)(20) to the Act, which requires the Secretary to establish and implement quality standards for suppliers of certain items, including consumer service standards, to be applied by recognized independent accreditation organizations. Suppliers of DMEPOS must comply with the quality standards in order to furnish any item for which payment is made under Part B, and to receive and retain a provider or supplier billing number used to submit claims for reimbursement for any such item for which payment may be made under Medicare. Section 1834(a)(20)(D) of the Act requires us to apply these quality standards to suppliers of the following items for which we deem the standards to be appropriate: Covered items, as that term is defined

in section 1834(a)(13), for which payment may be made under section 1834(a); Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4).

As stated above it is required for any and all suppliers to meet both business and product specific quality standards set forth by the MMA section 1834(a)(20). These standards have at the time of the writing of this letter not been published. It is a considered opinion that the final rule for competitive bidding cannot be adequately addressed or even effectively commented upon until such a time as all standards, rules and requirements have be set forth and reveled. It is suggested that the comments period be extended until a reasonable time after the publication of the Quality Standards. These Standards are an integral part of the competitive bidding process and a direct effect on suppliers' actions.

Regarding Financial Standards (proposed §414.414(d))

Section 1847(b)(2)(A)(ii) specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary. Evaluation of financial standards for suppliers assists us in assessing the expected quality of suppliers, estimating the total potential capacity of selected suppliers, and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts. Ultimately, we believe that financial standards for suppliers will help maintain beneficiary access to quality services.

Therefore, as part of the bid selection process, the RFB's will identify the specific information we will require to evaluate suppliers, which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency. We welcome comments on the financial standards, in particular the most appropriate documents that will support these standards. CMS-1270-P 85 We found that in the demonstration, general financial condition, adequate financial ratios, positive credit history, adequate insurance documentation, adequate business capacity and line of credit, net worth, and solvency, were important considerations for evaluating financial stability.

It is an acceptable concept that a contract should be entered into with a solvent company. However the ideas set forth in the Financial Standards portion of the proposed rule have raised several issues that could be detrimental to small and mid-sized suppliers.

A significant portion of the DMEPOS industry is as defined by the IRS, categorized as small business. These businesses are oftentimes owned by individuals and families. Requirements such as credit history, business capacity, established lines of credit or overall net worth may not, because a substantial amount of the information would be dependent on personal information,

accurately reflect the health of the organization or its capacity to enter into contract and provide skilled quality-based services. Current suppliers have clearly met all general, local, state and national requirements in order to do business. It seems that changing those standards after in some cased decades of quality service to beneficiaries is a questionable action on the part of CMS.

Since the majority of DMEPOS are suppliers with less than 10 employees, a SBA definition, the financial standards clearly and unjustly favor the large corporation or multi-supplier group.

There is concern as to the accuracy of both personal and business credit reporting agencies that may adversely effect a contact decision. Business credit reporting agencies such as Dunn and Bradstreet, by their own admission, are not responsible for verification of payment reports. These types of agencies depend on businesses to supply information at a considerable cost: either by single payment or subscription bases. This cost may prevent access. The agencies are under no obligation to remove adverse information. It should be noted that a business must even pay for their credit report and analysis.

This concern for accuracy begs the question as to an appeal process for inaccurately reported information resulting in a contract denial.

Also, the question must be raised, "why would business and financial requirements of a general supplier or organization be different from that of a supplier engaging in competitive bidding. If the overall goal of CMS as stated is to "help maintain beneficiary access to quality services" should not the requirements be equal?

K. Opportunity for Participation by Small Suppliers

> In developing bidding and contract award procedures, section 1847(b)(6)(D) of the Act requires us to take appropriate steps to ensure that small suppliers of items have an opportunity to be considered for participation in the Medicare DMEPOS Competitive Bidding Program. Section 1847(b)(2)(A)(ii)) of the Act also states that the needs of small suppliers must be taken into account when evaluating whether an entity meets applicable financial standards. Size definitions for small businesses are, for some purposes, developed by the Small Business Administration (SBA) based on annual receipts or employees, using the North American Industry Classification System (NAICS). Based on the advice from the SBA, we expect that most DME suppliers will fall into either NAICS Code 532291, Home Health Equipment Rental, or NAICS Code 446110, Pharmacies, since the SBA defines these small businesses as businesses having less than $6 million in annual receipts.

As previously stated a large part of the DMEPOS industry is comprised of small businesses, with considerably less that $6 million or even $1 million in annual receipts. Consideration for the

Submitter : Ms. Nancy Eldridge **Date:** 06/30/2006

Organization : ASHT

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

I am an Occupational Therapist & a Certified Hand Therapist with 16 years experience specializing in treatment for rehabilitation of the upper extremity. The difference between my credentials/ability to provide upper extremity orthotics/equipment for optimal(or at least safe) care & those of a DME vendor,is comparable to the difference between a certified technical mechanic and an auto part sales person. If one needed an outboard constant velocity joint repaired in his front wheel drive, he might initially save money going to the parts sales person who gave him a "deal",however after the car wreck encurred form improper repair, he would find tht the true cost is much higher. I have lost count of the number of patients who were harmed by an orthotic provided by an unskilled person. How cost effective has it been for a patient who had to have Carpal Tunnel surgery after being fitted with an inappropriate or ill fitting wrist brace that put more pressure on the Median nerve because it was at the wrong angle? What about the folks who were issued a Tennis Elbow strap & developed palsy of the wrist/hand requiring months/years of Physical/Occupational therapy or permanent debility because of compression to the Posterior Interosseous Nerve of the forearm? I'm sure the sales person told them "That looks good" when fitting the patient with it. Also delays in supply of an orthosis can have dire results if the the provision of it comes after the healing window of opportunity. This especially can & does occur with such things as post surgical tendon repairs or finger joint replacements where the delay actually renders the surgery useless or worse. Although statistics my show reduced cost to a particular cost center, the greater cost far outweighs any perceived gain. Before anyone votes on this measure he/she needs to consider how they would feel if he/she or a loved one lost functional use of their hand because the vendor of an ill fitting orthotic obliviously said: "That looks good".
Nancy J. Eldridge OTR/L,CHT

Submitter : **Mr. Mike Bailey** **Date: 06/30/2006**

Organization : **Handi Medical Supply, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

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

Dear CMS Representatives;

Enclosed you will find comments made by the officers and leaders of Handi Medical Supply, Inc. 2505 University Ave West St. Paul, Minnesota 55114 regarding the Center for Medicare and Medicaid Services program CMS 1270-P Competitive Bidding Program. Our comments are as follows:

(General Comments)

We believe that CMS should stagger the bidding in MSA s in 2007 to ensure that this program is rolled out appropriately. Further we believe that the final rule should include the MSA s and the selected items in CMS s final rule regarding competitive bidding. Adding this information to the final rule will enhance the HME small provider s ability to create networks. We believe that the network feature of this rule can benefit the smaller supplier. Having said this, time is essential in identifying partners with whom you would decide to partner within a business arrangement.

Regarding the number of suppliers awarded winning bids in a MSA. It is our belief that CMS should select a number of suppliers that was greater than the 100% capacity needed to fill the orders of Medicare Beneficiaries in a MSA. We propose that the capacity number be 130-140% to ensure the timely delivery of products and services to the Medicare population.

We also feel strongly that a certified financial statement should satisfy CMS rather than an audit financial statement. The cost of an audited statement is approximately 100% more for audited results. This requirement by CMS would be a substantial financial burden on small to mid size HME providers.

In the propose rule CMS is asking HME providers to provide CMS on a quarterly basis the following information: # of items supplied, HCPC code, Manufacturer, Make and Model number. It is our opinion that CMS can electronically extract this information from there is system processing provider s claims. And for this reason should not be required to submit to CMS by the provider.
(Deficit Reduction Act of 2005)

The proposed CMS rule states that oxygen equipment will be capped at 36 months. We are concerned with this cap as we are not sure that analysis has been performed reviewing the cost to manage an oxygen dependent customer when the customer owns their own liquid cryogenic vessels. Currently under Medicare the contents are included in the monthly fee. We believe that the purchase by Medicare of lbs of liquid oxygen purchased by most customers each month will exceed the fee currently paid by Medicare for both the Liquid oxygen system and the oxygen contents of the system. In this analysis the expenditures for Medicare would increase rather than decrease and not satisfy the intent of the Deficit Reduction Act of 2005. The requirements for both routine and preventative maintenance of oxygen concentrators also concerns us as the equipment required and training necessary to provide routine and preventative maintenance on a oxygen concentrator is expensive and beyond the ability of most Medicare beneficiaries. Will CMS compensate the HME provider for routine and preventative maintenance? If this maintenance is not performed the oxygen dependent customer is at risk of receiving sub-therapeutic levels of oxygen further complicating their condition which could result in physician visits and hospital admissions. Finally there are a number of oxygen concentrators on the market that are capable of transfilling oxygen tanks. These units cost 200-300% more than a traditional oxygen concentrator. Thousands of these units are currently being utilized by Medicare beneficiaries. If the proposed changes take place we believe that many HME providers will switch out the transfill system for a non transfill system. This will create a great deal of issues with Medicare beneficiaries

Submitter : **Ms. Kendyl Brock** **Date: 06/30/2006**

Organization : **American Society of Hand Therapists**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Regarding the proposed rule to require competitive billing for DME devices, including splints for upper extremity issues, I have several issues to bring to your attention. 1. As opposed to DME providers, treating clinicians consider many different factors when prescribing splints, including ADL performance, disease processes, underlying secondary conditions, and patient compliance. Sometimes, only one particular style or brand may meet all of these needs and choosing a different style simply to meet cost factors may exacerbate a patient's condition. 2. If an incorrect style is chosen by a DME provider and the patient incurs further or differing injury, who is responsible for the patient's worsening condition? I have a difficult time both ethically and legally taking responsibility to accept a treatment plan for a splint under my care that I did not have the opportunity to prescribe and find to be detrimental to my patient. 3. Very little profit is built in to the prefabricated splint, and with the very real concerns that this proposed rule has caused to arise, is it worth the very small cuts this rule will make to risk further injury to patients?
I appreciate your time and attention to this matter and suggest that alternate ways of saving money be addressed, such as placing a greater emphasis on conservative management and preventative care.

Submitter : Mr. Allen Hunt **Date:** 06/30/2006

Organization : Visiting Nurse Services of Michigan

Category : Health Care Provider/Association

Issue Areas/Comments

Issue

Issue

Impact of bidding program on hospital based DMEPOS.

Submitter : **Dr. Ron Chadwick, PT** **Date: 06/30/2006**

Organization : **Wrangell Medical Center**

Category : **Critical Access Hospital**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

RE: Proposed Rule for Competitive Acquisition of Certain DMEPOS

My name is Ron Chadwick, PT, DPT, C-Ped and I work in a rural Critical Access Hospital on an island in Southeast Alaska. We serve a population that has fluctuated from over 3000 to currently somewhere around 1500-2000. Access to other communities of significant size requires plane or boat transportation and shipping is by plane or barge. Because of the small size our hospital has been providing DME to the residents as we have to stock many of the items for our use as a hospital including the oxygen and are best suited to provide this for the community. I also am certified as a pedorthist and have been providing the community with diabetic shoes, inserts and at times am called upon to modify braces under my license as a PT. As you can see this setting can t fit with the norms when it comes to labor distribution because of the size of the community and isolation secondary to distance and access.

Prior to setting up our own DME we had to provide the oxygen to the locals as outside companies could not get the product here in a timely manner and it was not cost effective in time or money for them to personally come to the community to service the equipment. That along with providing essentials in the form of braces, splints, walkers, canes, etc. without getting reimbursed led to this change. Now we have a mechanism to get reimbursed for the services that we are providing making the hospital more financially more viable thus keeping it open for this community and the nearby villages or isolated cabins. My clients now can get a walker the same day they break a leg versus waiting till the next barge comes in or for the next commercial flight if the company was willing to pay the postage. When it comes to oxygen they come by the hospital and get a new tank or our staff delivers it to their home and they are never without. For custom inserts they can be fabricated and delivered within 2 days versus waiting 6-8 weeks for an outside provider and the modifications can be done immediately. Some items still take time to receive but the essentials are almost always available. I would hate to see them lose that benefit in this new program.

With this scenario in mind I hope that when the decisions are made that they will not adversely affect the care that we can provide to the residents of this remote rural community. I strongly believe that our clients deserve choices and when we provide the DME service they are alerted to the fact they can shoes whether to get the product locally or wait for it to be shipped in from Sitka or Juneau. I have rarely had a client want to wait for the necessary item. Thanks for your help in this important matter as it applies to the struggling rural communities.

Sincerely,
Ron Chadwick, PT, DPT, C-Ped
Wrangell Medical Center
Wrangell, AK 99929

Submitter : Dr. Dennis Gumm **Date:** 07/01/2006

Organization : APMA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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). 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).
Discrimination in the "Medical Market-Place" will only lead to decreased competition and increased costs for the Medicare/Medicaid program and potentially compromise patient care.
Sincerely, Dennis R. Gumm, DPM

Submitter : Mrs. Carol Ryall **Date:** 07/01/2006

Organization : Fort Hill Pharmacy, a member of NEMED

Category : Other Technician

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

I am concerned that if the winning bidders in our areas cannot serve Medicare beneficiaries well enough, the elderly will suffer. For instance, today I had a customer, not a Medicare beneficiary, but a different insurance. We were not enrolled with her insurance. She had just had a traumatic injury and extensive surgery done on her knee.She needed a list of equipment - wheelchair with elevated legs, bathtub seat, toilet safety rail, anti embolism stockings, etc.. She was in no position to pay out of pocket. I called around until a found a local company that took her insurance and she went to them with driving instructions in hand. I called Lincare. They did not carry the bathtub seat, the toilet safety rail, and they did not have anyone to measure her for stockings. I sent her to the small company in Norwich. Now, if Lincare wins the bid in this area, which no doubt they will, people like her will have no place to go. If Lincare is the only company left she will have to shop at Walmart or on the internet. Her needs will not be met.
Many, many of our Medicare beneficiaries are on state insurance, or Medicaid. While Medicare does not cover everything they need, Medicaid usually does. For instance, all bathroom safety equipment is covered by Medicaid. Compression stockings and anti embolism stockings are covered by Medicaid. These items are not even stocked by Lincare.
I am a BOC Certified Fitter. I fit many local ladies with breast prosthesis forms and bras after they have had breast cancer. I also fit lymphedema sleeves for them or gentlemen who have lymphedema from past lung surgeries. You will not find a Lincare anywhere that services this population. There is a Hangar Orthopedic about 15 miles from us but both of their fitters are male. They do not offer breast prosthesis fittings. They handle mostly specialty braces and AFO's. It is the SMALL providers who service these people the best. The "big guys" do great on what they specialize in. It is my strong fear that if the little guys are eliminated, the big guys will keep on doing what they do well. They may change their business plans to pick up a little extra business here and there. However, they are not equiped to handle all the things "us little guys" do. We take care of the Medicare beneficiaries and people with other insurance. Our small businesses are going to suffer - but in the end the people in our communities who are ill - they are going to suffer the most.
This could be anyone - you - your siblings - your parents - your friends. Anyone can be diagnosed with a life altering disease at any moment. Small providers MUST be allowed to exist and compete in order for people's medical needs to be met.

Education and Outreach

Education and Outreach

If competitive bidding takes place and eliminates small providers the Medicare beneficiaries in our area are going to suffer. For instance, if a CVS or Lincare in our area wins the bid for glucose monitors our customers are going to be left high and dry. When I sell a glucose monitor I spend 15-30 minutes training them and/or their family member on how to use the meter. Often they return within a day or two with a couple of follow up questions. It is important for their control of their glucose to be able to understand the function of their glucose meter. The mail order companies and the chain drug stores DO NOT train their customers. They fill the order. Done deal. Our store even offers in home training. I have MANY customers who are pretty much homebound. I visit them with their new meter for training.In this business, the training is extremely important with the equipment.
Another example would be compression stockings. Our store has several certified fitters on staff. While this is not an item covered by Medicare, the Medicare beneficiaries use a LOT of compression stockings. They could suffer from edema due to varicosities. They could suffer from edema due to chemo or past surgeries. We measure and fit all compression strengths. Again, this service is offered, at no additional charge, in their homes if needed. If a chain store wins the bid and our store closes the Medicare beneficiaries are going to be in a tight spot. Many of them just do not understand about compression stockings. A little old lady, with a size 5 shoe, but a 9" ankle, will buy a size small if she has to choose while standing in a CVS aisle. Her circulation will suffer which would cause cellulitis or other complications. This will cause physician visits, hospitalizations, etc.. They need education. They need fitters to help them so their health is not endangered.
Our store offers personalized service and we are available for training on everything from glucose meters to the best way to put on a back brace. This is not something the chain stores are able or willing to offer. They may offer a lower bid because they do not have to pay qualified staff to take care of many of these services.
I believe the steps that are being taken are not going to save Medicare money in the long run. Patients are going to be the ones paying the price with their health. The system we have in place now works. The allowables are something the suppliers have learned to deal with. The customers are being serviced. Their health is being maintained. Equipment is available when needed. Discharge planners can function in their jobs when they are trying to get clients set up for life at home. The bidding process should not even be started until the needs of the Medicare beneficiaries is studied further.

GENERAL

GENERAL

A comment on Financial Reporting: CMS needs to clearly define the financial documentation they are going to require. We currently pay an accounting firm to do our books. We also pay a computer company to keep us updated with current technology in order to be able to bill Medicare. CMS needs to be aware that we may not be able to produce - or pay for- the same level of information that a large traded company may be to produce. We simply are not set up the same.
In closing, I believe that accredition is a good idea. It will eliminate "fly by the night" crooked operators. It will help to guarantee that Medicare beneficiaries are being serviced by deligent businesses. I believe competitive bidding should be POSTPONED until better preparation can be made. I believe the present set up is going to ensure the doom of MANY small DME companies that are presently servicing the Medicare population very well. Competition in the DME field will be eliminated. Customer service will suffer in the name of $$$ savings. People will suffer. I believe the allowable system should be left in place. I don't think a government agency - CMS - should be taking steps that will hurt small businesses across the country. If competitive bidding goes through - and small businesses close - many Medicare beneficiaries will be dependent on charities or their families to supply them with what they need. There will be no one to turn to for guidance on equipment or brace choices. Beneficiaries that don't have baby boomer children with extra $$$ to help them are going to be hurt the most. This is going to be a sad sad time for our aging population - and are ill population of all ages. Small DME businesses must be allowed to compete and flourish or people are going to suffer.

Opportunity for Networks

Opportunity for Networks

We do appreciate the proposal in the rule that would allow small providers to form a network. However, this is not actually feasible. We have a small provider in Norwich and one in Old Saybrook and one in East Lyme. They are our competitors and each is over 30 minutes away. We each service a different area. We each are limited by our size. It would be difficult to band together to establish a network. My company has one delivery person. So does the company in Norwich. Presently, we work together when needed in order to help our service area. For example, when the owner of the company in Norwich goes on vacation the woman in his store will call us with any hospital bed orders. None of us ever wants to tell a customer we can't help them. We always help them or make the phone call to a competitor to see if they can. For example, today, I had a customer that needed a amputee wheelchair with anti-tippers. He was being discharged from the hospital. I did not have one in stock so I referred them out to someone that did. Our system works well the way it is now. The small suppliers take the time to meet the needs of our customers. To be required to take the additional time to form bidding networks is not feasible. We are all pretty busy and working within tight budgets already. America was built on competition being allowed between businesses. Competition is healthy and keeps prices feasible and services at decent levels. If the small businesses get eliminated because a big player, such as Lincare, wins local bids, service will suffer. There is no reason for them to stay late on a Friday night to take care of a customer if they are the only business in town. A small DME company knows our service level insures our future success. How many customers won't be served because a bigger company doesn't strive for excellent customer service?

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

We are a small pharmacy/DME company. Even though we are a small store, about 2500 square feet, we are the ONLY full DME store in a 30-40 minute drive from our area. We have a Lincare nearby but they only do respiratory products and very limited DME. I believe accreditation for suppliers is necessary in order to eliminate badly run organizations. However, the final rule on the quality standards should be IN PLACE for a time frame before bidding begins. We are concerned about becoming certified but are not anxious to spend the money and find out we have chosen the wrong accreditation agency. We run a nice outfit that services our population well. We care about our customers and we want to be around for them in the future. If these new proposals go through without some actual proper planning, the Medicare beneficiaries in our area are going to be the ones to suffer. Our employees can always find jobs if our store ends up being one of the stores that closes because we do not choose the right agency or we do not win a bid. Our Medicare beneficiaries in this area are going to be in a good deal of trouble.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Submission of bids is going to very difficult. I've already attended one class with a 2 hour introduction to it. We are going to have to pay someone - travel and time - to figure out how to proceed with this bidding process. It is going to be time intensive and expensive. In the end we will most likely NOT win a bid because we are a small provider.
I know the competitive bidding program has been approved and is going to move forward. I think this is a sad state of affairs. Our nation is going to suffer. This should be tabled - stopped - cancelled.
The present system of allowables works well. Suppliers supply decent equipment. People are serviced well - especially by small providers. The baby boomers are aging - small equipment companies need to be there.
Small equipment companies are not prepared to figure out how cheaply they can sell a piece of equipment. We already have budget constraints to work with. Now we must time how long it takes to order a walker, unpack and display it. How long it takes to take in a request for a walker, how much time we spend with the customer in instruction and training, how much time to get the doctor's paperwork finished, how much time to drive and deliver the equipment, how much time our delivery tech must take to access their home environment, etc...
Big businesses have the $$$ to pay someone to access these things. We really don't. We work quickly and accurately. We deliver quality with care.
I wish this competive bidding program could be abolished. I'm sure I'll lose my job when the pharmacy ends up closing. I'm not concerned about myself. I'm concerned about the people I see everyday who will have no place to get their needs met.
This program was not planned out well enough. Small business were not visited. Active discharge planners in hospitals and rehab centers were not visited. MEDICARE BENEFICIARIES were not visited. Slow down the process. If the goal is to save money, it can be done in a better way. More study needs to be done. When we've talked to state representatives who are VOTING on these items - they are not even really familiar with the needs of the people in their districts. They need to know what a family goes through when they are trying to take care of an ill family member in their home. A CVS or Lincare is not going to meet their needs.

Submitter : **Dr. Brian Dechowitz** **Date: 07/01/2006**

Organization : **Pine Street Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

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.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,
Brian A. Dechowitz, DPM

Submitter : Dr. Joseph Hylinski **Date:** 07/01/2006

Organization : APMA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Podiatrists are considered as physicians under CMS and should be afforded the same ability to provide DME products to their patients as the MD/DO without competitive bidding. I use DME products in my practice as an adjunct to treatment of their pedal concerns. The inconvenience to my patients if they have to go to another vendor for these products is another source of antagonism created between patients and government. It is totally patient insensitive.

Submitter : **Mrs. Janine Turner** **Date: 07/01/2006**

Organization : **Mrs. Janine Turner**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-1270-Attach-1.DOC

ATTACHMENT TO #1270

June 25, 2006

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.

My name is Janine Turner, and I am an occupational specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I have specialized in the treatment of hands and upper extremities for 11 years as an OTR and an additional 4 years as a COTA. I am currently working in a private practice the services a large part of the hand therapy market in our local area as well as seeing people from a larger region who have limited availability to quality healthcare. I frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk. As patient enter our practice, we evaluate their rehabilitation and orthotic needs strictly addressing the most cost effective way to provide the needed service. Often a combination of orthoses (prefabricated and custom) can increase our reliance on a home program substantially reducing the number

of visits and healthcare dollars needed for additional therapy. For this system to work, especially for the clients who live very far away and have limited access to ongoing rehabilitation, they need to become independent in their home program in a single visit. Often prefabricated orthoses with or without modifications can help simplify a patient's program and increase compliance thus goal achievement.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations. It is essential that the skilled therapists have the opportunity to provide the patients with the correct DME. Cheaper products offered with inadequate skill for fitting and complete education result in higher costs to the healthcare system in the long run.

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, 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. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a

competitive bidding process. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Janine P. Turner, MS, OTR/L, CHT

Submitter : Dr. Patricia Schultz **Date:** 07/01/2006

Organization : Podiatrist- Solo Practice

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1271-Attach-1.PDF

ATTACHMENT TO #1271

Patricia M. Schultz, D.P.M.
8920 Colesville Road
Silver Spring, MD 20910
(301)589-1066

June 30, 2006

Mark B. McClellan, MD, PhD
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P Electronic Comments

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 modify the physician definition from 1861(r)(1) to 1861(r)(3) 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 to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. In my practice, I use a wide variety of DMEPOS items, particularly for elderly diabetics.

If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide. Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient. As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries. Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included.

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)(3) definition of physician in finalizing its regulations.

Consider if the following scenario occurred to your family member on a Friday afternoon: I diagnose your loved one with a fracture of the mid-foot, and I 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, the patient will not have access to the necessary protection over the weekend, and will risk re-injury while waiting for access to an approved supplier.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Patricia M. Schultz, D.P.M.

Submitter : Dr. Barney Greenberg **Date:** 07/01/2006

Organization : Florida Podiatric Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Dr. Robert Sage** **Date: 07/01/2006**

Organization : **Associated Foot and Ankle Clinic**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 22, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

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).

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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.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Robert M. Sage, DPM

Submitter : Mr. Javier Rocha **Date:** 07/01/2006

Organization : San Miguel Medical Supply

Category : Other Health Care Provider

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

With regard to competetive bidding. CMS has taken an extemely narrow view to ensure that small suppliers are adequately represented among contract suppliers. CMS should expand the market share to allow greater participation by small suppliers instead of favoring larger suppliers. I do not believe that competitive bidding will help either the supplier nor the patient. It will end up costing more in administrative cost and implementation. Further more the timeline is vague and unreasonable to allow smaller suppliers the time for completing the accreditation requirements when these requirements still have not been implemented. CMS should reconsider a more realistic timeline if we must proceed with competetive bidding.

Submitter : Mr. Brent McNutt **Date:** 07/01/2006

Organization : Global Medical Equipment and Supplies, Inc.

Category : Home Health Facility

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Allow any small provider that's willing to accept the low bid to be an option for the patient when choosing their provider. As a reward for the low bidder pay him 5 to 10% higher than everyone else. By doing this you will allow patients to have a lot more choices which will keep all providers in check for quality service while still having the downward bidding pressure by rewarding the low bidder with slightly higher reimbursement. If a provider doesn't have to worry about unsatisfied customers switching to the competition the provider isn't going to be inclined to give as high of quality of care. Example: If a provider gets a problematic call from a home oxygen patient in the middle of the night he may well tell them that if this is an emergency they need to call 911 and go to the emergency room. This would result in higher Part A utilization which could more than offset bidding savings. The preservation of a wide selection of providers is also important in the event of natural disasters. If only a few oxygen providers are left in each area with a lot higher ratio of patients per employee they may not be able to handle their customers. If there is no other choice many customers will overflood the hospitals or simply perish. Please allow any willing provider who has put in a bid and is willing to accept the low bid to provide service if the patient chooses their company.