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

Organization : **Dr. Bruce Greenbaum**

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

Bruce Greenbaum, D.P.M.

Submitter : **Dr. Christian Robertozzi** **Date: 06/25/2006**

Organization : **American Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

ADVANCED FOOT and ANKLE CARE, PC
Stephen Bui, DPM, AACFAS
Gary Levat, DPM
Christian Robertozzi, DPM, FACFAS, FACFAOM*
*Diplomate, American Board of Podiatric Orthopedics and Primary Podiatric Medicine
*Diplomate, American Board of Podiatric Surgery
Certified in Foot Surgery
*Diplomate, The American Board of Quality Assurance and Utilization Review Physicians

Please reply to:
The Norman Silbert Medical Arts Building
222 High Street, Suite 201
Newton, New Jersey 07860
Tel: (973) 579-1300
Fax: (973) 579-5777
Website: www.AFACare.com

Vernon Medical Arts Building
212 Route 94, Suite 1C
Vernon, New Jersey 07462
Tel: (973) 209-2300
Fax: (973) 209-8204

June 22, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician in finalizing its regulations.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

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

Sincerely,

Christian Robertozzi, DPM

gw

Submitter : **Dr. John Parmelee** **Date: 06/25/2006**

Organization : **Covington Foot & Ankle 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,

John Parmelee, DPM

Submitter : **kevin herauf** **Date: 06/25/2006**

Organization : **tulsa hand therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

As a certified hand therapist I am want to be sure that our patients have access to the appropriate prefabricated orthosis/splints during their treatment. Our patients need appropriate care without delay, and without having to go elswhere for timely treatment.

thank you

Kevin Herauf, MS, OTR/L, CHT

Submitter : Kathleen Hanlon **Date:** 06/25/2006

Organization : NH Hand Therapy Center, Inc.

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-379-Attach-1.DOC

#379

June 25, 2006

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

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

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

My name is Kathleen Hanlon, PT, CHT, and I am a physical specializing in the treatment of upper extremity disorders. I am also a certified hand therapist since 1991, 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 private practice and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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

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

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

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, a specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

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

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

Sincerely,
Kathleen Hanlon, PT, CHT
NH Hand Therapy Center, Inc.

Submitter : **Dr. Daniel Park** **Date: 06/25/2006**

Organization : **Arnot Ogden Center for Wound Healing**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Dear Dr. McClellan:

I am requesting that the Centers for Medicare & Medicaid Services 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 I prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) 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 obtain 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 should 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.

If I am forced to send my patients elsewhere for medical devices, my patients can potentially be harmed. For example, if I treat a patient with an acute foot/ankle injury, I may determine that an immobilizing brace is necessary to stabilize the foot/ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not the DMEPOS supplier due to the new competitive acquisition program, the patient will need to go elsewhere and risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications. It is also essential that I be present to make sure the items fit properly and that the device does not cause any complications.

I am the Director of Podiatric Wound Care at the Arnot Ogden Center for Wound Healing in Elmira, NY and I see on a daily basis the devastating effects of improperly worn medical devices. Many of the patients I see are metabolically, immunologically, and vascularly compromised. The slightest irritation can lead to serious ulceration/infection and even amputation. The supplying of medical devices to treat podiatric conditions should be left to trained and experienced podiatric physicians who understand the biomechanical and medical implications of wearing such devices.

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,
Daniel S. Park, DPM
668 Park Place
Elmira, NY 14901

Submitter : **Dr. Stanley Beekman** **Date: 06/25/2006**

Organization : **Dr. Stanley Beekman**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 25, 2006

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

Dear Dr. McClellan:

I am writing the Centers for Medicare & Medicaid Services (CMS) to please revise the physician definition used in the proposed rule that would regarding the 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 part of my patient care. For example, when a patient has a fracture of his metatarsal with edema, I would prescribe a walking boot. My patients depend on me to provide the best care. I follow all the applicable standards and follow all the laws and regulations that apply to MD s and DO s.

Regarding the patient with the fracture, how am I in good conscience supposed to allow him/her to leave my office with an unimmobilized foot knowing full well that the patient can cause additional damage to his fracture site?

There are other instances that illustrate this. I was just written up in a book regarding stroke patients. The Cleveland Clinic had prescribed and dispensed a brace to a patient, who had problems that were unable to be rectified. The patient came to me and I made a simple adjustment that fixed the problem. If you would like the book or photo static copies of the applicable pages, please let me know. I bring up this to show that podiatric physicians are trained to handle bracing better than anyone. Podiatric physicians are trained in biomechanics, and understand the function of the lower extremity better than anyone. This allows us to make proper prescription and adjustments to orthotics.

Please modify the physician definition from 1861(r)(1) to 1861(r) before finalizing the regulations for the competitive acquisition program. I feel it is in the patients best interests to allow me to continue to supply DMEPOS items for my patients only. I also believe that it is only fair that I should have the same regulations as any other physician. .

Sincerely,

Stanley Beekman D.P.M

Submitter : **Dr. Arnold Beresh** **Date: 06/25/2006**

Organization : **VPMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

PENINSULA FOOT & ANKLE SPECIALISTS, PLC DR. ARNOLD S. BERESH
Certified, American Board of Podiatric Surgery DR. MARC A. GARFIELD
2202-A Executive Drive 527 Oyster Point Road, Suite 3
Hampton, Virginia 23666 Newport News, Virginia 23602
(757) 827-7111 fax (757) 827-7164 (757) 249-0450 fax (757) 249-0454

June 25, 2006
1. Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments
Dear Dr. McClellan:
I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r)(3). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.
Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.
Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DMEPOS items as an integral part of patient care is no different than that of my MD and DO colleagues.
For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased 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,

Arnold S. Beresh, DPM

Submitter : **Dr. James Benedict**

Organization : **Dr. James Benedict**

Category : **Physician**

Date: 06/25/2006

Issue Areas/Comments

GENERAL

GENERAL

Practice Limited to Disorders of the Foot and Ankle
Phone 330-673-3505
Fax 330-673-4888

Dr. James E. Benedict
Diplomate, American Board of Podiatric Surgery
Podiatrist
1627 E. Main Street
Kent, OH 44240

June 25, 2006

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

Dear Dr. McClellan:

I am a podiatrist practicing in a small town in Ohio. I have been in practice for 22 years and see patients from surrounding rural communities. My patients are uncomfortable in traveling to larger cities. I am writing to request that the Centers for Medicare and Medicaid Services(CMS) modify the proposed definition for physicians for the competitive acquisition program for DMEPOS from 1861(r)(1) to 1861(r) so as not to exclude podiatric physicians.

I am unable to compete with larger providers of Durable Medical Equipment but feel that having my patients have access to DME that I can dispense to them from my office would prevent them from having to travel to another location to receive supplies that they could receive from me. It is feasible that my patients could be forced to travel to the Cleveland, Akron, Youngstown, or Canton area to receive medical supplies that I would have available in my office. This would cause my patients a hardship in having to travel to another location to receive equipment or supplies. This is especially difficult with a fracture or sprain.

The proposed rule change would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to an entire Metropolitan Statistical Area (MSA). I only want to provide DMEPOS to my patients, not an entire MSA.

The CMS definition of physician would exclude podiatrists. I urge CMS to change the definition from 1861(r)(1) to 1861(r) so that podiatrists have the same ability to treat our patients as MD and DO physicians have to treat their patients.

I strongly believe that it is in my patient's best interest to be able to receive DMEPOS directly from me so that I know exactly what they are receiving and can be assured that they receive the type of DME that I can personally provide. It seems unreasonable to expect the patient with a foot injury to have to travel to another location to receive DMEPOS from a supplier whom I have no control over what they dispense. I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians.

Sincerely yours,

James E. Benedict, D.P.M.

Submitter : Ildiko Paulovits **Date:** 06/25/2006

Organization : North Jersey Hand Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I have had experience with a workman's compensation insurance company that sends it's clients to the lowest bidder for DME. The patients are not happy, the physicians are not happy and most of all the patients do not get what they need to return to function. I work directly with two hand surgeons and have worked hard to obtain my CHT (certified hand therapist) designation. My physicians expect and recieve the highest level of service for their patients. Sending patients on a search for another facility where they will encounter a person who is not qualified to assess and supply them with the DME that they require will only result in patients needing even more expensive care ie. surgery, further doctor visits and needless pain and suffering.

Please reconsider this cost saving measure and look to the long term outcomes that occupational therapists and certified hand therapists can ensure for medicare patients.

Thank you,
Ildiko Paulovits OTR, CHT

Submitter : **Dr. David Garchar** **Date: 06/25/2006**

Organization : **Ryan Foot and ANkle 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 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 have been prescribing and supplying DMEPOS items to Medicare beneficiaries as an integral part of patient care for 4 years. 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 Garchar, DPM
Ryan Foot and Ankle Clinic
Charlotte, NC 28025

Submitter : Dr. Jason White

Date: 06/25/2006

Organization : Podiatry Solutions of WNY, PLLC

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 25, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r)(3).

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r)(3) definition of physician in finalizing its regulations.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, this is just one of the many tasks I will not be able to perform in order to benefit the health and well being of my patients.

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

Sincerely,

Dr. Jason T. White
Lockport, NY

Submitter : Mrs. Deborah Kreimeyer **Date:** 06/25/2006

Organization : American Society of Hand Therapists

Category : Occupational Therapist

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

I would like to see the language of 'occupational therapist and physical therapist' be added to orthotist, as those who are qualified to make more than minimal adjustments to splints. I work in an orthopedic surgeon's office, and often have to make modifications to off the shelf thumb splints for them to fit correctly. Also I make decisions about which splint seems to fit the patient and their needs most adequately.

GENERAL

GENERAL

I have made several comments already in the specified fields above, but I would like to add a few more.

As a certified hand therapist in a physician's orthopedic practice, I am concerned that our Medicare patients will not get the best care. Many of our patients can not leave the office without a support applied to the upper or lower extremity. For example, tendon repairs must be carefully supported after removing the post-op splint dressing. If these patients must leave the office to get an off the shelf splint, we will need to put on some type of plaster or fiberglas support until they can get to a supplier. This would result in another charge for the patient(for the plaster splint) that they would not have had, if we could have applied the off the shelf device in the first place. The other problem with this is that patients actually have to get to the supplier. Some people don't follow through very well, and if it involves a trip across town or farther away,they may not go. I work in northern Iowa, and many of our patients already drive a distance to get here.

I am also concerned that patients may not be fit with the correct device in some instances, which would limit the effectiveness of the treatment. I sometimes will look at 3 different thumb splints with the patient before we decide which one best suits the patient.

I have also had occasion to see patients that were fit with a wrist splint somewhere else, but it did not fit them well, so they didn't use it. When we tried a better fitting splint, they used it and got better.

Thank you for your time in reading my comments. We're just trying to do a good job for the patients we treat.

Terms of Contracts

Terms of Contracts

According to the proposed rules, only the contractor that issued the off the shelf orthosis to a beneficiary can be allowed to modify it if needed. If I see a patient who is developing skin breakdown from an ill fitting splint late on a Friday afternoon, do I do nothing to modify the splint, even though the patient may not be able to see the supplier until Monday AM? Or do I assume liability for a splint that I did not issue or bill for, and go ahead and fix the splint? These are some of issues that I will face if the current proposal goes through.

Submitter : veronica penney

Organization : veronica penney

Category : Occupational Therapist

Date: 06/25/2006

Issue Areas/Comments

GENERAL

GENERAL

I am an occuaptional therapist specializing in Hand Therapy. I occassional use specialized prefabricated splints such as for PIP extension and I stock these for my patients. On the occassions that I have needed to get these splints from local DME suppliers, I have had to look up all the ordering info so the DME supplier can order it for them since the DME supplier is completely unfamiliar with these specialized products. By not allowing Occupational therapists to provide prefab splints directly, you would be adding confusion to the process for the patient and causing the OT to do work they are not reimbursed for since we will need to select the othoses and assist the DME supplier in ordering the right one. The patient will also experience a time delay as the OT stocks these splints and they are special order to the DME supplier.
It is in the best interest of the patient to allow OT to continue to provide some prefab splints especailly the L code for reverse knuckle bender.
Thanks

Submitter : Mr. Anthony Beraldi **Date:** 06/25/2006

Organization : Mr. Anthony Beraldi

Category : Pharmacist

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Dear CMS,
I am a pharmacist in Iowa. Our business currently provides DME, mostly diabetic supplies. It is not a very large part of our business, however, I am concerned that in the future my patients may not be allowed to get their supplies from me. I agree with the comments of our national pharmacists associations that obtaining accreditation will like be very expensive. I hope that as the new system for patients to get their DME supplies is developed, CMS recognizes the importance of patient/provider relationships.

Thank you,

Anthony Beraldi, RPh

Submitter : Dr. M Ottinger **Date:** 06/25/2006

Organization : Foot and Ankle Group, PC

Category : Physician

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

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,

Mary Ottinger, DPM

Submitter : **Dr. Michael Buchmeier** **Date: 06/25/2006**

Organization : **Netcare Pharmacy *Medicare # 1237510002**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

FR: I.V. CARE OF SA, INC dba: NETCARE PHARMACY 6-26-2006
6428 BANDERA RD, SAN ANTONIO TX 78238 MEDICARE #1237510002
MEDICAID # 167964901 AND 16796402

AS A DME SUPPLIER NETCARE PHARMACY STRONGLY OBJECTS TO THE IDEA FOR A DME COMPETITIVE BIDDING PROPOSAL.

REASON #1 MANY PATIENTS NEED THEIR DME SUPPLIES IMMEDIATELY AND CANNOT WAIT 2 WEEKS FOR MAIL ORDER SUPPLIES. NETCARE HAS 3 DELIVERY PERSONNEL THAT PROVIDES SAME DAY DELIVERY OF BOTH RX AND DME SUPPLIES AT NO COST TO THE PATIENT.

REASON #2 MANY PATIENTS REQUIRE A DEMONSTRATION FROM PHARMACY PERSONNEL FOR PROPER USE OF THE PRODUCT AND SUPPLIES. THIS IS IMPOSSIBLE WITH MAIL ORDER.

REASON #3 PHYSICIANS FREQUENTLY SWITH THE PATIENT TO A NEW UPDATED DEVISE. THIS AGAIN WILL REQUIRE PHARMACY PERSONNEL TO EDUCATE THE PATIENT AS WELL AS PROVIDING THE NEW SUPPLIES IMMEDIATELY.

REASON #4 BENEFICIARIES NEED ACCESS OF CHOICE BOTH FOR CONVENIENCE AND SAFETY. LIMITING DME PRODUCTS TO A FEW SUPPLIERS WILL CONFUSE AND FRUSTRATE MANY BENEFICIARIES AND MAY DELAY THEIR PROPER TESTING AND/OR MEDICATION REGIMENS, WHICH IN TURN MAY MEAN MORE E.R. VISITS.

THANK YOU,

MIKE BUCHMEIER, RPH, PHARM-D

Submitter : Ms. Spring Harkins **Date:** 06/25/2006

Organization : American Society of Hand Therapists

Category : Occupational Therapist

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I work for three hand surgeons and we supply soft neoprene finger and hand splints as well as fabricate our own. There is a great deal of fitting involved with post-surgical hands and these concerns for the safety of the surgery and potential for damaging edema resulting from a poor fit are my main concerns with our office not being the supplier for our patients. Many of these may be HCPCS coded but some are not and are considered 99070 supplies. We do not want the patient going to a local drug store and trying to fit themselves, nor do we want someone not knowledgeable about the post-op course of therapy and the amount of time and length of wear of said orthoses.

I have practiced Occupational Therapy for 32 years and have been a Certified Hand Therapist since 1991. Our results with reconstructive hand surgery are better because we are able to reach for whatever orthosis best serves our patients' needs. Our MD's all order the orthoses and direct the care of their patients knowing that we will summon them if a fit cannot be made or if there is a concern that the patient cannot don and remove the orthosis independently. This is a crucial need: The instant fit or trial of an orthosis specifically for the patient's needs, at the moment it is ordered, with no further travelling or office visits or copays for the patients to contend with. Many have travelled far distances to see us and expect to get what they need with this one trip, often made at the expense of the patient or a family member not able to go to their jobs that day in order to bring the patient in to see the MD. We are uniquely qualified and able to discern proper fit and function of the orthoses.

Please allow small well qualified professionals such as Hand Therapists to continue to fit and supply DMEPOS orthotics and scar pads. Thank you for the opportunity to respond to you. Spring Harkins, OTR/L, CHT June 25, 2006

CMS-1270-P-393 **Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**

Submitter : Ms. Jeanne M. Harper **Date & Time:** 06/25/2006

Organization : St. Mary's Regional Medical Center

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-393-Attach-1.RTF

CMS-1270-P-393-Attach-2.RTF

CMS-1270-P-393-Attach-3.RTF

CMS-1270-P-393-Attach-4.RTF

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. Michael Fein** **Date: 06/25/2006**

Organization : **Dr. Michael Fein**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 25, 2006

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

Dear Dr. McClellan:

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

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

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

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

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

Sincerely,

Michael Fein, D.P.M.

Submitter : **Ms. Jeanne M. Harper** **Date: 06/25/2006**

Organization : **St. Mary's Regional Medical Center**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment "orthosesCMScomment.rtf"

CMS-1270-P-395-Attach-1.RTF

#395

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 Jeanne M. Harper 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 regional medical center in an underserved area of northern Nevada. I see & splint patients in the acute care units of the main hospital and in the outpatient office across the street. I frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider **and** a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, and the potential risks of not providing needed appliances, 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 in a timely manner.

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, 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, functional outcomes, 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. When we assess the upper extremity disorder, we consider not only the mechanics of the device, but also the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs. 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. The doctor could be unhappy that his patient did not get the exact orthosis that he prescribed. As a hand therapist, I routinely stock those off the shelf orthoses (OTS) 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,

Jeanne M. Harper, OTR/L, CHT

Submitter : Mrs. Rosemary Sullivan **Date:** 06/25/2006

Organization : Mrs. Rosemary Sullivan

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachement.

CMS-1270-P-396-Attach-1.DOC

#396

06-25-06

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

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

My name is Rosemary Sullivan, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I have been treating individuals with hand and upper extremity conditions for the past 12 years as a therapist for the Veteran's Administration. Working for another federal agency, I am not sure that the proposed regulations will apply to my practice, but I would like to speak on behalf of those who do provided billable services to 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, cognitive abilities, 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. In addition, even when patient's are referred to me for provision of an othosis alone (i.e. not as part of the ongoing therapy process), I have to take the needs of the individual into consideration as two patients with the same diagnosis may not have the same splinting needs.

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

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

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

A patient's needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, a specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.

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

Sincerely,
Rosemary Sullivan, MA, OTR/L

Submitter : **Dr. Marc Borovoy** **Date: 06/25/2006**

Organization : **Associated Podiatrists P.C.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

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,

Marc A. Borovoy

Submitter : **Mrs. Valerie Vollman** **Date: 06/26/2006**

Organization : **Mrs. Valerie Vollman**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-398-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 Valerie Vollman 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 an outpatient hand 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,

¬¬¬¬¬¬Valerie Vollman, LOTR, CHT

Submitter : **Dr. Bruce Blank** **Date: 06/26/2006**

Organization : **Ohio Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 25, 2006

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

Dear Dr. McClellan:

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

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

Through educational programs, we at the Ohio Podiatric Medical Association have educated our members about the proper indications of DMEPOS for our patients and the importance of adherence to the existing 21 supplier standards. We are subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

As currently proposed, CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As physicians in the Medicare program, we should have those same rights. We use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician.

The following is one of many examples why it is necessary for Doctors of Podiatric Medicine to competitively bid to supply DMEPOS only to our patients:
We see and treat patients with various fractures of the foot and ankle. If any of us treats a patient with a fracture and decide that it is medically necessary and appropriate to use a walking cast brace, it only makes sense that we should be able to supply the item in the office instead of having the patient leave, risking further injury, to receive the DMEPOS item elsewhere.

We need to ensure that the fracture is protected and that the walking cast brace fits properly. If we are not suppliers in the new program, we will not be able to treat these Medicare beneficiaries appropriately and patients will suffer.

Examples of problems which will be encountered if the patient has to receive the DMEPOS item elsewhere are: further displacement of the fracture requiring surgery, excessive swelling leading to compartment syndrome and its associated risks, and a closed fracture becoming more unstable resulting in an open fracture requiring surgery, hospitalization and very significant additional costs.

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

Sincerely,

Bruce G. Blank, DPM, FACFAS
President, Ohio Podiatric Medical Association

Submitter : **Dr. Gerald Falke** **Date: 06/26/2006**

Organization : **Podiatry Associates of Hagerstown**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 25, 2006

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

Dear Dr. McClellan:

I am writing to encourage CMS to use physician definition 1861(r)(3) in its proposed rule establishing a competitive acquisition program for DMEPOS.

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient management. The people who will be most affected by the proposed regulation are patients, like mine, who depend on me to use my best medical judgment and skills.

While I agree with CMS s decision to permit primary care physicians to continue to prescribe and dispense DMEPOS to their respective patients, I cannot agree with the decision to withdraw that privilege from podiatric physicians. Many of us have held a valid DMEPOS supplier number for many years, have adhered to all supplier standards and are subject to the same Stark requirements that apply to MD and DO physician suppliers.

Podiatric physicians are the major primary care providers of foot and ankle services to all demographic groups nationwide, including seniors. I am certain that this change will create unique and potentially risky patient management difficulties. For example, when a patient suffers multiple fractures requiring a walking boot for immobilization of the injured foot and leg, the patient will be forced to travel to another location to obtain the item, risking further injury in transit.

On a more pragmatic level, this change is painfully reminiscent of the arguments used in the 1980 s to bring about deregulation of the utilities, while being fully cognizant of the likelihood that there would be no economic benefit to the public.

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

Sincerely,

Gerald I. Falke, DPM

Submitter : **Ms. Beth Birmingham** **Date: 06/26/2006**

Organization : **Dekalb Medical Centers Rehab Results Group**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

"Proposed Rule for Competitive Acquisition of Certain DMEPOS" CMS- 1270-P
I am an Occupational Therapist. I see indivduals who have had hand injuries, and I am seen as the Arthritis specialist in my clinic. Many of my patients have autoimmune types of arthitis which cause debilitating deformities of the hand. Some of them require hard splints I make; others will benefit from soft splints we purchase, and some transition from one to the other or use a soft in the day and a hard splint at night. The splints are specific to different joints that deform with arthritis and are not found in drug stores. Each person has an individualized plan thought out with clinical reasoning and with the stage of arthrtis and functional needs they have with their daily routine. I believe I do make a difference in many patients lives by enabling them to still use their hands and helping them remain productive members of society. If this rule is past, I believe it will severely hamper the ability of all the Occupational Therapists to provide the best care possible to an individual. It's not just about giving out durable medical equipment; it's about problem solving what an indivdual's needs are to help them compensate for an injury or a disability and orthotics is just one part of a bigger plan of care.
They could also be taught how to use their orthotics with their daily tasks using joint protection techniques and proper ergonomics. Or taught home methods, as well in the clinic recieve modalities, that decrease swelling and pain. They also learn adaptive equipment that help them for example grip when they can't make a full fist. A number of things are taught/modified/performed to help the individual with the problems they have performing daily tasks. Our ability to provide quality care to each individual in a timely manner will be hampered if this rule goes through, if they need orthotics. As a patient advocate, please do not pass this rule and challenge their ability to get the assistance they need any facility they go.
Sincerely,
Beth Birmingham, OTR/L

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

Organization : Strength Training Inc.

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I feel it would be agrave mistake to enforce this rule for the following reasons:
1. As a therpist I can asses the patients needs and specific deficits. In many cases a certain brand of orthosis is the only one appropriate for a particular patient. Bidding for the lowest priced brand would eliminate many orthoses that would be appropriate.

2. Many times the lowest brice orthotic is found outside the area where the patient lives and must be shipped. Delays in shipping and aquisition of the orthotic by the patient can interfere with critcal time lines for certain injuries which can result in loss of range of motion, further deformity of the extremity, and decreased function.

3. Another issue here is the legal ramifications if a patient comes to me for treatment but has an orthosis from another entity and it is inaproprately adjusted or fabricated. Do I adjust it and become liable even though I did not supply it. Almost all off-the-shelf splints have no warranty that includes a skilled technition to adjust the splint. As a therpist I am specifically trained in this area.

I emplore CMS to reconsider this rule. I think it would be the beginning of a serious decline in the quality of patient care and many other complications that would be far more expensive than a splint or orthotic such as corrective surgery, more therapy, or adaptive equipment to help the patient adapt to a permanent functional deficit.

Respectfully

Ty J. Pehrson
Hand Therapist

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

Organization : **Gary Prant**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 25, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

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 Austin Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

Gary D. Prant, D.P.M.
Austin, Texas

gprant@yahoo.com

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

Organization : Linda Grodner

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-404-Attach-1.DOC

CMS-1270-P-404-Attach-2.DOC

404

June 25, 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 Linda Grodner and I am an occupational therapist specializing in the treatment of upper extremity disorders. I have specialized in the treatment of hands and upper extremities for 26 years. I am currently working in an orthopaedic physician's office 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,

Linda Grodner, OTR
2904 Ryecroft Road
Birmingham, AL 35223

Submitter : Ms. Nancy Mitchell **Date:** 06/26/2006

Organization : Cottage Health Systems

Category : Nurse

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I feel we are doing our patients, especially senior citizens a HUGE
disservice by not allowing options for them in choosing a reliable glucose meter. Cheap is not the best way to go...Shame on whoever proposed this....it is truly a sad day for older Americans when our health care system is concerned more with their "bottom line" than a proper care of our seniors.

Submitter : Mrs. Cheryl Kunkle **Date:** 06/26/2006

Organization : Orthopaedic Associates of Allentown

Category : Occupational Therapist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

/Users/cherylkunkle/Desktop/sampleltr-1.doc

Submitter :

Date: 06/26/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Marc L Bendeth, DPM

Submitter : michael kramer

Organization : michael kramer

Category : Individual

Date: 06/26/2006

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

I am very concerened about the 36 month cap associated with this new legislation and the impact it will have on patient care.

Regulatory Impact Analysis

Regulatory Impact Analysis

I know many people that have had euipment replaced over the years by their DME company. My concern is that after the 36 month period, how will these patients be served or taken care of by organizations that are no longer being paid to do so. Unfortunately, the patient provider relationship was always based on compensation for the service and once that stops the service will go away.

Tis legislation will eliminate many small providers and cause great disruption to patients. I expect that over time, it will be reversed and at that point there will be far fewer providers in the business which may be too late.

THis legislation has already impacted many potential providers as they are choosing to start other kinds of businesses rather than DME. With the growing aging population in this country, we should be doing all that we can to make sure that the brightest people consider this market as an opportiunity to provide a service and provide for their own families.

Submitter : **Dr. Jill Stepnicka** **Date: 06/26/2006**

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

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. In its current form, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care. If I am no longer able to supply those items if I am not selected as a DMEPOS supplier under the new program, my patients will suffer.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician s ability to provide medically necessary and quality care to Medicare beneficiaries. Again, I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Sincerely,

Jill K. Stepnicka, D.P.M.

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

Organization : **Carteret 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,

David Shansky , DPM
768 Roosevelt Ave.
Carteret, NJ 07008

Submitter : **Dr. David Freedman**

Organization : **Dr. David Freedman**

Category : **Physician**

Date: 06/26/2006

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Dr. McClellan:

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of my overall patient care. My patients rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. 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 and/or ankle pain and swelling following an injury, I then diagnose the patient with a fracture and determine that a walking boot is necessary for immobilization of the injured foot and ankle. 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 and ankle. If the patient is unable to bear full weight on the injured extremity, and I need to dispense crutches but would not be able under this new bidding process then 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 J. Freedman, DPM, FACFAS

Submitter : Dr. Matthew DeWitt

Organization : Dr. Matthew DeWitt

Category : Physician

Date: 06/26/2006

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

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

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

Matthew T. DeWitt, DPM
DeWitt Foot & Ankle, LLC
3645 N. Briarwood Lane Suite A
Muncie, IN 47304
O: 765-284-3879
F: 765-289-4655

Submitter : **Dr. Mark Block** **Date: 06/26/2006**

Organization : **Dr. Mark Block**

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:

Unfortunately the definition of physician has complicated the competitive acquisition program as it relates to Podiatric Physicians. This technical issue needs to be addressed. 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,
Mark S Block DPM
Insurance Chairman/CAC Representative Florida Podiatric Med. Assoc.
First Vice-President FPMA

Submitter : Ms. Carol Harm

Organization : Ms. Carol Harm

Category : Other Practitioner

Date: 06/26/2006

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

I am writing to 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.

My name is Carol Harm. I have been an occupational therapist for 26 years. 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 of the individual patient. 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. In some situations where I have been forced by private insurance contracts such a HMO s, I have had to defer specific splint selection to providers approved by the insurance company. Often, the choices of splints have not been adequate for the needs of the individual patient and sometimes a necessary type of splint is not even available as an option. This is, I believe, just one of the dangers of such contracts. There have been times that my patients have come back to me with an inappropriate, an inadequate splint or even NO splint. As a result, expenses actually end up INCREASING due to the need to do additional custom fabricated splinting or to send the patient back to the surgeon for additional care as a result. Often the lack of an appropriate splint can delay healing or necessitate treatment that goes beyond what it should had the appropriate splint been available from the beginning!
Hand therapists typically treat very acute patients, and the ability to immediately dispense and adjust an orthosis is crucial to outcomes for these patients. In the course of treatment, there are 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.

Submitter : Mr. Patrick Healy

Date: 06/26/2006

Organization : Upham's Corner Health Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Using the lowest bidder has the potential to cost more in the long run. If the DMG provider does not properly train the user, erroneous clinical information will impact on the clinical decision-making resulting in poorer health and emergency room care. The quality of the equipment used has been demonstrated to have been counterproductive economically. We have had several instances where people relied on their Tru-Track glucometer and based on these erroneous results had themselves sent to the emergency room by ambulance. Use of a higher quality machine would have resulted in the appropriate decision and no emergency room visit or ambulance transfer would have been necessary. Poor equipment will contribute to poorer patient compliance, resulting in poorer glucose control contributing to the long term complications and costs of diabetes. Thank you for this opportunity to comment.

Submitter : **Dr. Richard Feldman**

Organization : **Dr. Richard Feldman**

Category : **Physician**

Date: 06/26/2006

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Richard B. Feldman, D.P.M., F.A.C.F.A.S., LLC

Submitter : Dr. Bret Ribotsky

Date: 06/26/2006

Organization : Dr. Bret Ribotsky

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

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

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,

Bret Ribotsky, DPM, FACFAS, FACFAOM
561.447.8700

Submitter : Mrs. Judith Neumann **Date:** 06/26/2006

Organization : American Society for Hand Therapists

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I am an OT and provide hand/wrist splints to patients, both off the shelf & custom fabricated. When I get a patient with carpal tunnel, for example, I may use one of several off the shelf splints or may custom fabricate one. The correct splint to use is the one that fits the patient and provides the proper support. Deciding which splint on the basis of cost, provides the wrong splint to 90% of patients. This approach is like buying one size boot for an entire army or one type of vehicle for all military personnel, regardless of needs, shapes or sizes. We all know that decisions made strictly on $$$, result in materials that don't work, don't fit, and fall apart in the shortest possible time. Occupational Therapists fabricate splints that fit because they are custom made. They are cost effective as the materials are relatively inexpensive, durable, and remoldable. Costs for the services of a therapist are much less than an orthotist and cover more treatment needs than just splinting. Asking a sick or injured patient to see a number of providers to get the 'approved & covered' materials is a waste of time, money, and added stress to a person who already has pain and/or other symptoms.
Please stop this proposal. It is the wrong solution to rising health care costs and ultimately will cost more money for poorer solutions.

Submitter : Ms. susan marlin **Date:** 06/26/2006

Organization : visiting nurse association of boston

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Having potentially low-cost providers offering generic equipment and little training or support to patients would actually lead to higher long-term costs for CMS(since the poor equipment and little training leads to lower patient adherence to glucose monitoring and overall treatment guidelines, leading to more long-term complications, more ER visits, and higher overall costs).

Submitter : Peter Thomas

Date: 06/26/2006

Organization : Peter Thomas

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

My wife and I own an independent community pharmacy outside Huntington, WV. I request that diabetes testing supplies be exempt from the Competitive DME Bidding process. Since some of diabetic patient travel over 45 minutes to get to my pharmacy to get diabetic supplies, how much farther will they have to travel if diabetic supplies are not exempt. I do educate and counsel my patients on diabetic monitors and supplies and I am planning to expand this aspect of my pharmacy business. I also help with compliance by noticing if they are getting testing supplies on a regular basis. One of most important aspects of controlling diabetes is frequent testing by patients. Even if they are supplied by a mailorder supplier, I doubt they will ask them how they are controlling their diabetes or what have been their blood sugar readings on glucose monitor. I hope CMS will see the value of face to face interaction with a pharmacist and exempt diabetes supplies from Competitive DME Bidding.

Submitter : Mrs. Nicole Bickhart

Date: 06/26/2006

Organization : OTR/L, CHT

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-421-Attach-1.DOC

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

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

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

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

My name is Nicole Bickhart, 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 an outpatient rehabilitation, 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,

Nicole Bickhart, OTR/I, CHT

Submitter : **Dr. Joel Epstein** **Date: 06/26/2006**

Organization : **American Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

Fee Schedules for Therapeutic Shoes

Fee Schedules for Therapeutic Shoes

June 12, 2006

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

Dear Dr. McClellan

As a podiatric physician who has been in practice for more than 25 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. Most of my patients are elderly and it would be quite a burden on them and the people that transport them to not be able to acquire goods needed at one location. Often family members or friends need to take off of work to bring patients to the office or they have to pay for cab transportation to come to the office. If they also needed to go to an outside source to receive DMEPOS products it would definitely be more costly and inconvenient. In fact, many may not even go to pick up the supplies they need.

I use a wide variety of DMEPOS items, including walking boots for foot fractures and ankle braces for acute ankle injuries. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result. I cannot imagine telling a Medicare beneficiary that I am unable to supply an ankle brace to treat an ankle injury and he or she must travel across town to obtain an item that is both medically necessary and appropriate.

Please reconsider your proposal and exclude all physicians, include podiatric physicians, from the new competitive acquisition program for certain DMEPOS. Instead allow me, as a qualified supplier, to continue to directly supply items to Medicare beneficiaries.

Sincerely,

Joel Epstein, D.P.M.,P.A.
Diplomate, American Board of Podiatric Medicine
Fellow, American College of Foot Surgeons

Submitter : Miss. anna gevorkyan **Date:** 06/26/2006

Organization : Miss. anna gevorkyan

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community pharmascist, I respectfully request that diabetes supplies be exempt frome the Competitive DME Bidding process.
It is imperative that patients retain current level of care receved at the retail pharmacy level.
If competitive bidding becomes a relity for diabetes testing supplies at the retail pharmacy level,it will detrimentally impact the patients health and well-being.
Diabetes education is crucial to the health and well-being of our patients:
Retail pharmacists offer critical services to patients by offering education on daily diabetes care, medications/side effects/possible drug interactions,and training on blood meters and testing care.
Retail pharmacists have the ability to impact patient adherence in all aspects of diabetes care and provide a local presence for assistance with copmlications of therapy.
retail pharmacists work in conjunction with the patients physicians in an effort to facilitate the best possible diabetes care.
thank you

Submitter : Mr. Michael Jones

Organization : Med-South, Inc.

Category : Home Health Facility

Date: 06/26/2006

Issue Areas/Comments

GENERAL

GENERAL

Do it right the first time. (See Attachment)

CMS-1270-P-424-Attach-1.DOC

#424

"General"

Getting It Right

CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. Under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

CMS should stagger the bidding in MSAs over a twelve-month period to allow for an orderly roll out of the program. A staggered rollout will allow for problem identification and correction before these problems become widespread.

CMS should publish an implementation timeline that at a minimum identifies the following steps and expected completion dates:

a.) Publication of Supplier Standards
b.) Approval of accrediting organizations
c.) Issuance of final regulation
d.) Publication of final 10 MSAs and product categories
e.) Commencement of bid solicitations
f.) Conclusion of bid solicitations
g.) Announcement of winning bidders
h.) Education of beneficiaries and medical community
i.) Implementation within each MSA.

The Program Advisory And Oversight Committee (PAOC) should be included in the review of public comments and in the development of the final rule. Failure to include the PAOC goes against the very purpose for establishment of the PAOC.

Michael Jones
Med-South, Inc.
35501

Submitter : Mr. David Kwiatkowski

Organization : Advanced Home Care

Category : Other Health Care Professional

Date: 06/26/2006

Issue Areas/Comments

GENERAL

GENERAL

I believe that homecare is not the problem in rising Medicare costs. The data shows that hospitals and medication are resposible for these increases. Homecare is the solution in reducing the total Medicare output.

Submitter : Ken Magee

Date: 06/26/2006

Organization : Ken Magee

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-426-Attach-1.DOC

#426

June 15, 2006

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

Dear Sir/Madam:

I am writing to submit comments regarding CMS-1270-P.

Payment Basis

It is unfair to expect a contract supplier to assume responsibility for a Medicare beneficiary that has been renting oxygen equipment or other rental equipment from a non-contract supplier that is not willing to continue provision of equipment under the grandfathering clause. It is possible that many patients may only have 1, 3, or who knows how many months left under their rental period. The contract supplier would receive few, if any, rental payments before this equipment would convert to purchase. It is not possible to factor a cost for this into our bid price.

Competitive Bidding Areas

It is recommended that CMS should stagger the bidding in MSAs in 2007 instead of implementing all 10 areas at once. This would allow CMS to identify problems and correct them before these problems are widespread in all 10 MSAs. It is imperative that the first 10 MSAs and the product categories are identified in the final rule to begin to give providers ample time to prepare for the competitive bidding process. Under the timelines that CMS has established, it is going to be impossible for small providers in these large MSAs to identify other providers for potential networks and to work through the legal processes to form these networks.

Criteria for Item Selection

All products and HCPCs codes that are going to be competitively bid in each MSA should be published in the final rule. There are many providers that may specialize in only one HCPCS code in a product category and they should not be kept from bidding. Is it your intent to have Respiratory Therapist, who may not have wheelchair experience, delivering wheelchairs, because they can't bid on respiratory products only?

Real Cost

It is also important that in both selection of MSAs and product selection, when CMS is projecting the potential savings, that full costs of implementation and overhead are

factored into this process. The costs to implement and administer this project are going to be significant, and these costs cannot and should not be ignored when calculating the savings to be achieved through competitive bidding.

Submission of Bids under the Competitive Bidding Program

It is important to require the suppliers that are winning providers be physically located within a competitive bidding area. This would eliminate a tremendous amount of fraud and abuse in the Medicare program (with the exception of mail order supplies). Drop shipping non-supply items is unsafe. If companies were required to have a physical location in the competitive bidding area, this would eliminate a significant portion of the fraud and abuse that is currently taking place in our industry. With the way the proposed rule is currently written, CMS is perpetuating the problem, not helping to solve it!

Conditions for Awarding Contracts

Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now and publish that criteria. CMS should grandfather all providers accredited by organizations that meet the criteria that CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM. The quality standards will have a significant impact on the cost of servicing our beneficiaries. Until these quality standards have been released and providers can implement them, as well as see the costs of becoming accredited (both internal costs and the actual cost of the accreditation process), then it is impossible to prepare bid pricing. Companies that have not gone through the accreditation process can submit unrealistic bid prices due to the fact that they have not completed the process nor obtained accreditation. These low bids can significantly impact final pricing. And if these companies choose not to get accredited and drop out of the contract supplier group, they have lowered pricing for these products.

CMS should require accreditation of all locations of a company. It is not appropriate to think that if one branch of a business such as Wal-Mart is accredited, that all branches of the business provide the same level of service. This would also give the national companies an unfair advantage over the single location companies, because they could accredit one branch and spread that accreditation cost over many locations, while the single location small provider will have to absorb the large cost of accreditation and factor that into their bid price.

It is also important to note that the timelines that CMS are considering for implementation of competitive bidding are unrealistic based on accreditation requirements. For the majority of companies in this industry, they have not prepared for nor gone through the accreditation process. This is a time-consuming process and one that many companies do not want to prepare for until they have all the answers. Providers want to see final quality standards and then a list of the accrediting bodies recognized by CMS before they begin the lengthy, expensive process of accreditation. It requires a

minimum of 6 months to prepare for your initial survey plus the majority of accreditation bodies require that companies be in compliance with quality standards for a minimum of 4 months prior to survey. So, realistically, providers going through accreditation for the first time will need 10-12 months to complete that process. Add on to that timeframe another 4-8 weeks after the survey before the accreditation body notifies the provider of the "official" results of their survey. So, it is important to realize that on average, CMS should expect it to take a minimum of one year to complete the accreditation process and become officially accredited. This doesn't even take into consideration the tremendous backlog that all accrediting bodies are going to face once quality standards are finalized and accreditation organizations are selected. It is unrealistic to think that this won't add additional time to the already lengthy process.

CMS should not artificially limit bids by disqualifying bids above the current fee schedule. Otherwise, the competition is not truly competitive based on market prices. If you are barely making a profit now and accreditation increases cost how can not submit a bid that is higher than the current fees.

There is no incentive in the proposed rule to exclude lowball bids, as bidders will assume they will be paid an amount higher than their bid. Bid evaluation and selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS should identify processes through which they will be able to determine that the bids are both rational and sustainable.

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

CMS' process to determine the number of suppliers to meet projected demand in an MSA and its methodology to estimate supplier capacity, are stacked in favor of large high volume national and regional suppliers despite CMS' assertion that the NPRM provides opportunity for small suppliers to participate. Moreover, there are no guarantees that any of the winning bidders will be small businesses or a network of small businesses. National companies who could pull resources from other areas could submit bids with projected unlimited servicing capacity. This would unfairly limit winning suppliers and exclude many businesses from participation.

Determining Single Payment Amount for Individual Items

The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiaries. Providing rebates is contrary to laws applicable to the Medicare program such as the Anti-Kickback statute and the Beneficiary Inducement Statute.

Terms of Contracts

It is unrealistic to state that contract suppliers cannot refuse to repair or replace patient-owned equipment subject to competitive bidding. Many providers only provide one or two types of concentrators, for example, and based on the above statement, CMS would now expect contract suppliers to be able to service, repair and replace every type of concentrator made today. This is yet another example of how CMS is asking providers to continue to increase their costs, yet we are asked to significantly decrease our reimbursement. Not only does it increase a provider's costs to stock parts for every type of concentrator, but you must also train staff to be able to repair and service every type of concentrator.

Opportunity for Participation by Small Suppliers

CMS needs to define the definition of small business as it relates to the competitive bidding project. Is the $6 million in annual sales total sales for the company or Medicare sales only? Is this tracked by supplier number or by the company? These decisions impact many things as they relate to the proposed rule including requirements for reviewed financial statements versus audited financial statements.

Opportunity for Networks

Requirements for sub-contractors need to be clearly defined. If a contract supplier chooses to use sub-contractors, do they need to meet the same requirements as a contract supplier in terms of accreditation, financial standards, etc.? If so, how will CMS ensure that this happens?

For networks to be formed and to be anti-competitive, CMS will have to provide some type of data for providers to use to ensure that networks aren't formed that exceed the 20% of market share. Providers aren't going to want to go to the time nor expense to form a network and then find out when the application is submitted, that the network isn't eligible. This is another reason that financial standards need to be clearly defined up front by CMS in terms of their requirements regarding financial stability, financial ratios and what they should be, etc. Providers need detailed information so they can use this data to determine suitable partners for networks.

Clearly defined contract requirements also need to be outlined in the final rule so that providers ensure they meet CMS guidelines.

10 days is probably not a reasonable timeframe to resubmit an application if one of the members of the network is determined to be ineligible. The network will have to search for a replacement provider, determine that they can meet CMS guidelines and then have another legal contract drawn up for the revised network. This timeframe should be extended.

Thank you for your consideration of these comments. I appreciate the opportunity to submit these comments.

Sincerely,
Ken Magee
Palmetto Oxygen
803-926-0252

Submitter : Dr. GREGG HARRIS **Date:** 06/26/2006

Organization : GREGG HARRIS,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,

GREGG HARRIS, DPM

Submitter : Dr. Gregory Costanzo **Date:** 06/26/2006

Organization : Dr. Gregory Costanzo

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Dr. McClellan:

I am currently a podiatrist residing in and providing services in the mountains of western North Carolina. I have been participating in the durable medical equipment program for a number of years. I have found that providing these services to my patients , has been a real convenience and timesaver for them. I also have been able to ensure better health care outcomes over their foot health conditions.

It has come to my attention that there is a proposal pending before the Center for Medicare and Medicaid services(CMS) pertaining to competitive bidding to supply durable medical equipment to our patients. It is my understanding presently podiatrist will be categorized under the nonphysician DMEPOS grouping 1861 (r) 1. And as such , will be unable to provide these services for my patients. I would encourage you to classify podiatrist under the 1861(r) definition, and allow me to continue to provide these goods and services to my patients

Sincerely,

Gregory R. Costanzo DPM
Asheville , North Carolina

Submitter : Dr. Scott King **Date:** 06/26/2006

Organization : Ottumwa Foot and Ankle Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Dr. McClellan:

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

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

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

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

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

Sincerely,
Scott B. King, DPM

Submitter : Ms. Megrette Hammond **Date:** 06/26/2006

Organization : Wentworth-Douglas Diabetes Program

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

I am strongly against competitive bidding for the following reasons. Selecting a meter for a patient is a process that must meet the needs of the patient. Many patients have other conditions that make it difficult for them to use certain meters:vision, cognitive issues, desire to use alternate test sites, dexterity to name just a few. Having only a few meters often creates barriers for the patient, which decreases the frequency of testing -- and ultimatly harms his health.
I would strongly advise Medicare to not adapt this policy and allow patients to choose the meter that best meets their needs.
Respectfully,
Megrette Hammond M.Ed., R.D., CDE
Diabetes Educator
Wentworth-Douglass Hospital
Dover NH 03820

Submitter : Mr. David Kwiatkowski **Date:** 06/26/2006

Organization : Mr. David Kwiatkowski

Category : Health Care Provider/Association

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

How will you consider low ball bidders in the process? There are some companies out there who do not understand their costs. Costs include the service personel, equipment, and overhead.

What if a bidder bids $1 knowing they will receive a contract and if I understand correctly, the median price will be used? If this occurs, companies will go out of business and patients will lose access to providers who can sustain the low ball pricing.

How will you handle patients who move their residence with oxygen when it purchases and the patient owns 32 months into a 36 month rental term?

Submitter : **Dr. edward buro** **Date: 06/26/2006**

Organization : **mayfair foot care**

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,

Edward Buro DPM FACFAS

Submitter : Mr. Ronald Goss **Date:** 06/26/2006

Organization : Medicap Pharmacy

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a community independent pharmacist, I respectfully request that diabetes testing supplies and diabetic shoes 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 realty for diabetes testing supplies at the retail pharmacy level, it will detrimentally impact the patient's health and well-being. Diabetes education on the proper use of testing supplies is crucial to the health and well-being of our patients. Retail pharmacists offer critical clinical services and diabetes care to patients on a daily basis in conjunction with dispensing of diabetic supplies. These services cannot be provided via mail order which is the likely only way in which supplies will be provided if competitive bidding is required for diabetic supplies.

Submitter : Dr. Andrew Schneider **Date:** 06/26/2006

Organization : Dr. Andrew Schneider

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am writing as a podiatric physician who currently dispenses DMEPOS items to my patients. 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.

I am in danger of losing my ability to appropriately treat my patients. 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.

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. 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.

Thank you for your consideration,
Andrew J. Schneider, DPM

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

Organization : **Integrated Physician Systems**

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:

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 have been doing this for over 15 years in private practice. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r) definition of physician in finalizing its regulations.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

I urge CMS to reconsider its definition of physician and to apply the broader definition that includes podiatric physicians. Thank you for your consideration.

Sincerely,

Rob Katz, DPM, MBA
Past President, Florida Podiatric Medical Association
Integrated Physician Systems

Submitter : Dr. Gene Graham **Date:** 06/26/2006

Organization : Dr. Gene Graham

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Docket: CMS-1270-P
Please understand what a terrific hardship it will be on our Medicare fracture patients to have to leave our office to be fit somewhere else for a walking cast/fracture cast while they are injured. Not only is this unwise, it is also unsafe and may cause further damage to our patients. Please include Podiatric Physicians in the same category as Physicains and DO's. We are treating these patient's for the same problem and should not have our patients hindered in their care due to non-inclusion as a physician.

Submitter : Dr. Kenneth Malkin **Date:** 06/26/2006

Organization : Dr. Kenneth Malkin

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : Dr. Pamela McGaw **Date:** 06/26/2006

Organization : The Medicine Shoppe #1844

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a community independent pharmacy, I respectfully request that diabetes testing supplies and other related diabetic supplies be deemed exempt from the Competitive DME Bidding process. It is critical that our patients retain their current level of care they receive at our retail pharmacy level. If competitive bidding becomes reality for diabetes supplies, it will significantly and detrimentally impact our patient's health and well being. As a retail pharmacist, I offer critical clinical services by offering daily education on diabetes care as I see my patient's face to face. 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. As a retail pharmacist, I work in conjunction with the patient's physician in an effor the facilitate the best possible care. Taking this away from our patients would be a critical error. Please reconsider this issue.

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

Organization : Ryan Foot and Ankle Clinic

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 26, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician for four years, I regularly 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 sustains fractures involving the forefoot from an injury, immediate immobolization in a walking boot is required to prevent pain, re-injury or further fracturing and non-healing of the injury site, possibly requiring extensive surgery. If I no longer function as a supplier, the patient will be forced to travel to another location in the city of Charlotte 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 injuries to their foot, leg or hip.

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,

Dr. Jeffrey J. Glaser

Submitter : Dr. Steven Moskowitz **Date:** 06/26/2006

Organization : Dr. Steven Moskowitz

Category : Physician

Issue Areas/Comments

GENERAL

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June 26,2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r)(3).

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights. I use DMEPOS items as an integral part of patient care and believe that CMS should use the 1861(r)(3) definition of physician in finalizing its regulations.

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

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

Sincerely,

Dr. Steven E. Moskowitz

Submitter : **Ms. Katherine Mason** **Date: 06/26/2006**

Organization : **Apple Physical Therapy**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

Proposed rule for Competitive Aquisition of certain DMEPOS-1270-P

Dear Sirs,

I am am Occupational Therapist, Certified Hand Therapist, with 36 years of experience,the past 25 years specifically in Hand Therapy.

In this capacity I have a great deal of experience in the provision and adjustment of pre made upper extremity orthotic devices and braces.

The following are my comments on the specific nature of this part of therapeutic practice and the proposed rule on competivie bidding which would have a very negative effect on my ability to best treat Medicare patients.

Unlike a store clerkt as a DMEPOS supplier, Occupational therapists have expertise in not only the device to be provided but in the specific disability or mechanical insufficiency caused by the disease or injury process which will be remediated by the orthotic. This allows us to respond to the specific nature of the problem and to provide the best device and adjust it to maximally potentiate remediation of the condition or promote ADL function and independence. It can be done in clinic, during treatment and in immediate response to need, rather than delayed by the necessity of transport to a separate facility and special order of the orthotic by the DMEPOS store.

This aspect becomes critical after surgery when protection of the repair is paramont and the patient is most vulnerable. OTs have the expertise in handling injured tissue and following appropriate protocols which at times require 2x week revision of orthotic position in response to inflammation or revision of soft tissue stresses.

It would seem that this isssue also becomes a legal and ethical concern should the patient present with an orthotic provided by a clerk that is inappropriate or which needs adjustment as part of the protocol of treatment within our scope of practice. Do we assume the liability for the orthotic issued by a non professional?

Thank you for considering these comments,

Katherine E Mason, M Ed, OTR/L, CHT

Submitter : Dr. Steven Moskowitz **Date:** 06/26/2006

Organization : Dr. Steven Moskowitz

Category : Physician

Issue Areas/Comments

GENERAL

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

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

Sincerely,

Dr. Steven E. Moskowitz

Submitter : Mrs. Debbie Phibbs **Date:** 06/26/2006

Organization : NW Hand and NW Ortho

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-443-Attach-1.DOC

CMS-1270-P-443-Attach-2.DOC

#443

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, particularly in the rural clinical setting in which I practice.

My name is Debbie Phibbs, OTR/L, 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 an outpatient orthopedic clinic in a rural environment where options for treatment are limited, 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 if, with its possible delay, knowing that they are inadequately fitted and/or unprotected? In our rural setting, there may not be another option for care in reasonable proximity for the patient. 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 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,

Debbie Phibbs, OTR/L, CHT
Camano Island, Washington, 98282

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