Submitter :

Date: 06/27/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

Ann Anderson, DPM

Submitter : **Ms. Amy Piazza** **Date: 06/27/2006**

Organization : **Easton Orthopaedic Group**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-547-Attach-1.WPD

#547.

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

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 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 Amy Piazza, 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 Easton Orthopaedic Group, and frequently treat Medicare beneficiaries that require custom and/or off the shelf orthoses.

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

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, 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 meets the needs of the 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 orthosis. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthosis 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 the proposed regulation.

Sincerely

Amy M Piazza, OTR/L, CHT

Submitter : Dr. Gary Hoberman **Date:** 06/27/2006

Organization : Dr. Gary Hoberman

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

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

Sincerely,

Gary J. Hoberman DPM

Submitter : Mrs. Beth Bergeron

Date: 06/27/2006

Organization : Harris Methodist Fort Worth

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-549-Attach-1.TXT

CMS-1270-P-549-Attach-2.DOC

#549

docdispatchserv[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 Beth Bergeron, 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 at Harris Methodist Hand Clinic and 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, Beth

Bergeron, OT, CHT Sample Letter

Submitter : Mr. Michael McDonald

Organization : Clinical 1 Home Medical

Category : Health Care Industry

Date: 06/27/2006

Issue Areas/Comments

GENERAL

GENERAL

My name is Michael McDonald and I am President of Clinical 1 Home Medical a Weymouth, Ma based home respiratory and DME company.

1. I am shocked that CMS has not proposed the quality standards yet. With 2007 right around the corner, one would think that CMS would give small businesses a chance at meeting the proposed standards. With the MSA's not published yet, providers simply can not make prudent business decisions regarding the future of their business.

2. There should be no 'name brand' mandate by CMS. As it stands right now, unfortunately patients receive the lowest cost product due to reimbursement cuts. We are unable to provide most name brand products at the current reimbursement level and certainly will not be able to provide the best, highest quality products in the market after the bidding starts.

3. The reimbursement 'inducement' is illegal and should be taken out.

4.CMS is going to receive lowball offers from providers who simply will not be able to provide any type of quality service to the patients. CMS has to understand that it costs providers a certain amount of money to provide home medical and respiratory services to the patient population that we serve. All lowball, below threshold bids should be thrown out.

5. There should be a mandate that would call for a certain amount of small providers per MSA.

6. The PAOC committee must be included in the final rule making.

Thanks,

Michael McDonald

Submitter : Mr. Tim Miller

Date: 06/27/2006

Organization : Mr. Tim Miller

Category : Home Health Facility

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

How can this even be considered as a saving! The logistics that will go into this will most likely exceed the savings. Why would you let unqualified bidders take part in this process. Isn't anyone concerned that this might make the whole structure of DME/HME's as we know them to be today, will undoubtedly be a thing of the past. The customer, your population, the very people who have put you in office will suffer the most. If the NPRM ruling does not get more specific in a very short amount of time, and competitve bidding goes to the next stage, this industry, in my opinion will implode! Just think, your love one has no choice but to go into a care facility to get better, rehab, or pass away. Being in this industry for over 20 years anyone can observe that in a home setting people do much better then if they were in a sterile, cold brick box!! Plus that cost savings alone is substantil. Our government needs to look else where for funds. Not in the sector that everyone and someone you know, will utilize sometime in their lives. We need to able to offer superior products and service to our citizens. The citizens of this great country expect or should demand the services that we are entitled to and have worked for! Not what a small group of people purpose for us, that probably have not had the unfortunate task of using, this life extenting, comforting, and healing industry. That takes place, in better place, YOUR HOME.

Submitter : **Dr. Ryan Lemmenes** **Date: 06/27/2006**

Organization : **Dr. Ryan Lemmenes**

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, Ryan Lemmenes DPM

Submitter : Mrs. Trudy Venette

Date: 06/27/2006

Organization : West Melbourne Health and Rehab Center

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

West Melbourne Health and Rehabilitation Center
2125 West New Haven Ave.
West Melbourne, FL 32950

June28, 2006

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

To whom it may concern:

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

I am the Administrator at West Melbourne Health and Rehabilitation Center, located at 2125 West New Haven Ave., West Melbourne, FL 32950. We are 180 bed facility, employing over 200 employees, and offer skilled nursing and rehabilitation services.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,
Trudy Venette, NHA FL, NY, MA, NH, HI

Submitter : Dr. Roxanne Kimminau

Organization : Medicap Pharmacy

Category : Pharmacist

Date: 06/27/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

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

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

Organization : East Bay Hand Medical Center

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Subject: Competitive acquisition for DMEPOS

I am writing you today to protest the proposed legislation for bidding on DME especially as they pertain to prefabricated splints. I am a occupational therapist and certified hand therapist in a private clinic. We treat post operative and cumalative trauma upper extremity clients. Often our treatment requires the use of prefabricated splints and orthotics to optimize rehabilitation outcomes. Therefore I have the following concerns about my patients splinting needs supplied by an outside provider:

1. As a therapist who works directly with my clients I have to have specific knowledge and expertise in the disease process and post operative requirements of my clients. When picking out a splint we have to address the physical support of the device in relation to the diagnosis along with functional , ADL and ergonomic requirements of the device. I dont think an outside provider can address these needs adequately without a direct one to one relationship with the patient.
2. Once the splint has been issued by an outside entity, the can the primary therapist adjust it when we were not the primary suppliers?, are their legal issues modifying the outside splint? Who is legally responsible if the splint is inadequate or causes harm?
3. Will an outside entity provide a specific brand if requested? are they close by? Will the spint be provided promptly, Many times with our referral doctors the patient has to go straight from a cast to a functional splint. Is the patient supposed to hold their hand until they are transported to this supply clinic?

In conclusion this new process appears to be a potential detrement to good patient care due to poor continuity between the doctor, clinic and patient.

sincerely

Mike Marsh, OTR/L, CHT

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

Organization : Georgiana Health and Rehabilitation

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

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

To whom it may concern:

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

I am the Administrator at Georgiana Health and Rehabilitation. We are a 91 bed facility located in Georgiana Alabama. A rural part of the state. We employ about 100 employees and offer extensive therapy services.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,

Matt Goolsby
Administrator

Submitter : **Mr. Joe Dampeer** **Date: 06/27/2006**

Organization : **Sumter Health & Rehab, LLC**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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

I am the Administrator at Sumter Health & Rehab, LLC located at 1505 East 4th Ave., York, Alabama 36925. We are a Skilled Nursing Home with 125 licensed beds, 150 employees, and offer Physical Therapy, Occupational Therapy, and Speech Therapy.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,

Joe E. Dampeer, NHA

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

Organization : Robert Wolff

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Exempt therapist & physicians from competitive bidding when splint is supplied in the course of treatment as my care may be delayed or compromised. Competitive bidding may sound good, but it'll cost Medicare MUCH more in the long run.

Submitter : **Dr. Darren Cowl** **Date: 06/27/2006**

Organization : **Family Podiatry Clinic**

Category : **Physician**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

June 27, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Darren R. Cowl, DPM

Submitter : **Mr. Jeff Burchfield** **Date: 06/27/2006**

Organization : **Northway Health and Rehab**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

June 27, 2006

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

To whom it may concern:

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

I am the Administrator at Northway Health and Rehab. We are a 113 bed long term care facility in Birmingham Alabama. We employee around 125 people and have a specialty Alzheimer's unit.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,

Jeff Burchfield, Administrator

Submitter : **Dr. Todd Skiles** **Date: 06/27/2006**

Organization : **Dr. Todd Skiles**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 27, 2006

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

Dear Dr. McClellan:

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

Sincerely,

Todd C. Skiles, DPM, FACFAS

Submitter : Mr. marc cornelius

Organization : ocala health and rehabiliation center

Category : Long-term Care

Date: 06/27/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 28, 2006

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

To whom it may concern:

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

I am the Administrator at Ocala Health & Rehabilitation Center, a Skilled Nursing facility. Our address is 1201 SE 24th Rd., Ocala, Fl. 34471. My facility is licensed for 180 residents and I employ over 200 staff members. Although we offer many services, we are one of the few facilities in Marion County that offers a secured Alzheimer's Unit.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,

Marc Cornelius
Administrator, NHA

Submitter : Ms. Casey Hoover

Organization : Heartland Rehabilitation Services

Category : Occupational Therapist

Date: 06/27/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-563-Attach-1.DOC

#3563

Sample Letter

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

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

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

My name is Casey Hoover, 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 over 5 years. I am currently working in Jacksonville, FL, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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

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

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

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

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

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

Sincerely,

Casey Hoover, OTR/L

Submitter : Jean Reger

Organization : Jean Reger

Category : Nurse

Date: 06/27/2006

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

There are small suppliers such as Neighborhood Diabetes are dedicated to provide in home meter training which is so important to first time users...or being able to use their "call in" support line with any questions or concerns.These types of services,not to mention other types of training and diabetic education help keep people on track and not end up with complications requiring hospitalization.

Submitter : CHRIS MOORE

Date: 06/27/2006

Organization : HAND SURGERY OF NORTHERN MICHIGAN

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

OUR OFFICE IS OPPOSED TO THIS RULE. OUR THERAPIST PROVIDE EXCELLENT CARE SUPPLY PRFABRICATED ORTHOSES. THIS RULING WOULD LIMIT ACCESS TO BETTER CARE THRU EXPERTISE AND OPTIONS CURRENTLY AVAILABLE. HAVING THE PATIENTS LIMITED TO SPECIFIC ORTHOSIS IS NOT BENEFICIAL & SACRIFICES MEDICAL CARE. PLEASE DO NOT CONSIDER THIS RULING.

Submitter : Mrs. Linda Donaldson **Date:** 06/27/2006

Organization : medical retirement

Category : Nurse

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Having been a health care profesional and now a patient, is is deplorable to me how insurance companies and government are taking healthcare out of my Doctors' hands and deciding what is best for me. Patients need and deserve choice, more education in prevention and treatment, instead of fighting over whether we can have reliable diabetes test strips. By maintaining good control of my diabetes, I expect to never need an amputation or kidney dialysis. All it takes is patient motivation which sadly, is lacking even in the best medical practices. If some patients aren't motivated, why must we all suffer? I paid out of pocket for the meter that I can rely on most for accurate glucose management. Most strips are the same price except for the CHEAP ones that give inconsitent results. Perhaps government officials should end up on Medicare? The rules would then change for the better. My choice of an acid blocker has already been denied. I've taken all of the others and to change back to a lesser effective one would mean more of other expensive medications to control another illness.

Also, I'm a polio survivor and I'm not sure why Orthotics and prosthetics are even being included in the bidding process. Each piece of this equipment is unique to the individual and choice for patients MUST remain in the hands of our Orthotists and us.

Since when does an insurance adjuster know better than my Doctor or my Orthotist? Answer this and we have the solution to the bidding process. Eliminate it, PLEASE~!

Submitter : Mr. Greg Dockery

Organization : Legacy Health

Category : Health Care Professional or Association

Date: 06/27/2006

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my concerns regarding the Centers for Medicare and Medicaid Services' (CMS) competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other supplies ("DMEPOS")
I am the Administrator at Legacy Health and Rehab located in Fort Smith, AR as we have 115 beds and employ around 130 employees and we specialize in short-term and long-term rehab and have a certified Alz/Dementia unit.
The proposed rule is a significant change to the current "any willing provider" environment. As a care-giver and long-term care professional, requiring skilled nursing facilities to competively bid in order to continue to receive Medicare Part B reimbursement for certain DMEPOS items could directly impact our ability to provide the best possible care to resident/patients.
Medicare Part B residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other speciality items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.
At Legacy Health & Rehab we have numerous residents whose care could be interrupted as a result of the implementation -- jeopardizing their health and safety.
The proposed rule has the potential to compromise a resident's access to specific service and products, resulting in long-term increased costs of care.
I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home patients should not be threatened or compromised by a mandate whose impact, although well-intended, is not conducive to the long-term care environment or continuum.

I appreciate your attention to this matter.

Sincerely,
Greg Dockery
Admin of Legacy Health & Rehab

Submitter : Dr. Harvey Lefkowitz

Organization : Dr. Harvey Lefkowitz D.P.M., P.C.

Category : Physician

Date: 06/27/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-568-Attach-1.DOC

#568

Dr. Harvey Lefkowitz, D.P.M., P.C
641 W. Nine Mile Road
Ferndale, Michigan 48220

June 16, 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 that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

As a podiatric physician of 24 years, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge that Centers for Medicare & Medicaid Services (CMS) to apply 1861(r) physicians definition so that podiatric physicians may bid to supply DMEPOS items to only their patients and so that they may execute physician authorizations.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program, If physicians can no longer supply DMEPOS items, patients will suffer, and CMS will suffer economic loss and increase liability system wide.

Consider a patient who presents with the chief complaint of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot is necessary to treat the fracture. 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 could result, which could result in other additional injuries. This could make a treatable fracture with a walking boot into a surgical problem costing CMS thousands of dollars, instead of a few hundred dollars.

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, 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, and in turn more expense to the system for treatment. This is not only bad medicine, it is bad business for CMS.

There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. **AGAIN I REQUEST THAT CMS APPLY THE 1862 (r) PHYSICIAN DEFINITION SO THAT PODIATRIC PHYSICIANS MAY BID TO SUPPLY DMEPOS ITEMS TO ONLY THEIR PATIENTS AND SO THAT THEY MAY EXECUTE PHYSICIAN AUTHORIZATIONS.**

Sincerely,

Dr. Harvey Lefkowitz, D.P.M.

Submitter : Ms. Carol Kroboth

Date: 06/27/2006

Organization : Medical Facilities of America, Inc.

Category : Long-term Care

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

See Attached

CMS-1270-P-569-Attach-1.DOC

#569

June 27, 2006

Department of Health and Human Services
Centers for Medicare & Medicaid Services
http://www.cms.hhs.gov/eRulemaking

Attention: CMS-1270-P

RE: Request For Comments - Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Oher Issues

May 1, 2006 Federal Register: 42 CFR Parts 411, 414, and 424
Document Identifier CMS-1270-P

Medical Facilities of America, Inc. operates thirty one skilled nursing facilities in the state of Virginia. We thank you for the opportunity being provided to comment on the proposed implementation of Competitive Bidding Programs for items covered by the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) provision.

Part II Provisions of the Proposed Regulations

- **Section F:** **Submission of Bids Under the Competitive Bidding Program** "We are proposing that providers that furnish Part B items and are located in a competitively bidding area and are also DMEPOS suppliers, must submit bids in order to furnish competitively bid items to Medicare beneficiaries. Providers that are not awarded contracts must use a contract supplier to furnish these items to the Medicare beneficiaries to whom they provide services. However, a skilled nursing facility (SNF) defined in section 1819 (a) of the Act would not be required to furnish competitively bid items to beneficiaries outside of the SNF"...

We understand the intent of this proposed regulation is to reduce the Medicare cost of DMEPOS supplies. We also appreciate SNFs are being recognized as suppliers that furnish Part B services only to their own patients and would not be required to furnish supplies to beneficiaries outside of the SNF.

We believe one method to save Medicare dollars would be to pay skilled nursing facilities through their Intermediaries for all Medicare services and supplies provided to their patients covered under Medicare benefits. This would save both Medicare and the Providers cost associated with

maintaining the Supplier status and the bidding process. A bill could be submitted to the Medicare Intermediary for all Medicare services and supplies provided to qualified Medicare beneficiaries. The Intermediary could pay the SNF Provider based upon a percentage of the published fee schedule for all part B services and supplies. This could include Part B services currently paid for by Intermediaries such as physical and occupational therapies to supply items currently under the DMEPOS program such as enteral nutritional supplies and colostomy supplies.

Skilled Nursing Facilities currently file claims through their intermediary for the majority of services and supplies provided to Medicare beneficiaries. The exception to filing claims with the intermediary has been for items included in the Durable Medical Equipment Prosthetics, Orthotics, and Supplies provision of Medicare Part B. Currently a skilled nursing facility that admits patients that require DMEPOS items must apply for a DMEPOS supplier number, in addition to being certified as a Medicare Provider in order to receive reimbursement for DMEPOS supply items provided to patients. This proposed rule will add a third set of requirements for SNFs interested in billing for supplies included in the DMEPOS program.

We believe the greatest savings related to the DMEPOS supply items for skilled nursing facilities would be to reimburse SNFs through the Intermediary at a percentage of the fee schedule for DMEPOS supplies provided to the SNF Medicare patients. Cost savings could be recognized related to:

- Eliminating Medicare cost for reviewing SNF DMEPOS Supplier applications & the cost associated with the National Supplier Clearing House sending out people to inspect SNFs, when other groups are already in place to perform inspections
- Medicare cost associated with the review of SNF competitive bids
- Medicare cost associated with the SNFs accepting a percentage of the fee schedule without going through the bidding process
- Eliminating Providers cost associated with preparing and maintaining the DMEPOS supplier number
- Providers proposed cost associated with submitting DMEPOS competitive bids

Another alternative would be to continue having SNFs bill DMEPOS supply items, and accept a percentage of the fee schedule, instead of going through the bidding process. This would not have the same impact as billing the Intermediary for supplies, but saving could be provided with:

- Medicare cost associated with the review of SNF competitive bids
- Medicare cost associated with the SNFs accepting a percentage of the fee schedule without going through the bidding process
- Providers proposed cost associated with submitting DMEPOS competitive bids

The proposed rule states "Providers that are not awarded contracts must use a contract supplier to furnish these items to the Medicare beneficiaries to whom they provide services." This alternative allows for Providers to set up full assignment contracts with approved suppliers.
Under a full assignment contract the supplier provides the supply items and bills Medicare for the supplies. Supply items are delivered to the skilled nursing facility, and the employees of the SNF provide all of the services needed to ensure the supplies are appropriately connected, cleansed, flushed, monitored, changed / replaced. Skilled nursing services associated with DMEPOS are considered routine services and are not reimbursed by Medicare, for non Part A patients. It seems

this alternative could be a real windfall for supplier companies, but it would result in a reduction of reimbursement for the Providers.

Medical Facilities of America currently has DMEPOS supplier numbers which are only utilized for enteral nutrition. If these rules are placed into regulation we will then need to maintain our Medicare Provider status, our DMEPOS status, in addition to bidding for the opportunity to be paid for providing nutrition to our patients that must receive nutrition through a tube.

Part III Collection of Information Requirements, Section 414.412 Submission of Bids Under the Competitive Bidding Program

- … " The burden is estimated to be 70 hours per bid"

- **Section F: Effect on Suppliers** …"we assume that a supplier that bids will spend $2,187.50 ($31.25*70) to prepare its bid.

Currently skilled nursing facilities must become a DMEPOS Supplier utilizing the CMS-855S application. The April 21, 2006 Requirements for Providers and Suppliers To Establish and Maintain Medicare Enrollment, published in the Federal Register 42 CFR Parts 424 VI – Regulatory Impact Analysis estimated cost to complete the 855S application is $900 per supplier.

Based upon the calculations in the proposed rule an additional $2,187.50 would be added to a Providers expense. A skilled nursing facility that only utilizes the DMEPOS provision to provide nutrition to patients within their own facility would need to expend over $3,000 to potentially be eligible to bill for these nutrients.

If all SNF billing was processed through the Medicare Intermediary, and Part B payments were made at a percentage of the fee schedule, it would reduce the cost for the Provider as noted above, and reduce the cost to Medicare related to the time to review both 855S applications and DMEPOS competitive bids.

Thank you for your considerations of these comments. If you should have questions concerning these comments you can contact me at (540) 776-7535 or at the address below.

Sincerely,

Carol R. Kroboth

Carol R. Kroboth
Vice President of Reimbursement
Medical Facilities of America, Inc
2917 Penn Forest Boulevard
Roanoke, VA 24018

Submitter : Dr. Anthony Giordano **Date:** 06/27/2006

Organization : Dr. Harvey Lefkowitz D.P.M., P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-570-Attach-1.DOC

#570

Dr. Anthony Giordano
641 West Nine Miles Road
Ferndale, Michigan 48220

June 16, 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) apply 1861(r) physicians definition so that podiatric physicians may bid to supply DMEPOS items to only their patients and so that they may execute physician authorizations. I believe that the proposal, if finalized in its current form, could interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

I am a podiatric physician who has been in practice for 4 years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, or ankle braces used for acute ankle injuries. I realize that CMS is still determining which items will be subject to competitive bidding but I believe that if an item is medically necessary in caring for a patient, a physician should be ale to supply it.

AGAIN I RESPECTFULLY REQUEST THAT CMS APPLY THE 1862 (r) PHYSICIAN DEFINITION SO THAT PODIATRIC PHYSICIANS MAY BID TO SUPPLY DMEPOS ITEMS TO ONLY THEIR PATIENTS AND SO THAT THEY MAY EXECUTE PHYSICIAN AUTHORIZATIONS.

Sincerely,

Dr. Anthony Giordano

Submitter : Dr. Michelle Jupin **Date:** 06/27/2006

Organization : Dr. Harvey Lefkowitz D.P.M., P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-571-Attach-1.DOC

#571

Dr. Michelle Jupin D.P.M.
641 West Nine Mile Road
Ferndale, Michigan 48220

June 16, 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 who has been in practice for 3 years, I am concerned with the recent proposal from the Centers of 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 request that the Centers for Medicare & Medicaid Services (CMS) apply 1861(r) physicians definition so that podiatric physicians may bid to supply DMEPOS items to only their patients and so that they may execute physician authorizations

I currently am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients a 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. I use a wide range 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.

I REQUEST THAT CMS APPLY THE 1862 (r) PHYSICIAN DEFINITION SO THAT PODIATRIC PHYSICIANS MAY BID TO SUPPLY DMEPOS ITEMS TO ONLY THEIR PATIENTS AND SO THAT THEY MAY EXECUTE PHYSICIAN AUTHORIZATIONS.

Sincerely,

Dr. Michelle Jupin D.P.M

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

Organization : Lineville Health and Rehabilitation

Category : Long-term Care

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

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

CMS-1270-P-572-Attach-1.PDF

#572

Lineville Health & Rehab.
88073 Hwy. 9
Lineville, Al. 36266
256-396-2104

June 28, 2006

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

To whom it may concern:

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

I am the Administrator at Lineville Health & Rehab.88073 Hwy. 9 Lineville, Al.36266. We are a 101 bed facility. We employ approximately 130 employee's. Lineville Health & Rehab. offers O.T. P.T. and S.T.

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

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

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

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

I appreciate your attention to this matter.

Sincerely,
Judy Roberson
Judy Roberson
Administrator

Submitter : Dr. Leon Sidorek **Date:** 06/27/2006

Organization : Dr. Leon Sidorek

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern,
I am a podiatrist who practices in a rural area and supplies (DMEPOS) from 1861(r)(1) to 1861(r)(3).
I am concerned if we are not allowed to dispense dme's,as this would be a great hardship to my patients.Many of my patients are diabetic and depend on us for not only their diabetic foot care but their shoe gear.Unfortunately, these patients would not be able to obtain these products without traveling a long distance, which for many is not possble. Thank you for your attention to this issue.

Sincerely,
Leon C.Sidorek, DPM

Submitter : **Mr. Barry Hix** **Date: 06/27/2006**

Organization : **Empi**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1270-P-574-Attach-1.PDF

#574

Empi®
Your Partner in Rehabilitation Outcomes

June 26, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
ROOM 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1270-P

Re: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Dear Administrator McClellan:

Empi, Inc. ("Empi") is pleased to have the opportunity to comment on the proposed rule, CMS-12710-P, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") and Other Issues. Empi is the leading Medicare provider of transcutaneous electrical nerve stimulation ("TENS") device which are used to relieve pain and promote recovery. Empi respectfully requests that the Centers for Medicare and Medicaid Services ("CMS") exercise its statutory discretion to not select TENS devices as one of the initial product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program. As we explain below, including TENS devices in the 2007 phase-in would force CMS to try to configure a competitive bidding program best suited for commodity type products into one dealing with differentiable products, which could compel many beneficiaries to use inferior TENS products without achieving measurable savings for the Medicare program. Since we understand the policy directive you have been charged with, which is to attempt to lower health care costs while preserving quality, we look forward to working with CMS on the continued implementation of the competitive bidding program and the specifics of the TENS market.

Background: TENS and Empi

TENS is an FDA Class II medical device that employs low-level electrical stimulation to relieve pain and promote recovery. TENS is most commonly used to treat back pain, but is also effective for the treatment of arthritis, strains and sprains, and neuralgia, among other conditions. TENS is frequently prescribed as an adjunct to physical therapy for conditions related to chronic pain and post-surgical or post-trauma acute pain. TENS works in two ways: first, by using

5909 Baird Road • St. Paul, MN 55126-4099 Tel: 651.415.9000 FAX: 651.415.8535 www.empi.com

electrical stimulation to disrupt the body's transmission of pain messages; and second, when the stimulation is sufficiently intense to cause mild muscle twitching, by inducing the body to produce its own natural pain reliever, a neurohormone called endorphin.

TENS provides patients and clinicians with a safe and cost-effective alternative to drugs for the relief of pain. And, given the removal of Vioxx™ and Bextra™ from the market during the latter part of '04 and early '05, physicians are faced with an increasingly limited armentarium of pain interventions. The result is a national health care crisis resulting from physical dependence and addiction to opiates and narcotics. In the U.S., more than 200 million prescriptions are written for opiates such as Oxycontin™ each year (Dendrite International 2004). The direct and indirect cost associated with these medications can be reduced by increased reliance on non-systemic interventions such as TENS.

Empi is a market-leading manufacturer of electrotherapy devices based in St. Paul, Minnesota, with facilities in South Dakota, Kentucky and Florida, and is the leading Medicare provider of TENS devices. Empi's digital Epix VT uses a microprocessor to store twelve distinct pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients and to make the devices easy to use by patients. The Epix VT is the only available TENS device to incorporate this feature. The Epix VT is also the only TENS device on the market to feature biosourced, biaphasic waveform, which ensures the constancy of the electrical stimulus, and provides an additional measure of patient comfort and safety. These unique features make the Epix VT the most popular TENS device on the market.

Finally, Empi is the only TENS manufacturer to provide periodic post-sale monitoring of its devices, an essential product support service. Empi provides TENS devices to over 187,300 patients per year with an effective, low cost pain therapy treatment, which is in many cases a preferred alternative to prescription drugs which have systemic side effects and potentially higher costs. In addition, to support these devices and this service level, Empi has developed nationwide service capabilities and a robust and on-going research and development program to continue to improve the products.

The Proposed Rule: Selection of DMEPOS Product Categories

As the Proposed Rule observes, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") "mandates a larger role for competitive bidding within the Medicare program," including the establishment by the Secretary of Health and Human Services ("HHS") of "competitive bidding programs for the furnishing of certain DME and associated supplies."[1] Section 1847(a)(1)(B)(ii) of the Social Security Act (the "Act") gives CMS the authority to phase in the competitive bidding program with its direction to focus, "first among the highest cost and highest volume items or those items that the Secretary determines have the largest savings potential."[2]

Among the factors that CMS proposes to weigh in "making determinations about an item's potential savings as a result of the application of competitive bidding," are different items'

[1] 71 Fed. Reg. 25657 (May 1, 2006).
[2] 42 U.S.C. 1395w-3(a)(1)(B)(ii).

annual Medicare DMEPOS allowed charges.[3] CMS estimates that "approximately 10 product categories will be selected for competitive bidding for 2006 and as many as 7 or 8 of the selected product categories will be among the 10 largest in terms of allowed charges. The remaining 2 or 3 product categories will come from the top 20 eligible DMEPOS policy groups and their 2003 allowed charges."[4]

TENS Devices Should not be Subject to Competitive Bidding in 2007

CMS should exercise its discretion under Section 1847(a)(1)(B)(ii) of the Act to exclude TENS devices from the 2007 phase-in of the competitive bidding program for several reasons. First, TENS devices in fact constitute a miniscule percentage of Medicare charges. Second, because until CMS has a better understanding of how to do competitive bidding in a non-commodity environment, the competitive bidding program defies the wide variation in quality—and, accordingly, price—within the TENS device market. By grouping all TENS devices within a single product category for the purpose of competitive bidding this will induce many patients to purchase inferior devices. Third, some TENS device manufacturers, including Empi, include within the cost of their devices a post-sale periodic monitoring services to ensure that the device is functioning properly. Low-cost providers generally do not. This would further complicate the nature of competitive bidding since not every medical device company would be offering similar products when they were to make their bid.

1. TENS Devices are a Low-Volume Product Category Relative to Other DME

The total allowed Medicare charges for TENS devices is very small relative to other DME products, with annual expenditures of approximately $10 to $15 million. Indeed, as Table 4 in the Proposed Rule indicates, TENS devices constituted less than one-tenth of one percent of allowed Medicare charges for DMPOS. Nor are TENS devices among the twenty-four highest volume DME items listed in Table 3 of the Proposed Rule.[5] Moreover, the overwhelming majority of DMEPOS reimbursed by Medicare are compressed into a very few high-volume product categories. According to the Proposed Rule, the top five categories alone account for a full 77% of allowed Medicare charges, with proportionate volume declining dramatically thereafter. Several policy groups, such as oxygen, wheelchairs, and diabetic supplies have charges in excess of $1 billion. Indeed, TENS devices, at number 20 on the list, account for only .4% of the charge volume of the fifth-ranked product category, Hospital Beds/Accessories, and about 12% of the charge volume of the tenth-ranked product category, Lower Limb Orthoses. As such numbers suggest, TENS devices are not among Medicare's "highest cost and highest volume" DMEPOS items, and do not offer the program substantial "savings potential," as required by the Act.

2. Including TENS Devices Within the First Phase of the Medicare Competitive Bidding Program Will Compel Many Patients to Purchase Inferior Devices

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[3] 71 Fed. Reg. at 25671.
[4] *Id.* at 25691.
[5] *Id.* at 25670.

Available TENS device vary widely in quality and technological sophistication; accordingly, the market is properly stratified by price. We are concerned that the competitive bidding program is not yet structured to take into account these variances and we believe that it will require a significant amount of planning and development to design the program to be effective in achieving the dual goals of saving money while providing consumers with appropriate high-quality healthcare. As we described above, Empi's digital Epix VT uses a microprocessor to store twelve different pre-programmed electrotherapy regimens, thus affording clinicians the flexibility to tailor treatment to the needs of individual patients. This kind of customization is unavailable on the typically imported non-digital devices with which Epix VT competes. The same features that make the Epix VT the most popular TENS device, however, even with the advances in technology, also make it more costly to manufacture, and hence, by necessity, more expensive. Empi simply cannot and should not compete on price with the low-cost, technologically inferior, imported devices. To require Empi to do so by including TENS devices in the 2007 phase-in of competitive bidding before the sophistication of competitive bidding processes can be developed after seeing how the market reacts to competitive bidding in the easier commodity product categories would be to treat as fungible products that, in reality, are highly differentiated in terms of clinical efficacy. Inferior devices will prevail in a poorly designed competitive acquisition process, and as a result patients will receive sub-optimal therapy.

3. Many TENS Device Manufactures do not Provide Periodic Service and Monitoring of Their Devices

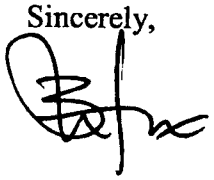
Finally, Empi provides post-sale periodic service monitoring of its Epix VT devices in order to ensure that they continue to function properly. By contrast, many of the low-cost TENS device manufacturers do not offer this important service. As in the case of pre-programmable therapy regiments, this feature contributes to the relatively higher cost of the Epix VT. Again, by treating as fungible TENS devices, such as the Epix VT, that include this important monitoring service and less expensive devices that do not, a competitive bidding process that is not properly designed to take into account this service component would ensure that many Medicare patients are deprived of a superior product.

For the reasons outlined above, primariliy that including TENS devices in the 2007 phase-in portion of the competitive bidding program would not result in measurable savings to the Medicare program, TENS devices should not be part of the phase-in program. Including TENS could also put in place a competitive bidding system that could have as an unintended consequence of an appropriate policy initiative, the result that many beneficiaries would be compelled to use inferior TENS product. CMS should therefore exercise its statutory discretion to not select TENS devices as one of the ten product categories that will be subject to the 2007 phase-in of the Medicare DMEPOS competitive bidding program.

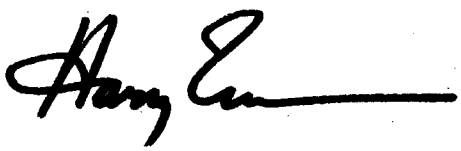
We look forward to working with CMS over the next two years on refinements to the Competitive Bidding Program to ensure that beneficiaries will have access to high quality TENS devices and that a competitive bidding scenario can be developed that works in a non-commodity marketplace. We would be happy to meet with your staff to discuss TENS products and their Medicare market in more detail and to continue to provide assistance in developing ways to

lower Americans' healthcare cost while providing the high-quality, technologically advanced medical devices Americans deserve and desire.

Sincerely,



Barry Hix, MBA, MPH
Vice President – Marketing and National Accounts



Harry L. Zimmerman
Executive Vice President – General Counsel

cc: Laurence Wilson, Director, Chronic Care Policy Group

Submitter : **Ms. Rochelle Archuleta** **Date: 06/27/2006**

Organization : **American Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-575-Attach-1.DOC

#575

American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

June 27, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Dr. McClellan:

The American Hospital Association (AHA), on behalf of our 4,800 member hospitals and health care systems, and 35,000 individual members, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning competitive bidding for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). This proposal is of great interest among hospital-based DMEPOS providers and could adversely impact the continuity of care for post-acute patients and hospitals. CMS must ensure that hospital discharge planners assisting patients' transition from the hospital to home/community are not hindered by being forced to deal with multiple external DMEPOS vendors, which would delay discharge and increase the cost of care.

Background on Hospital-based DMEPOS Programs

Hospitals providing DMEPOS differ significantly from commercial vendors that provide only DMEPOS. For hospitals, DMEPOS are integrated into a multi-disciplinary package of medical services, which often involves complex care, continues beyond the inpatient setting and may include a combination of outpatient services, home health care, inpatient rehabilitation, skilled nursing, DMEPOS delivery/service/education, and other services. Timely access to the DMEPOS prescribed by hospital physicians is essential for proper execution of a patient's plan of care, including a return to home and community with maximum function and quality of life.

Hospitals also differ from commercial DMEPOS suppliers because they must preserve a positive, ongoing relationship with the community, and meet extensive mandatory certification and quality criteria in order to participate in the Medicare program.

Hospitals provide DMEPOS to patients in several ways. Some hospitals operate a DMEPOS operation that serves only their patients, others provide DMEPOS for the community-at-large, others rely solely on external DMEPOS vendors, and the remaining hospital-based DMEPOS programs are hybrids.

General Concerns

The proposed rule raises several broad concerns about CMS' plans to phase-in competitive bidding for selected DMEPOS items. First, the proposed rule lacks specificity for many key components of the agency's competitive bidding program, such as an explicit recommendation on the DMEPOS items to be included in Phase I, a targeted list of metropolitan areas to be included in Phase I, specific quality criteria and a concrete description of the price-setting methodology, among other provisions. These should be clearly articulated in a proposed rule and subjected to public comment, which has not been done in this case. Second, CMS' effort to collect direct beneficiary input on DMEPOS priorities and needs, as discussed at the recent DMEPOS Payment Advisory and Oversight Committee meeting, was limited and unrepresentative of the patient population. Finally, the AHA is concerned that CMS treats hospital-based DMEPOS programs the same as commercial suppliers when they are not, and when hospitals were not part of the competitive bidding pilot demonstrations in Florida and Texas.

Although hospital-based DMEPOS providers were not included in the billing pilots, several questions and concerns about unintended consequences remain. The medically complex patients served by hospital-based DMEPOS are more sensitive to disruptions in DMEPOS access, and product selection could adversely impact the recovery and healing process, as well as delay discharge from the hospital.

Given these issues, CMS should implement the following recommendations:

- Issue an interim final rule to allow CMS to present a more detailed proposal for public comment and to garner further input from stakeholders. The lack of detail in the proposed rule makes it difficult for stakeholders to meaningfully comment.

- Proceed cautiously in implementing competitive bidding for DMEPOS providers that also are health care providers since they were not involved in the pilot. In particular, CMS should give consideration to the hospital-specific recommendations made below, which preserve continuity of care for Medicare beneficiaries in hospitals who need DMEPOS.

Hospital-specific Recommendations

Payment Basis
CMS intends to use its statutory authority to adjust Medicare payments for DMEPOS products in other parts of the country that do not participate in competitive bidding based on the agency's experience with products included in the competitive bidding program. For example, if CMS

achieves a 20 percent savings on hospital beds through competitive bidding in participating metropolitan areas, the agency could reduce Medicare payments throughout the country (not necessarily by 20 percent) without requiring a competitive bidding process in the new areas. CMS notes that it has "not yet developed a detailed methodology" for using this authority and invites comments on this issue. **Without a specific proposal to comment on, we strongly object to CMS using the final rule (or a manual instruction) to spell out the agency's detailed plan for using this authority.** Instead, CMS should develop a detailed methodology and issue a comprehensive description of its proposal for public comment.

Criteria for Item Selection

The proposed rule notes that CMS "may elect to phase in some individual product categories in a limited number of competitive bidding areas in order to test and learn about their suitability for competitive bidding." **We urge CMS to forgo applying competitive bidding to any DMEPOS not included in the two Medicare demonstration projects.** CMS first should fine-tune the competitive bidding methodology using only piloted DMEPOS before deciding whether to expand competitive bidding to products not included in the demonstrations.

We are especially concerned about preserving high-quality care for medically complex patients needing DMEPOS. For these patients, DMEPOS requiring clinical intervention (e.g., requiring support from a licensed clinician including on-site care and evaluation; consultations with the treating physician; patient education on disease management and equipment use and maintenance; 24-hour coverage for medical issues or questions that may arise) is often part of the patient's care plan and, therefore, there is greater sensitivity to disruptions in DMEPOS access and quality that could delay discharge from the hospital, or, once home, restrict healing and create clinical complications. These types of DMEPOS products are used by more medically acute patients who should not be subject to the early stages of DMEPOS competitive bidding, which is certain to involve trial-and-error that could negatively impact DMEPOS access and quality for these vulnerable patients. **CMS should exclude from the competitive bidding program those DMEPOS products that require clinical interventions.**

Under the proposed rule, CMS plans to group DMEPOS into product categories composed of related items and to require a contract to provide all items within a product category. However, this approach is likely to result in product categories that include items that both do and do not require clinical intervention. For instance, if CMS groups all respiratory DMEPOS into one competitive bidding product category, it would inappropriately include certain DMEPOS that are used by very sick patients. For example, continuous positive airway pressure (CPAP) services for sleep apnea patients requires oversight from a state-licensed respiratory care practitioner, and should not be grouped with lower-level respiratory DMEPOS. It would be similarly inappropriate to include bi-level therapy devices that provide pressure to maintain an open airway during sleep for patients with various neuromuscular diseases. And, competitive bidding would be inappropriate for ventilator services for patients with respiratory failure or chronic respiratory disease.

Submission of Bids under the Competitive Bidding Program
The competitive bidding pilots highlighted the extensive administrative resources required by the participating DMEPOS chain organizations to develop a bid. However, some hospitals operating effective DMEPOS programs may not have the resources to develop a bid without detracting from patient care. Therefore, **hospital-based DMEPOS programs should be eligible to participate in the competitive bidding program, if they communicate to CMS that they are not submitting a bid price, but accept the single price determined through the bidding process.**

Conditions for Awarding Contracts
Quality Certification. Many hospitals with certified DMEPOS programs have acquired external certification from organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) through one of two means: They have either received external certification specifically for the DMEPOS operation or the DMEPOS operation has been included within the hospital's overall certification due to its integrated relationship with other hospital operations. **To avoid duplicative effort and cost, hospital-based DMEPOS programs that are integrated within the hospital's broader quality accreditation should be allowed to fill this requirement through the hospital's comprehensive accreditation. In addition, hospital-based DMEPOS programs that are not included in the overall hospital quality accreditation, but are certified separately by an external accreditation entity, should not be required to obtain new certification until the current one expires.** We can provide more detailed input regarding the final DMEPOS supplier quality standards after CMS publishes them.

Opt Out for Health Care Providers. The proposed rule would require that competitively bid DMEPOS under Medicare Part B be provided by contract suppliers that serve the entire competitive bidding area. These suppliers must submit bids and attain certification that quality standards have been met. To access DMEPOS for their patients, health care providers that are not awarded contracts must use contract suppliers to furnish DMEPOS items subject to competitive bidding. The proposed rule would allow skilled nursing facilities (SNFs) and physician practices to opt out of the requirement that the entire competitive bidding area be served and would thereby be eligible to serve only their patients. Like SNFs and physician practices, most hospitals also focus on providing DMEPOS to their own patients. As such, **we recommend that hospitals also be given the option to participate in the competitive bidding program by electing to provide DMEPOS products solely to their patients, rather than requiring hospital-based DMEPOS suppliers to serve the community-at-large.**

Adequate Selection of Brands and Products. According to the proposed rule, individual products subject to competitive bidding will be identified by HCPCS codes and further described at the time of CMS' request for a bid. Hospitals are concerned that DMEPOS competitive bidding will severely limit beneficiary choice of brands and products due to new cost pressures on suppliers that could lower quality and lessen variety in DMEPOS inventories. **To uphold high quality of care, CMS must require that suppliers provide an adequate selection of brands or products within each HCPCS code subject to competitive bidding.** DMEPOS brands are not always

interchangeable. We acknowledge the enormous challenge in addressing this issue, but we urge CMS to minimize the unintended consequence of reduced beneficiary access, choice and quality. This is especially important for medically complex patients, including patients with one or more chronic diseases. These patients often require a specific brand or product to meet their clinical needs and maximize their quality of life.

Determining Single Payment Amounts for Individual Items
CMS expects to set the single payment amount at the median of the bids for each DMEPOS product selected for competitive bidding. We oppose this method because it favors national chain suppliers that deliver a large volume of DMEPOS. It is unreasonable to adopt a methodology that guarantees that half of "winning" bidders, those with bids above the median price, would be paid less than their bid. In addition, since the submitted bids apparently will not be weighted by supplier capacity, the bid from a supplier with very limited capacity would have the same impact on the single payment amount calculation as a supplier with a large capacity. Therefore, **we urge CMS to adopt a payment methodology similar to the approach used in the pilot programs, which ensures that most contract suppliers are paid no less than their bid amount. We also are concerned that the median price would be capped at the fee schedule price, which does not account for costs associated with complying with quality standards and acquiring quality accreditation.**

Terms of Contracts
Lack of timely DMEPOS access would be harmful for patients who are clinically ready to return to home or the community. In particular, timely DMEPOS access is critical for medically complex patients with very specific DMEPOS needs, such as high-flow oxygen via a tracheostomy tube. Delaying the discharge of Medicare beneficiaries due to restricted and untimely availability of specific DMEPOS would produce serious problems for patients' continuity of care and also for the hospital. Therefore, preserving the ability of hospitals to provide DMEPOS to their patients is essential for patient continuity of care and the efficiency of hospital operations. CMS' plans to require that certain DMEPOS be provided by mail-order DMEPOS companies would be especially detrimental to timely hospital discharge due to slow access. **Therefore, from the hospital perspective, it is essential for CMS to ensure that DMEPOS be made available on a timely basis and to sanction providers for untimely service.**

In addition, CMS must ensure that DMEPOS suppliers do not implement shortcuts in response to new competitive bidding cost constraints by reducing the quality of their DMEPOS inventory, excessively limiting the range of products offered or reducing their customer service resources needed to respond to special requests and questions. Such actions would delay discharge and jeopardize patients' clinical progress. The final rule needs to take additional steps to prevent these problems, including specific sanctions that would apply to contract suppliers failing to meet these needs.

Physician Authorization/Treating Practitioner
CMS proposes to implement a physician authorization mechanism that allows a physician or treating practitioner to specify that a particular DMEPOS item is necessary to avoid an adverse

medical outcome, but the agency provides few details on this provision. The specific requirements of this provision will significantly impact the new competitive bidding program, especially for medically complex patients. **We urge CMS to develop a streamlined and expeditious process that facilitates the role of physicians as the key decision-makers for each patient.**

We also urge CMS to clarify "adverse medical outcome" in a manner that recognizes the harm of delays that cause untimely discharge for patients. Further, CMS should provide for expedited appeals to ensure disputes are settled quickly in order to facilitate timely DMEPOS access upon discharge from a hospital. The failure of this provision would cause unnecessary delays for the patient and, in many communities, would exacerbate back-ups in the hospital that can needlessly postpone the admission of new patients requiring acute care.

Quality Standards and Accreditation for Suppliers of DMEPOS
As discussed earlier, many hospital-based DMEPOS have certification from an external entity such as JCAHO, the Community Health Accreditation Program, and the Accreditation Commission for Health Care, Inc. **Hospitals and other health care providers with certified DME programs should not be required to acquire new certification until the current certification expires.** By allowing this grace period, CMS would avoid imposing a redundant cost on DMEPOS providers. However, since the final quality standards are not yet published, it is impossible to comment at this time.

The AHA appreciates this opportunity to submit comments on CMS' plans to implement competitive bidding for selected DMEPOS. Please address any questions about our comments and recommendations to me or Rochelle Archuleta, senior associate director of policy, at (202) 626-2320 or rarchuleta@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

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

Organization :

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : **Mr. Ernie Culpepper** **Date: 06/27/2006**

Organization : **Albany Home Patient Care**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Service is really going to suffer as a result of these areas. There will be many situations where a patient will be getting equipment from a provider far away when there is one nearby. As a result, lead times on maintenace calls will increase dramatically. I forsee companies telling patients they will have to wait days or weeks for a service call. What recourse does a patient even have when a contract is 3-5 years long? Competition will be all but eliminated.

Criteria for Item Selection

Criteria for Item Selection

The spiltting up of items into so many groups is ill-conceived. Now, instead of having one provider taking care of all their equipment needs, patients could potentially have 3 or 4 different companies. Many of our patients have several different categories of equipment from us and know our technicians quite well as a result. They are comfortable with our customer service staff as well as our techs, who come directly into their home. Under this plan, patients will have to deal with multiple companies, each with different policies, different technicians, different phone numbers, etc. This will no doubt increase the stress level of patients, especially the oldest and most frail. Even now, some patients become very confused as to which company is providing what and who to call when they need service or supplies. This will be compounded greatly by this plan. Again, competition will be a thing of the past in DME.

Payment Basis

Payment Basis

The idea of giving a rebate to the beneficiary is very poorly thought out. If the point of all this is to save money, how does giving a rebate to the patient accomplish this? DME companies will already be stretched to the limit by these reimbursment cuts, now they may have to shell out more money as a rebate. This is completely absent of logic.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Why have the approved accreditation bodies not been named yet? It seems very premature to be initiating competitive bidding without even have named these organizations. And how is it possible for all these companies to be accredited in this time span? Many small companies will be forced out of business by this blatant procrastination on the part of CMS.

Submitter : **Mr. Kenneth Fasse** **Date: 06/27/2006**

Organization : **Northwood, Inc.**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Opportunity for Networks

Opportunity for Networks

See the attached document from Northwood, Inc. concerning Section L. Opportunity for Networks. The attached document contains specific comments and concerns on this section.

CMS-1270-P-578-Attach-1.DOC

#578

NORTHWOOD, INC.

Concerns Regarding Notice of Proposed Rule Making (NPRM)
National Competitive Bidding (NCB)

L. Opportunity for Networks

General Concerns:

Per comments published under section L. of the NPRM, CMS' view of supplier networks does not reflect the breadth and sophistication of DMEPOS networks currently operating in both the public and private sectors. Currently, regional and national network organizations serve hundreds of thousands of Medicare beneficiaries with secondary coverage sponsored by the network entity's large group customers (e.g. the General Motors Corporation / Delphi National DMEPOS Program which includes over 300,000 Medicare Beneficiaries currently).

Based upon current NPRM draft rules as presented in CMS-1270-P, established and more qualified DMEPOS networks could be excluded from the competitive bidding program. If rules remain unchanged and are not adjusted to reflect current market conditions relative to supplier networks, the NCB process will be deprived of the competitive value and high quality services that established provider networks offer. The current draft rules for networks are unfair and are based upon outdated information and will not aid a process which is designed to achieve a "best value" outcome for taxpayers and beneficiaries alike.

Please find points 1 – 4 below addressing specific items contained in the introductory paragraph under "L. Opportunity for Networks":

1. **CMS proposes "allowing providers the option to form networks for bidding purposes".** As indicated above, this is an outdated viewpoint as many large, fully operational and well-organized DMEPOS networks currently operate in the HME marketplace. While some providers may opt to form an "ad hoc" network pursuant to NPRM rules, these providers will have no experience conducting network operations. Yet those networks that have experience risk being excluded due to their size and other factors contained in the NPRM.

2. **CMS indicates that "Networks are several companies joining together via some type of legal contractual relationship to submit bids for a product category under competitive bidding".** Again, this is an outdated viewpoint as many DMEPOS networks currently exist and have been operating for over a decade serving large sponsors of group health benefit programs. Customer groups under contract with experienced networks have not only benefited by reducing their DMEPOS expense by 20% or more via a competitive bid process but they have also realized improvements in quality and related administrative services.

3. **CMS states that "This option will allow suppliers to band together to lower bidding costs, expand service options or attain more favorable purchasing terms".** This is a very myopic view of the level of sophistication and availability of established, fully operational and experienced provider networks. In addition, many of these networks offer extensive group purchasing programs to their network providers and, due to their size, are able to negotiate the discounts necessary to compete with large national providers. Existing networks already offer a full range of DMEPOS products and services beyond the scope of those to be included under NCB.

4. **CMS states that "We recognize that forming a network may be challenging for suppliers, and it also poses challenges for bid evaluation and program monitoring". "Networking was included as an option in the demonstration project, but no networks submitted bids." "Still, we believe that networking may be a useful option for suppliers in some cases, so we propose to offer it as an option".** Once again, this is an outdated viewpoint as many DMEPOS networks currently exist and have been operating for well over a decade serving large sponsors of group health benefit programs. Evaluating a network bid will be no more challenging than evaluating a number of individual bids. Furthermore, larger more established DMEPOS networks regularly conduct extensive beneficiary satisfaction programs as a component of their normal operations. These quality control procedures would be helpful and assistive to CMS' program monitoring.

   In a competitive bidding program conducted in the private sector for a large nationwide manufacturer during the Balanced Budget Act of 1997 timeframe, no less than 5 large networks competed for this contract. It is well documented that industry-leading networks provide significant

savings in the private and public sectors on actual procedures as well as related DMEPOS administrative services. The option for network participation in competitive bidding as outlined in the NPRM will be useless to CMS if larger, more established and competitive networks are excluded.

Comments on Seven (7) NPRM Rules Contained in Bullet Points Following Section L – Opportunity for Networks

Pursuant to the first bullet point regarding legal entity – termination of primary contractor, CMS should require network providers to enter into a third party beneficiary agreement giving CMS the option to avoid nullifying an entire arrangement with CMS if the primary contractor is terminated. Such agreements are common in the private sector especially with Health Maintenance Organization (HMO)/DMEPOS provider network contracts.

CMS' draft rules outlined in bullet points 2, 3 and 7 regarding legal contracts, independent eligibility to bid and billing/payment on behalf of suppliers are all reasonable and necessary in the opinion of this respondent.

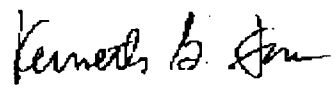
Bullet point 4, applicable accreditation/quality standards should be modified to provide CMS with the option of working with the administrator to replace a network provider that falls out of compliance or permit the network administrator to replace the provider with another provider meeting the approval of CMS.

Bullet point 5, the network cannot be anti-competitive and combined market share cannot exceed 20 percent of the Medicare market within a competitive bidding area, is potentially problematic for larger, more qualified and established networks. Recognizing that CMS wishes to ensure a competitive environment among suppliers for bidding, CMS should modify its 20 percent rule so that it may be applied at the discretion of CMS if less than 5 bids in total, including the bids of any otherwise qualified networks (large or small), are received per given competitive bidding area.

Bullet point 6, a supplier may only join one network and cannot submit individual bids if part of a network, should be modified so that a

supplier may join up to 2 networks for competitive bidding. This change recognizes that many suppliers currently participate in several networks and would ensure that the participating supplier is not disadvantaged by a requirement to commit to a single network bid. Limiting provider network participation to just one network will not result in the most competitive environment for bidding.

Submitted By:



Kenneth G. Fasse
President
Northwood, Inc.

June 27,2006

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

Organization : **Occupational & Hand Therapy, Ltd.**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-579-Attach-1.DOC

CMS-1270-P-579-Attach-2.DOC

CMS-1270-P-579-Attach-3.TXT

#579

Sample Letter

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

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

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

My name is Paulette Yager 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 20 years. I am currently working in an out-patient clinic which specializes in hand/upper extremity treatment 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,

Paulette Yager, OTR/L

#579

Sample Letter

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

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

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

My name is Paulette Yager 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 20 years. I am currently working in an out-patient clinic which specializes in hand/upper extremity treatment 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.

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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, Paulette Yager, OTR/L

Submitter : Mr. Sam Jarczynski **Date:** 06/27/2006

Organization : Rx Stat, Inc.

Category : Health Care Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

How can a supplier prepare for the bid process if we do not know where it will be? The MSA selection is flawed in itself. Is it published MSAs or an MSA that CMS creates? You can't just make stuff up as you go.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

CMS has not approved the accrediting bodies let alone the accredidation standards. It would be very foolish to try and rush this matter through. Beneficiaries will suffer just as they are now suffering because of nebulizer medication ASP policy. Patients are going without medications because of cuts in reimbursement.

Submitter : **Dr. Timothy Tillo** **Date: 06/27/2006**

Organization : **American Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Dr. McClellan:

I would like to convey my thanks to CMS for meeting with the American Podiatric Medical Association (APMA) on June 21,2006 at CMS Headquarters. As a representative of APMA at that meeting, I had the opportunity to express my concerns to representatives from the Chronic Care Policy Group and Division of Community Post Acute Care.These CMS representatives were gracious enough to meet with APMA on very short notice to discuss : CMS-1270-P: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654, May 1, 2006.
Based upon our meeting we understand that it is the agency s position that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires CMS to establish a competitive bidding program for all suppliers of DMEPOS.
There are provisions within the proposed rule that will negatively impact a podiatric physician s ability to supply medically necessary and appropriate DMEPOS to Medicare beneficiaries as an integral part of patient care.
According to CMS, podiatric physicians will be eligible to competitively bid to supply DMEPOS items in a MSA but since CMS did not recognize podiatrists as physicians for purposes of the proposed rule, podiatric physicians will not be able to bid to supply DMEPOS items to their patients only. In the proposed rule, CMS defined physician using the narrow 1861(r)(1) definition, which applies to MDs and DOs only. This conflicts with the 1861(r)definition which is utilized by Medicare and includes podiatrists as physicians. Since the prescribing, fabricating, fitting and dispensing of DMEPOS is within our scope of practice as defined by state law, this proposed action is in direct conflict with those laws as written, in that we are physicians within the role and scope as defined by state law.

In order to be consistent, I think it is important for CMS to revise the physician definition to 1861(r) so that all physicians recognized by Medicare are able to bid to supply items to their patients only.
As a practicing podiatrist for more than 15 years, I routinely prescribe DME for my patients. Consider the patient with a foot fracture. In order to protect this patient, facilitate healing, and prevent further injury, a removable walker boot is often dispensed.
At one point of service, this patient is properly treated according to the standard of care and the risk of injury is lessened.
If I can not precribe DME, patients will suffer the added burden of traveling to another site to obtain the necessary DME. What is more, they will be unprotected and at risk while en route.
Since prescribing DME is an integral part of my podiatric practice,
I urge CMS to recognize podiatrists as physicians as stated in 1861(r).
I appreciate the opportunity to offer these comments.

Sincerely,

Timothy H. Tillo,DPM

Submitter : **Mrs. pamela schmidt** **Date: 06/27/2006**

Organization : **Mercy Home care**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

As a provider of Home Care, I am writing to urge you to cosponsor H.R. 3559, "Medical Durable medical equipment Access Act of 2005." introduced on July 28 by Rep. David Hobson(R-OH) and Rep. John Tanner(D-TN).

This bill is critically important to protecting beneficiaries and to preserving the nation's critical homecare infrastructure, which is an important part of the answer to the looming Medicare and Medicaid crisis. H.R. 3559 would protect Medicare homecare beneficiaries and small businesses that provide homecare by amending several of the "competitive bidding" requirements for homecare that were included in the Medicare Modernization Act of 2003 (MMA).

I am concerned that some of the contracting provisions in MMA could have the effect of restricting competition, reducing access to homecare, and hurting small homecare providers. Remember that oxygen is a drug and needs to be followed up on just as you would for any other prescription. Can the seniors and disabled who receive homecare be able to take care of this equipment? Think of your mother or father on oxygen and having to take care of their equipment by themselves could they? There are so many sides to this bill that I feel that you as a congressman/congresswoman need to re-think your stand and support H.R. 3559 which would amend the MMA to protect patient access to homecares.

Can your mother or father, seniors and disabled who receive homecare count on your support? You make the decision but remember those you will be directly effected. REMEMBER THE PEOPLE!!!

I would be happy to follow up with you if you have any questions, please feel free to contact me at 563-875-2746

Sincerely,
Pam Schmidt RRT, RCP
Respiratory Therapist

Submitter : Mrs. Susan Leftwich **Date:** 06/27/2006

Organization : Occupational & Hand Therapy Ltd.

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-583-Attach-1.DOC

CMS-1270-P-583-Attach-2.DOC

Sample Letter

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

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

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

My name is Susan Leftwich, 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 outpatient upper extremity hand clinic and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an 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

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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,

Susan R. Leftwich, OTR/L, CHT

#583

Sample Letter

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

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

Sincerely,

Susan R. Leftwich, OTR/L, CHT

Submitter : Dr. B. A. Pontani **Date:** 06/27/2006

Organization : Southeast Texas Center for Wound Care

Category : Physician

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

I am writing to make specific comments about the proposed competitive bidding process as it applies to DMEPOS suppliers. I am the Medical Director of the Southeast Texas Center for Wound Care in Conroe, Texas. I am a Board Certified Family Physician and am also a Certified Wound Specialist by the American Academy of Wound Management. I run a very busy Wound Care Center and am concerned about the current policy and its potential impact on patient care. My two principle areas of concern apply to Negative Pressure Wound Therapy (NPWT) and support surfaces for offloading.

A significant portion of my patient population is currently covered by Medicare in some form. Those that are not elderly are disabled relating usually to their underlying disease process. This population is prone to diabetes, hypertension, peripheral vascular disease, renal failure and limitation of movement that leads to pressure ulcers. I have had success with NPWT, specifically the KCI Wound VAC (from KCI in San Antonio, Texas) and have had very good outcomes in these difficult wound healing problems. I also have extensive experience in ordering appropriate support surfaces for offloading: beds, wheelchair cushions and various other offloading devices.

My first area of comment applies to Conditions for Awarding Contracts. The idea of accreditation of suppliers and quality standards is not clear. The level of clinical knowledge that has been obtained from study and use of the product should be one area that is evaluated before contracts are awarded. Another aspect is the level of clinical support, training and education that is provided by the supplier to both the practitioner ordering the product as well as to the patient using the product. I have years of experience using the KCI Wound VAC and feel that it is a far superior product to any potential competitive bidder that does not have the studies or the long standing use to provide any kind of quality or clinical outcome assessment.

Support surfaces for offloading are extremely important for my patients well being, protection and prevention of wounding. I have personally experienced the wide swings in quality from different suppliers and am concerned that without specific standards to prevent problems, our patients will suffer and ultimately the bill will be higher if we have to hospitalize these patients for long term care.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

My second area of comment applies to Physician Authorization/Treating Practitioner. I quote Section 1847(b) (7) of the Act provides authority to establish separate categories for items within HCPCS codes if the clinical efficiency and value of items within a given code warrants a separate category for bidding purposes. The physician is allowed to order a specific item, brand or mode of delivery and the contract supplier is required to furnish that item or mode of delivery. However, in the case of NPWT, if the bid and payment prices have been reduced to the lowest quality item that does not have the scientific studies to back it up (NPWT provided with just gauze in the wound bed) the supplier will not stay in business very long providing the more efficacious product that may be more expensive up front. Clinical outcomes must be addressed where patient care is at question. I have found that what seems to be the most expensive up front provides long term cost savings by shorter healing times, reduced hospital lengthy of stay and reduced complication rates and reduced further surgical interventions.

I quote again, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. This points out that no matter what the physician or practitioner prescribes, the supplier is going to get paid at bid price, no matter what they supply. Quality is being sublimated to low bid price. This will effectively limit the practice of medicine by the physician or practitioner because the patient will not get what is ordered if the supplier cannot provide it due to financial losses incurred. In most cases, the beneficiary cannot come up with the money to provide these services themselves, and will ultimately lose out on potential limb and life saving technologies that have been reduced to the low bid contracts.

Submitter : Mrs. Rhonda Walker **Date:** 06/27/2006

Organization : Olen Medical Supply

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1270-P-585-Attach-1.RTF

CMS-1270-P-585-Attach-2.DOC

#585

June 27, 2006

CMS
NCB Proposed Rule
Reference: File Code CMS 1270-P

Please accept the following comments regarding the implementation of the National Proposed Rule Making for Competitive Bidding.

I am a female, a business owner, and someone who supports government attempts to reduce waste and generate efficiencies for our tax payer. I do not support what I believe is a critically flawed attempt to generate short term savings on the backs of patients and the small providers those patients depend on for their care.

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

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

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

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

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

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

a. Financial Standards: By requiring small providers to follow the guidelines CMS is proposing would cause extreme financial hardship for small providers if they are required to submit a formal audit which can cost $10,000 to $15,000. We recommend that a credit worthiness status be

determined through bank credit, vendor credit, or years in service, measurements rather than an actual audit. In order to be nondiscriminatory and to encourage full participation by quality providers, the financial standards must not be financially burdensome to the small provider.

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

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

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

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

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

The provision that a beneficiary with a capped rental product can move to a contracted supplier

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

The GAO recommends using mail delivery for items. Medicare has demanded updates on usage and now they recommend mail delivery of wound care supplies, urology supplies, diabetic products, and ostomy supplies. These products take many visits and hours of help and instruction.

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

Who addresses change of condition?

Who addresses the teaching component?

Who addresses quantities?

Since mail order sends supplies automatically, who discontinues service?

Will mail delivery have different rules?

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

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

These views are my own, and those expressed by small business owners in my interest. I do not believe the intention of NCB was to wipe out a significant chunk of small business owners who take pride in what they do. I am very afraid that will the result if NCB is implemented without addressing the comments above.

Rhonda K. Walker, Owner, Olen Medical Supply

415 S. Summit, Arkansas City KS 67005

#585

June 27, 2006

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NCB Proposed Rule
Reference: File Code CMS 1270-P

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determined through bank credit, vendor credit, or years in service, measurements rather than an actual audit. In order to be nondiscriminatory and to encourage full participation by quality providers, the financial standards must not be financially burdensome to the small provider.

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

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Since mail order sends supplies automatically, who discontinues service?

Will mail delivery have different rules?

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

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

These views are my own, and those expressed by small business owners in my interest. I do not believe the intention of NCB was to wipe out a significant chunk of small business owners who take pride in what they do. I am very afraid that will the result if NCB is implemented without addressing the comments above.

Rhonda K. Walker, Owner, Olen Medical Supply

415 S. Summit, Arkansas City KS 67005

Submitter : **Dr. Robert Russo**

Date: **06/27/2006**

Organization : **Dr. Robert Russo**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

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,

Submitter : **Dr. Lawrence Robinson** **Date: 06/27/2006**

Organization : **Methodist Alliance Infusion Services**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-587-Attach-1.DOC

#587

Methodist Healthcare

June 27, 2006

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

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

Dear Dr. McClellan:

Methodist Alliance Infusion Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Methodist Alliance Infusion Services, is a home infusion service based in Memphis, TN. As a part of the Methodist Healthcare System, an integrated healthcare delivery system, we provide home infusion services for the 6 hospitals within the Methodist Healthcare System. Methodist Alliance Infusion Services provides home infusion therapy, including home enteral nutrition, to approximately 850 active patients. We receive approximately 1,800 new referrals each year, of which 40% will be Medicare patients. Methodist Alliance Infusion Services is a Medicare Part B DMERC provider.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive

Alliance Health Services
• **Infusion** • Home Care • Home Medical Equipment • Hospice • Lifeline
6423 Shelby View Drive • Suite 104 • Memphis, TN 38134 • (901) 516-1500 • Fax 901-380-7252

bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which r equire ex traordinary expertise f or s afe and ef fective p rovision. T hese dr ugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at (901) 516-1685.

Sincerely,

Lawrence A. Robinson, M.S., PharmD
Administrative Director

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Submitter : **Ms. Rebekah Bradford** **Date: 06/27/2006**

Organization : **Certified Pedorthist**

Category : **Other Health Care Professional**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I am VERY CONCERNED about the many changes being made concerning Medicare. I recently completed my certification as a pedorthist anticipating the rumors that certification will be a must if I want to continue working with diabetics and their footwear. I do not regret studying to receive my certification. Now, however, I am concerned with the bidding process being considered by Medicare. I am presently the only person in our city (and probably our county) who has the certification. But, we are within 30 miles of Ft. Worth and 45 miles from Dallas. I am concerned that larger companies in these areas will be able to win the bid. I also continue to hear rumors that we will have to be accredited in the near future. This costs thousands of dollars. As a new business that I've worked so hard for, it's hard to think that another "major rule" will be placed upon me before I can hardly get it going! On page 156 of the Notice of Proposed Rulemaking, it states that CMS expects there will be 50% fewer DMEPOS providers doing business with Medicare than currently exist. What a crock!

Perhaps Medicare should consider covering more DME as a prevention than trying to put providers out of business. For instance, why not provide items for the bathroom such as grab bars and bath stools instead of paying for hospital treatments for fractured hips?

PLEASE, think about the outcomes of what the bidding process will bring. Maybe Medicare will save money, but will our community as well as others across the United States have to spend more in unemployment and welfare? It won't be a very pretty picture!

Submitter : **Mrs. kim thruston** **Date: 06/27/2006**

Organization : **american society of hand therapists**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-589-Attach-1.DOC

#589

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 Kim Thruston, 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 Charlottesville, Virginia at an outpatient rehabilitation 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,

Kim Thruston, MOT, OTR/L, CHT

Submitter : **Dr. James Farrell** **Date: 06/27/2006**

Organization : **Westside Podiatry Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, AFO s 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. This is especially difficult for many of my older patients who must make arrangements to be driven to the office since they no longer drive. If they needed to go elsewhere to obtain a supply item they may be delayed since they often have difficulty finding rides and this would delay there care longer. My older patients really appreciate not having to make extra trips to obtain the supplies I currently can provide but would be unable to do in the system as it currently proposed..

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

Sincerely,

Dr. James Farrell
315-685-3338
27 Fennell St
Skaneateles, NY 13152

Submitter : **Dr. Kathleen Lynch** **Date: 06/27/2006**

Organization : **Westside Podiatry Center**

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, AFO s 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. This is especially difficult for many of my older patients who must make arrangements to be driven to the office since they no longer drive. If they needed to go elsewhere to obtain a supply item they may be delayed since they often have difficulty finding rides and this would delay there care longer. My older patients really appreciate not having to make extra trips to obtain the supplies I currently can provide but would be unable to do in the system as it currently proposed..

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,

Kathleen Lynch D.P.M.
315-217-0004
4671 Onondaga Blvd Suite 120
Syracuse, NY 13219

Submitter : **Dr. Michael Cornelison** **Date: 06/28/2006**

Organization : **Dr. Michael Cornelison**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-592-Attach-1.DOC

Attachment to #592

Michael J. Cornelison, DPM, FACFAS
10353 Torre Avenue, Suite C
Cupertino, California 95014

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,

Michael J. Cornelison, DPM, FACFAS

(408) 446-5811 **drcornelison@yahoo.com**

Submitter : Ellen Weinman **Date:** 06/28/2006

Organization : North Jersey Hand Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1270-P-593-Attach-1.DOC

ATTACHMENT TO # 593

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 Ellen Weinman, 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 setting with two hand surgeons, 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 orthosis, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

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

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

Ellen E. Weinman, OTR, CHT

Submitter : **Dr. Richard Bronfman** **Date: 06/28/2006**

Organization : **Arkansas Foot and Ankle Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The 1861(r)(1) definition of physician needs to be changed to 1861(r)(3). As a podiatric physician it would be almost impossible for me to successfully bid against a major supplier of DME, while MDs and DOs can competitively bid to supply their patients and execute physician autherizations. This would be detrimental to my ability to care for my patients as well as detrimental to my business. This was not the intent of the competitive bidding legislation. I served eight years on the PPAC and I know that using the 1861(r)(3) is the correct definition for this rule and the most efficient use of CMS resources.

Thank you for your consideration,

Richard A Bronfman DPM

Submitter : **Mr. Gerald M. Hutch** **Date: 06/28/2006**

Organization : **Low Vision Montana**

Category : **Consumer Group**

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

LOW VISION AID EXCLUSION
Docket # CMS 1270-P

The proposal to categorize all appliances with lens as in the same category as eyeglasses and to exclude all these low vision aids is unrealistic, to the extreme. Senior citizens who are on Medicare and are affected by such diseases as macular degeneration, RP and diabetic retinopathy can not be help to lead productive useful lives with eyeglasses. Proper examination by eye care professionals can prescribe low vision aids that are useful to these individuals. The use of a CCTV, which uses a system of lens and electronics to magnify an image, cannot in any way be compared to eyeglasses, either in usefulness or function.

This rule change has the potential to put vision impaired citizens in a dark corner of the world. Newspapers, magazines, hand written letters from family and friends will no longer be able to be read. Citizens who have been an active part of their community will now be shut out with the lack of ability to acquire this needed equipment. This proposed excluded equipment can prevent secondary injuries that lead to nursing home living, ER visits, etc.

Low Vision Montana, a non profit organization of concerned citizens is dedicated to helping the vision impaired find the tools and equipment necessary that will lead to independence and will allow them to participate in those activities that they thought that they had lost with the onset of vision loss.

Gerald M. Hutch
Member Board of Directors
Low Vision Montana
1111 E, State Street
Helena, MT 59601-5135
406-443-2947
modrepro@mt.net

Submitter : **Ms. Valerie Brady** **Date: 06/28/2006**

Organization : **Ms. Valerie Brady**

Category : **Occupational Therapist**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P
Position: Request that Medicare revise proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries 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 Brady, I am an OT specializing in the treatment of upper extremity disorders. I am also a certified hand therapist.I work in a private practice, PT owned, busy, orthopedic office located in a Bone and Joint Center where patients are referred to therapy immediately following MD appointments and who often require protective, post operative splints that are custom fabricated or off the shelf splints that must be modified to fit correctly. Frequently these patients are Medicare and Medicaid beneficiaries.

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 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, that meet thier specific needs. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.
There are many DMEPOS items that provide significant profit, allowing large and multiple item suppliers to possibly discount their UE orthoses. However, when a supplier is limited to UE 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 UE 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 for the opportunity to comment on this proposed regulation.

Submitter : **Mr. David Weiss** **Date: 06/28/2006**

Organization : **Westfield Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am strongly opposed to any CMS proposal that would limit a beneficiaries choice in providers. Limiting choice to a mandatory mail order for blood glucose supplies is inappropriate and incovenient for the beneficiary. CMS must prohibit any automatic fill practices, without a refill request by the patient. This can lead to abuse and unnecessary cost to the Medicare system.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding process should exclude common supplies such as blood glucose products. These readily available products should remain "readily available" at local businesses. Blood glucose products should not be equated to large and often specialized rental items.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

I have concerns over the possible rebate amounts for providers that submit bid that are lower than the established single payment amount. I suggest that CMS consider an "any willing provider" provision, at least for small businesses that will be disadvantaged in the bid process. With pricing established for a three year period, there needs to be a process for adjustments should the manufacturers of the equipment raise the acquisition costs higher than the CMS established reimbursement.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I am concerned that my locally owned pharmacy will not be able to participate in the competitve bidding process with large national suppliers. It will be a burden upon the beneficiaries if they loose access to local suppliers. I urge CMS to allow small suppliers to be allowed to accept the established single payment amount if they choose. The bid process will give a unfair advantage to large national suppliers. There need to be procedures in place to allow the small HME providers, primarily locally owned retail pharmacies, to participate in Medicare B. Competitive Bidding is intended to reduce expenses, but should not be a the expense of small businesses. An "any willing provider" designation should be included in the rules to allow a provider to determine if they want to and can afford to participate at the established payments.

Submitter : **Mr. Robert Hachey** **Date: 06/28/2006**

Organization : **Bay State Council of the Blind**

Category : **Consumer Group**

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Please reconsider the low vision aid exclusion.
Low vision aids such as glasses, magnifiers and closed circuit TV systems help elders who are losing their vision remain independent. In some cases, they can mean the difference between living in a nursing home and remaining in one's community. They allow continued access to visually impaired Americans of all ages. By eliminating the low vision exclusion, CMS could save money and help improve the quality of life for visually impaired Americans. Some of these devices also help visually impaired persons to safely travel on foot and via public transportation.
Bob Hachey
President
Bay State Council of the blind
bhachey@comcast.net

Submitter : **Bonnie Redmond** **Date: 06/28/2006**

Organization : **Bonnie Redmond**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

My name is Bonnie Redmond, and I am an occupational therapy student who will potentially be involved in the treatment of upper extremity disorders. This upcoming fall I will complete my final internship before entering the field. During this time I will have the opportunity to work in a highly specialized hand clinic. At this facility, I will treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

Therapists are unique from other suppliers of DMEPOS. They work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. While orthoses are a critical component in the treatment of 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 the 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.

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,
Bonnie Redmond, OTS

Submitter : Mrs. Mary Ann Cope

Date: 06/28/2006

Organization : HomeChoice Partners, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-600-Attach-1.DOC

ATTACHMENT TO #600

HomeChoice Partners℠
The Infusion Therapy Specialists

June 27, 2006

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

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

Dear Dr. McClellan:

HomeChoice Partners, Inc. is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

HomeChoice Partners, Inc. is a regional home infusion provider with seven offices located through out the Mid-Atlantic and Southeastern regions of the United States. HomeChoice's 180 healthcare professionals and support staff provide high tech intravenous therapies to an ongoing census of over 2000 patients and have provided care to tens of thousands of patients during the past decade. HomeChoice is a JCAHO accredited full service infusion provider of compounded intravenous medications, enteral and parenteral nutrition, administration supplies and infusion equipment. Our multidisciplinary team of clinical pharmacists, board certified RNs (CRNIs) and certified nutritional support dietitians monitor the patient's clinical status and progress toward therapy goals.

CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal a nd engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at (757) 855-4255.

Sincerely,

Mary Ann Cope, R.Ph.
President/CEO

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association