Submitter : Mr. JAIME PLA **Date:** 06/26/2006

Organization : EQUIPOS PRO CONVALECENCIA

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

PUERTO RICO HAS BEEN CONSIDER AS ONE OF THE POTENCIAL AREAS FOR COMPETIVE BIDING.IT SHOULD BE NOTED THAT PUERO RICO NO LONGER HAS THE AMOUNT OF PATIENTS IN THE TRADICIONAL MEDICARE PROGRAM, SINCE CLOSE TO 50%OF THE PART B PATIENT ARE NOW ENROLL IN A MEDICARE ADVANTAGE PROGRAMS .PUERTO RICO IS AS OF 2006 NO LONGER A HAVY USER OF DME EQUIPMENT UNDER THE TRADICIONAL MEDICARE PART B PROGRAM. THERE IS NO NEED TO CONSIDER PUERTO RICO AS A POTENCIAL DME AREA FOR COMPETIVE BIDDING. SAVING WOULD NO BE BIG AND THE COST OF IMPLEMENTING THE BIDDING PROCESS IN PUERTO RICO WILL BE TO COSTLY

Submitter : Ms. Robynn Stolte **Date:** 06/26/2006

Organization : Cascade Rehabilitation

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an occupational therapist working in hand therapy. I am writing with concerns regarding the competive bidding system proposed by this rule. Most particularly, I am concerned that if this rule passes, and I cannont obtain the competitive bid to provide prefabricated splints, I will need to send patients to other locations for an emergent need. The patients I see are mostly acute or sub-acute, requiring possible quick changes in their care, including their splinting plan. It seems impractical to take the time for the patient to leave our facility for a splint I can provide and educate the patient in correct wear and care in a few minutes. I am also concerned that I will need to provide modifications to inappropriate splints provided to the patient by other suppliers, assuming liability for the splint. I have had experiences of needing to replace splints provided by others that were inappropriate and/or uncomfortable to wear. Competitive bidding may provide a minimal savings with prefabricated splint costs, but may have ramifications with rehabilitation costs and our ability, as therapists, to provide adequate care.

Submitter : pam gaboury **Date:** 06/26/2006

Organization : norton medical center

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I feel it is very determental to implement Competive Bidding for diabetic supplies. I work closely with several independent organization that put patient care and patient teaching first. Doing this saves money, in the long run, because there is clearer understanding and less waste. Thank you
pam gaboury

Submitter : Mr. Patrick Cabrera **Date:** 06/26/2006

Organization : Mr. Patrick Cabrera

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

question how will competitive bidding affect the beneficiary? by forcing providers to compete for low reimbursements this gives less options for the patient thereby forcing the companies that do win the bid to give below quality service and potentially reducing the cost so much that the patient has no choice except to pay for the product themslves. for any beneficiary that lives in a rural area could be affected dramatically either by paying for the product themsleves, not getting the product or having to wait several days to get serviced. ultimately the the patient will lose.

Submitter : Tobi Gilbert **Date:** 06/26/2006

Organization : KSF Hand Therapy Houston Texas

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am protesting the establishment of this rule as it would be medically irresponsible to send a patient with a fragile and complicated injury such as a tendon laceration or trauma to anyone other than their treating therapist for an orthotic. The patient would be at risk of permanant disabilty or injury and the cost to Medicare would actually increase with all the fixes that have to be done to accommodate such a pointless and ineffective rule. Anyone who truly understands what orthotics are for in hand therapy would know better. Please do not implement this stupid and irresponsible idea that will only end up costing everyone more money, inconvenience and result in poor quality of care for medicare beneficiaries.

CMS-1270-P-448-Attach-1.TXT

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS

CMS1270P 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 Tobi

Gilbert and I am an occupational therapist specializing in the treatment of upper extremity disorders. I have specialized in the

treatment of hands and upper extremities and fabricated orthotics on a daily basis. I am currently working in Houston, Texas, 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. A post

surgical patient with a specific injury such as a tendon laceration would have to have their splint fabricated, fit, and adjusted by the

treating clinician or risk further injury/impairment. 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. However, more often most of

these pre-fabricated orthotics do not fit and the patient needs a custom splint due to deformity or other special considerations.

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, Tobi Gilbert, LOTR

Submitter : Mr. GREG KOLACINSKI **Date:** 06/26/2006

Organization : MARK DRUG HOME HEALTH

Category : Health Care Provider/Association

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

SMALL BUSINESSES LIKE OURS HAVE MADE AN IMPACT ON THE HEALTH CARE FIELD BY GIVING PERSONAL SERVICE TO OUR PATIENTS FOR MANY YEARS. iF COMPETETIVE BIDDING DOES NOT ALLOW ME TO BID OR IF PRICES COME IN SO LOW THAT I CANNOT KEEP MY BUSINESS THEN NOT ONLY DO THE PATIENTS LOSE, BUT ALSO MY EMPLOYEES. ALL COMPETETIVE BIDDING DOES IS DRIVE UP ADMINISTRATIVE COSTS AND LIMIT ACCESS. NEITHER OF THESE HELP THE PATIENT.

Submitter : Miss. susan arnold **Date:** 06/26/2006

Organization : wolfe county health care center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Nursing facility residents are very vulnerable and have a higher intensity level of care needs. Any interruption in services due to competitive bidding could result in negative outcomes for the comprised frail residents in nursing facilities.

Submitter : Mr. Stephen Ledbetter **Date:** 06/26/2006

Organization : Medicine Shoppe #503 & 751, & Ridgway Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a community independent pharmacy, I respectfully request that diabetes testing supplies be deemed exempt from the Competitive DME bidding process. It is imperative that patients retain their current level of care received at the retail pharmacy level. If competitive bidding becomes a reality for diabetes testing supplies at the retail level, it will detrimentally impact the patient's health and well being. Diabetes education is crucial to the health and well being of our patients. Retail pharmacists offer critical clinical services to patients by offering education on daily diabetes care, medications/side effects/possible drug interactions, and training on blood glucose meters and testing procedures. Retail pharmacists have the ability to impact patient adherence in all aspects of diabetes care and provide a local presence for assistance with complications of therapy. Retail pharmacists work in conjunction with the patients' physicians in an effort to facilitate the best possible diabetes care.

Submitter : Dr. Jennifer Feeny **Date:** 06/26/2006

Organization : Dr. Jennifer Feeny

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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)(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,
Jennifer K. Feeny, DPM

Submitter : Mr. Patrick Cabrera **Date:** 06/26/2006

Organization : Mr. Patrick Cabrera

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

if the federal government is looking to save medicare. homecare is not the problem, by far homecare is the most cost-effective and represents a very modest portion of the total medicare budget. if cms is looking for the biggest bang for the buck first they should look at the areas to save the biggest amount, such as hospitalization and nursing homes and even drs visits. also to exclude the top 3 msa's cms is sending the message that is contradicting. the demand for homecare has increased along with the medical needs of a growing population of older americans, but spending for homecare is clearly not the problem with medicare, in fact, its part of the solution.

Submitter : **Dr. Heather Snyder** **Date: 06/26/2006**

Organization : **Albemarle Family Foot & Ankle**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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,

Heather Snyder, DPM, FACFAOM

Submitter : Mrs. Janice Tomachick **Date:** 06/26/2006

Organization : LIberty Commons

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

I do not believe that one company can be the "chosen one' for any large demographic area. When this happens the consumer (the patient) suffers with less than optimal service. The majority of patients using many of these supplies are elderly and need in home training and ongoing support. Many small providers do this as part of their service. Without this type of one on one service available the amount spent by the federal government for in hospital stays will increase. I would be very skeptical of any one company getting all that business, it decreases their appetite to satify, but increases their desire to look for ways to keep their bottom line as low as possible and usually customer service is the first to go.

Submitter : Dr. Robert Lenfestey **Date:** 06/26/2006

Organization : Piedmont Foot and Ankle Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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.

Submitter : Dr. Erin Hess **Date:** 06/26/2006

Organization : The Medicine Shoppe

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacy, I respectfully request that diabetes testing supplies be deemed exempt from the Competitive DME Bidding process.

If competitive bidding becomes a reality for diabetes testing supplies at the retail pharmacy level, it will detrimentally impact the patient's health and well-being. Diabetes education is crucial to the health and well-being of our patients:

* Retail pharmacists offer critical clinical services to patients by offering education on daily diabetes care, medications/side effects/possible drug interactions, and training on blood glucose meters and testing procedures.
* Retail pharmacists have the ability to impact patient adherence in all aspects of diabetes care and provide a local presence for assistance with complications of therapy.
* Retail pharmacists work in conjunction with the patients' physicians in an effort to facilitate the best possible diabetes care.

Please consider these points while considering the fate of this issue.

Sincerely,
Erin Hess

Submitter : **Dr. David Wood** **Date: 06/26/2006**

Organization : **Dr. David Wood**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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, DPM s. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

My patients will suffer if they are unable to receive DMEPOS items at the time of treatment. Often they have limited transportation and are unable to go across town to get these items. I noticed years ago that patients often times would not fill their prescriptions for durable medical equipment because they did not have time or transportation. This lead to a longer recovery time or other injuries related to the original injury. I prescribe and supply select DMEPOS items as part of patient care and 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. I do not know if this was purposeful discrimination against the DPM degree or just an oversight, but I am asking you to include doctors of podiatric medicine in your definition of physician.

If I see a patient who I diagnose with a fracture, 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, and that the patient does not walk on the broken foot for another week before getting the walking boot at another facility. If I am not a supplier in the new program, then 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,

David Chris Wood DPM

Submitter : Mr. James Doughfman **Date:** 06/26/2006

Organization : Carter's Pharmacies and Home Medical Supplies

Category : Health Care Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I'm confused. Since CMS currently has the authority to adjust the fee schedule for medicare B items and services, why is it necessary to create a competitive bidding model. It seems obvious that by limiting the competitors in the marketplace, you only succeed in reducing the quality of the goods and services available to your beneficiaries. If you want to save money, reduce the reimbursements and let us figure out how to handle it. If your beneficiaries want to give up their right to choose, they will join an HMO. I think most recipients prefer to choose the company that provides the best product and service for their needs. Unless all accredited providers are allowed to provide services, quality will suffer.

Submitter : Dr. Ira Meyers **Date:** 06/26/2006

Organization : Montgomery Podiatry Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 25, 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.
Prior to becoming a DMEPOS supplier three years ago, I would refer my patients out for the prescribed item. I often incurred times when an item was inappropriately substituted. I also had other experiences with the patient becoming very frustrated because I couldn t just dispense the necessary item at the time of service. As a result, the patient would forgo getting the item.,which then negatively impacted the outcome of the treatment.
I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,
Ira Meyers, D.P.M.

Submitter : **Dr. Teresa Tobin** **Date: 06/26/2006**

Organization : **Montgomery Podiatry Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 25, 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.
Prior to becoming a DMEPOS supplier three years ago, I would refer my patients out for the prescribed item. I often incurred times when an item was inappropriately substituted. I also had other experiences with the patient becoming very frustrated because I couldn t just dispense the necessary item at the time of service. As a result, the patient would forgo getting the item.,which then negatively impacted the outcome of the treatment.
I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,
Teresa Tobin, D.P.M.

Submitter : **Tim Thorsen** **Date: 06/26/2006**

Organization : **Spine**

Category : **Physical Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Spine & Sport is a small private practice owned by a physical therapist in the rural cummunities of Rhinelander, Eagle River,and Tomahawk, Wisconsin. In our rural areas, we do provide durable medical equipment and supplies to Medicare patients. We supply primarily niche market items including off-the-shelf, semicustom and custom braces, orthotics, and assistive devices.

Our primary concern is whether we would be able to continue to meet the needs of Medicare and Medicaid patients in our area with these types of supplies. We have been slowly building an inventory of requested items over the past few years and our actual profit in this area is minimal. Would we be considered an exempt rural area with our low population density or would we be grouped with a larger population area?

As physical therapists and specialists with biomechanical and movement dysfunction expertise,we have the training and background to be extremely effective in fitting off-the-shelf, semi-custom, and custom braces, orthotics, or other durable medical equipment to increase function and quality of life for individuals. I am sure
my colleagues in metro areas that may be subject to DMERCs have the potential to increase services to Medicare and Medicaid patients while decreasing costs.

I would urge CMS to revise the proposed regulations and establish a process that will enable physical theapists to continue to furnish orthotics and other durable medical supplies that are critical to the care of their patients. Likewise, I adjust off-the-shelf AFO's, semi-custom orthotics, and custom orthotics(as do other physical therapist) as a routine part of my practice. Frequently, this may even be done at no cost and as part of the plan of care with even greater precision than other providers.

In conclusion, I look forward to you answering my questions amd how we would be immediately affected. In areas that are affected, I would consider examining what physical therapists are able to provide in an effective, efficient, and fiscally responsible manner.
If DMEPOS is provided strictly through a competitive bidding program, it may result in patients getting less service for more money and/or decrease their access to things that would benefit them greatly at a reasonable price.

Sincerely, Tim Thorsen

CMS-1270-P-462-Attach-1.DOC

#462

June 15, 2006

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

RE: Proposed Rule for Competitive Acquisition of Certain DMEPOS

Dear Dr. McClellan,

Spine & Sport is a small private practice owned by a physical therapist in the rural communities of Rhinelander, Eagle River, and Tomahawk, Wisconsin. In our rural areas, we do provide durable medical equipment and supplies to Medicare patients. We supply primarily niche market items including off-the-shelf, semi-custom, and custom braces, orthotics, and assistive devices.

Our primary concern is whether we would be able to continue to meet the needs of Medicare and Medicaid patients in our area with these types of supplies. We have been slowly building an inventory for requested items over the past couple of years, and our actual profit in this area is minimal. Would we be considered an exempt rural area with our low population density, or would we be grouped with a larger population area?

As physical therapists and specialists with biomechanical and movement dysfunction, we have the training and background to be extremely effective in fitting off-the-shelf, semi-custom, and custom braces, orthotics, or other durable medical equipment to increase function and quality of life for individuals. I am sure my colleagues in metro areas that may be subject to DMERCs have the potential to increase services to Medicare and Medicaid patients while decreasing costs.

I would urge CMS to revise the proposed regulations and establish a process that will enable physical therapists to continue to furnish orthotics and other durable medical supplies that are critical to the care of their patients. Likewise, I adjust off-the-shelf AFO's, semi-custom orthotics, and custom orthotics (as do other physical therapists), as a routine part of my practice. Frequently, this may even be done at no cost and as part of the plan of care with even greater precision than other providers.

In conclusion, I look forward to answering my questions above and how we would be immediately affected. In areas that are affected, please consider examining what physical therapists are able to provide in an effective, efficient, and fiscally responsible manner. If DMEPOS provided strictly through a competitive bidding program may it may result in patients getting less service for more money and/or decrease their access to things that would benefit them greatly at a reasonable price.

Sincerely,

Tim P. Thorsen, P.T., M.T.C.

TPT/pkg

Submitter : **Mr. Arnel Dodson** **Date: 06/26/2006**

Organization : **Criticare Home Health Services**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1270-P-463-Attach-1.DOC

#463

CHS CRITICARE
Home Health Services, Inc.
1006 West 6th Street Lawrence, KS 66044

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

Re: Written Comments file code CMS-1270-P

Issue Identifier: *Section F. Deficit Reduction Act of 2005 (Pub. L. 109-171)*

Section 5101(b) of the DRA amending section 1834(a) (5) of the act to limit monthly payments for oxygen equipment to a 36 month period of continuous use with transfer of ownership to the beneficiary should be repealed for the following reasons.

The justification for medical oxygen therapy has been well established. Beneficiary longevity and quality of life are greatly enhanced by the provision of continuous oxygen therapy for those that the medical criteria for coverage have been met. The need for, effects of, and cost effectiveness of home oxygen therapy have been well documented as well. The ownership of oxygen equipment by vulnerable patients needs to be eliminated and the competitive bidding model needs to be seriously modified before implementation, if not eliminated outright as well.

Issue Identifier: *Section E. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).*

Repeal of Section 5101(b) of the DRA amending section 1834(a)(5) of the act should be repealed for the following reason(s):

Comment(s) regarding the stated objectives of the Medicare DMEPOS Competitive Bidding Program are as follows:

> **Stated Objective:** *"...To limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program..."*

Beneficiaries will have increased out-of-pocket expenses for beneficiary owned (13 month capped rentals from Jan. 1, 2006 or 36 month rental oxygen) equipment whose ownership has been transferred to the beneficiary

Medicare has for years stated that backup systems are unnecessary. Providers will no longer be able to provide such services to beneficiary owned systems. Service call charges will apply whenever a beneficiary owned system (specifically, oxygen concentrator) fails and the beneficiary will pay out-of-pocket a much larger charge for repairs and maintenance fees.

There will be no financial incentive for providers to provide 24 hour emergency services to beneficiaries with patient owned equipment and such services will be provided on an unassigned basis (more out-of pocket charges) if the beneficiary can even "find" a provider willing to service them.

Current capped rental rules allow for breaks in service – what about breaks in oxygen equipment services? The payment methodology for "capped oxygen" has not been established.

Medicare purchased equipment beneficiaries will have much larger out-of-pocket expenses for DMEPOS obtained through the program due to limited manufacturer and supplier warranties. Beneficiaries will be responsible for charges related to evaluation, pickup and delivery, repair labor and shipping costs for beneficiary owned items under warranty.

Beneficiaries will be responsible for supplier and/or manufacturer's non-warranty service charges for equipment failure and/or maintenance.

Examples: Humidifier changes, Service calls for regulator installation, Access to contracting suppliers will be difficult at best. Non-emergency equipment issues will cause beneficiaries to incur added costs.

"...under new section 1834(a) (5) (F) (II) (bb), maintenance and servicing payments for beneficiary owned oxygen equipment (for parts and labor not covered by the supplier's or manufacturer's warranty) will be made only if they are reasonable and necessary..."

"...In a future rulemaking, we will propose to revise regulations found in part 414, subpart D to incorporate these DRA provisions...."

> A second objective of the Medicare DMEPOS Competitive Bidding Program as stated is: *"To assure beneficiary access to quality DMEPOS as a result of the program".*

What about blind, arthritic and otherwise disabled beneficiaries who require assistance?
The ownership (and resulting responsibility for maintenance and repair) of equipment for this vulnerable patient population is dangerous. Filter changes, analysis of oxygen concentration, beneficiary added costs (Service Calls for patient owned equipment) and after hours calls, will all be passed through to the beneficiaries.

The added costs to contract suppliers for gasoline, mileage, overtime, etc. were previously by providers at no cost under the rental program – once the beneficiary "owns" their equipment, no responsibility of a supplier to continue with services (even if the supplier remains in business) will create an undue burden on this vulnerable patient population. Limited or non-existent access by contract suppliers to CMN, qualifying information for emergency services will likely cause the supplier to provide services unassigned because they are unable to give the beneficiary an informed ABN regarding services and qualification of beneficiaries for patient owned concentrators will be unavailable for after hour's services.

Issue Identifier: *Section C. Payment Basis, Number 2. General Payment rules (Proposed § 414.408 (c-j)).*

> *"...Each item of DME that is paid for under these sections is classified into a payment category, and each category has its own unique payment rules..."*

Beneficiaries will not have access to newer technology for competitively bid products.
The conclusion that "*...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...*" is flawed.

The elimination of over half of the suppliers in an area of evaluation is expected, even heralded by the CMS personnel according to a recent teleconference. Participants were told that it is estimated that over half of the providers currently providing services will not be included in the competitive bid program. Where will the beneficiary find a provider to provide services? How will they identify a contract provider? How will the provider provide informed consent for services when the first contact with the beneficiary will be an after hours, emergency telephone call? These are all very serious issues, which will require attention before competitive bidding for services is implemented.

Identification of beneficiary eligibility for DMEPOS either capped or purchased will prove time consuming and for after hours services, impossible. Based upon the 2003 figures for oxygen equipment provided, there are an estimated eleven million oxygen patients currently served by the fee for service system. Putting so large a population of frail, elderly, infirm patients who are dependent upon oxygen services at risk is an example of

government "unconcern" on an unprecedented scale. When disaster strikes, contracting suppliers will not know if a beneficiary "qualifies" for equipment, indeed, the supplier will not even know who the beneficiaries are who own equipment. Serious consideration must be given to providing contract suppliers with qualifying information, patient information and patient addresses for beneficiary owned equipment in order to mitigate emergency services when needed. Remember, this is a vulnerable patient population whose medical necessity for oxygen has been established. The delay between finding a supplier and receiving services will likely cause increased emergency room visits and subsequent hospitalization. Where will the "savings" be with that?

The inability of a contracted, competitive bidder to service "all" manufacturer "types" of equipment will prove problematic at best. Accreditation and the still to be announced "Quality Standards" will likely cause a provider to provide the cheapest, but standard type equipment for beneficiaries serviced. Supplier Accreditation requires following manufacturers recommendations for service interval, filter changes (both internal and external) and maintenance. Some services require internal repair and replacement of items which beneficiaries will be unable to perform. At present, no training of beneficiaries for internal annual bacteria filter changes, is recommended by the manufacturer(s). Patient owned equipment will fail – who will repair or replace it?

Additional equipment service and maintenance intervals will prove problematic. Enteral pump certification, liquid oxygen stationary and portable annual recertification, oxygen cylinder hydro-testing, conserver testing and/or recertification, etc. will all fall by the wayside when beneficiaries own such complicated, maintenance intensive and critical (to their health) equipment.

Some examples of problem areas where "service" is paramount by the supplier are enumerated below. The examples are given to show that this vulnerable patient population require a level of expertise and "service" which is not recognized by a model for the lowest bid – patient's are NOT a commodity, and the medical service provided by a DMEPOS supplier is not simply a piece of equipment that one can purchase.

Note: These patients may suffer great harm, even death if their special equipment and service needs are not met.

- Transtracheal Oxygen patients – these patients require specialized instruction, care and supplies. A contract supplier must be able to provide such services or should not be allowed to accept such patients. A Respiratory Therapist is usually specially trained to address specific patient issues such as catheter care, cleaning and instruction.
- Tracheostomy patients – again, such patients require specialized instruction, care instruction and supplies, usually by a Respiratory Therapist.
- High Oxygen Liter Flow patients – such patients require special attention to their oxygen needs – a "standardized" approach to their care will prove both dangerous and inadequate.
- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
- Patients without caregivers/family helpers – DMEPOS providers often assist patients in the home without reimbursement simply because the service interval has been increased for at risk patients. The low bid scenario will eliminate such assistance and these patients will utilize the ambulance, emergency room and hospital services at a much higher cost to the Medicare Trust Fund.
- Deaf patients – special patient populations require added time and instruction, even specialized equipment services. These un-reimbursed "services" will not be available under the competitive bidding model.
- Disabled patients (wheelchair bound) – these patients are often unable to perform routine daily maintenance of equipment due to their disability. Such services are un-recognized by the competitive bidding model and will be unavailable or at an increased cost to the beneficiary.

- Ventilator patients – this high risk patient population must not be forgotten. Numerous factors regarding mobility, emergency services and patient/caregiver instruction will be unavailable in the competitively bid "product". A lack of professional services will place this patient at great risk of injury or death.
- Medicated patients – many patients suffer from confusion and/or medication effect(s), causing them to be unable to perform simple tasks such as filter and humidifier changes, etc. Who will provide these services using the competitive bidding model? These patients are often confused and unable to understand instructions, much less perform complex maintenance on medical equipment.
- Hospice transfers to Medicare – patients who revoke hospice services to enter the Medicare program will not have access to services and/or will be required to change suppliers. Such continuity changes are distressing and often dangerous to this special population of patients. A contract supplier will be required to provide equipment, but will they be able to provide the "service" that these critically ill patients require?
- No transportation patients (no drivers license or vehicle) – public transportation is not everywhere, these patients will likely over-utilize emergency services when their equipment fails as they are likely unable to afford the service charges that will be required of a contract supplier.
- No telephone patients – this patient population will not even be able to "call" a contract supplier for emergency and/or after hour services, even if they are able to identify such a supplier. Who will care for them when a disaster strikes? Who will know that they even need assistance?

SUMMARY:

The effect of the DRA and competitive bidding will prove catastrophic for oxygen patients, in particular. The drive to homogenize and standardize service will prove only to limit beneficiary access to medically necessary therapy. The services provided by oxygen suppliers are not "commodities" to be bought and sold. Perhaps we should distribute the home telephone numbers of the congressmen and women in the districts where oxygen patients reside in order for the beneficiaries to call them when their oxygen concentrators fail (and they will fail) and no supplier will be willing or able to come to the beneficiary's residence to assist them. What will happen to the beneficiary? They will be forced to use the ambulance services to transport them to the hospital for care. The average cost will increase exponentially for "oxygen services"; it will simply be called something else, and be paid for by another part of the same Medicare Trust Fund (same payer, different pocket).

Competition implies a number of factors – including beneficiary access to "service" – the implication that an oxygen concentrator is simply a commodity to be bought and sold is inherently fallacious. It is the "status quo" which provides the beneficiary with the most choices of equipment product(s), services and providers. It is the "status quo" which provides small businesses with the incentive to purchase innovative and "new" technologies to provide an ever increasing "improvement" in the quality of care and services associated with oxygen use. Competition is "alive and well" with the current fee-for-service program and will certainly be eliminated once the initial bidding has been accomplished.

Find an amount you think is fair to pay, and the market will decide if the reimbursement level is sufficient to continue to provide "quality" patient care. Services are already less than they were before due to the annual cuts in reimbursement to providers for equipment services such as oxygen concentrators – portable oxygen is not reimbursed at anyone's definition of "fair" – the arbitrary decision to allow approximately $31.00 per month for unlimited portable oxygen cylinders and/or liquid oxygen fills bears no basis in reality to the true costs of such a service – a single liquid oxygen fill costs more than the monthly reimbursement rate for the same – and many, many beneficiaries need 2 or more fills per month in order to meet their ambulatory level of activities – when liquid oxygen is unavailable to the beneficiaries, and it will not be available under competitive bidding – the quality of life and activity levels of beneficiaries will be greatly curtailed.

Access to new technology will be stifled – travel will be limited to what the beneficiary can afford to pay for privately – and no out of MSA competitive bidding area provider will be willing or able to provide services for the new reimbursement amount, whatever it may be. The intake process alone, considering paperwork burden, compliance with standards of care, etc. will cost the provider more than reimbursement (which, by the way, is

the current situation as well, except they can attempt to at least break even if they provide a concentrator at the current low level of reimbursement).

The lack of providers (over half are expected to close their doors with competitive bidding), standardization and homogenization of equipment (no "new" technologies will be provided – after all, we are just "selling" a product, not services) will occur in order for the few, surviving, large companies to provide the lowest level of equipment services they can. Large companies may well be able to "lowball" the bidding and control the process through size and financial reserves that are unavailable to the average small business owner. It will be only a few years before the surviving companies raise the prices to a sustainable level – it is inevitable that once the monopoly has been established, it will become "apparent" that service is something that both the Medicare program and the beneficiary require.

Who will you ask to provide these services then? All the small companies will have closed their doors, and frankly, having observed the past twenty years of bureaucratic bungling and over-regulation fostered by HHS and CMS, how will you induce them to come back? Large companies have an unfair advantage in the initial stages of a competitive bidding model – and the inability of smaller companies to enter into the recommended "network model" due to antitrust provisions, competitive distrust and lack of financial/legal resources will prove the death of the current home healthcare services.

Small companies will be unable to compete with larger companies based upon price only, the current level of care and service component that allows small companies to "out-compete" the larger companies drives the improvement of services throughout the industry, not just in oxygen services but in all aspects of durable medical equipment services. The provision of better warranties and quality of equipment, personal customer service, commitment to new and "improved" technology will simply not be available under the proposed competitive bidding model. Everyone will get the "same" equipment, and the "same" poor level of service – which I anticipate to greatly impact morbidity and mortality of the beneficiaries under such a system.

The beneficiaries are NOT interested in having the "lowest bidders" minimum level of equipment and services – they expect and deserve the "best" level of service possible for the "least" amount of out-of-pocket expense available – there can not be "shopping around" for a better company when the lowest bid model drives services – what you see will be what you get – and it will be miserable and dangerous for the beneficiaries.

Face it, small companies and large companies are paid the same for equipment – the only reason beneficiaries use small, local companies is that the personal level of service and commitment to quality care that is available to the beneficiary from the smaller companies far outshines that provided under the large, low bid model. Insurers such as HMO's already attempt to provide the lowest bid model of care, and the entry and exit of HMO's into various markets has proven that such a service level is unacceptable to the American Public.

There is likely a "firestorm" of beneficiary protest just now beginning, and the HHS and CMS are going to be directly in the center of it. It is certainly prudent to consider pricing when considering buying an automobile. It does not make sense when purchasing critical, medically necessary equipment AND services for beneficiaries who rely on the home healthcare system to keep them alive.

You might save money by purchasing a used automobile and performing the maintenance and service on it yourself, but do you really think an ill, medicated, and worried, short of breath oxygen patient would choose to do so? The implied lack of understanding (seen in the DRA provisions) of what the current healthcare system provides to beneficiaries is staggering.

It is the "quality" of care at the lowest "price" that we are all trying to achieve. The figures show that homecare saves millions over emergency care and hospitalization. The true "cost" of the services and equipment provided by the DMEPOS provider is a bargain – the DRA makes it a flea market auction. That may be fine for knick-knacks and such, but when it comes to the life and health of the beneficiary, second-hand and/or bargain equipment will prove to be no bargain. It is only the health and well-being of the beneficiary that is being bargained for.

Submitter : **Dr. Paul Jones** **Date: 06/26/2006**

Organization : **Instep Foot and Ankle**

Category : **Physician**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

June 26, 2006

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

Dear Dr. McClellan:

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.

Thank you for taking the time to consider my concerns. This interupts a very important service in assuring the compliance of individual patients.

Sincerely,
Paul Clint Jones, DPM

Submitter : Ms. Tammy LeSage **Date:** 06/26/2006

Organization : Ms. Tammy LeSage

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-465-Attach-1.DOC

405

June 26, 2006

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

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

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.

To Whom it May Concern:

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

My name is Tammy LeSage, 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 St. Augustine, FL, 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,

Tammy J. Lesage MOT, OTR/L, CHT
Assistant Professor
University of St. Augustine for Health Sciences
1 University Blvd
St. Augustine, FL 32086-5783
904-826-0084 ext. 269

Submitter : Mr. Daniel Reif

Date: 06/26/2006

Organization : The Meidicine Shoppe

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacy, I respectfully request that the Competitive DME bidding process be dissallowed. Especially in the respects of Diabetic Supplies. I believe that it is important that these patients be allowed to maintain their current level of care. There have been many changes in Medicare in the last 6 months that has brought forth mass confussion of my customers. I believe by adding one more hurdle for them, you will have a detrimental impact on my patient's health and well-being. With respect to my diabetic customers, they come to me for the services I provide them which they may not get from another pharmacy. We offer education on a daily basis, reviewing their medications and side effects and discussing these issues with my customers. In addition we have the ability to impact patient adherence in all aspects of diabetes care and provide a local presence for asistance with complications of therapy. By doing so and working hand and hand with physicians we facilitate the best care one may achieve. In doing so, we may cut costs to medicare by preventing other issues that might be associated with improper adherence of testing of blood sugar. We feel if we are able to work hand and hand, we may provide the best possible care for our customer. By implementing the competitive bidding you will be tying our hands so we may not provide this care. Please reconsider. Thank you.

Submitter : **Dr. Howard Imanuel** **Date: 06/26/2006**

Organization : **Dr. Howard Imanuel**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Mark B.McClellan, MD,PhD
Administrator
CMS
Department of Health & Human Services
Attn: CMS-1270-P

Dear Dr.McClellan:
In the proposal that would establish a competitive Acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies(DMEPOS), the CMS used the definition of physician that omits podiatric physicians. I strongly urge the CMS to revise their definition from 1861(r)(1) to 1861(r).
I prescribe and supply certain DMEPOS items as an intregal part of patient care. I DO NOT supply such items to persons not my patients, and believe that requiring me to do so would harm those Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and adhere strictly to the existing 21 supplier standards. I am also subject to the same Stark requirements as well as other regulations 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 firmly believe that I should have those same rights. I use DMEPOS items as an integral part of total patient care and believe CMS should use the 1861(r) definition of physician while it finalizes its regulations.
If in examining a patient I have made a diagnosis of a heel fracture or partially ruptured Achilles tendon, I may deem it necessary for that patient to be placed in a fracture walker. I feel it is essential for that patient to be off-loaded from the injury site to prevent further insult to the extremity, and I certainly do not want my patient forced to risk additional damage by having to seek the fracture walker at some other distant locale. Further, I need to examine the patient as he is being fitted for the DMEPOS device to be certain that it would not cause additional trauma due to poor fit/function for his unique anatomy and problem. If I am not that patient's supplier, I would not be capable of doing that, and the patient would suffer the brunt of that situation.
I am pleading with CMS to reconsider its position on the definition of "physician", and to use the broader definition of the word, the 1861(r) definition of physician.
Thanking you in advance, I remain
sincerely yours,

Howard M.Imanuel,DPM, FACFAS

Submitter : Dr. Nicholas D'Angelo **Date:** 06/26/2006

Organization : Dr. Nicholas D'Angelo

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 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,

Nicholas D'Angelo D.P.M.

Submitter : **Dr. Peter Wiggin** **Date: 06/26/2006**

Organization : **Ohio Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Peter A. Wiggin, D.P.M., F.A.C.F.A.S.
74 Wood Street
Mansfield, Ohio 44903
Tele#(419) 756-1875

June 23, 2006

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

Dear Dr. McClellan:

I am writing on behalf of Medicare beneficiaries treated by Podiatrists in Ohio including patients whom I treat. In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment DMEPOS, CMS used an improper definition of physician that excludes podiatric physicians. I am writing to request that CMS change the definition from 1861(r) (1) to 1861(r). The current definition in the proposed rule will hurt Medicare patients throughout the country.

When required for optimum patient care, we prescribe and supply certain DMEPOS items. We don t supply items to those who are not our patients. I believe that requiring us to do so would harm Medicare beneficiaries who are our patients.

As currently proposed, 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 physicians in the Medicare program, we should have those same rights. We use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Peter A, Wiggin, DPM
1st Vice President, Ohio Podiatric Medical Association

CMS-1270-P-469-Attach-1.DOC

#469

Peter A. Wiggin, D.P.M., F.A.C.F.A.S.
74 Wood Street
Mansfield, Ohio 44903
Tele#(419) 756-1875

June 23, 2006

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

Dear Dr. McClellan:

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As currently proposed, 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 physicians in the Medicare program, we should have those same rights. We use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Peter A, Wiggin, DPM
1st Vice President, Ohio Podiatric Medical Association

Submitter : **Date: 06/26/2006**

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

Administrative or Judicial Review

Administrative or Judicial Review

- This section of the NPRM has been interpreted to say that there will be no questioning/judicial recourse when it comes to conflicts between suppliers and CMS in the following areas: establishment of payment amounts, awarding of contracts, designation of CBAs, phased-in implementation of the competitive bidding program, selection of items for a competitive bidding program, and bidding structure/number of contract suppliers. This proposed regulation must be amended so that suppliers will have some options when a disagreement arises between the supplier and CMS. It is proposed that a committee composed of impartial individuals who are well versed in the Competitive Bidding Program and the DMEPOS arenas be formed to hear such disagreements and offer suggestions to remedy these situations. If this proposal is implemented, the suppliers will have an outlet for their grievances and a potential solution to the dispute.

Competitive Bidding Areas

Competitive Bidding Areas

- When speaking of phasing in CBAs over several years, the manner in which CBAs will be selected is noted. The NPRM states that CBAs may be smaller than MSAs, the same size as MSAs, or larger than the MSAs. This section also states that the three largest MSAs (NY, Chicago, and LA) will be eliminated from the first round of competitive bidding in order to gain experience with the process before expanding into extremely large areas. If CMS is concerned about competitive bidding programs in large areas, it is proposed that the CBAs do not encompass more than one MSA. It appears that if more than one MSA was included in a CBA, the same concern would be present: dealing with extremely large CBAs while simultaneously learning about the competitive bidding program. Therefore, it is suggested that one CBA does not encompass more than one MSA.
- The statement that DMEPOS demand from non-Medicare individuals might make it less likely that a non-contract supplier would exit the market sounds positive for the supplier. However, it appears that this will be highly unlikely given that the majority of individuals who use DMEPOS products are Medicare users. This statement, although it could be seen as somewhat comforting for the supplier initially, should be removed from the document as it is fostering false hopes for the non-contract suppliers in the competitive bidding program.
- The statement that 'the competition for market share among winning suppliers will act as a market force to maintain a high level of quality products' should be removed from the document as well. There is a concern that just the opposite is true: because competitive bidding removes a significant amount of competition in the DMEPOS industry, the suppliers will be less motivated to offer high quality items. In addition, because only one single payment amount will be reimbursed for a certain product, there is also concern that there will be a lack of motivation to provide high quality DMEPOS products to the consumer.

Conditions for Awarding Contracts

Conditions for Awarding Contracts

- It has been noted that there may be a grace period allotted for those suppliers who have not had time to become accredited prior to submitting bids. However, the length of time of that grace period is not quantified in the NPRM. Because it is estimated that it will take anywhere from 6-12 months to complete the accreditation process, and to allow the accrediting organizations to adapt to the significant increase in demand upon them by the suppliers to become accredited, it is recommended that this grace period be 18 months. In this proposal, the 18 months would begin only after the specific accrediting organization names and the standards are released to the public. Another proposal would be to implement a process to phase in the accreditation process. For example, after the names of the accreditation organizations and the standards are released, the largest suppliers making up the top 25% of the CBA market share would be required to be accredited in the first 9 months, the next 25% in 12 months, the next 25% in 15 months, and the smallest 25% would have 18 months to become accredited. This would allow the accrediting bodies adequate time to adjust to the increase in demand for accreditation.
- There needs to be a specific amount of time defined for when a bid is due back to CMS after a supplier has received a RFB. This length of time should be defined to eliminate any confusion. Because it is estimated that a single bid will take approximately 70 hours (perhaps more initially while suppliers are becoming acquainted with the bidding system), it is recommended that this period of time be 9 weeks.
- The proposal to use data from the last 2 years to determine trend analysis as well as utilization measurements is questionable. Because some areas that are located in the top 10 MSAs have been affected by acts of nature as of late (Hurricane Katrina, for example), the data collected over the last 2 years will be significant skewed. In addition, it is proposed that 2 years of data will not be enough to recognize significant trends in the utilization of DMEPOS. Therefore, it is recommended that CMS use 5 years of data to determine these trends. It is felt that this increase in the amount of time studied will allow for a more accurate analysis of trends and utilization.
- In response to the request for comments about weighting individual items in a product category, the scenario in which the weight is determined by the fee schedule payment is opposed because it only takes into account cost but does not consider usage.

- In the scenario in which a competitive range would be used to determine the contract suppliers, how would the competitive range be determined? It is understood that a competitive range was selected during the demonstration projects after the composite bids were calculated, but there is nothing outlining exactly how the competitive range was calculated. This should be clarified prior to final approval of the NPRM.
- The scenario in which the pivotal bid is based on a target number of winners is opposed because it may not provide the CBA with the necessary capacity required to adequately provide for that particular CBA. In addition, a scientific method in determining the target number is not outlined in the NPRM. Selecting an arbitrary number for the target would not be a legitimate method in determining an appropriate target.

Criteria for Item Selection

Criteria for Item Selection

- It is agreed that a relatively large number of suppliers for a particular group of items would likely increase the degree of competition among suppliers and increase

the probability that suppliers would compete on quality for business and market share. However, as the NPRM reads, the competitive bidding program expects to limit the number of contract suppliers to approximately half of the current number. This significant decrease in the number of suppliers will, intuitively, limit competition. The concern is that the competitive bidding program will in fact have the opposite effect: by limiting the number of suppliers, the competition will decrease and, therefore, the motivation to provide quality products will also significantly decrease. In addition, it will become more and more difficult for the beneficiary to gain access to any DMEPOS products that he/she may require, especially for those individuals living in more rural areas. This may in turn result in an increase in falls and other injuries requiring hospitalization leading to an increase in Medicare reimbursement for hospitalization costs.
- The statement that the Competitive Bidding Demonstrations Projects provided useful information is not disputed. In researching the results of the projects, it was found that in one of the projects, a single large national company serviced the oxygen requirements of 70% of the beneficiaries who live in that CBA. This documented finding further fuels the fear that the competitive bidding program will significantly limit competition among suppliers which will in turn limit quality, access, and choice for the beneficiaries.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

- Rebates may prove to be very confusing to both the suppliers as well as the beneficiaries, especially if the supplier is not permitted to advertise the rebate that is available. Although advertisement of the rebate may not be allowed, beneficiaries will discuss HME providers amongst themselves. Therefore, the fact that one provider offers a rebate while another one does not will be spread by word of mouth. This rebate program, then, will put some providers in a significant disadvantage when compared to the other providers. In addition, legal issues are raised by the idea of rebates. Therefore, the entire section of this document having to do with rebates should be deleted.

Education and Outreach

Education and Outreach

- Request for clarification: where will the bidder s conferences be held? Initially, will they only be in the 10 MSAs that will originally be involved? What about in 2009? It would be helpful to allow those suppliers who will be introduced to the Competitive Bidding Program in 2009 to speak with those suppliers who were introduced in 2007. Are there any plans to hold conferences where this could occur?
- The NPRM states that 'publications may also be available on the CMS websites' Will the CMS website be revamped to make it more user-friendly? As evidenced by the recent Medicare Part D enrollment period, the website is confusing and quite difficult for Medicare beneficiaries to maneuver. It is highly suggested that the website be renovated for easier management.

GENERAL

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- If a supplier has been selected as a winner and is a participant in the competitive bidding program, is that supplier able to stop participating in the program if it chooses? If so, there should be specific guidelines set up for such a scenario.

- It is estimated that implementing the competitive bidding program for HME will eliminate 50% of the current HME businesses from the industry. This number is a significant decrease in the number of providers, and it is believed to be unacceptable.

Implementation Contractor

Implementation Contractor

- Given the large scope of the Competitive Bidding Program and of the job duties of the CBIC(s), it seems as if using only one CBIC would not be adequate to correctly implement the program (especially since it is estimated in another section of the document that it will take 9.4 hours to evaluate each bid). Therefore, it would appear that proper implementation would require multiple CBICs. However, the utilization of multiple CBICs would increase the cost to the Medicare program, which is counterintuitive to the entire premise of the program: cost savings. In hiring the CBICs, proper consideration should be given to ensure that both correct and effective implementation of the competitive bidding program is guaranteed and that cost savings to the Medicare program is a priority.

Opportunity for Networks

Opportunity for Networks

- Clarification is requested on this concept of forming networks. If a network is formed between several suppliers, is each separate supplier required to supply all of the items that the network bid on? If this is indeed the case, it is proposed that the primary network entity submit the bids for all product categories/items and have them available so that each of the separate suppliers in the network is able to order them. Therefore, the supplier would still 'carry' each of the products, albeit on an 'ordering' basis (if the supplier does not choose to regularly stock those products).
- Request for clarification: does the network bid for all of the single suppliers in the network, or does each single supplier in the network submit individual bids for all of the product categories?
- It is proposed that if a network is formed, it is responsible for submitting the bids for all of the separate entities forming that network. However, the financial responsibility (reimbursements, etc&) would solely fall on the single suppliers of that network. This will assist in eliminating confusion and limiting mistakes, and it will decrease time between submitting requests for reimbursement and actually receiving that reimbursement for the supplier.
- It is stated that 'if any member of the network falls out of compliance with this requirement [meeting accreditation and quality standards, quality of care, service and items], we would have the option of terminating the network contract.' In response to this statement, it is proposed that if an individual supplier in a network has fallen out of compliance with these requirements, the network will be given a certain length of time (30-60 days) to attempt to remedy the situation without affecting the remaining entities that comprise the network. Remedy could be defined as assisting that supplier in once again becoming compliant with the requirements and/or removing that entity from the network. This will allow those remaining entities in the network to go unpunished for the acts of another supplier.

- It is understood that the intent of the NPRM is to prevent networks from controlling the majority of the market share in a particular area, hence the limit to 20% of the market share. However, in certain scenarios, this limitation would actually allow other companies to have majority of the market share, completely contradicting the original intent of the rule. For example, if there are five providers for a certain area and three of those providers are in a network, they can only collectively represent 20% of the market share for that area. In turn, the remaining two providers will each get 40% of the market share. From this example, it appears as if joining a network may be detrimental to a provider s success.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

- It is stated that demonstration suppliers were either able to increase their market share or did not notice much change in their market share during the demonstration. However, upon researching the demonstration projects, the fact that several small suppliers experienced a decrease in their market share was documented. The information in the literature regarding suppliers who noticed an increase in their market share referred to large suppliers.
- Several small suppliers offer somewhat limited DMEPOS product line (they may offer bedrails for hospital beds, but not hospital beds, for example). Therefore, if suppliers must bid on each item in a product category, several small suppliers will be forced to either eliminate that product line entirely or significantly increase that product line so that they carry all items in the product category even though they have not needed to carry that full product line in the past. Therefore, it is recommended that small suppliers be allowed to bid on individual items in a product category, but not necessarily all items in that category.

Payment Basis

Payment Basis

- Because the single payment amount for a product will be different from one CBA to another, it is proposed that, when determining a single payment amount for a product in a non-competitive bidding area, the single payment amount from a CBA that is comparable in size and make-up (demographics, etc...) to the non-competitive bidding area is used. In addition, it is proposed that the comparable non-competitive bidding area is located in close proximity to the CBA that is being used to determine the single payment amount.
- The requirement to obtain competitively bid items from a contract supplier will be extremely confusing to the traveling beneficiary and will limit their access to DMEPOS while they are away from their permanent residences. This could result in a decrease in efficiency for both the suppliers as well as the beneficiaries, which will in turn result in an increase in costs. If this particular section of the NPRM is passed, significant education to both the suppliers and the beneficiaries will be essential to the success of this section to ensure that all those involved understand how to find various CBAs and which DMEPOS products are included in the competitive bidding program for each CBA. In addition, as the section currently reads, the supplier will be reimbursed the single payment amount of the CBA of the beneficiary s permanent residence. Because all suppliers will be experiencing a significant decrease in reimbursement rates once competitive bidding is implemented, we propose that the supplier outside of the beneficiary s permanent residence area be reimbursed either (a) the regular fee-schedule amount for the product if the area traveled to is not a CBA or (b) the higher of the single payment fees of the two CBAs, if the area outside of the beneficiary s permanent residence is not in a CBA. This break for the suppliers will perhaps assist in the monetary loss experienced by them throughout the competitive bidding process.
- It is proposed that the wording under the 'Limitation on Beneficiary Liability for Items Furnished by Non-contract Suppliers' is modified. With the current language, it seems as if there is nothing preventing a beneficiary from knowingly patronizing a non-contract supplier to obtain a competitively bid product for that area with the intent of not having any financial liability for that product. The wording should be amended to state that if a beneficiary chooses to obtain a competitively bid product in a CBA from a non-contract supplier, then the financial liability for the product will be solely on the beneficiary or a secondary insurance that agrees to assist in payment for the product. However, if the non-contract supplier attempts to obtain reimbursement from Medicare for the competitively bid product, Medicare will deny the payment and the financial liability will therefore fall on the beneficiary.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

- The NPRM states that 'This issue [not requiring a contract supplier to provide every brand of products included in a HCPCS code. &the single payment amount for the HCPCS code would apply] will be studied in more detail by the OIG in 2009.' What about those CBAs for 2007? Will this rule apply for them?

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

- This section refers to the fact that any supplier wishing to participate in the competitive bidding program must first meet certain quality standards and be accredited by an approved accreditation organization. The question remains: when will the quality standards and the names of the approved accreditation organizations be released to the public? If the first round of competitive bidding is to be implemented in 2007, then the accreditation standards and approved organizations should be announced as soon as possible. In addition, the competitive bidding program should not be implemented until the very end of 2007, and even then, it should only include those suppliers who have already been accredited (prior to June of 2006). This will allow those suppliers who have not yet had time to become accredited/meet quality standards to indeed be compliant with Medicare regulations and therefore be eligible to participate in the competitive bidding program.
- This section also outlines the standards that CMS will use to evaluate the approved accreditation organization(s). It states that CMS will 'provide written notice of the withdrawal to all accredited suppliers within 10 days of CMS s notice to withdraw approval of the accreditation organization.' However, there is not follow-up of this statement to outline what follows for those suppliers who were accredited by that organization. There are two suggestions to fill in this gap: (1) The individual suppliers will finish out their 3 year contract while still participating in the competitive bidding program and will then be surveyed by a different CMS approved accrediting organization.
(2) Upon losing its ability to be an approved accrediting organization, the accrediting organization will be required to refund the funds that the individual suppliers issued to that company in order to become accredited. The suppliers will then have a reasonable amount of time (15 months) to become accredited by an approved

organization.
- Request for clarification: if CMS would like to withdraw its approval from an accrediting organization, would the organization receive a summary of deficiencies from CMS prior to its hearing (if the organization chooses to request a hearing)?
- Request for clarification: The NPRM states that 'We believe this case affirms the principle that the Secretary has the discretion to interpret the statute and to assign a product to a particular Medicare category even when this will result in non-coverage determinations by Medicare.' This is interpreted as saying that Medicare is able to add a product to a product category even when the product will not be reimbursed by Medicare. In what type of situation would this be done? Why assign a product to a product category when there will be no reimbursement for that product?

Regulatory Impact Analysis

Regulatory Impact Analysis

- This section states that the bidding will take place in fall of 2006. Because it is already June of 2006 and neither the standards nor the names of the approved accrediting bodies have been released to the public as of yet, it is proposed that the bidding be placed on hold until all standards, rules, regulations, and accrediting bodies have been approved and released to the public.
- The statement 'Since suppliers can choose whether to submit a bid for the competitive bidding program, the regulation imposes no direct costs' is misleading. It is true that suppliers are able to choose whether they will or will not participate in the competitive bidding program. However, if they choose to, then significant costs will be imposed on them. If they choose not to, then they will not be a contract supplier for Medicare, which will most likely lead to a significant loss in revenue for the supplier. It is true that there is a choice available, but it is more of a choice of whether to participate and attempt to compete or to no longer vend DMEPOS products.
- The statement 'The average product group savings rate in the demonstration ranged from 9-30% in a CBA round with most product groups around a 20% savings' is noted. The question remains, was the quality of the products evaluated? In addition, how many suppliers lost business/went out of business as a result of the program?
- This section states that 'while there may be some decrease in choice of suppliers, there will be a sufficient number of suppliers to ensure adequate access.' The first comment on this statement is that there will most definitely be a decrease in choice of suppliers. Secondly, clarification is request on how CMS will ensure that the number of suppliers will be adequate for the number of beneficiaries. Thirdly, it is noted that adequate does not always equate to easy access for beneficiaries, especially for those living in rural settings. Because there will be a decrease in their choice of contract suppliers, access will be significantly limited for many beneficiaries.
- It is surmised that there will be an improvement in the quality of the products offered to the beneficiaries because of the close scrutinizing of the suppliers by CMS. However, upon researching the demonstration projects, it appears that the quality of the products did not improve. How will the implementation of national competitive bidding differ in this aspect from the demonstration projects?

- This section states that because there will be a decrease in the number of suppliers in the competitive bidding program, there will be an increase in volume for each supplier. However, upon researching the demonstration projects, it appears that several contract suppliers experienced either stagnation in their volume or a significant decrease in their volume. If this is in fact true, this statement should be stricken from the document because it is offering false hope to potential contract suppliers in the national competitive bidding program.
- This section also discusses affected suppliers and eligible products/product categories. Because it will assist in determining whether or not a supplier participates in the competitive bidding program, the hastened release of the chosen products and product categories to the public will be greatly appreciated.
- From the demonstration projects, it appears as if approximately 50% of those suppliers who will submit bids will not be selected as winners. This seems like a significant decrease in the amount of suppliers, and once again the question of how CMS will ensure adequate access to DMEPOS products is presented. In addition, this will mean a significant decline in competition. Because there is a potential for suppliers to concentrate more on cost rather than quality, it will be imperative for Medicare to implement quality standards for the products in the competitive bidding program.

Regulatory Impact Analysis

Regulatory Impact Analysis

- The estimate of submitting one bid is $2187.50. Because this cost is in addition to the costs suppliers will incur to become accredited, and because this estimate is for one bid submission only, it appears that small business will definitely have difficulty competing with the larger DMEPOS suppliers. If smaller business were to enter into a network situation, would the network be able to submit the bids for the smaller suppliers?

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

- It is stated that 'there will be an administrative process to ensure that all information the supplier supplied is accurately captured and considered in the bid evaluation process'. This is a necessary component of this program, as the supplier information is vital to obtaining appropriate bids. However, it seems as if this administrative process would require an increase in man-power, which would increase the cost for the Medicare Program. In fact, it has been documented that properly implementing a national competitive bidding program would require CMS to hire a significant amount of persons. The estimates reveal that the additional number of individuals required to run such a program would be 2500, which would increase the entire Medicare staff by greater than one-third. From these figures, it appears that the competitive bidding program will not be the cost-saving program that it originally planned to be. In addition, who will make up this administration? Will they be experts in the field of DME?
- The statement that 'suppliers would be required to submit a separate bid for all items that we specify in a product category' requires clarification. For example, if a supplier is part of a network, would the network be responsible for submitting a bid for all of the items in a product category, but the individual supplier only be responsible for supplying those items in that category that they choose to vend? Or would each individual supplier in that network be required to submit a separate bid for all of the items in a product category?

Terms of Contracts

Terms of Contracts

- The NPRM states that 'the length of contracts may be different for different product categories, and we propose to specify the length of each contract in the Request for Bids.' Having multiple different deadlines for multiple different product categories would most certainly be time consuming, costly, and confusing for all of those involved. It is proposed that the length of contracts for all product categories for an individual supplier be on the same 3 year cycle as that supplier s accreditation requirement. Another proposal would be to have all suppliers in one CBA be accredited in the same year and then have the length of contracts for all product categories in that CBA be on the same 3 year cycle as that CBA s accreditation requirement. Either one of these proposals would simplify the process for all involved. The CMS representatives would be able to concentrate on a few CBAs/suppliers across the country at one time instead of being constantly inundated with bids for multiple different product categories from multiple different suppliers. In addition, they would limit the chance of error occurring on the side of the suppliers because all of their bids and accreditation would be renewed at the same time.
- The NPRM states that the supplier must factor the cost of furnishing items in this situation [when a non-contract supplier opts not to take advantage of the grand-fathering clause] into their bid submissions. Clarification of the appropriate method suppliers should use to determine this cost is requested. It seems that if suppliers were asked to estimate these figures, the resultant number would be an arbitrary number. If this clause is left in the NPRM, it is proposed that information (trend analysis and usage statistics) that CMS has gathered from that particular CBA be released to all suppliers so that they may make an educated bid.

Submitter : Mr. Bryan C. Thompson, R.Ph **Date:** 06/26/2006

Organization : The Medicine Shoppe, Urbana, OH

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-471-Attach-1.DOC

#471

June 23, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

I would like to thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. In response to this opportunity, I offer the following comments for consideration as CMS develops this proposal.

- **General Comments for the Proposed Regulation**
  - After reading the proposed regulation, I have yet to find a clear reason behind this proposed bidding program. I have worked in the pharmaceutical business for 16 years and from that experience I have no doubt that this proposal would provide difficulties for beneficiaries. When making any medical decision, the patient must be thought of first and foremost. By limiting access to patients' medical supplies you are, in turn, disregarding their needs. As the Department of Health and Human Services, I would like to assume that you believe a patient's needs come before financial needs, yet this proposal seems to prove otherwise.
- **Competitive Billing Areas**
  - I strongly oppose CMS' proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers. Mail order is never a solution when dealing with medical supplies. Sending certain medical supplies, for example diabetic testing strips, can damage these supplies—excessive heat, rough handling and postal service x-ray machines all can have an effect on these necessary supplies. Automatic refilling can also lead to patient abuse, something neither the Department of Health and Human Services nor I wish. In addition to these concerns, forcing beneficiaries to switch to mail order restricts their choice. It is essential for beneficiaries have local access to their supplies. This proposal would severely restrict beneficiaries' access to needed supplies which could, in turn, compromise my patients' health.
- **Criteria for Item Selection**
  - The competitive bidding program should <u>not</u> include common DMEPOS supplies such as diabetic testing supplies. These are supplies that need to be readily available to patients. If CMS intends 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 provided through a central supplier.

- **Opportunity for Participation by Small Suppliers**
  - I urge CMS to take steps to ensure that small suppliers—which make up the majority of pharmacy-based suppliers—can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to compete in large metropolitan areas. President Bush has repeatedly stressed the importance of small business growth. As a federal agency, it makes sense to encourage this growth, rather than proposing regulations that would squelch that growth.
  - After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.
  - As stated repeatedly, CMS must take these steps to preserve the beneficiaries' convenient access to DMEPOS supplies and to maintain established patient/provider relationships.

Currently, I provide durable medical equipment, orthotics and supplies to my patients; and without serious revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

In conclusion, I strongly urge CMS to reconsider their proposed regulation on DMEPOS. This is something that could change the entire face of the pharmaceutical business and anything so monumental should be given your utmost care and consideration.

Thank you for considering my view and I encourage you to contact me if you would like to discuss first hand any of the points I have made in this letter.

Sincerely,

Bryan C. Thompson, R.Ph
The Medicine Shoppe
821 Scioto Street
Urbana, OH 43078-2223

Submitter : **Mrs. Michele Hamm** **Date: 06/26/2006**

Organization : **Premier Home Care, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

First, thank you for the opportunity to share my concerns on the Competitive Bidding Issues. The proposed methodology for selecting the 10 MSAs for 2007, at present this limits the small business to participate, due to lack of time to build or create a network in order to bid or participate. With past and present buzz of the importance of Accreditation, I believe only accredited providers should be eligible to submit bids. This in turn, would require CMS to identify the criteria it will use to identify the accrediting bodies. Rebates, this is unclear how this will work, providing rebates is contrary to other laws applicable to the Medicare program ie, Anti-Kickback Statue and the Beneficiary Inducement Statue. I believe there is a lot of work to be completed before such an undertaking can come to be. I ask that these major points be addressed before this program is rolled out. Again, the small business (DME providers) need to be apart of this, as we are a major player in the healthcare of many patients across the nation. We must remember our first and foremost concern is our patients and their healthcare needs. Again, thank you for this opportunity.

Submitter : Ms. Emily Holzberg **Date:** 06/26/2006

Organization : Santa Clara Valley Medical Center

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Upper Extremity Orthosis could be fabricated and issued by train therapists.

CMS-1270-P-473-Attach-1.RTF

#473

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

I would like to request that Medicare revise the proposed regulation to allow trained and qualified therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

My name is Emily Holzberg and I am an occupational therapist specializing in the treatment of upper extremity disorders. I have specialized in the treatment of hands and upper extremities for 5 years.and I am certified in the state of California for the advanced practice of hand theray. I am currently working at the hand therapy clinic at Santa Clara Valley Medical Center, the county of Santa Clara hospital and frequently treat Medicare and Medicaid beneficiaries that require custom or off the shelf orthoses/ splints or braces that require modifications..

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. These orthosis require constant adjustments and modifications as the client progresses.

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 or the surgery will be a failure. 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. Not to

mention, these clients often have monetary and mobitily constraints that will make it more difficult to go from one provider to another to obtain the proper orthosis.

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. This is a dangerous and unethical position you are putting me and my clients in if you do not revise this.

Sincerely,

Emily Holzberg, MS, OTR/L, HT

Submitter : Dr. Terence Pedersen **Date:** 06/26/2006

Organization : Yankton Foot & Ankle Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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,

Terence S. Pedersen, DPM, FACFAS

1000 West 4th Street, Suite 2
Yankton, SD 57078

Submitter : **Date: 06/26/2006**

Organization :

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
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Dr. McClellan,

I am a podiatrist in Clearwater, Florida who prescribes and dispenses durable medical equipment to my patients for foot and ankle pathologies. I have been in practice over twenty eight years, and my main goal is to do what is best for my patients. I know my patients foot and ankle health problems. Therefore I can prescribe and dispense the most specific functional equipment for their problem. I am able to do this timely by not sending it out to a DME company. That way there is less chance of complications due to time delay of treatment. For acute problems they leave my office with correct splints, braces and crutches. I am able to determine in my office if the durable medical equipment is helping immediately.

I request that the Centers for Medicare and Medicaid Services (CMS) modify the definition used for the new competitive acquisitions program from 186 (R) (1) to 1861 (R).

Allowing podiatrist to continue to be able to dispense DME s for their patients only will be much better for patient care. If I am required instead to bid to supply the entire Metropolitan Statistical Area (MSA) my patients will negatively suffer.

Sincerely.

Tyler B. Brahm D.P.M.

Submitter : Ms. Bernice Kandarian **Date: 06/26/2006**

Organization : California Council of Citizens with Low Vision

Category : Consumer Group

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

The reaction of the California Council of Citizens with Low Vision to the recent Notice of Proposed Rule Making is one of disbelief and extreme disappointment. We believe that to deny coverage for low vision devices and at the same time allow coverage for devices that ameliorate other disabling conditions is grossly discriminatory. Furtthermore, to base such denial on the statutory exclusion of coverage for "eyeglasses" is an egregious misunderstanding of the purpose of these devices and of the intent of Congress on the part of the agency.

We need not dwell on the argument that this proposed policy would be discriminatory. How is it different to provide a device to make more mobile a person who can't walk, for example, and at the same time, disallow a device that improves the visual function of someone with severely impaired vision? The essence of discrimination is treating similar situations differently.

The issue which should perhaps receive our main emphasis is the utter dissimilarity between eyeglasses and low vision devices. Eyeglasses are optical systems to aid the vision of a person who has essentially normally functioning vision and only an optical defect in the eye. In other words, they are designed to compensate for a refraction error in the eye. Eyeglasses typically correct vision to normal 20/20 or very close to that. Low vision devices, though they may include optics, are prosthetic in nature, designed to allow as much visual function as possible for a person whose vision is impaired in ways other than refractive errors. These devices do not ordinarily bring vision up to normal or near normal. Thus to equate eyeglasses with low vision devices is like equating running shoes with prosthetic legs or bicycles with wheelchairs.

As evidence of Congressional intent in this regard, let us point out that the statutory definition of blindness, though couched in terms of visual accuity, is specified as with maximum correction in the better eye. Thus, when someone says "Without my glasses, I am legally blind," he/she is speaking nonsense. Legal blindness, and, we would argue, vision impairment in general, is functional limitation of vision which cannot be corrected by lenses.

Therefore, there is, in our opinion, no rational or legal basis for this proposed rule and we, the members of the California Council of Citizens with Low Vision, are opposed to its finalization.

Submitter : Mr. Andrew Gomory **Date:** 06/26/2006

Organization : Lingraphicare America, Inc.

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-477-Attach-1.DOC

#477

June 21, 2006

Lingraphicare America, Inc. submits these comments in support of the exemption of Speech Generating Devices (SGDs) and related items from Medicare "competitive bidding." Our device is the Lingraphica, and is grouped under code E2510.

In summary, competitive bid would not save Medicare money and would be a disservice to patients for the following reasons:

- Our device is specially designed for adults with aphasia – there is no alternative.
- An extremely high level of service is required to determine if our device is appropriate and to support it in the field.

We specialize in serving only one group of patients: adults with aphasia. The majority of our patients have had a stroke and are elderly. This group presents very differently from other groups that typically utilize AAC devices like ALS, CP and autism. Our patients have incurred brain damage later in life, after their initial acquisition of language and typically have the following issues:

- Some level of language impairment involving the ability to formulate speech in addition to a physical impairment in producing speech.
- Physical impairments typically include weakness, limb apraxia (usually on the dominant side) and vision problems and can range from minimal to extreme.
- Speech difficulties can be present in many ways:
  - Word retrieval (classic Broca's aphasia)
  - Physical speech generation (apraxia)
  - Generation of nonsensical speech (fluent aphasia)
  - Loss of grammatical structure
- The ability to understand spoken speech varies from minimal to nearly normal.
- Writing and reading abilities are often severely impaired.

The Lingraphica has evolved to meet the special needs of persons with aphasia and is therefore significantly different from other devices. In a large number of cases of aphasia the ability to recognize images is left intact even when the ability to use words has been impaired. Because of this, the Lingraphica enables persons with aphasia to generate speech entirely through the use of images. Because of the wide range of abilities of persons with aphasia the Lingraphica is designed to be extremely flexible. This includes pre-recorded speech, dynamically recorded speech, dynamically synthesized speech, multiple methods of message formulation and multiple methods of device access. Low-functioning patients can begin work at the word level or select words and phrases that are created for them. As the patient gains more experience and higher-function they can dynamically create novel utterances of unlimited complexity. In all cases, images are the basis of creating spoken speech.

Because of the unique nature of our functionality we rarely compete with other devices. Rather, we work with SLPs to determine if our device is right for a patient.

It is more difficult to determine if an aphasic patient can use an AAC device than with other disabilities. Our sales model recognizes this difficulty and is different from all other manufacturers. Instead of having a representative bring a device to a patient for an evaluation, we loan our device to the SLP who works with the patient for several weeks to determine if it is appropriate. In addition, the device is always sent home to ensure that the patient will be able to use the device for functional communication without the support of the SLP.

We provide unlimited support for the life of the patient. This typically involves training multiple care-givers as well as working directly with the patient.

Our device is evolving rapidly to take advantage of advances in computer hardware and software as well as incorporate the knowledge we have acquired working with patients with aphasia. Built-in cameras, 3-dimensional images, images set in natural scenes as opposed to grids of cards, animation are but a few of features that distinguish the Lingraphica from other devices and make it particularly appropriate for adults with aphasia. Our device is actually becoming more different from other devices and is likely to continue its greater differentiation in the future.

Thank you for your consideration.

Andrew Gomory
CEO Lingraphicare America, Inc.

Submitter : Dr. Jeffrey Crowhurst **Date:** 06/26/2006

Organization : Dr. Jeffrey Crowhurst

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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,

Jeffrey A. Crowhurst,DPM
Ottawa, Illinois

Submitter : Mr. Redge Campbell **Date:** 06/26/2006

Organization : Harrison Medical Center

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

As a hand therapist and director of rehabilitation I am writing to express my concern over limiting providers of prefabricated orthotics. A hand therapist combineds clinical expertise in the treatment of hand disorders with his or her skills in identifying and supplying hand orthotic devices. By limiting access to preferred providers who are likely disconnected from the clinical presentation of the patient we have an increased likelihood of poor fitting, incorrect splinting, and reduced access to the necessary training to fully optimize the splint provided. Please ensure that hand therapists are always in a position to use their expertise to correctly identify the most appropriate custom or prefabricated splint and, more importantly, to provide the necessary oversight and follow up to ensure the money spent for this splint is not wasted on the wrong device or the ill fitting device.

Thank you

Redge Campbell MS OTR/L
Director of Rehabilitation
Harrison Medical Center
Bremerton, WA

Submitter : Dr. James Hardison **Date:** 06/26/2006

Organization : Arch Podiatry Associates, P.A.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-480-Attach-1.DOC

480

Arch PODIATRY Associates PA

Dr. J. Kevin Hardison & Dr. Chaitalee Kardani

Diseases and Surgery of the Foot and Ankle / Diabetic Foot & Sports Medicine Specialists

Utilizing State-of-the Art Diagnostic Ultrasound, Digital X-Rays, and Shockwave Therapy

Treating Adults & Children For:

- Heel Pain
- Foot & Ankle Pain
- Bunions
- Hammertoes
- Orthotics
- Ingrown Toenails
- Warts
- Skin Problems
- Athlete's Foot
- Difficulty Walking
- Fractures
- Sports Injuries
- Sprains
- Tendonitis
- Bursitis
- Capsulitis
- Flat Feet
- Fallen Arches
- Arthritis
- Neuromas
- Diabetic Footcare
- Diabetic Shoes
- Wound Care
- Corn & Calluses
- Fungal Toenails

June 23, 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)(3).

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)(3) 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 be forced to go elsewhere to have their prescriptions filled. This will put them at greater risk for further injury.

Charlotte Sports Science Centre
335 Billingsley Rd Suite 102, Charlotte, NC 28211
(704) 632-8032 Fax: (704) 632-8034
www.archpodiatry.com

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

J. Kevin Hardison, D.P.M.
President
Arch Podiatry Associates, P.A.
335 Billingsley Rd Suite 102
Charlotte, NC 28211
(704) 632-8032
Fax: (704) 632-8034
khardison@archpodiatry.com

Submitter : **Dr. Mitchell Waskin** **Date: 06/26/2006**

Organization : **Foot & Ankle Center, L.L.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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)(3).

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

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

Sincerely,

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

Submitter : **Dr. Jack Ressler** **Date: 06/26/2006**

Organization : **Dr. Jack Ressler**

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 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. A large number of my patients are diabetics and require the SADMERC approved shoes and insoles. Due to potentially serious conditions, if proper shoe gear is not worn, diabetic shoes and innersoles play an important role in the everyday routine of my diabetic patients. Many patients who used to get their diabetic shoes and insoles from outside sources such as companies that provide them with their diabetic supplies and others that are not really aware of their Podiatric needs are very impressed with the type of product myself and some of my fellow Podiatrists supply. It is of great importance to be included in the professional company of MDs and DOs that supply our patients with much needed knowledge and proper evaluation for their needed DMEPOS items.
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,
Jack E. Ressler D.P.M.

Submitter : Dr. Brandi Johnson **Date:** 06/26/2006

Organization : Advanced Foot & Ankle Center of Tampa Bay

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

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 surgeon. I 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.

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. The patients will be put to an inconvenience and a risk of further injury.

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,

Dr. Brandi M. Johnson, DPM
Advanced Foot & Ankle Center of Tampa Bay

CMS-1270-P-483-Attach-1.DOC

#483

June 26, 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 surgeon. I 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.

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. The patients will be put to an inconvenience and a risk of further injury.

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,

Dr. Brandi M. Johnson, DPM
Advanced Foot & Ankle Center of Tampa Bay

Submitter :

Date: 06/26/2006

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Mr. 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)(3).

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)(3) 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,
Jerry L. Gross, DPM

Submitter : Dr. James Judge **Date:** 06/26/2006

Organization : Wake Foot and Ankle Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-485-Attach-1.DOC

#485

June 23, 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)(3).** □ □

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 the specialist whom the MD and DO are sending their patients to for this current care.

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)(3) 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 and cause further harm and enormous extraneous cost to CMS.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians. □ □

Sincerely,

Dr. James M. Judge

Submitter : **Dr. Lloyd Trichell** **Date: 06/26/2006**

Organization : **Dr. Lloyd Trichell**

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 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,

Lloyd Trichell, DPM

Submitter : Dr. Michael Nirenberg **Date:** 06/26/2006

Organization : Dr. Michael Nirenberg

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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,

Michael Nirenberg, DPM
50 West 94th Place
Crown Point, IN 46307

Submitter : Mr. Brian Laney

Organization : Center for Sports Medicine

Category : Occupational Therapist

Date: 06/26/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-488-Attach-1.DOC

Brian A. Laney OTR/L, CHT
7234 Goldenrod Court
Ooltewah, TN 37363
423-238-4421

#488

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 Brian Laney, 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 Chattanooga, TN, 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,

Brian A. Laney OTR/L, CHT

Submitter : **Dr. Harvey Danciger** **Date: 06/27/2006**

Organization : **Dr. Harvey Danciger**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attatchment

CMS-1270-P-489-Attach-1.WPD

#489

June 26, 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,

Harvey R. Danciger, D.P.M.

Submitter : **Ms. Greg Lord** **Date: 06/27/2006**

Organization : **Ms. Greg Lord**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1270-P-490-Attach-1.DOC

CMS-1270-P-490-Attach-2.DOC

#490

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P, Mail Stop C426-05

7500 Security Boulevard

Baltimore, MD 21244-1850

To Whom it May Concern:

1. In any cases, there is not sufficient detail that explains what the final rule may specify. In addition there is a tremendous amount of detail to digest. An extension of the comment period by an additional 60 days is required to enable appropriate consideration of the issues raised by the NPRM and to ensure that all providers have adequate opportunity to submit well thought through comments.

2. CMS is already over 12 months behind the original implementation timeline (which was thought by many to be aggressive to begin with). CMS needs to republish an updated implementation timeline with key events clearly identified. The implementation of NCB must be delayed for a minimum one year.

3. In the documents presented for comment, it is stated that the results from the demonstration projects in Polk County and the three counties in the San Antonio offered "mostly favorable" data with nearly a 20% overall savings. The data is reported to have indicated beneficiary access and quality of service remaining "essentially unchanged." These statements lead to at least two questions:

    a. What were the negative results encountered in the demonstration projects and in which areas? To what degree did negative results counter-balance "mostly favorable" data.

    b. Is the statistical and qualitative data public, and if so, where can it be found? If not, why not?

4. The final quality standards are not yet published. The draft standards published in 2005 generated over 6,000 comments which indicate significant problems with the proposal. Due to the integral part these standards play in the overall plan, they must be published as quickly as possible and be subject to additional industry review and comment prior to continuing with the bidding process.

5. There was universal agreement that a key implementation criteria was the use of specific standards a bidder would have to meet (a.) to submit a bid and (b.) to be awarded a bid. The proposed rule is unclear in terms of what the standards are, how they will be applied, and when they will be applied. Standards must be clearly stated and be used to pre-screen all submitted bids. The screening process (standards and timing) needs to be defined. If an entity does not meet all standards, that bid should not receive further consideration.

6. The proposed rule indicates a grace period will be provided if bidders are not yet accredited. There should be no grace period. If an entity is not accredited at the time of submitting a bid, that bid should not be considered.

7. There is a significant lack of inclusion of small businesses. Specific inclusions of a limited number of small businesses in each MSA must be provided for. In addition, small businesses will be unnecessarily burdened by several provisions in the Proposed Rule. These include abut are not limited to:

   a. Financial Standards: By requiring small providers to follow the guidelines CMS is proposing would cause extreme financial hardship for small providers if they are required to submit a formal audit which can cost $10,000 to $15,000. We recommend that a credit worthiness status be determined through bank credit, vendor credit, or years in service, measurements rather than an actual audit. In order to be nondiscriminatory and to encourage full participation by quality providers, the financial standards must not be financially burdensome to the small provider.

   b. Assuming that a small provider cannot provide all product categories is incorrect. Many "small providers" offer the full line of DME defined by CMS.

   c. The statement that 90% of providers fall under the "small provider" definition and that many of them would not be able to participate and in fact would probably go out of business is discriminatory and prejudicial.

   d. The requirement that a bidder cover all the geography in a CBA presents problems for small suppliers. Many providers in rural areas have been in business anywhere from 5-25 years and should be exempt from CB. Please define "rural areas".

8. Significant problems exist in how to verify the "capacity" of bidders. Looking at history and allowing a 20% growth appears reasonable. Gauging capabilities of new suppliers and existing suppliers claiming significant growth capabilities is extremely subjective and risky.

9. CMS proposes to extend CB beyond specific Mass in certain instances. CMS should confine bidding to those MSA boundaries as required in the original legislation.

10. Introduction of a "rebate" system will create confusion and complexity to an already strained market place. Allowing this would cause confusion to the beneficiary and open a door for collusion and fraud. Please explain how this provision is not prohibited by the Stark regulations. CMS should eliminate any rebate provisions from the Proposed Rule.

11. The provision that a beneficiary with a capped rental product can move to a contracted supplier and that contracted supplier is then subject to a limitation due to payments made will not work.

12. The use of networks will assist small businesses. However additional details must be provided.

13. Creating a new pricing methodology should be published in the Federal Register with opportunity for comment. Creating new HCPCS codes for already existing codes should not be allowed. Publishing this data in provider updates is not acceptable.

14. The GAO recommends using mail delivery for items. Medicare has demanded updates on usage and now they recommend mail delivery of wound care supplies, urology supplies,

diabetic products, and ostomy supplies. These products take many visits and hours of help and instruction.

a. How will you handle a situation in which a supplier, not licensed (not required) in their state of residence services a patient in a state requiring licensure?

b. Who addresses change of condition?

c. Who addresses the teaching component?

d. Who addresses quantities?

e. Since mail order sends supplies automatically, who discontinues service?

f. Will mail delivery have different rules?

15. Should a provider accept an invitation as a sub-contractor to an entity awarded a bid (the contractor) and it is later determined that the contractor has in any way violated the conditions of the bid, what are the ramifications for the sub-contractor?

16. Will providers awarded a bid be subject to subsequent Medicare Replacement Policies or will there be special policies issued for these companies?

Greg Lord

624 Sudbury Avenue

Bismarck, ND 58503

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P, Mail Stop C426-05

7500 Security Boulevard

Baltimore, MD 21244-1850

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Greg Lord

624 Sudbury Avenue

Bismarck, ND 58503

Submitter : Mr. Bryan Giller **Date:** 06/27/2006

Organization : Sunrise Home Health Care

Category : Health Care Industry

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Our Company Sales are below 6 Million, however we are able to grow our business through superior service. 'Sunrise' has been Accredited since 1997. In our MSA of the Philadelphia Region, competition is High. By out performing the 'competition', my company succeeds and the Patients Benefit.

Please implement a Bidding System that allows Qualified Bidders the chance to do business at the Winning Bid amount. I believe the exclusion of Qualified Bidders, of whom would agree to the new bid amounts, is unfair and will ultimately lead to poorer service for Patients.

By limiting the number of winning bidders, you are Removing Competition. Any company can say that they can provide Superior Service at a lower bid. Let the Health Care Professionals decide which company performs the best and therefore deserves the right to service their patients.

THERE IS VALUE in Small Suppliers under Competitive Bidding. Companies like mine will help insure that Patient Care will not be sacrificed as a result of lower reinbursements.

It is difficult for me to imagine Competitive Bidding being implemented in my MSA of Philadelphia. There are so many people who need DME and I honestly believe that if Competive Bidding is implemented in its present form, the resulting monopoly of large companies will negatively effect the Industry.

Thank You, Bryan D Giller Pres.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Our Company received Accreditation by the Joint Commission in 1997.
You must have the supplier standards set before the implementation
of the Bidding Process. This is paramount to a Fair Bidding Process.
Thank You, Bryan D. Giller

Submitter : Dr. Kevin Molan **Date:** 06/27/2006

Organization : Dr. Kevin Molan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26,2006

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

Dear Dr. McClellan:

I am writing to request that the Center for Medicare and Medicaid Services(CMS) modify the physician definition used for the new competitive acquisitionprogram from 1861(r)(1)to 1861(r)(3).

As a podiatric physician, I prescibe and supply DMEPOS items to medicare beneficiaries as an integral part of my patients care. These patients rely on me to use my best medical judgment and clinical skills in treating their conditions. I am required to maintain a DMEPOS supplier number, adhere to the current suppler standards and subject to the same Stack regulations that apply to MD and DO suppliers. I feel podiatric physicians should receive 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 ability to execute a physician authorization.

In my practice, I utilize a variety od DMEPOS items. For example, when a patient presents with a metatarsl fracture and requires immobilization of the injured part, a walking boot can be promtly dispensed. If I no longer have this ability, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulation for the competitive acquisition program. I would like to continue to supply DMEPOS items for my patients only and if I am required to instead bid to supply the entire Metropolitan Statistical Area(MSA) my patients will be negatively impacted.

Sincerely,

Kevin S. Molan, DPM
Charlotte, NC

Submitter : **Dr. Donald Adamov** **Date: 06/27/2006**

Organization : **Irwin B. Malament, DPM, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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)(3). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only through my practice. If we are 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, we are required to obtain a valid supplier number and must adhere to all of the current supplier standards. We are 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 we are not a DMEPOS supplier in the new competitive acquisition program because we were unsuccessful in competing to bid to supply to the entire MSA rather than just to our 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)(3) so that we are eligible to bid to supply items to our 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,

Donald J. Adamov, DPM
Indianapolis, Indiana

Submitter : **Dr. Rudolf Meier** **Date: 06/27/2006**

Organization : **Dr. Rudolf Meier**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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,

R. Kurt Meier, III DPM
Brick, NJ 08724
icfeet@tellurian.com

Submitter : Dr. Samir Vakil **Date:** 06/27/2006

Organization : Dr. Samir Vakil

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).
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.
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.

Respectfully,

Samir Vakil, DPM

Submitter : **Mrs. Melanie Trook** **Date: 06/27/2006**

Organization : **St. Francis Hospital Outpatient Rehab, Tulsa OK**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attached letter

CMS-1270-P-496-Attach-1.DOC

#496

June 26, 2006
TO: CMS Comments on Open Issues

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 Melanie Trook, OTR/L, CHT, 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 have treated patients with upper extremity injuries since 1978, and have fabricated and dispensed hundreds of orthoses in my practice. I currently work for Saint Francis Hospital Outpatient Rehabilitation in Tulsa, OK, and frequently treat Medicare and Medicaid beneficiaries who require custom and/or prefabricated orthoses for protection/support or to enhance function and range of motion.

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.

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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 prefabricated 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 prefabricated 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, many DMEPOS suppliers are retailers, without specific medical training and licensure. You would be losing an important component in the treatment of the upper extremity beneficiary; that is, the therapist input and expertise in the supply of a prefabricated orthosis.

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

Sincerely,

Melanie A. Trook, OTR/L,CHT
Occupational Therapist
Certified Hand Therapist
Licensure Oklahoma OT-165

Submitter : **Dr. Edward Prikaszczikow** **Date: 06/27/2006**

Organization : **Dr. Edward Prikaszczikow**

Category : **Physician**

Issue Areas/Comments

GENERAL

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June 26, 2006

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

Edward Prikaszczikow DPM
427 Kanesville Blvd
Council Bluffs, Iowa 51503
(712)328-0297

Re: Competitive Acquisition Program for DMEPOS

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).

I have been practicing Podiatric Medicine in Council Bluffs, Iowa for over 26 years. 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 Prikaszczikow DPM

Submitter : **Dr. Robert Olson** **Date: 06/27/2006**

Organization : **Carolina Orthopaedic and Sports Medicine Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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)(3). 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 risk for complications.

Please change the physician definition from 1861(r)(1) to 1861(r)(3) 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,

Robert C. Olson, D.P.M.

Submitter : **Dr. Bruce Fridinger** **Date: 06/27/2006**

Organization : **Dr. Bruce Fridinger**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 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:

Please consider a proposal for 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,

Bruce Fridinger DPM DABPOPPM

Submitter : Mrs. Barbara Nagiewicz **Date:** 06/27/2006

Organization : HealthSouth

Category : Occupational Therapist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

Durable medical goods suppliers are at times orthotist/prothetists who are quite capable of supplying these splints - but most often the patient is only seen by a sales person who has no knowledge of the patients needs or what would best help the patient. This would be a grave disservice to your medicare patients and would probably be a waste of money.

Submitter : Dr. Timothy Quist

Date: 06/27/2006

Organization : Concord Foot & Ankle Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Concord Foot and Ankle Clinic
Timothy A. Quist, D.P.M., P.C.
24021 US 33 East, Elkhart, Indiana 46517
Phone: (574) 875-8698

June 27, 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,

Timothy A. Quist, DPM

Submitter : Mrs. Lori Riddick **Date:** 06/27/2006

Organization : Mrs. Lori Riddick

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-502-Attach-1.TXT

CMS-1270-P-502-Attach-2.RTF

#502

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 Lori T. Riddick, 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 had therapy clinic, and frequently treat Medicare 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,

Lori T. Riddick, LOTR, CHT

#502

docdispatchserv[3].txt

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

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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,

Lori T. Riddick, LOTR, CHT

Submitter : **Ms. Patricia Holt** **Date: 06/27/2006**

Organization : **Diabetes Resource Center**

Category : **Dietitian/Nutritionist**

Issue Areas/Comments

GENERAL

GENERAL

Please do not limit diabetes patients to only the lowest choice company for blood glucose meters and supplies. Having no choice will result in a lower quality meter that will not be able to be tailored to a client's specific needs re: strip handling, vision, ability to obtain adequate blood drop for older, cheap strips, or memory capacity. With type 2 diabetes increasing in the US at such a rapid rate, the more indiviualized to a client's needs a meter is, the more likely they are to use it as a tool to obtain better blood sugar control, saving us $$$$ in the long term. Cheap meters, inadequate training, limited storage of blood sugar testing results often = less testing, inadequate information to make appopriate changes in lifestyle and/or medications and increases the liklihood of expensive cardiac disease/bypass, blindness, amputations and dialysis. Quality companies do not ship supplies unless the need is verified. They do not change a prescribed meter to the cheapest available, and bill for the largest amount. Qaulity companies do not send substandard meters and lance devices that will break with repeated use, so they may ship and bill for another. They are willing to provide an individualized alternative (meter, or lance device, or gauge lancet) better suited to the client and will reinforce the initial teaching with the client (if older, this may have to be repeated several times). Please consider the lifelong need for ongoing blood sugar testing so diabetes patients have the data needed to stay as healthy as possible. You would want personalized choices for your own family with diabetes, not one size and price fits all. Thank you for your consideration.

Submitter : Dr. Michael Hass **Date:** 06/27/2006

Organization : New England Podiatry Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.
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 urge CMS to modify the physician definition from 1861(r)(1) to 1861(r) befor finalizing the regulations for the competivie acqusition program.

Sicerely

Michael I Hass, DPM

Submitter : **Dr. Alan Green** **Date: 06/27/2006**

Organization : **New England Podiatry Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I request that 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 supply items to my patients only. If I am required to bid to supply to an entire Metropolitan Statistical Area, my patients my no longer be able to get medically appropriate and necessary 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.
I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely

Alan H green, DPM

Submitter : **Date: 06/27/2006**

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 27, 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,

William T. Vondette, DPM, FACFAS

Submitter : **Mr. Robert Riffert RPh** **Date: 06/27/2006**

Organization : **The Beaverton Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I stronly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies through designated providers.

Criteria for Item Selection

Criteria for Item Selection

The competetive bidding program should not include common DMEPOS supplies such as diabetic testing supplies.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I urge CMS to ensure that small suppliers, like community pharmacies, can participate in the bidding program.
Any small supplier willing to accept the single payment amount should be allowed to join as a contracted supplier.
The majority of DMEPOS supplies we dispense are glucose test strips, inhalation products and ostomy supplies. Our patients find it convenient and we are sure of their complete health care.
I believe that fragmenting our health care system any more, is detrimental to patient health.

Submitter : **Dr. Stephen Tubridy** **Date: 06/27/2006**

Organization : **New England Podiatry Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am writing to urge the Centers for Medicare & Medicaid Services to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthectics, orthotics and supplies from 1861(r)(1)to 1861(r).
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.
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.
I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely,

Stephen P Tubridy, DPM

Submitter : **Mr. Michael Bartz** **Date: 06/27/2006**

Organization : **William Beaumont Hospital-Home Medical Equipment**

Category : **Home Health Facility**

Issue Areas/Comments

GENERAL

GENERAL

See attachment for complete comments

CMS-1270-P-509-Attach-1.DOC

CMS-1270-P-509-Attach-2.DOC

Beaumont®Home Medical Equipment
William Beaumont Hospital

June 22, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
42 CFR Parts 411, 414 and 424
(CMS-1270-P) RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Colleagues:

William Beaumont Hospital d.b.a. Beaumont Home Medical Equipment, welcomes the opportunity to comment on this proposed rule which would implement competitive bidding programs for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act.

Beaumont Home Medical Equipment is a large, hospital-based provider of home medical equipment, clinical-respiratory care, and adaptive rehabilitation equipment. The following comments reflect the collective experience of us as DMEPOS providers and our assessment of the impact the above rule would have upon beneficiaries of the Medicare/Medicaid program.

COMMENTS/ISSUES/QUESTIONS:

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system which might more aptly be described as "Selective Acquisition." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services.

Reasonable and significant cost-savings from providers can and should ultimately be achieved without eliminating normal competition in the marketplace and without eliminating virtually the entire, existing DMEPOS provider panel. At bottom, we believe that creation of a "limited provider panel" through the proposed national competitive bidding (NCB) program is bad policy for beneficiaries and providers alike. While this NCB option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service, ultimately shifting increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB..

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: Beaumont Home Medical Equipment recommends that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be better, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

Beaumont®Home Medical Equipment
William Beaumont Hospital
1200 Stephenson Hwy Troy MI 48083
Phone 248.743.9101 Fax 248.743.9111

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

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" version of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provide clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". CMS should not proceed with competitive bidding until it is certain that this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

Accreditation is and should be required for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

Beaumont®Home Medical Equipment
William Beaumont Hospital
1200 Stephenson Hwy Troy MI 48083
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It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

FUNDAMENTAL ISSUES: The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum.

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REBATE COMMENTS/ISSUES:

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise, and potentially fraud-encouraging concept that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities, could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home are not only dangerous from a patient safety perspective, but also extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

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The process for the establishment of networks needs better definition. It is unclear as to the required corporate structure, the responsibilities of the network providers to the network administrator, the patient and CMS. The accreditation requirements for potential established or new provider networks are also still very unclear.

The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Respectfully submitted,

Michael G. Bartz
Director - William Beaumont Hospital – Beaumont Home Medical Equipment

Beaumont®Home Medical Equipment
William Beaumont Hospital

June 22, 2006

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

Re: Centers for Medicare & Medicaid Services (CMS)
42 CFR Parts 411, 414 and 424
(CMS-1270-P) RIN 0938-AN14
Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Colleagues:

William Beaumont Hospital d.b.a. Beaumont Home Medical Equipment, welcomes the opportunity to comment on this proposed rule which would implement competitive bidding programs for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act.

Beaumont Home Medical Equipment is a large, hospital-based provider of home medical equipment, clinical-respiratory care, and adaptive rehabilitation equipment. The following comments reflect the collective experience of us as DMEPOS providers and our assessment of the impact the above rule would have upon beneficiaries of the Medicare/Medicaid program.

COMMENTS/ISSUES/QUESTIONS:

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system which might more aptly be described as "Selective Acquisition." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services.

Reasonable and significant cost-savings from providers can and should ultimately be achieved without eliminating normal competition in the marketplace and without eliminating virtually the entire, existing DMEPOS provider panel. At bottom, we believe that creation of a "limited provider panel" through the proposed national competitive bidding (NCB) program is bad policy for beneficiaries and providers alike. While this NCB option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service, ultimately shifting increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB..

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: Beaumont Home Medical Equipment recommends that CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

CMS' process to determine the number of suppliers to meet projected demand in an MSA, along with its defined methodology to estimate supplier capacity, appears to heavily favor the large, high volume regional suppliers, rather than the smaller, independent DMEPOS providers.

CMS' assertion that the NPRM provides an "equal" opportunity for small suppliers to participate is questionable, and there appears to be no guarantee that any of the winning bidders might be a small business, or even a network of small business providers.

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be better, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

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1200 Stephenson Hwy Troy MI 48083
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CMS should explain and clarify what specific measures will be used to decide and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS: Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?

How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?

How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

The NPRM clearly states that providers must meet "quality standards," yet the proposed "final" version of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provide clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

Ultimately, in the interest of establishing and providing some type of a baseline "provider standard," only accredited providers should be eligible to submit and be awarded "winning bids". CMS should not proceed with competitive bidding until it is certain that this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

Accreditation is and should be required for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

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It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule. The quality standards will ultimately affect the overall cost of servicing beneficiaries and are an integral part of the bid process. Therefore, CMS should consider further extending the NPRM comment period and any subsequent implementation plan(s), at least until those "definitive" quality standards are available and have completed the actual rule making process.

It is unrealistic to classify this process as a competitive bid when bidders are ultimately being encouraged, and essentially being forced to bid below a pre-determined price level. The result of this rule could result in bid awards that are established at unrealistic and unsustainable pricing levels. To maintain the integrity of the bidding process, CMS should have some way to objectively evaluate bids for statistical validity, sustainability and overall economic reasonableness. A mechanism for unreasonable bids needs to be incorporated in the final rule to weed out and eliminate purely "lowball" bids.

The prohibition on entities' ability to change ownership during specific periods of the bid award seems overly intrusive and an infringement on an entity's basic business rights.

FUNDAMENTAL ISSUES: The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum.

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William Beaumont Hospital

REBATE COMMENTS/ISSUES:

The NPRM mentions a rebate option that contracted providers may choose to underbid and utilize based upon the idea of increasing patient volume...We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise, and potentially fraud-encouraging concept that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. Rebates could and would potentially encourage an increase in over utilization and could result in beneficiaries placing pressure on their healthcare providers to order unnecessary products and services. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities, could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home are not only dangerous from a patient safety perspective, but also extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids. In the demonstration projects, some items were bid higher than the current Medicare allowable at that time. Mandating that all "winning" bids below the current Medicare level is ultimately short-sighted and unrealistic in that it effectively could negate reasonable and sustainable pricing levels which are based upon actual activity-based operational costs.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

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The two initial Competitive Acquisition demonstration projects in TX and FL ultimately neglected to look at the overall impact and costs that NCB will place on other areas of the healthcare continuum.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

The NPRM in effect will result in an unfunded federal mandate for other associated members of the healthcare continuum as they seek to move and transition patients to the most clinically appropriate and cost-effective setting of care. To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

This concludes our comments. We value our partnership with CMS in our common mission to provide quality health care services and products for Medicare beneficiaries.

Respectfully submitted,

Michael G. Bartz
Director - William Beaumont Hospital – Beaumont Home Medical Equipment

Submitter : **Dr. Ronald Etskovitz** **Date: 06/27/2006**

Organization : **New England Podiatry Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies, the Centers for Medicare & Medicaid Services used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).
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

Sincerely

Ronald B Etskovitz, DPM

Submitter : Dr. Allen Marangoni **Date:** 06/27/2006

Organization : Wheeling Jesuit University

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

The importance of quality product can not be ignored. A cost cutting provider is likely to give the lowest quality product and after sale services. The result of this for physical therapy is likely to be more falls, and skin break down, fractures and even death in a population that is already at risk. Removing day to day competition by placing non-providers out of the loop has never been a good way to get the best outcome and it is unlikely that this will be the first sucess story. I strongly discourage the direction that will remove daily competition and quality services from providers.

Allen Marangoni, PT, EdD, MMSc
Wheeling Jesuit University
Wheeling, WV
amaran@wju.edu

Submitter : **Dr. John Steinberg** **Date: 06/27/2006**

Organization : **Dr. John Steinberg**

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,

John S. Steinberg, DPM
Assistant Professor, Georgetown University
Washington DC

Submitter : **Dr. Albert Musella** **Date: 06/27/2006**

Organization : **Dr. Albert Musella**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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).

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.

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. There is no acceptable reason to treat a podiatric physician any differently than any other physician under this program.

Sincerely,

Albert Musella, DPM
Hewlett, NY

Submitter : **Dr. Angela Fraifogl** **Date: 06/27/2006**

Organization : **Dr. Angela Fraifogl**

Category : **Physician**

Issue Areas/Comments

GENERAL

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June 27, 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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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,

Angela Fraifogl, DPM

Submitter : **Mr. Ernest Smith** **Date: 06/27/2006**

Organization : **The Medicine Shoppe**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

We do Diabetes education and training at our pharmacy and have for quite a few years, even before it was popular to do. This education is crucial to the health and well-being of my patients. We know that we have reduced many patients needs for insulin and oral medications by being there for them in their times of need. By the use of testing supplies and diet and exercise, we have patients that are off all medication, saving everyone money and improving their general health and longevity. If we are not included in the delivery system of diabetic supplies, some of these patients will not get the type of help they need to continue their control of their diabetes.

I respectfully request that diabetes testing supplies be deemed exempt from the Competative DME Bidding process.

We also have DME equipment and realize that we can't compete with the big guys if our profit margins are cut, so even though I will try, I see little hope of retaining that business as far as medicare is concerned. There are a lot of places that do DME and do it well. The diabetes education, where we impact the future lives, is not done very well in most places. Please do not take this away from many local independent pharmacies that treat their patients as we do.

Please exempt diabetes testing supplies from the Competative DME Bidding process. Tkank You. Ernest Smith

Submitter : **Dr. Robert Frimmel** **Date: 06/27/2006**

Organization : **Dr. Robert Frimmel**

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 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 Frimmel,DPM

Submitter : **Dr. Stephanie Stewart** **Date: 06/27/2006**

Organization : **Dr. Stephanie Stewart**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Stephanie J. Stewart, D.P.M., A.A.P.W.C.A.
4801 Swift Road, Suite F
Sarasota, FL 34231

June 26, 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 urge the CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. 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.

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 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.

In my practice, I use a variety of DMEPOS items. As an example, when a patient presents complaining of foot pain and swelling following and 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 of the injured extremity, a fall might occur, which could result in other additional injuries.

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. It is important that I am able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,
Stephanie J. Stewart, D.P.M., A.A.P.W.C.A.

Submitter : **Dr. Thomas Morris** **Date: 06/27/2006**

Organization : **Fayette Podiatry Associates, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

Mark B. McClellan, Md, PHD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P

Dear Dr. McClellan:

It has come to may attention through the American Podiatric Medical Association that we may not be able to as physicians dispense durable medical equipment and supplies out of the office.

As you may or may not know may of our patients are elderly and are unable to travel to different locations, let alone to see their physician.

If we were not allowed to dispense out of the office this would be a great hardship for most of our elderly patients.

Please reconsider substituting the 1861 (R) physician definition for the restrictive 1861 (R)(1) definition.

This will allow the podiatric physicians such as myself to supply DMEPOS items to our elderly patients.

Sincerely,

Thomas K. Morris, D.P.M.

Submitter : Cheryl Meyer **Date:** 06/27/2006

Organization : ASHT

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-519-Attach-1.TXT

#519

HEALTHSOUTH HEALTHSOUTH 2 HEALTHSOUTH Corporati
on Cheryl Me

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. Phileo McAlexander** **Date: 06/27/2006**

Organization : **Group Health Cooperative**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

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 Phileo McAlexander, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I have specialized in the treatment of hands and upper extremities for 15 years. I am currently working Group Health Cooperative, 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.

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.
Phileo McAlexander, Occupational Therapist (OTR/L)

Submitter : **Dr. William Sutton** **Date: 06/27/2006**

Organization : **Dr. William Sutton**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

William C. Sutton, D.P.M., A.A.P.W.C.A.
4801 Swift Road, Suite F
Sarasota, FL 34231

June 26, 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 urge the CMS to modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. It is important that I am 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.

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.

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,

William C. Sutton, D.P.M., A.A.P.W.C.A.

Submitter : **Dr. Jaime Torres** **Date: 06/27/2006**

Organization : **Dr. Jaime Torres**

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 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,

Jaime r. Torres, DPM
212-777-6673

Submitter : Mr. MICHAEL MARNHOUT **Date:** 06/27/2006

Organization : BLUEGRASS OXYGEN INC.

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Why has CMS not released the ten MSAs for competitive bidding as of yet? If a provider has an office in Cincinnati, Ohio, and it is chosen as one of the ten MSA locations, how can a comprehensive business plan be formed to submit a realistic bid in such a short period of time?

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

It appears that CMS is going to include information from bidders in calculating the single payment amount (the winning bid amount) from unqualified bidders. How will CMS determine the financial capability of bidders to meet the financial and quality standards so that a "low ball bid" will not taint the calculation of the final amount? When will these standards be published?

GENERAL

GENERAL

Being in the home oxygen business for 26 years, I can assure CMS that we as providers are not the problem, but the cure for home oxygen usage. Too many questions remain unanswered and unaddressed to jump in and create such turmoil and havoc for our over 1 million Medicare beneficiaries who are on this life sustaining drug. Over 15 million people in the U.S. currently have COPD, these numbers will do nothing but rapidly increase in the future. A perfect example of such turmoil would be a patient owning their own equipment in a desolate, isoloated geographic location and this equipment malfunctioning with noone to respond to their needs. Let alone the lack of care and infection control in regards to the maintenaince of such equipment that could create a mild staph infection which would force hospitalization at a cost of $4,000 a day versus a total expenditure of $7.62 a day for home oxygen therapy. Doesn't this seem a little ridiculous? As a provider we want to be part of the solution to medicare's woes. I guarantee you that the current legislation will create nothing but additional cost for the Medicare system. Please reevaluate. Mike Marnhout, President of Bluegrass Oxygen

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

As recently stated by the Federal Register, 90% of all durable medical equipment companies are termed small businesses. What is CMS's plan to allow small providers the opportunity to compete in the competitive bidding versus corporate conglomerates? Why will the federal government not allow small providers the choice of accepting the lowest bid if they choose to do so? Is the federal government not concerned that this exclusion of small providers creates an anti-trust situation? Isn't this obviously putting the small business provider at an extreme disadvantage in this competitive bidding situation?

Regulatory Impact Analysis

Regulatory Impact Analysis

Has the federal government truly analyzed the expense of one day's admission into a hospital by an oxygen patient at approximately $4,000 versus the expense of approximately $2700 for a company to care and maintain their home oxygen needs? I can assure you that after being in this business for 26 years, a large portion of these patients are not only unable but not willing to care and maintain their equipment on a regular basis so that infection does not become an issue. What will a patient living in the mountains in Eastern Kentucky do when they are snowed in, on oxygen 24 hours a day, and cannot get a company to respond to their needs because they own their own equipment. If this were your mother or father, how would you feel about the federal governmetn placing this undue burden and fear upon your parents and family?

Regulatory Impact Analysis

The issue is competetive bidding, which, in regards to oxygen, will drive the medicare expense up due to the patient's inability to maintain and care for their own equipment.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Your current law reads and introduces the concept of "consumer rebates;" isn't this an inducement for medicary beneficiaries which may result in inappropriate medicare expenditures? Doesn't this idea contradict decades of health law that make it illegal for suppliers from offering inducements to beneficiaries to gain their business?

Terms of Contracts

Terms of Contracts

How will CMS determine what quality standards are used for the winning bidders and when will these be released for publication?

Submitter : **Mrs. Debra Zahnow** **Date: 06/27/2006**

Organization : **St. Joseph medical center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-524-Attach-1.TXT

Sample LetterRe: Proposed Rule for Competitive Acquisition of Certain DMEPOSCMS-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 Debra Zahnow, and I am an occupational therapist

specializing in the treatment of upper extremity disorders. I have specialized in the treatment of hands and upper extremities for two

years. I am currently working in an outpatient clinic at 3 local hospitals, 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,Debra Zahnow, OTR/LHand therapist

Submitter : **Mr. Raymond Dolan** **Date: 06/27/2006**

Organization : **Technical Gas Products Inc**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Key Concerns about Competitive Bidding
Notice of Proposed Rulemaking

This is a brief summary of some of the top concerns about the Notice of Proposed Rulemaking regarding competitive bidding published in the Federal Register May 1, 2006.

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

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

Make Competitive Bidding Competitive, and Sustainable
CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either.

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

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

Submitter : **Mr. Raymond Dolan** **Date: 06/27/2006**

Organization : **Individual**

Category : **Individual**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

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Notice of Proposed Rulemaking

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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. (AA Homecare)

Submitter : **Dr. Lincoln Wallace**

Organization : **Trimark Physicians Group**

Category : **Physician**

Date: **06/27/2006**

Issue Areas/Comments

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

June 27, 2006

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

Dear Dr. McClellan:

In my capacity as Board Chair of Trimark Physicians Group, 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).

Trimark s Podiatric physicians prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. As our patients, these beneficiaries rely on our Podiatric physicians for best medical judgment and clinical skills in treating them. The Trimark Podiatrists are required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and are subject to the same Stark requirements that apply to MD and DO physician suppliers. It is our belief that 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 their patients only and the right to execute a physician authorization.

The Trimark Podiatrists use a variety of DMEPOS items in their Practice. As an example, when a patient presents complaining of foot pain and swelling following an injury, a diagnosis of multiple fractures of the metatarsals may be made and a subsequent determination that a walking boot is necessary for immobilization of the injured foot with associated edema. If our Podiatrists are no longer able to 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.

We urge CMS to modify the physician definition used in the proposed regulation from 1861(r) (1) to 1861(r) (3) before finalizing the regulations for the competitive acquisition program. It is our strong desire that our Podiatrists be able to continue to supply DMEPOS items for their patients, and believe that if they are required to instead bid to supply the entire Metropolitan Statistical Area (MSA), their patients will be negatively impacted.

Sincerely,

Lincoln Wallace, MD, Chairman
Trimark Board of Directors

Submitter : **Dr. Annik Adamson** **Date: 06/27/2006**

Organization : **A.A. Podiatry, P.L.L.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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 thesame 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.

Submitter : **Dr. Kennon Martin** **Date: 06/27/2006**

Organization : **Paradise Podiatry Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 27, 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).

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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,

Kennon J. Martin, D.P.M.

Submitter : **Dr. Thomas Rappette** **Date: 06/27/2006**

Organization : **Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-530-Attach-1.RTF

CMS-1270-P-530-Attach-2.RTF

#530

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 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).

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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,

Thomas Rappette, DPM
1802 North Division

Morris, IL 60450
1-815-942-9050

#530

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:

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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,

Thomas Rappette, DPM
1802 North Division

Morris, IL 60450
1-815-942-9050

Submitter : **Mrs. Martha Feldman** **Date: 06/27/2006**

Organization : **MediDyne Corporation**

Category : **Other Health Care Provider**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

see attachment

CMS-1270-P-531-Attach-1.DOC

#531

DATE: June 27, 2006

TO: Department of Health and Human Services

FROM: Martha Feldman, MediDyne Corporation

SUBJECT: **CMS-1270-P, Criteria for Item Selection**

ENTERAL NUTRITION SHOULD BE EXCLUDED FROM ITEM SELECTION

Competitive Bidding for Enteral Nutrition has not been tested.

Enteral formula, equipment and supplies were included in the first round of bidding in Polk County, Florida in October, 1999, but were not included in the second round of bidding in Polk County, Florida in 2001. **"Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes."**[1] In the second site where bidding was conducted (3 counties in the San Antonio, Texas MSA) enteral nutrition was also not included in the bidding.

By excluding enteral nutrition from the second Florida bidding and the Texas bidding, the Competitive Bidding Demonstration failed to test or demonstrate the feasibility and program impacts of using competitive bidding to set prices for enteral nutrition. Further, the Competitive Bidding Demonstration, as implemented, did not demonstrate savings relating to enteral nutrition or that beneficiaries would have sufficient access and receive quality products.

It is not appropriate to include enteral formula, equipment and/or supplies in the Items selected for Competitive Bidding because Competitive Bidding for enteral nutrition has not been tested.

If necessary to meet the requirements of the Act, enteral nutrition in private homes could be included in Item Selection

Even though all enteral nutrition was dropped from the Competitive Bidding Demonstration after the first round of bidding, the Act may require that enteral nutrition be included in competitive bidding. If so, enteral nutrition in private homes (only) may be appropriate for Item Selection.

Enteral Nutrition in nursing facilities is not appropriate for Item Selection.

Enteral nutrition was dropped from the product categories tested because it is not overwhelmingly used in private homes.[2] It is covered by Medicare "for a patient who has

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[1, 2] Federal Register / Vol. 71, No. 83 / Monday, May 1, 2006 / Proposed Rules, page 25657.

(a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet"[3]. Qualifying conditions can include obstructions due to head and neck cancer or reconstructive surgery, inability to swallow following a stroke, and many other severe impairments.

As discovered during the initial Polk County, Florida bidding, patients with these conditions are not necessarily cared for in private homes. Some of those who qualify for Medicare Part B coverage are patients in nursing facilities. These patients are aged, congenitally impaired or severely injured and most have many other medical problems that complicate their treatment including multiple organ failures, diabetes, respiratory distress, renal insufficiency, skin breakdown, congestive heart failure, cancer, infections, circulatory issues, etc.

Enteral nutrition is utilized in nursing facilities a component in the treatment of the patients for whom it is prescribed. Enteral nutrition is prescribed by the physician with input from Nursing, Nutrition, Wound Care and other disciplines. Each medical condition a patient has is a factor in the selection of the enteral formula and method and rate of administration. Multiple diagnoses complicate the prescription, so nursing home populations require customized selection and adjustment of their nutrition components.

Changes in a patient's medical condition and response to the enteral prescription require changes in the enteral prescription as frequently as on a daily basis. Because of this, enteral nutrition in nursing facilities does not conform to the usual DME delivery system. It is not just ordered and delivered "off the shelf", but requires more physician, nursing facility staff and supplier time and more frequent deliveries, much like parenteral nutrition.

It follows that, for the same reasons that Parenteral nutrition is not included in Competitive Bidding, enteral nutrition for patients in nursing facilities should not be considered for Item Selection. The requirements for providing enteral nutrition to patients in nursing facilities more closely resemble those for providing parenteral nutrition than the requirements for providing DME.

MediDyne Corp. exclusively supplies patients in nursing facilities in order to focus on the unique requirements of the population. 100% of our business is Medicare Part B and most of our patients receive enteral nutrition and are dual eligibles.

The economics of providing enteral nutrition to patients in nursing homes differ from those of providing enteral nutrition in private homes. A significant proportion of long term care patients in nursing homes are funded by Medicaid programs that do not pay some or all of the 20% coinsurance under Part B. Suppliers who service nursing homes must write off the balance not paid by Medicaid, which can be up to the entire 20%. For example, New York Medicaid pays approximately 20% of the 20%

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[3] Medicare Supplier Manual, DMERC A, LMRP for Enteral Nutrition, Coverage and Payment Rules

coinsurance, so the amount that must be written off is approximately 16% of the Medicare allowable.

Because we serve the enteral nutrition needs of nursing home patients, we are disadvantaged in the competitive bidding process by the substantial write offs required for dual eligibles, who represent more than 80% of our patients. The proposed regulations do not address small, specialty suppliers such as ourselves. They attempt to minimize the impact of competitive bidding by assuming that Medicare is not a large portion of each supplier's business. This assumption is incorrect.

Enteral nutrition was dropped from the Florida Competitive Bidding Demonstration and was not included in the Texas Competitive Bidding Demonstrations because it was not overwhelmingly provided in private homes. This indicates that enteral nutrition is not appropriate for competitive bidding when it is **not** provided in a private home. For this reason and all of those detailed above, enteral nutrition in nursing facilities should be excluded from Item Selection for Competitive Bidding.

Submitter : **Mrs. Judy Gordon** **Date: 06/27/2006**

Organization : **Mrs. Judy Gordon**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Committee Members of the Program Advisory & Oversight Committee:

CMS -1270-P

NOT in support of competitive bidding for prefabricated orthoses

Recently, I have been treated at a facility providing occupational therapy services. The therapists have shared with me that there are pending guidelines and standards that will impact the therapy services they provide to their patients in the future. They have important concerns and I want to support them.

From my understanding, the Secretary of Health and Human Services is responsible for establishing a competitive bidding system for certain durable medical equipment, prosthetics and orthotics (DMEPOS). I understand CMS plans to implement competitive bidding for medical equipment provided to patients. My therapist believes that therapists could not compete for the opportunity to issue pre-made splints. This therapy service would be provided through some type of medical supplier. Because of this, I would need to go to another facility to receive the splints I would need. Too, it is not likely a therapist would be the one issuing the splint to me. I have three concerns. My first concern relates to creating a system where all providers of medical services do not have a fair opportunity to remain a provider of specific medical services. It surprises me, that at a minimum, the government would not create unique opportunities for providers that would be at an extreme disadvantage for this competitive bidding. Secondly, I would need to leave my therapist and go to another facility to receive my splint. This would be a huge inconvenience to drive to another location especially since I know my therapist is fully capable of providing this service. And third, it would disrupt the continuity of care between the physician, therapist and me. The new facility would not know me and my special needs. I cannot believe this would save money. By going to another provider, I have to believe this would ultimately cost more money. It seems extremely important that you consider exempting therapists from the competitive bidding system.

I am fully confident therapists have the knowledge and technical skills to evaluate, fabricate and dispense orthoses to patients. My physician would not refer me to a therapist if therapists were not highly qualified to provide this service. Today, occupational therapists and physical therapists are recognized as qualified providers for Medicare and Medicaid to evaluate patients, design, fabricate, and issue the appropriate splint. Both occupational therapists and physical therapists have at a minimum a bachelor or master s degree.

I agree with my physician and therapist that all the ramifications with competitive bidding have not been fully considered. Please know from my personal experience that occupational therapists and physical therapists are extremely important healthcare providers and providers of orthotics, and they have been instrumental in my care and the improvement in my medical condition.

Please do not change what therapy services are provided by occupational and physical therapists today! These therapists are fully qualified and capable of providing these vital services! They should not be subjected to the competitive bidding process.

Sincerely,

Judy Gordon

Submitter : **Margaret Coon** **Date: 06/27/2006**

Organization : **The Medicine Shoppe**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacist, I respectfully ask that diabetes testing supplies be deemed exempt from the Competitive DME Bidding process. It is imperative that patients retain their current level of care received at the retail pharmacy level. If competitive bidding becomes a reality for diabetes testing supplies it will have a negative impact of the patient's health and well-being. Diabetes education is crucial to the health and well-being of our patients.
Retail pharmacists offer critical clinical services to patients by offering education on diabetes care, medication/side effects/possible drug interactions and training on blood glucose meters and testing procedures. Retail pharmacists have the ability to impact patient adherence in all aspects of diabetes care and provide a local presence for assistance with complications of therapy. Retail pharmacists work with patient's physicians to facilitate the best possible diabetes care.

Submitter : **Mrs. Danica Loftin** **Date: 06/27/2006**

Organization : **Mrs. Danica Loftin**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-534-Attach-1.DOC

CMS-1270-P-534-Attach-2.DOC

#534

Comments on Competitive Bidding

RE: File Code CMS-1270-P

Rushing Implementation

Establish and announce who the MSA's are going to be for 2007 and beyond, in advance of competitive bidding implementation, so providers in that area can ban together or create networks to be successful in the bid process.

Establish and announce what products are going to be apart of competitive bidding to allow providers adequate time to establish what costs are involved in the servicing of a product prior to the bid process.

Accreditation Standards and Quality Standards in Place before Starting

Establish Quality Standards for Suppliers and have them in place before the competitive bidding process is rolled out. This will allow providers the ability to adequately evaluate what their bids can realistically be based on the new quality standards.

Establish who the Accreditation providers are going to be to allow providers the chance to get properly accredited. Need to grandfather all existing accredited companies and allow them time to meet the new requirements when they are up for re-accreditation.

Impact on Small Business

Don't restrict a provider's rights to sell their business just because they won the bid. Many things can happen to a provider, (ex: death, bankruptcy, business closure, etc) so CMS should have guidelines in place to adequately replace the provider in that MSA.

Most providers are independently owned small businesses. This group of providers will probably be put out of business as they cannot sustain the loss the Medicare revenue to their company.

Comments on Competitive Bidding cont.

RE: File Code CMS-1270-P

Patient Choice Eliminated

Patient choice will be eliminated. Beneficiaries will see a change in providers and the service levels they were accustomed to through their local provider. Many beneficiaries will be serviced by providers who only come to town one day a week and do no provide the after hour service they currently have. There will be an increase in patients seeking emergency room services because the out of town winning provider will/can not get to them in a timely manner.

The financial burden that has been placed on DMEPOS providers through a CPI freeze for the past seven years and then a decrease of up to 20% in January 2005 has placed a lot of providers at risk of staying in business. Pricing is based on 1986/1987 reasonable charges and everyone knows that today's prices for equipment and overhead are far higher than twenty years ago. The rush to competitive bidding without consideration to the financial burdens placed on providers by accreditation, capping of equipment and purchase of oxygen systems will put many small providers out of business. This is a group of small business owners who employee real people whose lives will be affected when the provider closes due to financial hardship. This will further decrease access to providers by beneficiaries in many locales throughout the nation.

True Cost of Competitive Bidding and Demon station Project Cost Analysis

The added levels of administration that are being added to review and maintain the competitive bidding process are not cost savings factors that were considered when the demonstration projects were being conducted. The savings being projected to Congress are not realistic numbers.

Make Rules Right First Time to Keep Competitive Bidding Sustainable

CMS has had to backdate and revise several times all policies it has put into place over the past 18 months. This places a burden on the provider to keep up with the guidelines by going back in time and then having to keep up with all the revisions that occur. CMS needs to decide on a policy-GET IT RIGHT THE FIRST TIME and go forward with a future date. Seems like CMS is generating paper to create, maintain or justify their jobs. (ex: backdate capped rental to 1/1/06 eff 5/30/06). Providers are not in compliance with existing supplier standards and beneficiaries were told one thing at the time of delivery of the equipment and now the provider has to spend extra money and time to explain that CMS changed the rule and backdated it six months.

#534

Comments on Competitive Bidding

RE: File Code CMS-1270-P

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Comments on Competitive Bidding cont.

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Submitter : **Mrs. Kristine Milliron** **Date: 06/27/2006**

Organization : **Orthopedic Specialists of Alabama**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am an Occupational therapist and Certified Hand Therapist that has been in practice for over 13 years. In our area of practice custom splints and prefabricated splints are essential to our management of a patients condition. We thoroughly assess the necessity and appropriate fit for each patient. If we have to send the patient to a different facility to receive such services, it would delay patient care significantly and probably cause more difficulties in rehabbing a patient due to the constant and frequent changes that are occurring. Outside suppliers would also not be able to know if there are contraindications for certain diagnosis and would not be able to adjust at a frequent rate. By not being able to perform these services within the scope of our treatment would significantly increase the cost for quality care and increase the time frame for return to independence. For example, we recently had to custom fabricate a splint due to severe deformities in her hand and fingers. She had already received one from a DME company and it was off the shelf. It did not fit properly and caused more deformities, increased pain and redness due to irritation. The patient then had to pay our of pocket due to insurance already paying DME company for a brace that was improperly fitted. Please feel free to contact me if I can be of any further assistance in determining who should or should not be allowed to provide splints.

Sincerely,

Kristine Milliron OTR/L, CHT

Submitter : **Date: 06/27/2006**

Organization :

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 am a podiatric physician from Asheville, NC and have been in practice since 1993. I am board certified by the American Board of Podiatric Surgery and am on staff at all our local hospitals. I am very concerned about the DMEPOS changes being proposed since the care I provide my patients will be compromised.

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,

Dr. Daniel Waldman

Submitter : Danica Loftin

Date: 06/27/2006

Organization : Criticare Home Health Service, Inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-537-Attach-1.DOC

#537.

Comments on Competitive Bidding

RE: File Code CMS-1270-P

Rushing Implementation

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Impact on Small Business

Don't restrict a provider's rights to sell their business just because they won the bid. Many things can happen to a provider, (ex: death, bankruptcy, business closure, etc) so CMS should have guidelines in place to adequately replace the provider in that MSA.

Most providers are independently owned small businesses. This group of providers will probably be put out of business as they cannot sustain the loss the Medicare revenue to their company.

Comments on Competitive Bidding cont.

RE: File Code CMS-1270-P

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The financial burden that has been placed on DMEPOS providers through a CPI freeze for the past seven years and then a decrease of up to 20% in January 2005 has placed a lot of providers at risk of staying in business. Pricing is based on 1986/1987 reasonable charges and everyone knows that today's prices for equipment and overhead are far higher than twenty years ago. The rush to competitive bidding without consideration to the financial burdens placed on providers by accreditation, capping of equipment and purchase of oxygen systems will put many small providers out of business. This is a group of small business owners who employee real people whose lives will be affected when the provider closes due to financial hardship. This will further decrease access to providers by beneficiaries in many locales throughout the nation.

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The added levels of administration that are being added to review and maintain the competitive bidding process are not cost savings factors that were considered when the demonstration projects were being conducted. The savings being projected to Congress are not realistic numbers.

Make Rules Right First Time to Keep Competitive Bidding Sustainable

CMS has had to backdate and revise several times all policies it has put into place over the past 18 months. This places a burden on the provider to keep up with the guidelines by going back in time and then having to keep up with all the revisions that occur. CMS needs to decide on a policy-GET IT RIGHT THE FIRST TIME and go forward with a future date. Seems like CMS is generating paper to create, maintain or justify their jobs. (ex: backdate capped rental to 1/1/06 eff 5/30/06). Providers are not in compliance with existing supplier standards and beneficiaries were told one thing at the time of delivery of the equipment and now the provider has to spend extra money and time to explain that CMS changed the rule and backdated it six months.

Submitter : **Ms. Debby Schwartz** **Date: 06/27/2006**

Organization : **Hand Surgery and Rehabilitation Center**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

As a Certified Hand Therapist and an Occupational Therapist, I see a specific need for supplying my patients directly with custom made and prefabricated splints. Often, I see my patients as new problems unfold and therefore I can offer them immediate help and support. I am extremely qualified in the care of the upper extremity and feel my patients will suffer by not being able to be fitted by my professional opinion for splints and orthoses. I feel the competitive bidding will directly impact negatively on patient care.

Submitter : **Elmo Baldassari** **Date: 06/27/2006**

Organization : **Elmo Baldassari**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 27, 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 to bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Dr. Elmo W. Baldassari, DPM
1360 Wyoming Avenue
Scranton, PA 18509

Submitter : Scott Harnden **Date:** 06/27/2006

Organization : Intermountain Orthopaedics

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 and frequently fit patients for pre-fabricated orthoses. As a therapist fitting orthoses to patients, I consider the disease process, anatomy, and mechanics of the patient. A supplier does not have the same educational background to consider these things compared to a physical or occupational therapist. Already, I have patients who sometimes get these supplies from an non-therapy supplier. Commonly, they receive the wrong type of hand/wrist splint, wrong size, or incorrect fit. I am wondering what I will need to do when this happens with the new process. Will I send the patient back so that Medicare will pay for a second one? Do I modify the splint and take a chance of being liable since it is not the correct splint in the first place? Unfortunately, these situations will increase costs to Medicare in my city and they will put the therapists in an ethical dilemna. In my opinion, in the end, the patients will suffer and medical costs will increase. Thank you for your time.

Submitter : **Mr. Mike Ohnemus** **Date: 06/27/2006**

Organization : **G R X Corporation**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacy, I respectfully request that diabetes testing supplies be deemed exempt from the Competitive DME Bidding process.

Submitter : **Ms. Leslie Youngblood** **Date: 06/27/2006**

Organization : **OSA**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am an Occupational therapist that works in an out patient hand facility. We work for several hand and general surgeons providing patients with DME and treatment related to the individuals needs. I am writing today with concerns of pt.'s being required to purchase DME's from a seperate location. In my first statement I stated individual needs and patients are very individualized. It is extremely difficult to categorize a person and slap a brace on them. Most individuals need some form of customization to be performed to the brace to meet the MD's request and our expertise meets the MD needs and we can adjust to fit each individuals pt.'s requirements. When a pt. has to travel to another facility to obtain a DME, we often find they "skip" the visit 2ndary to increased cost in travel expenses and/or difficulty in travel arrangement. THen the pt. might need modification to the DME product and having to make an additional trip to this location/facility again is timely and costly. Our pt.'s and MD's trust our "therapist" understanding of anatomical requirements and modifications to internal anatomical parts can make an OTC brace not fit properly and/or cause additional deficits to the pt. in the form of Decubitus Ulcers (if one time visit with no follow up) 2ndary to rubbing of a brace can continue to cause skin break down. Pt.'s needs are more specialized and having a perfect fit is essential to the recovery of a patient. Placing someone in a generic brace can cause more harm than good.

Reality is in the eyes of the patient. Forcing them to go here and there for individual care rather than sending them to their therapists, adds stress, increases the cost for the patient in the form of time and money, and potentially could cause them additional medical problems if they do not immediately go to the DME provider or the DME provider doesn't have a complete understanding of individual requirements of each patient. Slapping a brace on a person is just not part of a therapists role. We educate the patient to avoid hazards and educate them in methods of eliminating and modifying their lifestyles to avoid injuries and or diseases from reoccurring, thus in the long run, saving everyone money.

Please do not hesitate to contact me if you have any additional questions/concerns.

Leslie Youngblood, OTR/L, CSFA
205.838.3701

Submitter : **Dr. Richard Dellinger** **Date: 06/27/2006**

Organization : **Dr. Richard Dellinger**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-543-Attach-1.DOC

#543

Foot & Ankle Associates, PLLC

Calvin P. Britton III, DPM
Fellow, American College of Foot & Ankle Orthopedics & Medicine
Fellow, American Professional Wound Care Association

R. Alex Dellinger, DPM
Fellow, American College of Foot & Ankle Surgeons
CWS, Certified Wound Specialist

June 26, 2006

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

Dear Dr. McClellan:

I have recently read that CMS is proposing a rule establishing a competitive bidding process for certain DME items. I understand physicians are exempt, however podiatrists do not meet that definition of physician in this rule.

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 these items. (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. Many are diabetic, and suffer from amputations some times. It is critical they receive prompt DME items in some instances.

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. I see patients with metatarsal fractures, requiring a walking splint. I see diabetics with ulcerations that require certain braces. Their health will be at further risk if they have to go to a distant supplier of these DME items. 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,

R. Alex Dellinger, DPM
Foot & Ankle Associates of Central Arkansas

10018 W. Markham
Little Rock, Arkansas 72205
Ph: 501 - 534 - 8888 Fax: 501 - 534 - 8891

Submitter : **Dr. Bradly Shollenberger** **Date: 06/27/2006**

Organization : **Dr. Bradly Shollenberger**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

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As I practicing podiatrist for over 20 years, I have had ample opportunity to see examples of the many flaws embodied in a competitive pricing system for items such as DME. This type of equipment is often prescribed for the treatment of fractures and other injuries. As the system stands now, I am able to diagnose the injury and immediately supply the splint, brace, crutches etc. to treat it. If the proposed system goes into effect, I will have to tell my patient 'You have a broken ankle. Now..hobble to the nearest authorized supplier so you can begin your treatment. Oh...and try not to disrupt the fracture further in the journey.'
Time and time again, I have been forced by various managed care organizations to write an Rx for a splint or immobilizer and send the patient on their way. Invariably, they present for followup with an incorrect, mis-sized or otherwise inappropriate device, dispensed by an individual who's main concern is what time he breaks for lunch and what time does the ball game start tonight. Large DME corporations will inevitably win the pricing war but they have no regard for patient care.
Please do not be the latest in a long line of insurance entiities to rend still more control of patient care out of the hands of the very individuals that should be providing that care.
Respectfully,
Dr. Bradly Shollenberger

Submitter : **Date: 06/27/2006**

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

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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 important 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,

Raymond A. Fritz, Jr., DPM, FACFAS, FACFAOM, FAPWCA, C.Ped