Submitter : Mr. Mark Jones

Date: 06/23/2006

Organization : Jones Medical Equipment, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The standards for exempting rural areas from competitive bidding need to be examined. In our rural area, there are only 2 suppliers. Anything that would just leave one would cause a monopoly. Anything that would cause an out of town supplier to have this area would severely diminish the quality of service.

Submitter : Mr. Danny Hagan

Organization : Premier Home Care Inc.

Category : Health Care Provider/Association

Date: 06/23/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

There is no doubt in my mind the way it's written, if it goes into effect, it's to cause harm to senoirs. We need to take care of the patients, not deny them. Alot of patients, if they're not happy, they have the ability to go to another company, this will take that ability away. This government is always talking about helping the small business man, this bill will cripple him.

Normally we would all be for competition. But the way I interpret this is they're driving the caring, small business out of business.

Thank you,

Danny Hagan

Submitter : Mr. Brad Lipham

Organization : Durable Medical Equipment, Inc.

Date: 06/23/2006

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Too many things that pertain to competitive bidding and accreditation,which is tied to competitive bidding, have not been decided. Therefore the current time table is unreasonable.
The financial requirements on small business are unreasonable from a business standpoint.
The small business owner will be forced out of business with all the constraints this imposes(he is the only local provider in many areas).
The rebate system that is proposed is ridiculous
There is no right of administrative or judicial review for providers.
Beneficiaries will be subjected to inferior products and services with this plan.(quality standards must be in place first).
This is just poor legislation.

Submitter : **Dr. Fred Chantiles** **Date: 06/23/2006**

Organization : **Beech Tree Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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,

F.Don Chantiles DPM

Submitter : **Dr. David Miller**

Organization : **Beech Tree Podiatry**

Category : **Physician**

Date: **06/23/2006**

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,

David E. Miller DPM

Submitter : **Dr. Janet Simon** **Date: 06/23/2006**

Organization : **Podiatry Associates of New Mexico, LTD.**

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 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. In fact, it may be more crucial in many of my high risk diabetic patients who not infrequently present with undiagnosed fractures to my office.

Recently a long-term patient of mine presented for her regularly scheduled diabetic foot care appointment and related that she was noticing swelling in her foot. I diagnosed multiple metatarsal fractures and proceeded to immobilize her appropriately in a foot/ankle walker orthosis to limit weightbearing on the injured extremity. If I was not a DMEPOS supplier who successfully bid to provide these supplies this elderly lady would have had to go to another location creating increased stress for her and her family. For many of my patients obtaining these prescribed supplies in a timely manner would not occur increasing the risk of further 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,
Janet Simon, DPM, C.Ped.
Podiatry Associates of New Mexico
8300 Carmel NE #501
Albuquerque, NM 87122
Phone 505-797-1001
Fax 505-828-1571
E-mail: Janetpod@aol.com

Submitter : **Dr. Christopher Weaver** **Date: 06/23/2006**

Organization : **Beech Tree Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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,

Christopher Weaver, DPM

Submitter : Mr. Jeff Knight **Date:** 06/23/2006

Organization : Premier Home Care, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I run a DME company with 7 locations and the competitive bidding project has four major problems.

1. It will eliminate many dealers. I realize that that is the intent of this project, but what happens when you eliminate competition? You eliminate the need for service. You also reduce the beneficiary's choices. Much like a watered down form of managed care. Ultimately, the providers and the beneficiary's lose.
2. The movement for better technology and improved quality of life for the beneficiary will be eliminated. The winning bidders will be forced to use the basic, bare bone equipment for all of their Medicare patients. There will be no margin or motivation to provide anything more than what is mandated by the contract. Providers will become wholesalers of health products.
3. You destroy small business in this industry. Through starvation of the current small businesses and the elimination of any attractiveness for new businesses to startup in this industry, you will kill entrepreneuralship and hand homecare to the national companies who will create a monopoly and dictate to the patient and the goverment how homecare will be provided. (See Enron,MCI, Worldcom)
4. The rules are loosely written. This gives CMS and the politicians the ability to add, change, and delete as they see fit. There is no assurance to those providers that do win a bid that the rules will not change next year. This makes it impossible to budget, project or plan ways to run your business.

I am totally aware of the perils that face this country's healthcare system, namely the rising costs to Medicare. The Medicare system is in trouble with many problems on the horizon. Homecare, which represents less than 2% of the total Medicare budget, is the solution not the problem. Yet, our goverment thinks you should fix it from the bottom up instead of the top down. Homecare gets patients out of the hospitals and away from nursing homes. The places that eat up most of the Medicare and Medicaid funds. Our reimbursement is pennies in comparison to those facilities for similiar services (i.e. oxygen & ventilators).

The alternative to competive bidding would have been to do an informal bid of the top MSA in each state, calculate the average bid for each region, set those calculations as your new allowables for willing providers, mandate accreditation by one of the existing accreditation companies and lift the CPI freeze. This would have: Saved the Medicare system it's 10-15% savings it was looking for. Saved the Medicare system the cost of launching a full blown competitive bid project. Assured the continuance of competition, small business and quality service. Reduced the number of providers. And turned your focus to the bigger problems with Medicare spending(i.e Part D, medical facilities).

Regardless, I look forward to CMS' push to competitive bid all facets of the Medicare system and the fallout of telling its voting public that they are limited to minimal facilities, certain physicians, a couple of home health agencies and limited homecare companies.

Submitter : Mrs. Kathy Parris

Date: 06/23/2006

Organization : DSI Midwest Associates, LLC

Category : Individual

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

We understand that competitive bidding is being proposed to include services to nursing home residents. Specifically, enteral nutrition and support products present unique challenges that are not represented in the typical durable medical equipment delivery.

Many of the issues facing nursing facilities are:

" Physical limitation of the facility to adequately inventory the variety of supplies that are required to meet the changing needs of individual patients. Many facilities require weekly delivery due to the changing demographics of their patients.

" The interface between supplier and facility related to ongoing staff training, inventory control and patient compliance with physician orders.

" The frequent admission and discharge of patients between facility, hospital and other types of rehabilitation locations.

It is our opinion that competitive bidding will significantly reduce the quality of care that patients will receive. The frequency in which a patient s orders change with respect to product type, delivery method and calories per hour present unique problems that are not present with patients that are cared for in the home.

We plead our case and ask that Medicare reexamine the negative ramifications competitive bidding will have on the quality of patient care.

Submitter : Mr. Wayne Knewasser **Date:** 06/23/2006

Organization : Premier Home Care Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

Gap-filling

Gap-filling

Adequate representation from the manufacture and the technically qualifed supplier need to be considered when establishing current pricing. Guidelines need to be in place insuring the most current technology and product information are considered when establishing new pricing. The Gap Filling methodology proposed does not adequately address the accuracy needed for a fair pricing schedule.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

The proposed formation of a group of small suppliers banding together to form a new corporation allowing for coverage of a MSA is unrealistic. Expectations as to how this entity is to function within the guidelines of the competitive bid frame work are to idealistic to work. The success of any one individual is dependent on circumstances beyond their control. If this is your answer to include all suppliers in the bid process as directed by the MMA, it is not a well thought out plan as to the problems and consequences it will create. I oppose this type of joint venture.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Reasonable quality standards that are practical and realistic need to be in place prior to the inception of the competitive bidding program. Unreasonable demands for compliance on operational activities such as cash flow and product inventory levels are counter productive in producing a realistic competitive bid. Prudent business operations contradict several of the supplier standard requirements.

Submitter : Mr. Jerry Coverdale

Date: 06/23/2006

Organization : Broward Orthopaedic Specialist

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-311-Attach-1.DOC

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 Jerry Coverdale, and I am an occupational specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam
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,

Jerry J. Coverdale, OTR,CHT

Submitter : **Dr. Elliott Kramer** **Date: 06/23/2006**

Organization : **Dr. Elliott Kramer**

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.

Futhermore, if I am unable to meet all of my patients medical necessary needs as to DMEPOS , I will be unable have an completly intergrated podiatry practice to meet my patients.

Sincerely,

Elliott J. Kramer, DPM

Submitter : **Dr. Ira Deming** **Date: 06/23/2006**

Organization : **Ira M. Deming, D.P.M.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Ira M. Deming, D.P.M., F.A.C.F.A.S
8201 Sixteenth Street, suite 119
Silver Spring, MD 20910
301-589-5144

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.

I am currently chief of podiatric surgery at Suburban Hospital in Bethesda, Maryland and take emergency room call for that hospital. I see patients with foot and ankle soft tissue and osseous injuries including fractures and frequently utilize ankle splints as well as pneumatic cam walking cast braces for immobilization of these injured feet. If I diagnose a patient with a fracture of the foot or ankle, I may decide that it is medically necessary and appropriate to use one of these devices in order 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. In addition, I treat a large number of diabetic patients and have been active in wound care and limb salvage. The diabetic shoe bill has provided patients with the ability to be accurately fitted with appropriate shoe gear and is instrumental in reducing limb loss in these patients. If I am not a supplier in the new program, I will not be able to select and dispense appropriate shoe gear to this population. The reason I initially decided to participate as a supplier of diabetic shoe gear was that I had tired of seeing my diabetic patients wearing inappropriate and poor fitted shoes that had been supplied by so-called large and experienced DME suppliers. I even had 2 patients, who as a consequence of wearing poor fitting diabetic extra depth shoes that had been dispensed from a well known large area DME supplier, develop foot ulcerations that progressed to amputations. These were tragic and unfortunate occurrences that could have been avoided.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians. I would be more than happy to discuss this matter with you if you need further clarification.

Sincerely,

Ira Deming, D.P.M., F.A.C.F.A.S.

Submitter : **Kile Kinney** **Date: 06/23/2006**

Organization : **The Foot & Ankle Group,PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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:

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,
Kile W. Kinney, DPM

Submitter : **Dr. Louis MacDonald** **Date: 06/23/2006**

Organization : **Louis R. MAcDonald, DPM, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Louis R. MacDonald, D.P.M., P.C.
Diplomate, American Board of Podiatric Surgery
Diplomate, American Board of Podiatric Orthopedics and Primary Podiatric Medicine
225 Montauk Highway
Moriches, N.Y. 11955
[631] 878-3330

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).

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,

Louis R. MacDonald, DPM

Submitter : **Dr. Gary Kugler** **Date: 06/23/2006**

Organization : **Northern Virginia Podiatry Group, P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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:

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 (DPM) 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 a foot fracture, I may determine that fracture walker is necessary to stabilize fracture 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,

Gary Kugler, DPM

Submitter : **Kent Kronowski** **Date: 06/23/2006**

Organization : **The Foot & Ankle Group, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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:

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,
Kent E. Kronowski, DPM

Submitter : **Dr. Christopher Reeves** **Date: 06/23/2006**

Organization : **Dr. Christopher Reeves**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Christopher L. Reeves, DPM, AACFAS
Foot and Ankle Surgeon

Submitter : Mrs. Francisca Resto **Date:** 06/23/2006

Organization : Nutrition Care, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

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

Submitter : **Dr. David Schofield** **Date: 06/23/2006**

Organization : **Dr. David Schofield**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,
David M. Schofield, DPM

Submitter : **Ms. Kathy Hall** **Date: 06/23/2006**

Organization : **Knott County Nursing Home**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I have been employed in the long term care field for 28 years and have seen many positive changes that have improved the quality of life in our residents. However i oppose the proposed rule that would require facilities to competitively bid in order to receive Medicare Part B reimbursement for certain DMEPOS items. Competitive bidding has not been successfully tested in skilled nursing facilities. An interruption to the care of a resident could be harmful. Suppliers of products are highly specialized. the residents we serve require a higher acuity level than those who are served at home. This rule would adversely affect the elderly of our great nation.

Respectfully,

Kath Hall

Submitter : Mr. Todd Tyson

Date: 06/23/2006

Organization : Hi-Tech Healthcare

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The bidding areas need to be identified and phased in over time so providers can plan accordingly. I am located in metro atlanta and this will have a major impact on our strategic planning. I would prefer it be proactive and not reactive as far as a response.

Issue

Issue

Rebates have never been allowed with fererally funded programs in the past and seem to throw all caution to the wind with regard to kick-back for medicare referrals

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Small business exemption should vary with the size of the MSA because a small business in a MSA with fewer beneficiaries will be different for the small business in a larger MSA

Payment Basis

Payment Basis

The items from each category need to be identified so that we can analyze our cost in order to know what is an acceptable bid price. If items are not identified timely providers will not have time to prepare and bid may be too aggresive which will drive those winning bidder out of business if they do not know true cost to provide equipment and services.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Quality standards need to be appropriate , realistic and clearly defined. Currently there are a lot of unanswered question regarding these required standards and no one even knows which accrediting companies are approved.

Terms of Contracts

Terms of Contracts

The terms for a winning bidder need to be transferable to a qualified buyer, this will help to guarantee business values stay strong and allow providers an exit strategy that will protect owners and investments made in their businesses.

Submitter : **Dr. Marco Vargas** **Date: 06/23/2006**

Organization : **Dr. Marco Vargas**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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:

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,

Marco A Vargas DPM,AACFAS

Submitter : **Ms. Pamela Unger** **Date: 06/23/2006**

Organization : **Ms. Pamela Unger**

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-324-Attach-1.DOC

CMS-1270-P-324-Attach-2.DOC

#324

June 20, 2006

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

Dear Dr. McClellan,

Allow me to introduce myself, my name is Pam (Pamela) Unger, I am a physical therapist practicing for the past 30 years. Twenty-three(23) of those years specializing in wound management.

The "Proposed Rule for Competitive Acquisition of Certain DMEPOS" has the potential to greatly impact my ability to care efficiently and effectively for my patients, particularly those who present with diabetic neuropathic foot ulcers. These patients require immediate off-loading. Delay in this intervention could lead to partial or full amputation of their extremity.

To intervene appropriately, the patient may require an orthotic device, as well as a temporary shoe. When this device is fitted it will most likely require periodic adjustments and revisions based on repeated use and areas of high pressure.

When the complete evaluation and assessment is compiled, total contact casting may be the best intervention. At the time of application an assistive device (cane, walker, or crutches) is necessary. The patient is instructed in a partial weight bearing gait. Not having this equipment readily available is a significant safety issue, as well as patient compliance issue.

Patients that suffer from chronic venous insufficent leg ulcers also many times require splints to protect the area of ulceration, allowing the patient to return to work or daily activities without restrictions. These devices must be molded to the patient's lower extremity based on the thickness of the compression wrap.

Patients that suffer form pressure ulcers, particularly those that occur on the heel require immediate off-loading. This is acceptably accomplished using an off-loading device (multi-podus splint). Again this requires appropriate fitting and revisions. The same situation could occur when a patient presents with a sacral

or ischial pressure ulcer requiring off-loading, generally accomplished with a cushion. The chronically ill patient (spinal cord or head injured) certainly may require a special order cushion due to lack of functional mobility. I would be very cautious that appropriate education and a wide variety of quality cushions are available.

This is certainly a complicated issue, but I feel certain you can see the necessity of immediate intervention. Please feel free to contact me if you have any questions or concerns. Thank you for your time and consideration.

Sincerely yours,

Pam

Pamela G. Unger, PT, CWS
The Center for Advanced Wound Care®
St. Joseph Medical Center
640 Walnut Street
Reading, PA 19601
(610)378-2160

#324

June 20, 2006

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

Dear Dr. McClellan,

Allow me to introduce myself, my name is Pam (Pamela) Unger, I am a physical therapist practicing for the past 30 years. Twenty-three(23) of those years specializing in wound management.

The "Proposed Rule for Competitive Acquisition of Certain DMEPOS" has the potential to greatly impact my ability to care efficiently and effectively for my patients, particularly those who present with diabetic neuropathic foot ulcers. These patients require immediate off-loading. Delay in this intervention could lead to partial or full amputation of their extremity.

To intervene appropriately, the patient may require an orthotic device, as well as a temporary shoe. When this device is fitted it will most likely require periodic adjustments and revisions based on repeated use and areas of high pressure.

When the complete evaluation and assessment is compiled, total contact casting may be the best intervention. At the time of application an assistive device (cane, walker, or crutches) is necessary. The patient is instructed in a partial weight bearing gait. Not having this equipment readily available is a significant safety issue, as well as patient compliance issue.

Patients that suffer from chronic venous insufficent leg ulcers also many times require splints to protect the area of ulceration, allowing the patient to return to work or daily activities without restrictions. These devices must be molded to the patient's lower extremity based on the thickness of the compression wrap.

Patients that suffer form pressure ulcers, particularly those that occur on the heel require immediate off-loading. This is acceptably accomplished using an off-loading device (multi-podus splint). Again this requires appropriate fitting and revisions. The same situation could occur when a patient presents with a sacral

or ischial pressure ulcer requiring off-loading, generally accomplished with a cushion. The chronically ill patient (spinal cord or head injured) certainly may require a special order cushion due to lack of functional mobility. I would be very cautious that appropriate education and a wide variety of quality cushions are available.

This is certainly a complicated issue, but I feel certain you can see the necessity of immediate intervention. Please feel free to contact me if you have any questions or concerns. Thank you for your time and consideration.

Sincerely yours,

Pam

Pamela G. Unger, PT, CWS
The Center for Advanced Wound Care®
St. Joseph Medical Center
640 Walnut Street
Reading, PA 19601
(610)378-2160

Submitter : Dr. Barry Block **Date:** 06/23/2006

Organization : Podiatry Management Magazine

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 23, 2006
<p>
Mark B. McClellan, MD, PhD
<p>
Administrator, Centers for Medicare & Medicaid Services
<p>
Department of Health and Human Services
<p>
Attention: CMS-1270-P
<p>
Electronic Comments
<p>
Dear Dr. McClellan:
<p>
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 retired podiatric physician who prescribed and supplied select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients. If I had been instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients would not have been able get medically appropriate and necessary DMEPOS items from me even though they were integral to the care I provided.
<p>
Additionally, podiatrists should be able to execute a physician authorization when they determine that a particular brand of item is necessary for their patient.
<p>
Similar to MD and DO suppliers, podiatrists are required to obtain a valid supplier number and must adhere to all of the current supplier standards. They 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. Podiatrists use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.
<p>
For example, if they treat a patient with an ankle injury, they may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If they are not a DMEPOS supplier in the new competitive acquisition program because they were 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.
<p>
Please change the physician definition from 1861(r)(1) to 1861(r) so that podiatrists are eligible to bid to supply items to my patients only and execute physician authorizations. Podiatrists should be able to continue to provide medically necessary and appropriate care to the patients they serve.
<p>
Sincerely,
<p>
Barry H. Block, DPM, JD
<p>
Forest Hills, NY

Submitter : **Ms. Jane Johnson** **Date: 06/23/2006**

Organization : **Community Orthopedic Surgery and Huron Valley Hand**

Category : **Occupational Therapist**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

In reference to file code CMS_1270_P
Our Orthpedic Surgery practice supplies a variety of OTC upper extremity braces and supports for Medicare patients. Many of these are provided post operatively or due to pain, weakness or edema. It is essential that the patients be appropriately fit and instructed in the use of these items by a qualified Occupational or Physical Therapist. In this way patients can avoid prolonged periods of immobilization in a cast while reducing pain,regaining strengh, motion and use of their injured extremity for necessary ADL's most quickly. Many patients would have a significant safety risk for further injury if they were made to leave our clinics with out these items or had to wait to receive them.
Additionally we custom fabricate low temperature thermoplastic upper extremity orthotics that are highly specialized and custom fit for each patient. Some require the patient to be xrayed following fabrication to determine that there is correct alignment of injured bones and/or joints for healing. These orthotics require adjustment and revision through out a course of treatment in therapy. Again, it is essential that we continue to have the ability to fabricate and provide follow up with these patients within our clinic setting. These are HCPCS Level II L coded orthotics.

I would be eager to participate in compiling lists of these items which are necessary for us to provide in our clinics to adequately meet the needs of our Medicare patients.
Thank you.

Submitter : Mr. jaime pla **Date:** 06/23/2006

Organization : equipos pro convalecencia

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

on the issue of areas to be included, the area that is part of the puerto rico metropolitan area has been impacted by the medicare advantage program to such a degree that the population of traditional medicare patient does not require that a competitive biding progam be put into that area. if you look at the total expenditure dmerc for puerto rico 2005 and 2006 and the number of patients in medicare tradicional .those number to not merit to work a competitive bidding program for puerto rico.

Submitter : Angela Cotton **Date:** 06/23/2006

Organization : National Examining Board of Ocularists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-328-Attach-1.DOC

#328

Re: National Examining Board of Ocularists, Inc./Public Comment Concerning Proposed Rule CMS-1270-P

To Whom It May Concern:
On behalf of the National Examination Board of Ocularists, Inc. (NEBO) I am submitting the following comments to the above-referenced proposed legislation.

NEBO has been the certifying body for skilled ocularists for twenty-six (26) years without interruption. Throughout this period, NEBO has developed and administered a respected and important professional credentialing program, based on appropriate eligibility criteria and examination processes. The certification conferred by NEBO, Board Certified Ocularist™ (BCO™), is only available to candidates who satisfy the following requirements: (1) the completion of the education program of the American Society of Ocularists, Inc., or the completion of 10,000 hours of training and/or experience in the fitting and fabrication of ophthalmic prostheses; and, (2) successful completion of a comprehensive, psychometrically valid examination.

NEBO Comment Regarding: "Competitive Bidding Areas/Criteria for Item Selection"

Practitioners certified by NEBO fabricate ocular prostheses to be placed within live tissue. This type of prosthesis requires significant expertise in customizing the prosthetic to fit the individual, and therefore should not be an included under 42 CFR §414.402. Accordingly, NEBO understands and accepts that its certificants would be excluded from participation as a supplier in the proposed competitive bidding program, which is limited to off the shelf (OTS) prosthetics and orthotic goods. NEBO has no further comments with respect to this proposed regulation.

NEBO Comment Regarding: "Quality Standards and Accreditation for Supplies of DMEPOS"

NEBO has also reviewed the regulations related to the accreditation process for suppliers of DMEPOS. Based on our review of these regulations, it is our conclusion that, under 42 CFR §424.58, manufacturers of customized ocular prosthetics are excluded from this accreditation requirement because these items are not included within 42 CFR §414.402. NEBO has no further comments with respect to this proposed regulation.

Please contact me if you have any questions or would like additional information concerning the NEBO Certification Program. Thank you in advance for your consideration.

Very truly yours,

Angela Cotton, BCO
Chair, NEBO Board of Directors

cc: NEBO Board of Directors

Submitter : Dr. Jessica Rutstein **Date:** 06/23/2006

Organization : Foot and Ankle Treatment Center of San Antonio

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McMclellan,
I am writing to urge CMS to modify the physician definition to include podiatrists so that I may continue to provide my patients with proper DMEPOS items. I provide patients with devices they require based on clinical diagnoses and I adhere to all the CMS regulatory requirements. Part of my treatment includes having the patient stabilized upon leaving the office and feeling better. If the patients had to go elsewhere to obtain a stabilizing device, they could further injure themselves in the process. Please reconsider and modify the physician definition from 1861(r)(l) TO 1861 (r)(3) before finalizing the CMS regulations. Thank you for your time.
Sincerely, Jessica Rutstein DPM

Submitter : Ms. gail helling **Date:** 06/23/2006

Organization : Ms. gail helling

Category : Other Health Care Professional

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As the owner of four pharmacies in small towns,I feel strongly that patient access to counseling and ongoing education especially as it relates to diabetic supplies will be drastically harmed if pharmacies are no longer able to provide certain products. This appears to be the outcome if competitive bidding prceeds as proposed.

Pharmacists continuing education and participation in specialized certification programs often provides the only hands on access that many rural Americans have to expert routine healthcare guidance.

many times they are the only source of home medical equipment in a 10 to 20 mile radius. Without the ability to serve the Medicare patient, there will not be a large enough market to continue providing these items to the community at large. So, all patient access to medical supplies and equipment will be hurt in these rural communities as well as the ability to readily receive patient counseling.

It seems clear to me that pharmacies should be excempted from the competitive bidding provisions of the bill.

Submitter : Dr. Scott Kurecki **Date:** 06/23/2006

Organization : Scott P. Kurecki, DPM, PA North Port Foot Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Scott P. Kurecki, D.P.M., P.A.
Podiatric Physician & Surgeon
North Port Foot Clinic

CMS-1270-P-332 **Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**

Submitter : Mr. HAROLD W (BUD) TURNTINE **Date & Time:** 06/23/2006

Organization : AMERICAN SOCIETY OF OCULARISTS

Category : Health Care Provider/Association

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

SEE ATTACHMENT

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

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

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

Submitter : Dr. Robert Teitelbaum **Date:** 06/23/2006

Organization : Dr. Robert Teitelbaum

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I beleive that the bidding process for DME will be unfair to podiatrists across the country and will result in many patients not getting the equipment they need.

Submitter : Mr. HAROLD (BUD) TURNTINE **Date:** 06/23/2006

Organization : AMERICAN SOCIETY OF OCULAISTS

Category : Other Association

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

SEE ATTACHED

CMS-1270-P-334-Attach-1.DOC

This public comment is being sent to clarify information relating to Certifying the Board Certified Ocularists, Standards in Ocularistry and related information regarding the current V codes used to bill custom artificial eyes and related services (V2623 through V2629). It is being sent to establish a stance on behalf of the American Society of Ocularists to the proposed rule 1270 P:

It is with unanimous agreement that the American Society of Ocularists endorses the National Examining Board of Ocularists (NEBO) as the ONLY accredited certifying body currently in the United States and Canada for Ocularists. NEBO has a 26-year running history relating to the Board Certified Ocularists and working alongside the American Society of Ocularists. We have fostered affiliations with the American Academy of Ophthalmology (AAO), American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) and other organizations that recognize the professionalism and competence of the Board Certified Ocularist. It is our opinion that beneficiaries will be best served by NEBO-Tested Board Certified Ocularists due to the experience and related testing developed and conducted by this body. Interestingly enough, Canada currently recognizes and pays only providers that are Board Certified through NEBO. Additionally, NEBO is the only certifying organization for Ocularists that has been accredited by the National Organization of Competency Assurance (NOCA). This accreditation is through the National Commission for Certifying Agencies (NCCA).

In addressing Standards, it is our position that Ocularists professional guidelines are currently addressed in three specific areas: FDA, American Society of Ocularists Standards and the current CMS Standards.

FDA –

ANYONE making ocular prosthetics is considered by the FDA to be a custom device manufacturer and, as such, must apply for a registration manufacturing number. An Ocularist is considered to be a Class I and Class II manufacturer. The FDA has Rules and Standards that are demanded of these kinds of manufacturers called the QSIT Standards. These Standards address everything from a complaint file, to how to trace raw materials, to the disinfection and maintenance of equipment. Federal inspections can last up to one week often requiring the Ocularist to close his office during the inspection and auditing process. The Class I, manufacturer QSIT Status Standard is the more comprehensive of the two Standards. It is once again the belief of the American Society of Ocularist that this gives another complete layer of Standards to the beneficiary far about the average DME supplier.

AMERICAN SOCIETY OF OCULARIST –

The American Society of Ocularist has Rules and Bylaws that protect the patient/beneficiaries' rights. For example, a member of the American Society of Ocularist is not allowed to fit a stock, pre-made ocular prosthesis without recourse from our ethics and standards committee which, if not corrected, can lead to a termination of membership. Currently, we also have a Good Manufacturing Practice Standard that relates to manufacturing and fitting ocular prosthetics. This Standard addresses most of the FDA issues along with other Standards that are unique to the field of Ocularistry.

It is our belief that the American Society of Ocularist works in the best interest of the Medicare beneficiary and that all Ocularists should be Board Certified by the National Examining Board of Ocularists. Members are required to adhere to the Rules and Bylaws of the American Society of Ocularists and are encouraged to have a valid FDA registration number. Along with being in compliance with the current CMS Standards, we feel the beneficiaries' needs will not only be respected but protected and honored to the fullest extent.

Should you have any comments or question relating to this correspondence please contact me at your convenience.

Sincerely,

Harold W. (Bud) Turntine, B.C.O., B.A.D.O.
Vice President, American Society of Ocularists
6342 Long, Suite H
Shawnee, KS 66216
imakeis@aol.com
913.962.9299

Submitter : Mr. HAROLD TURNTINE **Date:** 06/23/2006

Organization : AMERICAN SOCIETY OF OCULARIST

Category : Association

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

SEE ATTACHED

CMS-1270-P-335-Attach-1.DOC

This public comment is being sent to clarify information relating to Certifying the Board Certified Ocularists, Standards in Ocularistry and related information regarding the current V codes used to bill custom artificial eyes and related services (V2623 through V2629). It is being sent to establish a stance on behalf of the American Society of Ocularists to the proposed rule 1270 P:

It is with unanimous agreement that the American Society of Ocularists endorses the National Examining Board of Ocularists (NEBO) as the ONLY accredited certifying body currently in the United States and Canada for Ocularists. NEBO has a 26-year running history relating to the Board Certified Ocularists and working alongside the American Society of Ocularists. We have fostered affiliations with the American Academy of Ophthalmology (AAO), American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) and other organizations that recognize the professionalism and competence of the Board Certified Ocularist. It is our opinion that beneficiaries will be best served by NEBO-Tested Board Certified Ocularists due to the experience and related testing developed and conducted by this body. Interestingly enough, Canada currently recognizes and pays only providers that are Board Certified through NEBO. Additionally, NEBO is the only certifying organization for Ocularists that has been accredited by the National Organization of Competency Assurance (NOCA). This accreditation is through the National Commission for Certifying Agencies (NCCA).

In addressing Standards, it is our position that Ocularists professional guidelines are currently addressed in three specific areas: FDA, American Society of Ocularists Standards and the current CMS Standards.

FDA –

ANYONE making ocular prosthetics is considered by the FDA to be a custom device manufacturer and, as such, must apply for a registration manufacturing number. An Ocularist is considered to be a Class I and Class II manufacturer. The FDA has Rules and Standards that are demanded of these kinds of manufacturers called the QSIT Standards. These Standards address everything from a complaint file, to how to trace raw materials, to the disinfection and maintenance of equipment. Federal inspections can last up to one week often requiring the Ocularist to close his office during the inspection and auditing process. The Class I, manufacturer QSIT Status Standard is the more comprehensive of the two Standards. It is once again the belief of the American Society of Ocularist that this gives another complete layer of Standards to the beneficiary far about the average DME supplier.

AMERICAN SOCIETY OF OCULARIST –

The American Society of Ocularist has Rules and Bylaws that protect the patient/beneficiaries' rights. For example, a member of the American Society of Ocularist is not allowed to fit a stock, pre-made ocular prosthesis without recourse from our ethics and standards committee which, if not corrected, can lead to a termination of membership. Currently, we also have a Good Manufacturing Practice Standard that relates to manufacturing and fitting ocular prosthetics. This Standard addresses most of the FDA issues along with other Standards that are unique to the field of Ocularistry.

It is our belief that the American Society of Ocularist works in the best interest of the Medicare beneficiary and that all Ocularists should be Board Certified by the National Examining Board of Ocularists. Members are required to adhere to the Rules and Bylaws of the American Society of Ocularists and are encouraged to have a valid FDA registration number. Along with being in compliance with the current CMS Standards, we feel the beneficiaries' needs will not only be respected but protected and honored to the fullest extent.

Should you have any comments or question relating to this correspondence please contact me at your convenience.

Sincerely,

Harold W. (Bud) Turntine, B.C.O., B.A.D.O.
Vice President, American Society of Ocularists
6342 Long, Suite H
Shawnee, KS 66216
imakeis@aol.com
913.962.9299

Submitter : **Barbara Owsley** **Date: 06/23/2006**

Organization : **Colorado Hand Therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment please

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. Patricia Stevens **Date:** 06/23/2006

Organization : Martha Jefferson Hospital

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an Occupational Therapist with a master's degree plus additional training and certfication of being a Certified Hand Therapist and 29 year if experience. I work closely with our physicians who are general orthopedic or plastic, general and hand/upper extremity surgeons,as well as, GP's Internal medicine,rheumatologists etc... These physicians depend on Hand Therapists to be highly knowlegable and skilled in the areas of deficits of patients they see and send their patients to us to be sure the correct splint and therapy is appropriate and successful. To have optimal outcomes, physicians need to refer patients very early in the post injury or surgery stages, sometimes the day of. They need to know that we know what to do and even more so WHAT NOT TO DO to jeapardize the patient's diagnosis or surgery adn outcome. We have to know the details of the injury, anatomy, surgery and recovery almost to the level the surgeon does to know what to do. WE, the therapists are the ones who are going to see those patients 1-3 times a week and spend the time to moniter all of the details of the outcome and make the appropriate modifications at the time needed. With each visit, esp. post-op we reassess and alter what is needed. The physicians do not have the time to moniter things this closely. They depend on us, the therapists, to be their eyes and ears and treat the issue as it arises. How can you expect a "vendor" to have any depth of idea of all of the anatomy, disease process, injury, surgery, complications potential and individual physican preference of how they like to have specific injuries or surgeries progressed? Do you have any idea what complications or potential liability issues could arise from inappropriately applied splints? The potential for poor outcomes OR the need for more procedures to try to correct the problems from inappropriate splints is very real and may cost you a lot more in long run. I have considerable concerns as to what do I do ethically if I have to have a "vendor" applied splint put on my patient and it isn't the correct splint or fit or it needs to be adjust THEN for the patients well-being and outcome. A therapist re-assesses and redirects therapy at EVERY visit. It is going to be difficult to impossible to have patients having to go to several locations to get the "pieces" of their rehabilitation. Isn't the reason we created primary care drs. is to be sure the patient's care is coordinated by one person? How efficient is it to have therapy with a qualified therapist and then having to send the person across town to get the cheapest splint from someone who isn't very knowlegable about what their diagnosis is or what is truly needed for an optimal outcome? Many vendors are only going to care about getting the cheapest splints and getting the contract and they could care less as to whether it is a decent splint or if it fits the patient well and is doing the correct job. There job is done when they make the sale!!!! There are many excellent over the counter splints out there and there are absolute garbage splints that I question if the manufacturer had any inkling as to any anatomical knowledge at all. If you or your parents or someone you loved who was on medicare had to be fitted for an appropriate over the counter splint to reduce pain, provide support during a healing phase, protect injuires or surgery or try to resolve sprains/strains, tendinitis or compressed nerves conservatively and avoid more invasive procedures like injections or surgeries------Who would you want to fit and alter that splint---?--a knowledgable PT or OT or Hand Theray specialist or a vendor? interested in making a buck by putting on whatever they could get a cheap contract price on a product???

Submitter : **Dr. Thomas Reed** **Date: 06/23/2006**

Organization : **Ankle and Foot Specialists of the Woodlands**

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)(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 weight bearing 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)(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,

Dr. Thomas M. Reed DPM
Practicing Podiatric Physicain for Over Twenty Three Years

Submitter : Dr. Donald Kollisch **Date:** 06/24/2006

Organization : Dartmouth Hitchcock Medical Center

Category : Physician

Issue Areas/Comments

Issue

Issue

My patients in rural NH have gotten great service from a small niche company - Neighborhood Diabetes - that has gone to their homes to help them select a home glucose monitor, instructed them in its use, and monitored their progress. I am very concerned that CMS-1270-P will reward with a virtual monopoly a large company that will offer only "cookie-cutter" services to my patients. I am CERTAIN that the excellent services of Neighborhood Diabetes have saved CMS money by helping my Medicare patients maintain better diabetes control. I think that Neighborhood - and other small companies - deserve protection, because of the quality of the service they provide and the money they therefore save. Please do NOT inmplement competitive bidding; it may work in an urban area, but NOT in rural New Hampshire.

Submitter : **Ms. Carolyn Phelan** **Date: 06/24/2006**

Organization : **Levas PT & OT Therapy Clinic**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-340-Attach-1.DOC

Sample Letter

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

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

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

My name is Carolyn Phelan, 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 private therapist owned clinic, 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,

Carolyn Phelan OTR/L,CHT

Submitter : **Dr. Eric Lullove** **Date: 06/24/2006**

Organization : **Eric J Lullove DPM PA**

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,

Eric J. Lullove, DPM
Boca Raton, Florida

Submitter : Mrs. Diane Coker **Date:** 06/24/2006

Organization : South County Hand Center

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-342-Attach-1.TXT

June 23, 2006 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 Diane Coker, and I am a physical

therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification

exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these

patients prior to sitting for the exam. I am currently working in Laguna Woods, California, 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. I have on several occasions been required to send a patient to an orthotist for an off the

shelf DME. Even though I sent these patients to an outside provider with a "shopping list" of a specific item number and size, the

patients have returned to my clinic with the wrong item or size. A six foot gentleman with a fractured wrist once came in with a

small size wrist support. He stated the orthotist just handed him a box, and did not even attempt to fit the brace on his hand. By

the time the patient came back to me, his hand was grossly edematous. This one act of carelessness set him back two weeks in

his rehabilitation program. 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. When

I must send these patients to an outside supplier, there is often a delay of several weeks before a "special order" is fulfilled. 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 losing

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, Diane Coker, PT, CHTdacoker@cox.net

cjohnson@smithbucklin.com Johnson, Chelli

Submitter : Mrs. Lisa Choe **Date:** 06/24/2006

Organization : Florida Orthopaedic Institute

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-343-Attach-1.DOC

#343

Sample Letter

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

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

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

My name is Lisa Choe, 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 Tampa, Florida, 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,

Lisa Choe OTR/L, CHT, MHA

Submitter : **Catherine Gouvin** **Date: 06/24/2006**

Organization : **Catherine Gouvin**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-344-Attach-1.DOC

#344

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 Catherine Patricia Gouvin, 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 worked in this specialty for more than 10 years. In that time I successfully treated many seriously injured people using custom made orthosis. One in particular suffered the tragic loss of his dominant arm at mid forearm level due to a table saw accident. The timely, successive orthoses that I made for him were the key to his success. As the ergonomic specialist for our community hospital, I no longer treat patients directly, but I am deeply concerned about the proposed legislation that would interfere with the CHT's ability to provide custom or off the shelf orthoses for their patients.

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 orthosis, 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,

Catherine P. Gouvin, OTR/L,CHT

Submitter : **Ms. Robin Miller** **Date: 06/24/2006**

Organization : **Fort Lauderdale Hand Clinic**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1270-P-345-Attach-1.TXT

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 Robin E. Miller, 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 been practicing, as a hand therapy specialist for 30 years. I own and run the Fort Lauderdale Hand Clinic 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 orthosis, 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 orthosis, 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, Robin E. Miller, OTR/L, CHT

Submitter : Mrs. Cathy Selzer **Date:** 06/24/2006

Organization : Mrs. Cathy Selzer

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an occupational therapist and a certified hand therapist. It is of great concern that health care providers such as myself and my colleagues may be forced to bid on providing durable medical equipment such as prefabricated splints and other upper extremity supports, only to lose the ability to dispense necessary durable medical equipment due to a lower bidder. As therapists, we are trained in specific disease processes and critical anatomy of the hand and upper extremity as well as in the treatment of specific diseases and appropriate post-surgical care. We are specially trained to evaluate a patient for the need of specific orthoses/splints and to appropriately fit a patient to prevent further injury or deformity. Furthermore, the evaluation process is ongoing, and the need for a specific orthotic/splint may change as the patient progresses through his/her rehabilitation, dependent upon the patient's individual response. Time is of the essence when providing these orthoses/splints to patients. In order to prevent further injury, protect a new surgery or respond to a patient's acute pain, quick turn-around is critical. Often, a patient requires immediate application of a device during their first visit to the therapist, or even in post-operative recovery. To expect a patient who is in acute pain to drive across town to pick up a device because it is more economical is not practical. Furthermore, many seniors who are Medicare recipients are unable to drive and have limited transportation options. Requiring a patient to obtain DME from a provider other than their physician or therapist may mean the patient won't get what they need, resulting in further injury and/or dysfunction. Additionally, patients improperly fitted with orthotics/splints by individuals without the appropriate training are at risk of further injury to soft tissues and joints. As a therapist with 10 years of experience, I have seen the results of patients wearing an ill-fitting device. The result is a patient who has more pain, edema, and tissue break down and who, therefore, is not compliant with the use of the device and whose healing may be delayed. Ultimately, the ill-fitting device must be replaced and therapy treatments may be extended to deal with the problems created. In the long run, no savings has taken place. On the contrary, it ends up costing the patient and the health-care system more.

Submitter : Mrs. Phyllis Monroe, MOTR/L, CHT **Date:** 06/24/2006

Organization : Mrs. Phyllis Monroe, MOTR/L, CHT

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

Please See Attached.....

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

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

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

Submitter : **Dr. Grace Torres-Hodges** **Date: 06/24/2006**

Organization : **Torres-Hodges, DPM, PA**

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 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,

Grace Torres-Hodges, DPM
June 23, 2006

Submitter : Mrs. Hueyru Sevidal **Date:** 06/24/2006

Organization : American Association of Hand Therapist

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am an Occupational Therapist and a Certified Hand Therapist. Aside from evaluating and treating patients who are in need of physical rehabilitation of the upper extremity, I also fabricate orthotics/splints for these patients. These comprise static/resting splints, splints to mobilize stiff and or contrated upper extremity joints, or aplints to provide comfort just as those who suffer from tendinitis or arthritis. There are many different types of splints and each of them custom made for the patients so the fit is according to each individual and so is the function of what each would be for. This is something that over the counter or off the shelf braces and splints could not provide. I also make dynamic and static splints to mobilize contractures, again this is something one could not purchase from pharmacies or any other medical facilities or made by anyone who's not trained to do such an orthotics. These dynamic splints have to be routinely, or regularly checked, upgraded and adjusted from the therapist who made them. A lot of them have to be checked on a daily basis, some weekly and some monthly depending on the function. Which is something that orthotist/prosthetists are unable to follow up. The prosthetists also are not trained to fabricate a lot of the dynamic splints that we as occupational therapists/certified hand therapists make.
In my opinion, using prosthetists instead of an occupational therapist for these splints and orthotics is not the route to go for quality patient care.

Submitter : **Dr. Beth Pearce** **Date: 06/24/2006**

Organization : **Dr. Beth Pearce**

Category : **Physician**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Proposed bill will be damaging to patient access to care and supplies. Many patients do not have adequate access to transportation and this places an undue hardship on them.

Submitter : **Dr. Laurie Nielsen-Haak** **Date: 06/24/2006**

Organization : **Foot & Ankle Centers of Ohio**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 24, 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,

Laurie A. Nielsen, DPM, AACFAS

Submitter : Kevin Berry **Date:** 06/24/2006

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 Competetive DME Bidding process.

It is imperative that patients retain ther current level of care received at the retail pharmacy level.

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.

Diabets 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, 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 in conjunction with patients' physicians in an effort to facilitate the best possible diabetes care.

Submitter : Mr. John Beville **Date:** 06/24/2006

Organization : Family Pharmacy of Glasgow, LLC

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am an independent community pharmacy practioner. As such, I respectfully request the area of supplies be excluded from competitive bidding. My reasoning is that most supplies, be they diabetes testing supplies or braces or bandages, should be easily and quickly accessable to all patients. In rural areas, like where I practice, requiring patients to travel out of town to obtain routine supplies in an unnecessary economic hardship. Pharmacies are the most accessable health care provider in today's marketplace, and most independence pharmacists only want fair compensation for what products and services they provide. Removing providers from the system simply because they are not big enough to competitively bid is tantamount to limiting physician care to only those that practice in large hospitals. Limiting access to health care at any level is a step backwards in quality of care and history seems to indicate that restrictive "pseudo-monopolization" of the marketplace leads to a dramatic rise in product cost (I offer as example the overall increase in Rx drug costs since the inception of Pharmacy Benefits Managers). Everyone agrees our tax dollars should be spent to maximum value, but, that does not preclude a fair market price for any product. I agree that runaway increases in health care costs can and should be curbed, but the proposed regulation is very short sighted with respect to the overall health impact on patients and the resultant potential long term costs that will follow. Taking away regular, personal contact with patients by substituting non-local providers removes an opportunity to regularly evaluate a patient's general well-being and perform proactive interventions that can result in better quality of life and lower health care costs. Please keep supply availability at the local level - for the sake of those you serve!

Submitter : **Dr. Larry Zonis** **Date: 06/24/2006**

Organization : **Dr. Larry Zonis**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 22, 2006

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

Dear Dr. McClellan:

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,

Larry Zonis, DPM

Submitter : **Ms. Lynelle Fleming** **Date: 06/24/2006**

Organization : **Ms. Lynelle Fleming**

Category : **Physical Therapist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Dear Sirs,
As a certified hand therapist since 1991 and physical therapist since 1974, I as very concerned about the above issue. I find myself thinking, I'll just do what I need to to take care of my patients and pay for it myself. This is not proper or right to limit what we can do for people because someone else might be willing to use a cheaper, inadequate brace. Braces or splints, prefab or custom, are chosen for the effect on the condition, disease or deformity to assist in improving function or decreasing pain, not always by cost.
Do not limit ANOTHER area of our practice, decreasing our ability to preform the work we were called to do. There should remain some trust that most of these professionals are attempting to work with the best of their abilities to make a difference.
Splinting is often at the core of our treatment in changing outcomes more effectively.
Thank you.

Submitter : Dr. Joseph Cavuoto **Date:** 06/24/2006

Organization : Dr. Joseph Cavuoto

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-356-Attach-1.RTF

#356

Dr. Joseph W. Cavuoto DPM
1147 Front Street
Uniondale, NY 11553
516483-8895

June 22, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the

patients I serve.

Sincerely,
Dr. Joseph W. Cavuoto DPM

Submitter : Dr. Jerry Jensen **Date:** 06/24/2006

Organization : Jammal Pharms, Inc

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacist, 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 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 patient's physicians in an effort to facilitate the best possible diabetes care. For these very valid concerns, I respectfully request that diabetes testing supplies be deemed exempt from the Competitive DME Bidding process.

Submitter : Mrs. Sofija Seymour **Date:** 06/24/2006

Organization : Mrs. Sofija Seymour

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am commenting not only on behalf on my profession, but also as a concerned granddaughter who fears her grandparents will not receive the proper care should they need a prefabricated orthotic. I am a physical therapist and certified hand therapist practicing in the state of Wisconsin at a specialty clinic devoted to treatment of upper extremity diseases and disorder. As providers/suppliers with expertise in the disease process of upper extremity disorders, we consider not only the mechanics of the device, but also the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc.

A patient's needs are thoroughly evaluated 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, it is not guaranteed that a beneficiary will be able to find a specific orthosis in their local area, potentially limiting beneficiary access to an important orthosis. I have already seen patients who come referred to our clinic in more pain because they were issued an incorrect orthosis from another supplier, who did not have the 6 years of schooling and 5 years of clinical expertise to make the appropriate choice in orthotics. In the long run this cost Medicare and this patient time and money. Delays in the supply of an orthosis will interfere with clinical reasoning and patient treatment. There are many times when a therapist must respond immediately to changing conditions in a patient's medical condition and/or recovery from that condition. In our clinic setting we see patients of an acute nature, leading to frequent changes in their orthoses to adapt to their rapidly changing condition. It is critical that we are able to respond to that need immediately!

There is a very small margin of profit in UE off-the-shelf orthoses. This position is supported by Medicare itself, who subsequent to the demonstration projects acknowledged in a public report that there would be only small savings from the inclusion of off-the-shelf upper extremity products in the competitive bidding system. Please take these comments into serious consideration. Place yourself in my patients shoes. We will all be medicare recipients someday. Are we making any true savings with this proposal or simply creating situations that could escalate into greater healthcare costs.

Submitter : Dr. Dipika Patel **Date:** 06/24/2006

Organization : Medicine Shoppe Pharmacy

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacy, i request that diabetes testing supplies, and medications be deemed exempt from the competitive DME bidding process. Retail pharmacist offers critical patient education on monitoring blood glucose, durg interaction, side effects of medication to these patients. Also, rural area pharmacies should be exempt from the competitive bidding process. This will ensure easy access to pharmacy and pharmacist whenever patient requires.

Submitter : Mr. Tim Gallegos **Date:** 06/24/2006

Organization : Todamar, Inc.

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Placing the diabetic testing supplies under Comptitive DME Bidding Process will surely impact patient health and well being. When a patient comes into a Pharmacy they are given professional and current accurate information concerning their disease state. This is information is presented in a professional understanding way and always maintaining the patients dignity. This promotes positve outcomes in the patient behalf and thus reducing the cost of Health Care. Every One in Congess would be so lucky to receive such care. I Feel competive bidding in any area of health care is a means of degrading patient care. You are not bidding on the best price for a Car-you are bidding on patient care??????????? Tim Gallegos, RPh

Submitter : Dr. Susan Scanlan **Date:** 06/24/2006

Organization : WA State Podiatric Medical Assn

Category : Physician

Issue Areas/Comments

Issue

Issue

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

Issue

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,
Susan Scanlan DPM
Executive Director WSPMA

Submitter : Mr. Robert Antonacci **Date: 06/24/2006**

Organization : The Medicine Shoppe Pharmacy in Peoria, IL

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please do not include Diabetic Testing Supplies in the Competitive DME Bidding process. Reimbursement is already at our cost. We maintain doing this part of the business because our patients need help with their testing and testing supplies along with education. You don't get that at the big chains, the discounters, or mailorder.

Submitter : Dr. William McShane **Date:** 06/24/2006

Organization : Harbor Podiatry,PC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-363-Attach-1.PDF

CMS-1270-P-363-Attach-2.DOC

#363

June 22, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. I want to be able to continue to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Submitter : Mr. Larry Schieber **Date:** 06/24/2006

Organization : The Medicine Shoppe

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacist, I respectfully request that diabetes testing supplies be deemed exempt from the competitive DME bidding process.

We take a gread deal of time to educate patients on the correct use of their diabetes testing products. 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 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 the patient by offering education on daily diabetes care, medication/side effects/possible drug interactions, and training on blood glucose meters and testing procedures. We also have the ability to impact patient adherence in all aspects of diabetes care and provide a local presence for assistance with complications of therapy.

I believe by restricting access, these services will be sevely dimished and the compliance and ultimately health of the patient will be compromised.

Submitter : **Dr. Robert M. Sage** **Date: 06/24/2006**

Organization : **Associated Foot and Ankle Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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:

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,

Robert M. Sage, DPM

Submitter : Dr. Timothy Messmer **Date:** 06/24/2006

Organization : Northwest Orthopaedic Surgeons

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-366-Attach-1.DOC

#366

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:

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,

Timothy E. Messmer, DPM
Anacortes, WA

Submitter : Mr. Wesley Miley **Date:** 06/24/2006

Organization : HOME OXYGEN

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community pharmacist with diabetes certification and extensive homecare experience in rural Mississippi I must say that competitive bidding will make it more difficult for diabetics to get the supplies and education they need-we rely on medicare reimbursement for supplies to be able to afford the personalized service we provide. Most patients will be unable to get meter training and followup ,if the lowest bidder "wins"-the patient "loses".

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

As a pharmacist with over 25 years experience in home medical equipment and supplies I feel that competitive bidding will effectively lockout most rural and small town providers such as local pharmacies who take care of their patients on a daily basis. They cannot afford to buy at trainload quantities,deliver, and educate the caregiver or patient on a low-ball,"cheapest junk you can find" bid. The timely delivery,set-up, and education in rural Mississippi settings should be compensated at a better rate than say in downtown Chicago or Los Angeles. Who is going to come out at 2AM and repair or replace that cheap piece of equipment that was bought an e-Bay price? It seems this idea is flawed.

Submitter : Dr. Kenneth Wichman **Date:** 06/24/2006

Organization : Podiatry

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 24, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Dept. of Health & Human Services
Electronic Comments

Dear Dr. Mclellan:

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 judgement and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. 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 ietms. As an example, when a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multi[ple 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.

As a profession, podiatry provides an integral role in foot care for the nation. I personally have been a podiatric physician in Manchester, Connecticut for 35 years. I pride myself on quality care that takes into account what is appropriate for my patients. I do not wish to see unnecessary roadblocks to being able to provide this level of care to my patient population.

I thanky you in advance for your consideration.

Sincerely,

Kenneth L. Wichman
Manchester Podiatry Center, P.C.
117 E. Center St.
Manchester, CT 06040
860-649-3338

Submitter : **Mrs. Patricia Grenz** **Date: 06/24/2006**

Organization : **American Society of Hand Therapist**

Category : **Physical Therapist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

See attachment

CMS-1270-P-369-Attach-1.DOC

#369.

June 24, 2006

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

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

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

My name is Patricia Grenz< PT, CHT, and I am an occupational/physical 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 Outpatient Physical Therapy Clinic, 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,

Patricia Grenz, PT, CHT
470 Lafayette Street
Denver, CO 80218

Submitter : Dr. Devin Trone **Date:** 06/24/2006

Organization : Medicap Pharmacy

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a Pharmacist, I respectfully request that Diabetes testing supplies be deemed exempt from the competative DME Bidding process. I think it is very important that patients retain their current level of care at the community pharmacy level. This bidding deal will have a detrimental impact on the health and well being of medicare recipients. Pharmacist play a key roll in the daily lives of medicare patients in education, adherence, care, and as a mediator with doctors and other health care professionals. If these patients cannot get their diabetes supplies from their community pharmacies they will lose all of those benefits they are currently recieving from thier pharmacies.

Thank you

Devin R. Trone Pharm.D.

Submitter : **Dr. Rupal Patel-Gupta** **Date: 06/24/2006**

Organization : **Atlanta Podiatry, P.C.**

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)(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 weight bearing 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)(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,

Rupal Patel Gupta DPM
770-418-0456

Submitter : Mr. Henry Goldberg **Date:** 06/25/2006

Organization : Mr. Henry Goldberg

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Therapists do not make orhtotics - we call them splints. We do nto make gadgets to last years and years. We make splints that can be changed at a moments notice to promote biological changes in healing tissues or to promote rest. We do this according to our expertise with a clincial condition or diagnosis. Sometimes a splint has to be provided immediately. A splint is only a part of the therapeutic process. Therapists do not sell their splints to make big bucks.

It is entirely specious reasoning to equate the often clever splints, which do borrow engineering analysis in their design, with the gadgetry made by orthotists. They make 'durable' equipment; therapists do not. Therapists use relatively inexpensive thermoplastics, and sometimes everyday objects like paper clips in creating a splint. Therapists cannot afford to enter a bidding contest, against people whose sole livelihood is the manufacture and sale of such gadgets.

Therapists should remain exempt from all bidding processes. If our patients cannot receive the care they need - if our ability to make inexpensive splints is discouraged because we cannot be reimbursed for a necessary intervention, then our patients will not be receiving good healthcare. Here's another blow to the healthcare system - for all of us. I can tell you I go out of my way to provide the smallest thermoplastic splint because I know it would be medically beneficial. I will certainly think twice, if I can't be reimbursed for a splint that fills a much larger role in a patient's recovery.

Submitter : **Dr. Bruce Hutchinson** **Date: 06/25/2006**

Organization : **Dr. Bruce Hutchinson**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

BRUCE T. HUTCHINSON, D.P.M., M.A.
1035 E. GRAND AVENUE, SUITE 102
ESCONDIDO, CA 92025
760-489-5858

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 entreat CMS to change the definition 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. 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 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.

For example, if I see a diabetic patient who I diagnose with a fracture of the mid-foot, as a consequence of Charcot Arthropathy I may decide that it is medically necessary and appropriate to use a walking boot as part of the treatment plan. I want to make sure the patient s extremity is immobilized and off loaded 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.

Please modify 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,

Bruce T. Hutchinson, DPM
Diplomate, ABPOPPM, QME
DME Provider# 0526100001

Submitter : **Barbara Onderdonk** **Date: 06/25/2006**

Organization : **Barbara Onderdonk**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

How absurd! Competitive bidding contracts on hand splints will be of no use to patients in need of them to support and protect healing fractures and joints. It will only confuse patients and doctors who won't know exactly what splint style and size to order, it will also obstruct, hamper, and delay the rehabilitation process, and be detrimental to a patient's overall outcome. I am a certified hand therapist since inauguration of certification in 1991, and have been providing occupational therapy to hand injured patients since 1977. There is much professional skill and expertise behind choosing and fitting the appropriate splint for a patient. These items come in many forms, styles, and sizes, and often need on the spot adjustments for proper fit. Splinting properly is an integral component of a hand rehabilitation program. Physicians can refer patients to an occupational therapist to determine which splint would best support and fit a patient based not only on the patients anatomy and injury, but also on their occupational needs. Many times a day I will try two or three, or more different splints before I choose the best one to dispense. As the patient improves, and swelling subsides, I will adjust the splint to maintain proper fit. Physicians can remove casts for earlier mobilization when they can trust that a correct and well fit splint will be provided by the therapist. This necessary evaluation service will not take place by a vendor pulling items off a shelf. In many cases, physicians will have no choice but to leave casts on longer, compromising early mobilization benefits to assuring adequate support to the injured tissues. Therapists must be able to provide splints as part of the rehabilitation service. Doctors rely on us to know the right kind and size of splint to provide, and to assure correct fit. Incorrect fitting can lead to skin breakdown, fracture and joint malalignment and inadequate patient compliance; all of which could lead to need of corrective surgeries. In understanding the professional component needed in orthotic provision, I implore you to revise the proposed regulation to allow therapists to continue to supply orthotics, without the obstructions and delays that the competitive bidding process would create.