Submitter : **Dr. Patrick Roberto** **Date: 06/29/2006**

Organization : **Academy of Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

Mark. B. McClelland, 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, 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,

Patrick Roberto, DPM

Submitter : **Dr. Benjamin Orndoff** **Date: 06/29/2006**

Organization : **Academy of Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

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

Sincerely,

Benjamin Orndoff, DPM

Submitter : Mr. Donald Knight, Jr. **Date:** 06/29/2006

Organization : Premier Home Care, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

To Whom it may concern,

I have really lost my patience with the government and what they are doing to the medical industry. I understand that the medical costs are well above what the country can support, but it does not make any sense how we are going about it.

The highest cost in America are in the hospitals, yet CMS wants to go after the DME companies. I guess it is easier to attack the weakest link in the medical industry. I suppose this battle has been lost, but maybe we can find a better way to make these cuts.

The first thing that CMS should not do, is rush the implementation of the competitive bidding. The government usually takes years to implement a major bill, but not in this case. The whole thing is moving way to fast without the proper investigations or case studies. There are so many variables that CMS has not taken into account in making it's descions.

If we must have competitive bidding, then shouldn't it be done fairly? Each market is different and has different overhead cost. CMS should not limit bids by disqualifying bids above the current fee schedule. There are small businesses that will not have a chance against the flooded market of the national companies. Maybe it's what they want to do, run the high service companies out of business. Makes alot of sense doen't it?

Speaking of service, CMS must realize that the patient is going to suffer more than anyone else. We all have realatives that are older and on Medicare that need medical treatment. They are going to have to pick up their own equipment supplies and medications. They are not going to get any help with their copays. If they can't pay, they go without medical treatment. Makes sense doesn't it?

If a DME company wants to make a bid, should it know all the facts to make an educated bid? CMS needs to disclose exactly what equipment DME's are bidding and what they are up against! I wonder has CMS empowered DME's with all the information in the bidding process? The answer is no.

Lastly, the whole idea of rebates is insaine. This is everything CMS has been against to keep the market place from corruption and monopoly. Has anyone ever heard of the Anti-Kickback Statute, or the Beneficary Inducement Statute? The small companies work hard at not allowing this to happen in our companies, now they may legalize it?

Thank you for your time in reading my thoughts,

Don Knight

Submitter : **Dr. Jason Hughes** **Date: 06/29/2006**

Organization : **Academy of Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

Mark. B. McClelland, 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, and supplies (DMEPOS), the Centers for Medicare & Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

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

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

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

Sincerely,

Jason A. Hughes, DPM

Submitter : Mr. David Marro **Date:** 06/29/2006

Organization : Peoples Medical

Category : Home Health Facility

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please consider these topics that related to competitive bidding fro DME. 1. Stagger the the bidding in MSA's to allow for an orderly roll out of the program it will help smaller DME companies time to create networks and help us to participate. 2.Make being accredited manatory this will keep quality standards in place & consistent. 3. Make competitive bidding competitive, CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. 4.Don't make it harder for a provider to sell their business by restricting the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's propertyrights. 5. Consider the impact on the patient, CMS cannot rely soley on costs & volume for product selection. Consider issuessuch as access & medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Submitter : BRUCE DAVIS **Date:** 06/29/2006

Organization : BRUCE DAVIS

Category : Other Health Care Professional

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

Concern over grouping items into product categories for bidding. If a small DME specializes in just a few categories but the bid area includes other items it does not carry or supply, then that DME will be excluded from the bid process. I understand the reason for combining but it may have a detremental impact on certain providers.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

1.Concern over the deciding of the bid price. Lowballing is a very real possibility and if lowballed, that particular bidder will not have to "live" with that price. The bids which are artifically low per statistical analysis need to be excluded from helping to achieve the pivotal bid amount.

2.Why can't a supplier bid a higher price than the current allowable amount for that item. Perhaps the current amount is too low.

GENERAL

GENERAL

Rebates:
How can CMS allow a company to offer a rebate to a beneficiary?
The idea runs contrary to everything CMS has stood for in the past. Beneficaries want quality service/products not money back. Wouldn't the rebate "do away" with the copay which is a legal problem.

Opportunity for Networks

Opportunity for Networks

Provider networks may be a good idea to assist small DME providers to gain access to competitively bid. Will the network have to be accredited?

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Concerned about Small DME providers not able to compete in a bid situation with larger companies which have economies of scale on their side. Many small suppliers may go out of business if unable to be competitive in the bid. We are at a distinctive disadvantage.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Want to see quality standards in place prior to any bidding taking place. Those standards will impact the cost of providing services.

Need to see the criteria which CMS will use to select accreditating organizations. This info needs to be published now.

Submitter : **Dr. Catherine Halinski** **Date: 06/29/2006**

Organization : **Foot and Ankle Care at Touch of Health Clinic**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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.

Submitter : **Mr. Al Hudson** **Date: 06/29/2006**

Organization : **Dean Health Systems**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

Dr. Mark B McClellan
Administrator, Centers for Medicare and Medicaid Services
Dept of Health and Human Services
Baltimore, MD

Rd: Proposed Rule for Competitive Acquisition of Certain DMEPOS

Dear Dr. McClellan:

Please share with other decision-makers at CMS my opposition to the proposal for competitive bidding for durable medical equipment providers. While I understand that there are probable providers who excessively mark up their goods, I believe this proposal is, to put it bluntly, an over-reaction to the problem.

I understand and appreciate concern to save tax dollars while providing good health care services to patients covered by Medicare and Medicaid, but limiting access for DME only to those with the lowest bids is simply wrong. (1) The medical and therapy providers who are directly involved in patient care should be allowed to provide braces and supports, because those providers will know best what each individual patient needs. My chief concern about this proposal is that approved DME providers would be put in the situation of issuing braces, supports, and equipment with little knowledge of each patient they are seeing. They would, of course, have a referral from a medical provider, and it would include a medical diagnosis but it would not include the functional status and requirements that would be well known to doctors and therapists who already know those patients.
(2) Patients who need equipment should not be required to travel unnecessarily to obtain that equipment. If the proposal is approved, patients will be required to travel across town or perhaps longer distances without necessary protective supports simply to obtain DME at another location. This is potentially harmful and an unnecessary burden on patients. Consider the example of a patient who requires a knee brace after an acute injury. Currently, the appropriate brace could be issued in a clinic setting by a medical provider or therapist who has evaluated the patient and know him or her well. Under the proposal, I believe that patients would have to travel to another facility (without brace perhaps risking further injury) to find an approved provider who may have an appropriate brace but will be starting afresh in evaluating the patient. More efficient and effective care would be delivered if DME could be provided at the site of medical intervention rather than requiring provision at specific sites by specific providers.
(3) There is currently a system in place that establishes allowable fees for medical goods and services, so it is not clear to me how the proposal to limit access to certain approved DME providers will save more money.

Thank you for your time in considering my comments.

Sincerely,
Al Hudson, PT, MHS
1805 26th St.
Monroe, WI 53566

Submitter : Mrs. Penny Carey **Date:** 06/29/2006

Organization : Johns Hopkins Home Care Group

Category : Other Health Care Provider

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

1. Quality Standards and Accreditation-Johns Hopkins Home Care Group strongly supports the need for consistent quality standards for all competitive bidding applicants. However, the proposed rule states that CMS and the accrediting body will determine the length of grace period based on the accrediting organizations ability to complete the accrediting process within each competitive bidding area. We request that CMS allow organizations, who have maintained an accreditation, to maintain on their current cycle and not obtain new certification until the current one expires.
4. Evaluation of Bids- The proposed rule states that HCPCS codes will be used to identify the individual products included in competitive bidding. Our organization is concerned that this will limit the beneficiary in their choice for brands and products and this may impact quality care We request that CMS monitor any negative clinical outcome that may be the result of limited products or decreased staff and modify the program to mitigate these situations. CMS must require that suppliers provide an adequate selection of brands of products within each HCPCS code to ensure that the highest level of quality is maintained. CMS must also hold manufacturers to a quality standard of product that meets the patient s clinical need and can be obtained at a fair market price.
b. Composite Bid methodology is logical and appropriate, but we feel strongly that CMS should request that providers be able to give feed back on HCPCS codes or categories selected in this method. In reviewing the weighting methodology, we would recommend that you use a two tiered weighting system. One tier would be based on volume; the second tier would be per unit cost.

Criteria for Item Selection

Criteria for Item Selection

The proposed rule supports section 1847 (a)(1)(B)(ii) of the Act, which will phase in competitive bidding first among the highest cost and highest volumes or those items that the Secretary determines have the largest savings potential. Johns Hopkins Home Care Group suggests that CMS only apply competitive bidding to those DMEPOS items that were included in the two Medicare demonstrations. CMS should fine tune the competitive bidding process ensuring that there is no negative impact to the beneficiaries, prior to considering expanding the competitive bidding program to include other DMEPOS items.
Preserving high quality, safe care is the focus of Johns Hopkins Home Care Group. Our organization is non-profit with a mission to serve patients in the Baltimore metropolitan area. We strongly advise CMS to not include DMEPOS requiring clinical intervention, monitoring and ongoing patient education into the competitive bidding program until further evaluation of these items validates a cost savings that does not impact quality care. For patients using this DMEPOS, the licensed clinician who educates beneficiary and family and continues to monitor the patient s progress is essential for maintaining the therapy prescribed. Medically complex patients, (those patients requiring multiple pieces of equipment, ongoing education in their home, 24 hour access to on call staff, coordination with the physician on care planning and visits by a Respiratory Care Practitioner as needed), often have this DMEPOS as part of their plan of care and disruptions in access and quality may delay discharge from the hospital, or once home may delay the progress and create further clinical complications.
These items should be excluded from the early stages of competitive bidding, which may have trial and error issues that could negatively impact the quality of life of these patients. Further, we recommend that CMS thoroughly evaluate the potential for Medicare savings for DMEPOS that require clinical interventions and other DMEPOS items not included in the pilot study before these products are considered for the competitive bidding program.
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 chronically ill 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. We strongly urge CMS to exclude DMEPOS items that require clinical intervention due to the advanced level of service required to support such patients and products.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

The proposed mode for single payment on an item in CBA does not take into account any effect for utilization and therefore if this methodology is selected you could be paid higher or lower then bid submitted. We support strongly the Principle 2 (as described in the proposed rule), due to CMS utilizing the adjustment factor. We believe this assures that all bidders are compensated for their original bid as well as maintains equality amongst the bids. While this proposal questions whether this approach is reflection of the actual winning bids accepted , we believe the use of the adjustment factor actually ties payment to the winning bid.

GENERAL

GENERAL

We need to assure that CMS understands that hospital owned homecare providers have a different focus then the commercial/privately owned companies. For Johns Hopkins Health System, DMEPOS items are integrated into a multi-disciplinary process of providing medical services, which often involve complex medical care and are essential to the coordination and safe discharge of patients into their home with the goal of maximizing function and quality of life. Timely access to these items prescribed by hospital physicians is essential for proper execution of the patient s plan of care. We would request that CMS exclude from the CBA program hospital owned home care providers differently, since they were not included in the pilot programs.

CMS effort to collect direct beneficiary input on the service provided by their homecare providers on certain DMEPOS items (as presented at the PAOC Meeting in May) was extremely limited and unrepresentative of the patient population.

Johns Hopkins Home Care Group continues to provide multi-disciplinary services to meet the needs of the patients. We have not modified the DMEPOS that we provide when Medicare rates have been cut, we continue to service the needs of the patient without compromising safe, quality care. Johns Hopkins Home Care Group would welcome any further discussion or involvement with CMS to assist with successful implementation.

Submitter : Mr. Roger Stutsman

Date: 06/29/2006

Organization : Premier Home Care, Inc.

Category : Home Health Facility

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As an Oxygen and DME provider I am very concerned with competitive bidding. If any business becomes revenue challenged many other elements of the business will also be affected. My patients expect and need to be seen on a regular basis to insure their equipment and supply needs are being maintained. With fuel costs approaching $3.00 per gallon, how will a company be able to continue to serve and provide patients with the quality and timely service they expect and require.

Submitter : Mr. Rowland Strickland **Date:** 06/29/2006

Organization : Stantonsburg Drug Company

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-875-Attach-1.TXT

June 28, 2006

To: CMS

Dear Sir:

Thank you for the opportunity to comment on the competitive bidding proposal. I would like to make a few points.

1. Competitive bidding is not in the best interest of Medicare beneficiaries when it comes to small rural communities. The bidding process will eliminate small independent pharmacies from providing much needed supplies that we have been providing for years. Our customers depend on the local Pharmacist for counseling and professional help with health related issues. Where will the patients get that special one on one attention they have been getting at their local pharmacy when they are in need? Hospitalization costs will soar as a result of the local pharmacist not being included in the patients overall health care plan.

2. Diabetic supplies being done through mandatory mail order is a terrible idea that may appear to save money, but will actually lead to rising costs with Emergency Room visits and also hospitalization costs as a result of complications of lack of blood sugar control. There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

3. Quality standards is a good idea, but should be put in place gradually to allow for small businesses such as independent pharmacies to adjust to the new standards and be allowed adequate time to become accredited.

4. Competitive bidding should not be allowed in MSA's with less than 500,000 people. This would help keep small business owners in rural communities open and therefore beneficiary access in these areas will not be compromised.

Thanks:

Rowland Strickland, RPH
105 S Main Street
Stantonsburg, NC 27883

Submitter : **Dr. Michael Holtz** **Date: 06/29/2006**

Organization : **Virginia Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare and Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r)(3). I am a podiatric physician and prescribe and supply select durable equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am 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 can not understand the rational for placing additional roadblocks if not hardships on our senior citizen population.

Similar to MD and DO suppliers, I am required to obtain a valid supplier number and must adhere to all 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.

The biggest impact would affect our quality of care. The risks of sending our patients to other suppliers when their need may be immediate, (referrals from ER s, Urgent Care Centers, Physician Offices), not only creates further risk to our patients but creates quality of care issues.. Hoping they can obtain the items we requested with no substitutions, the additional travel time and use of the extremity attempting to find these places of distribution places unreasonable burdens on them. I apologize to you but I can not fathom the reason one would want to place any of these further requirements on our patients more than they already have.

Please change the physician definition from 1861(r)(1) to1861(1)(3) so that I am eligible to bid supply items to my patients only and execute physician authorizations. I want to be able to provide medically necessary and appropriate care to the patients I serve.

Sincerely,

Michael Holtz DPM, FACFAS
Deb Chirtea, DPM, FACFAS
Michael Chung, DPM, FACFAS

Submitter : Mr. Richard Stoneking, PT **Date:** 06/29/2006

Organization : American Physical Therapy Association of New Jerse

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-877-Attach-1.DOC

June 29, 2006

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

RE: Proposed Rule for Competitive Acquisition of Certain DMEPOS

Dear Dr. McClellan:

On behalf of the American Physical Therapy Association of New Jersey (APTAnj) I would like to offer comment on the ''Proposed Rule for Competitive Acquisition of Certain DMEPOS.'' From our understanding, items such as off the shelf orthotics, wheelchairs, canes, and an assortment of other assistive devices will be subject to the competitive bidding process. Furthermore, ''winners'' of the competitive bidding process will not be required to furnish all brands within a product type.

It is important that physical therapists are permitted to dispense DMEPOS in order to optimize treatment for Medicare beneficiaries. During and after the assessment of a beneficiary's biomechanics, alignment, strength, etc., a need may arise to provide DMEPOS. When the physical therapist has a range of items available they can chose the most appropriate item that will result in the best functional outcome for the patient in the most timely manner. As an example, a beneficiary with plantar fascitis may express an antalgic gait as a result of severe pain. During the evaluation the physical therapist should have the ability to dispense a cane (to decrease weight on the affected side and improve gait and stability) and provide cushioned heel lifts and/or arch supports (orthotics) to support and relieve stresses on the foot. If the physical therapist cannot dispense off the shelf supplies, the patient may need to make another appointment with another provider in order to obtain them. Delaying the benefits of pain relief for the patient could result in a decreased response to treatment and an increase in cost to the Medicare system.

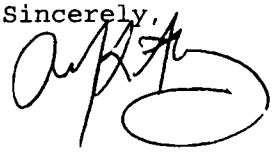
As essential participants in the health delivery system, physical therapists assume a leadership role in rehabilitation services, prevention and health maintenance programs, and professional and community organizations. In order to preserve, develop, and restore optimal physical function, physical therapists oftentimes rely on suppliers of durable medical equipment (DME) for their expertise and engineering input, availability, reliability, and quality of product(s) delivered. Based upon the patient, specific items are ordered to match the characteristic need of the patient. From a historical perspective, physical therapists have always maintained good working relationships with DME vendors. In response to the mutual trust and respect that has evolved, vendors frequently loan equipment to patients and providers. By so doing, patients are assured that their needs are perfectly met. From our perspective, the steerage or channeling of patients and providers to discount rate vendors will squelch the availability and quality of products supplied, and discourage manufacturers and suppliers from loaning equipment on a trial basis.

An additional matter of concern to our membership is the rule proposal statement that ''only devices molded and adjusted by certified orthotists will be covered by Medicare.'' Physical therapists, as well as occupational therapists and podiatrists, routinely make significant adjustments to orthotics including molding, strapping, bending of materials to fabricate orthoses, splints, and positioning devices. Those

skills are part of basic education, mandated in our state practice acts, and published in the American Physical Therapy Association's Guide to Physical Therapist Practice, Volume II. The "Guide" is a consensus document that is utilized by healthcare policy makers and administrators in making informed decisions about the delivery of physical therapy services. We at APTAnj recommend revision of the regulation to permit physical therapists to adjust orthotics.

Thank you for consideration of our comments.

Sincerely,



Richard L. Stoneking, P.T.
President
American Physical Therapy Association of New Jersey
1100 U.S. Highway 130, Suite 3
Robbinsville, NJ 08691-1108
Phone: (609) 208-0200 Fax: (609) 208-1000

Submitter : **Date: 06/29/2006**

Organization :

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-878-Attach-1.PDF

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 Jacksonville Health and Rehabilitation. We are located in Jacksonville Alabama, with the ability to provide the highest quality of care to 167 residents, with the help of over 175 care givers. Jacksonville offers an arrange of services to our community and surrounding area's including an Alzheimer's Unit, Rehabilitation Unit, Skilled Nursing Care, Physical Therapy, Occupational Therapy, Speech Therapy, and Hospice programs.

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 Jacksonville 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,

Freddy Skelton, NHA
Jacksonville Administrator
NHS Management, L.L.C.
Work (256) 435-7704
Fax (256) 435-6917

Submitter :

Date: 06/29/2006

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-879-Attach-1.DOC

Executive Director
American Thoracic Society

Gary Ewart
Director
Government Relations

Fran Du Melle
Director
International Activities

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1150 18th Street, N.W.
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Fax: (202) 452-1805
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Internet: www.thoracic.org

John E. Heffner, M.D.
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Mark B. McCellan, MD PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator McCellan:

The American Thoracic Society is a medical professional organization comprised of over 13,000 physicians, researchers, nurses, respiratory therapists and allied health care professionals who are dedicated to the research, diagnosis, treatment and prevention of respiratory disease. Our members treat Medicare beneficiaries with acute and chronic respiratory disease. As such, we are keenly interested in how the competitive bidding program for durable medical equipment will impact patient access to essential medical products and services.

The American Thoracic Society (ATS) appreciates the opportunity to offer the following comments:

Submission of Bids Under the Competitive Bidding Program
The ATS believes that competitive bidding will reduce access to portable oxygen systems. As noted in the HHS report on competitive bidding, access to portable oxygen systems for new patients – the patients mostly likely to impacted by business dynamics created by the competitive program – saw a statistically significant and clinically relevant 34% reduction in access to portable oxygen systems.[1]

As you know, Medicare pays for oxygen on a modality neutral basis – one payment regardless of the type of oxygen system provided to the Medicare beneficiary. The proposed competitive bidding rule maintains this modality neutral payment system.

The ATS has long recognized that a modality neutral payment system creates perverse economic incentives that encourage DME providers to give Medicare beneficiaries the least costly oxygen system – stationary systems, even when the more expensive portable systems are the best therapeutic option for many Medicare beneficiaries. The

[1] Source: Second Annual Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics and Supplies – HHS

ATS firmly believes the reduced access to portable oxygen systems observed in the Polk County demonstration is a direct result of the perverse payment system. Further, these access barriers to portable oxygen will only be exacerbated as the competitive bidding program expands into other locations. We strongly urge CMS to ensure Medicare beneficiaries have access to portable oxygen systems under the expanded competitive bidding program. The ATS strongly urges CMS to use the discretionary authority granted by Congress to develop a modality specific payment system for oxygen. The ATS envisions a payment structure that pays less for stationary concentrators, more for ambulatory systems (mobile systems weighing more than 10 lbs) and most for portable systems (mobile systems weighing less than 10 lbs). Additionally, we envision a system that explicitly recognizes and reimburses for the service component that DME companies provide to Medicare beneficiaries who use supplemental oxygen.

Monitoring and Compliant Services for the Competitive Bidding Program
As noted previously, the American Thoracic Society believes the competitive bidding program will reduce Medicare beneficiary access to portable oxygen systems. The experience in the Polk County, FL demonstration program can reasonably be expected to occur in other areas as the competitive bidding program expands. The ATS strongly urges CMS to conduct specific monitoring efforts on the provision of oxygen, and in particular access to portable oxygen systems, under the expanded competitive bidding areas.

Physician Authorization/Treating Practitioner
The ATS supports the proposal to allow physicians and other prescribing providers to select specific products within the DME product categories for Medicare beneficiaries to avoid adverse outcomes.

While the ATS supports the provision allowing physicians and other prescribing providers to select specific DME products to treat Medicare beneficiaries, the proposed rule does not establish an appeals or dispute resolution system for cases when the DME provider or an alternative DME provider in the competitive bidding area fails to provide the specific equipment selected by the physician. While such instances will likely be rare, our physician members and the patients they care for would appreciate CMS's guidance on how to resolve these situations.

Quality Standards and Accreditation for Suppliers of DMEPOS
The ATS observes no provider standards have been presented in the proposed rule for public comment. The lack of a specific set of provider standards available for public comment comprises a serious shortcoming of the proposed rule. Further, the ATS does not view the issuance of program notice on provider standards to be an adequate substitute for the public comment process.

The creation and enforcement of provider standards will have significant– and if done correctly – positive effect on the provision of DME goods and services. Provider standards will likely have impact beyond areas of competitive bidding. However, poorly

drafted or absent standards will only add to the regulatory burden without improving the services offered to Medicare beneficiaries. Because provider standards will likely have such a significant impact on DME providers across the industry, we feel the promulgation of the standards should be part of the public rule making process.

The American Thoracic Society appreciates the opportunity to comment on this important rule making effort.

Sincerely,

John E. Heffner, MD
President
American Thoracic Society

Submitter : **Dr. Esther Scherb** **Date: 06/29/2006**

Organization : **Latham & Watkins**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-880-Attach-1.PDF

CMS-1270-P-880-Attach-2.DOC

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File No. 025147-0000

June 29, 2006

BY ELECTRONIC MAIL

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

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

Dear Administrator McClellan:

On behalf of our client, Hoveround Corporation ("Hoveround" or the "Company"), we submit these comments on the above-referenced proposed regulations, which implement the Medicare Part B DMEPOS Competitive Bidding Program and revise the gap-filling payment methodology used to set fee schedule rates for new codes for DMEPOS items and services.[1] As a manufacturer and Medicare supplier of power mobility products, Hoveround expects to participate in the competitive bidding program and, for this reason, would be directly impacted by the proposals. The Company has concerns about some of the proposed policies and appreciates the opportunity to provide comments on this very significant new program.

With the competitive bidding program, the Centers for Medicare and Medicaid Services ("CMS") is ushering in a new chapter in Medicare history—setting payment for DMEPOS items used by beneficiaries in the home based not on fee schedule amounts, but rather on bid amounts submitted by DMEPOS suppliers. Hoveround's concerns and submitted comments are directed to the following areas in the proposed regulations:[2]

- Submission of Bids Under the Competitive Bidding Program
- Opportunity for Networks

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

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

- Conditions for Awarding Contracts
- Determining Single Payment Amounts for Individual Items
- Terms of Contract
- Physician Authorization/Treating Practitioner
- Payment Basis
- Gap-filling
- Administrative or Judicial Review

Summary of Comments

With this comment letter, Hoveround provides eleven recommendations for CMS's consideration:

(1) ***Secure Participation of Capacity Suppliers that May Not Have a Physical Location in the Service Area:*** Hoveround agrees with CMS's decision to permit suppliers that do not necessarily have a separate physical location in a competitive bidding area ("CBA"), but that offer services in the geographic area and have a demonstrated ability to do so, to participate in competitive bidding for that CBA. CMS should not limit indicia of capacity to having supplier numbers in a CBA, but rather should use meaningful indicia of capacity to serve a CBA.

(2) ***Classify Products Subject to Competitive Bidding Using Existing Medical Policy Categories and Consider Special Circumstances of Using Power Wheelchair Codes for Which There is Limited Experience:*** CMS proposes to conduct bidding for products grouped into "product categories." Hoveround recommends the use of existing Statistical Analysis Durable Medical Equipment Regional Carrier ("SADMERC") policy groups. Because these policy groups correspond to existing medical policies, the codes have a meaningful relationship to each other. Specialty suppliers can offer quality services to beneficiaries with certain medical conditions (*e.g.*, patients who need wheelchairs but not crutches), but—if the categories are not sufficiently narrow—suppliers with specialization in areas such as mobility needs will not be able to offer competitively bid items and services.

In addition, for purposes of competitively bidding power wheelchairs, Hoveround strongly believes that there is insufficient experience with the new HCPCS codes that are to become effective in October 2006. Special consideration should be given for situations where the Medicare program has significantly redefined a medical policy such that little or no information exists as to adequacy of coverage and/or fee schedule payment amounts.

(3) ***Ensure the Integrity of Bid Evaluations by Requiring Accreditation Prior to Bid Submission:*** CMS must take steps to safeguard the integrity of the bid evaluation process so that payment rates are realistic. This should include the requirement that suppliers be accredited prior to submitting bids. Only accredited suppliers can account for the initial and ongoing operational costs of accreditation in their bid proposals. At minimum, CMS should ensure that only the bids of suppliers

that meet the accreditation and quality standards are considered and selected as winning bidders.

(4) ***Cap Estimated Capacity Per Supplier When Selecting Winning Bidders to Preserve Competition and Beneficiary Choice:*** CMS proposes to determine winning bidders by selecting a "pivotal bid" from among the composite bids submitted by suppliers. This pivotal bid would be set at the point where expected combined capacity of bidders is sufficient to meet expected beneficiary demand for items in a product category in the CBA. Hoveround strongly believes that CMS should take steps to ensure that this approach is transparent and, importantly, does not result in selection of a small number of suppliers with large capacity to the detriment of the industry, the agency, and beneficiaries alike. It is in the interest of the program to preserve competition among suppliers so that there are several competing bids in subsequent bidding cycles and so that beneficiaries continue to have a choice in the products furnished to meet their medical needs. Hoveround recommends that CMS cap each supplier's capacity at 20% of anticipated demand to ensure that a small number of very large suppliers do not become the only winning bidders for a CBA.

(5) ***Tailor Program Requirements to Address Business Considerations of the DMEPOS Industry:*** In order to meet with success, the competitive bidding program must incorporate the practical realities and limitations of the DMEPOS industry. This might at first blush appear to be an obvious goal, but the means to accomplish this are not evident. To that end, therefore, Hoveround offers the following recommendations to modify four specific proposals:

(a) Proposed 42 C.F.R. § 414.422(c), which would require contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers, should be revised to reflect that suppliers in most instances cannot handle such work for products other than those that they sell and thus this proposal should not be finalized;

(b) Proposed 42 C.F.R. § 414.420, which would oblige contract suppliers to make a reasonable effort to furnish a particular brand or mode of delivery of an item, as prescribed by the physician or treating practitioner, should be revised to make clear that the contract supplier need not have the ability to offer it if the item is not part of the supplier's inventory;

(c) Proposed 42 C.F.R. § 414.422(d), which would place limitations on contract suppliers' ability to continue to participate in competitive bidding upon a change in ownership, should be modified to permit contract suppliers to continue to participate as such if the legal entity enrolled in the Medicare program does not change (*e.g.*, there has been only a change in stock or other equitable ownership); and

(d) CMS's preamble to the proposed regulations, which discusses a requirement that contract suppliers of power wheelchairs offer rental items, should be limited to discrete situations, so that suppliers are not

required to float a large volume of loans to subsidize rentals, particularly given that the vast majority (Hoveround's experience shows 99%) of patients requiring power mobility have chronic and progressive conditions that require them to use the equipment for extended periods of time.

(6) ***Adopt an Approach for Setting Payment Amounts that Reasonably Reflects Actual Bids:*** Proposed 42 C.F.R. § 414.416, which would use the median of the winning bids (*i.e.*, those at or below the pivotal bid) to set the competitive bidding payment amount for each product, may force contract suppliers either to furnish products at prices far below their submitted bids or to leave the Medicare program. To avoid such an inevitable result, CMS should adopt a payment methodology for competitive bidding that does not set artificially depressed rates below the bid prices of a substantial number of the winning bidders. The formula used in prior demonstration projects (which was also offered in the proposed rule as an alternative) should be adopted instead.

(7) ***Ensure Payment Rules Used For HCPCS Codes Revised Mid-Cycle Result in Reasonable Payment Amounts:*** Under proposed 42 C.F.R. § 414.426, CMS proposes special payment rules for circumstances in which existing HCPCS codes are revised in the middle of a competitive bidding cycle. In situations where multiple codes describing similar products are merged into a single code, Hoveround seeks modification of the proposal, so that codes that were competitively bid continue to be used, along with their established payment amounts, until the end of the current contract.

(8) ***Consider Sales Volume Assumption Used to Calculate Bids When Using Competitive Bidding Rates to Adjust Payment Amounts in Non-Competitive Bidding Areas:*** CMS should take care in implementing its authority beginning in 2009 to adjust payment in non-competitive bidding areas based on payment information determined under the competitive bidding program. Application of this authority should not result in a de facto "any willing provider" model, with competitive bidding rates being set nationwide. Competitive bidding rates assume a significant increase in volume to offset lower prices that would not exist in non-competitive bidding areas.

(9) ***Discard the Proposed Rebate Program:*** Hoveround joins the objections lodged by the rest of the DMEPOS industry concerning CMS's proposal to allow suppliers to give rebates to beneficiaries for items furnished through the competitive bidding program. This proposal implicates and may run afoul of the Federal Anti-Kickback Statute and blurs the line between permissible and impermissible rebates in an ill-advised manner.

(10) ***Safeguard Existing Medicare Appeal Rights:*** Hoveround requests that proposed 42 C.F.R. § 414.424 be revised to clarify that existing rights of beneficiaries and suppliers to appeal denied claims are unaffected by the prohibition on appealing certain determinations made in the course of conducting the competitive bidding program.

(11) ***Revise the Proposed Gap-Filling Replacement to Follow Statutorily-Required***

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

I. SECURE PARTICIPATION OF CAPACITY SUPPLIERS THAT MAY NOT HAVE A PHYSICAL LOCATION IN THE SERVICE AREA

[Submission of Bids Under the Competitive Bidding Program/Opportunity for Networks/Conditions For Awarding Contracts]

Hoveround believes that a relatively small number of large-capacity suppliers currently provide a significant volume of DMEPOS items to beneficiaries and that, without their involvement in competitive bidding, there is likely to be a shortage or total lack of availability of certain items in CBAs. Hoveround thus supports CMS's proposal not to require bidding suppliers to be physically located in the CBAs in which they submit bids. In addition, CMS should ensure that large chain suppliers cannot game this system. As written, the proposed regulations do not clearly prevent suppliers with multiple supplier numbers from submitting multiple bids in a single CBA. The regulations should be revised to prevent unfair practices.

Below we address recommendations on these two issues.

CMS Correctly Recognizes that No Physical Location Should Be Required

Hoveround agrees that physical location is an imprecise proxy for whether a supplier would be willing and able to serve Medicare beneficiaries in a given CBA.[3] Relying on physical location would prevent the participation of many suppliers, including several with large capacity that operate on a national scale. This in turn could have the perverse, unintended effect of drastically limiting the supply of products available for beneficiaries in CBAs. Hoveround therefore supports CMS's proposal not to require bidding suppliers to be physically located in the CBAs in which they submit bids.

CMS's proposal is in line with longstanding Medicare supplier standards. As the agency

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[3] 71 Fed. Reg. at 25672 (concluding that such a requirement would be "too proscriptive").

is aware, some large capacity suppliers use a centralized operation (at which billing, patient contacts, complaints and other matters are addressed), with warehouse locations across the U.S. from which products are delivered to patients for home use. These satellite warehouse locations do not have their own Medicare DMEPOS supplier numbers; rather, they are part of the national organization and operate under its supplier number. Medicare has a longstanding policy of permitting such organizational structures. The Medicare statute provides that all suppliers furnishing medical equipment and supplies to beneficiaries must obtain a supplier number, showing that they meet supplier standards. The statute calls for CMS to create a supplier standard requiring the supplier to "maintain a physical facility on an appropriate site."[4] Medicare Supplier Standard #7 implements this requirement, stating that a supplier must certify that it:

> Maintains a physical facility on an appropriate site. The physical facility must contain space for storing business records including the supplier's delivery, maintenance, and beneficiary communication records. For purposes of this standard, a post office box or commercial mailbox is not considered a physical facility. In the case of a multi-site supplier, records may be maintained at a centralized location.[5]

This supplier standard recognizes that some suppliers will be set up with multiple sites and that all of the functions of a Medicare supplier need not be performed at each site. The instructions for completing the enrollment application (Form CMS-855S) further clarify this point; CMS distinguishes between "new business locations"—for which a complete CMS-855S is to be completed and an entirely new supplier number is needed—and sites that are part of an organization with an existing supplier number, for which no reporting obligation exists.[6]

Hoveround has taken the approach of organizing itself with a centralized office and a number of warehouse locations. The Company believes that this approach allows it to more effectively interact with Medicare contractors and to provide consistent, high quality services to Medicare beneficiaries.

In sum, the key to success of competitive bidding is ensuring that suppliers who have the capacity to service CBAs can continue to furnish products to beneficiaries in those areas. Use of physical location as a gauge for supplier interest and ability to service a CBA would create product supply issues. It is also an imprecise method for determining whether a supplier can handle business in the area.

An accurate measure of supplier capacity is past business to beneficiaries in the area (*i.e.*, prior years' total allowed charges for products in the product category), coupled with the supplier's detailed business plan for expansion, if any. Notably, CMS proposes to use such

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4 42 U.S.C. § 1395m(j).

5 42 C.F.R. § 424.57(c)(7).

6 *See* Form CMS-855S (http://www.cms.hhs.gov/cmsforms/downloads/cms855s.pdf).

information in determining the capacity of each bidding supplier[7] and proposes to collect it through proposed Form B (Bidding Sheet)—the form that bidding suppliers would complete in submitting a bid for each product category in a CBA. On this form, CMS solicits data regarding the total revenue collected by the supplier, the total number of customers served in the CBA for the product category in the past year, and the percentages of those numbers attributable to Medicare. This form also asks bidding suppliers to describe their expansion plans for the CBA, if any.[8] Hoveround believes that this approach is sound and accurate and that it should be finalized as written.

CMS Should Limit Bids To One Bid Per Supplier

As described above, under existing Medicare DMEPOS supplier rules, a single organization may have multiple supplier numbers, provided that each location in its own right meets the Medicare supplier standards.[9] Particularly in the early stages of the program's implementation, CMS should be wary of the ability of suppliers with multiple supplier numbers to game the system in ways that could result in less savings and/or jeopardize the success of competitive bidding. Specifically, national chain suppliers with multiple supplier numbers can submit multiple bids for a single CBA in a way that limits competition. CMS should tighten its existing proposal to ensure that a *single organization* may only submit one bid.

Hoveround urges CMS to ensure that organizations with multiple supplier numbers are not incentivized to manipulate the bidding system by submitting an array of bids for a single product category in a CBA as a way of increasing its odds of being selected as a contract supplier. The purpose of competitive bidding is to achieve savings through the lowest competitive bid that can retain Medicare business. Without prohibiting the practice of a single supplier inappropriately submitting multiple bids, there is no way for Medicare to ensure that competition will not be unfairly impeded.

In proposed 42 C.F.R. § 414.418(b)(5), CMS explicitly forbids a supplier to submit a bid both on its own and as part of a network for a particular product category.[10] The reason for this provision is likely that CMS believes it is inappropriate for a supplier to take "two bites at the apple." Hoveround believes that this proposal should be taken a step further. CMS should include a requirement that suppliers with common ownership of 5% may only submit a single bid for each product category in a given CBA.[11] A similar restriction should be put in place for suppliers under control of other suppliers, so that only one bid submission for each product

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7 71 Fed. Reg. at 25676.

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

9 *See* 42 C.F.R. 424.57(c);

10 *See* 71 Fed. Reg. at 25683.

11 In many cases, the requirement that the supplier demonstrate past history of conducting business in the CBA may mitigate against a supplier's ability to game the system in this manner; however, out of an abundance of caution, Hoveround asks that CMS adopt a common ownership restriction.

category is made for each CBA. This could be accomplished by revising 42 C.F.R. § 414.412—the provision describing the rules for bid submission—to add a new subsection (h), stating (italicized language added):

> *A bidding supplier may only submit one bid per product category per competitive bidding area. Bidding suppliers with common ownership of 5% or more, or that are under control of another supplier, shall be deemed a single supplier for purposes of this section.*"

This change would go far toward ensuring that the bidding process is conducted on an even playing field—free from activities that can skew bidding and favor organizations with multiple supplier numbers over other bidders.

II. CLASSIFY PRODUCTS SUBJECT TO COMPETITIVE BIDDING USING EXISTING MEDICAL POLICY CATEGORIES AND CONSIDER SPECIAL CIRCUMSTANCES OF USING POWER WHEELCHAIR CODES FOR WHICH THERE IS LIMITED EXPERIENCE

[Submission of Bids Under the Competitive Bidding Program]

CMS proposes to conduct bidding for products grouped into "product categories," defined as groups of similar items used in the treatment of a related medical condition. Each group would be comprised of items defined by HCPCS codes. To bid on a product, a supplier would need to submit bids on the full spectrum of HCPCS codes contained in that product category—with a separate bid amount for each HCPCS code. CMS also proposes that the composition of the product categories may differ from one CBA to another, depending on whether the agency believes it will be able to realize savings for a particular product in a particular CBA.[12]

Hoveround strongly urges CMS to use the existing SADMERC policy groups as the product categories for competitive bidding, rather than inventing new and broader categories. The SADMERC policy groups are groupings of HCPCS codes that correspond to their assignment to medical policies. Thus, they are a rational grouping from a clinical perspective, in so far as they are likely to include items and services that beneficiaries with certain medical conditions might need. In addition, they are narrow enough to promote specialization among suppliers, which, in turn, may enhance the quality of services provided to beneficiaries.

A single supplier is likely to carry a wide array of products within a medical policy area. CMS must balance the desire to permit beneficiaries to use a single supplier for their DMEPOS needs (the "one-stop shop" structure), with the importance of promoting specialized, effective service. If CMS creates new, broad product categories, many, if not all, suppliers would not be able to provide an item for each HCPCS code. For instance, many power mobility suppliers carry only powered products (such as power wheelchairs and POVs) and do not necessarily carry

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12 71 Fed. Reg. at 25672-73.

other mobility equipment (such as canes, walkers, or manual wheelchairs). In opting to conduct bidding at the product category level, CMS highlighted that it favors that approach because it both allows suppliers to be specialized in their product offerings and permits them to take advantage of economies of scale. This rationale holds true for using the existing policy group definitions for the competitive bidding product categories as well. If broader categories are used, there is a greater likelihood that products for which no significant savings can be achieved would nonetheless be included in the competitive bidding program.

As to needed revisions to the applicable proposed regulation, 42 C.F.R. § 414.412, Hoveround asks CMS to revise subsection (c) so that it reads as follows (with proposed language in italics):

> Product categories include items that are used to treat a related medical condition. The list of product categories, and the items included in each product category that is included in a particular competitive bidding program, are identified in the request for bids for that competitive bidding program *and will correspond to the policy groups of the Statistical Analysis Durable Medical Equipment Regional Carrier, unless CMS determines there is good cause to align items differently for a particular competitive bidding program*.

In addition, Hoveround urges CMS to evaluate the impact of changes to policy groups that occur shortly before the bidding process. For example, the power mobility device benefit is in the midst of an extensive overhaul and remains in a state of flux. Most recently, 64 new codes were established, to become effective October 1, 2006. The payment rates have not yet been determined. Nor has a local coverage policy been finalized. In light of the changes here, if any of these new power mobility device codes are selected for a product category, this would add a layer of uncertainty about how to bid the codes for purposes of competitive bidding (and how to select winning bidders). Without weighing these uncertainties, an inappropriate array of codes may be selected for a product category. This may result in a tremendous disservice to Medicare beneficiaries—who would almost certainly be hit hard if capacity and pricing estimations are incorrect and there is a scarcity of certain power wheelchair products in their geographic areas.

Recognizing that there is no easy solution here, Hoveround suggests that CMS weigh carefully the option of using existing codes for competitive bidding purposes only. This would eliminate, or at least minimize, confusion and uncertainties, since both CMS and the supplier community understand historical pricing and capacity information. Bids could be based on informed experiences with the codes and CMS would be in a better position to select winning bidders because there would be available information on supplier capacity and beneficiary need in a specific area. One of the benefits of this approach is that there could be no question that savings could be projected. The new codes, once effective, could be used in all non-competitive bidding areas. After initial phases of the program, suppliers and CMS would have gained experience with the codes in other areas and there would be pricing and capacity data for the new codes.

III. ENSURE THE INTEGRITY OF BID EVALUATIONS BY REQUIRING ACCREDITATION PRIOR TO BID SUBMISSION

[Conditions For Awarding Contracts]

Hoveround strongly supports CMS's proposal to require suppliers to meet quality and financial standards in order to be awarded bids. The Company believes that it is also imperative that suppliers be accredited prior to submitting the bids and, at a minimum, that only the bids of qualified suppliers be considered in selecting winning bidders. Only by doing so can CMS ensure that the integrity of the bid evaluation process is maintained and results in reasonable competitive bidding payment rates.

In proposed 42 C.F.R. 414.414, CMS would require that each supplier meet basic eligibility requirements (such as complying with existing Medicare supplier standards), comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. To evaluate the bids themselves, CMS proposes a three-step process: (1) establish a single composite bid for each supplier for a particular product category; (2) array these composite bids from lowest to highest; and (3) select a pivotal bid (based on estimated beneficiary demand), with winning bidders being those at or below the pivotal bid.[13] The timing of CMS's determination as to whether a supplier meets the eligibility standards is key.

CMS proposes to allow a grace period during which bidding suppliers could come into compliance with the quality standards.[14] The agency does not otherwise address the order in which it will evaluate bid submissions. At the May 2006 Program Advisory & Oversight Committee ("PAOC") meeting, CMS officials indicated that the agency has not yet decided how to address this issue. Hoveround recognizes that a grace period would assist certain suppliers in becoming accredited, particularly given the compressed time after the quality standards are finalized in June 2006. Under no circumstances, however, should the grace period be permitted to undermine the integrity of the bidding process. There is a very real danger that, if CMS permits suppliers to submit bids prior to becoming accredited, these suppliers will drastically underestimate the operational costs involved in obtaining and maintaining accreditation.

Hoveround believes that suppliers will not be able to calculate bid amounts accurately unless they have first undertaken and completed the accreditation process. Inaccurate bids—particularly in an industry where accreditation has become the standard—could result in competitive bidding payment amounts that do not account for the recognized cost inputs in maintaining accreditation and that are inappropriately low. This in turn would either lead to beneficiaries receiving poor quality items and services or a complete lack of access to products because suppliers are forced to exit the Medicare program for financial reasons. To avoid such

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

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

results, Hoveround urges CMS not to permit a grace period.

If, however, CMS decides to offer a grace period notwithstanding these serious concerns, it is absolutely critical that the agency consider the supplier's ability to meet these standards *prior to selecting the pivotal bid.* Otherwise, the bidding pool will be tainted by bids of suppliers that are not qualified to provide competitively bid products to beneficiaries. Without up-front consideration of the eligibility requirements, Hoveround is concerned that competitive bidding payment rates will be artificially depressed and unreasonably low.

If CMS does decide to go forward with its proposal to permit a grace period, Hoveround recommends that the agency revise proposed 42 C.F.R. § 414.414 to specify that bids will be evaluated only if submitted by suppliers meeting the requirements listed in subsections (b)-(d). Specifically, those subsections provide that the supplier must meet basic eligibility requirements, comply with DMEPOS quality standards and be accredited by a CMS-approved accrediting organization, and meet applicable financial standards. The following two changes would accomplish this:

- First, the proposed regulation should provide that the conditions for awarding contracts are evaluated prior to evaluating bids. This order of operations could be explicitly set forth in a separate subsection, for instance, in a new subsection (e), stating: *"(e) Timing of conditions for awarding contracts. CMS will determine whether a bidding supplier meets the requirements in paragraphs (b) through (d) of this section prior to evaluating the bids as described in paragraph (f) of this section."* The lettering of the subsequent subsections would need to be shifted down one alphabetical letter, so that current subsection (e) becomes subsection (f) and so on.

- Second, proposed paragraph (e)(2)—which would be paragraph (f)(2) under the revised numbering suggested in our first point—should be modified accordingly, so it is clear that CMS would only include bids from qualified suppliers in its comparative evaluation of bid prices. The following added language is suggested: "[CMS evaluates bids submitted for a product category by— . . .] Establishing a composite bid for each supplier that submitted a bid for the product category *and met the requirements of paragraphs (b) through (d).*"

IV. CAP ESTIMATED CAPACITY PER SUPPLIER WHEN SELECTING WINNING BIDDERS IN ORDER TO PRESERVE COMPETITION AND BENEFICIARY CHOICE

[Conditions for Awarding Contracts]

Not only is it vitally important that CMS select only from qualified suppliers (as discussed above), but also Hoveround strongly believes that the contract award process must not result in the selection of only a small number of suppliers with large capacity. Hoveround is concerned that, as proposed, the selection process can easily result in only one or two suppliers with a very large capacity servicing a CBA. Such a result, for the most part, does not preserve the goals of a competitive program.

Specifically, under 42 C.F.R. § 414.414, CMS proposes to determine winning bidders by selecting a pivotal bid from among the composite bids submitted. As discussed above, the pivotal bid would be set at the point where the expected combined capacity of bidders is sufficient to meet expected beneficiary demand for items in a product category in the CBA. There is no transparent method to ensure that demand is not satisfied by one or two very large suppliers. At the same time, to preserve competition among suppliers, a reasonable number of low-priced bids should be able to prevail. Only in this way can future bidding cycles and savings continue to result from competitive bidding.

The Medicare statute requires selection of multiple bidders, and Hoveround supports CMS's inclusion of this requirement in the proposed regulations (proposed 42 C.F.R. § 414.414(g)). With only two suppliers retaining Medicare business in a region, however, there may be little to no competitively priced bids in the later phases of the program. Hoveround therefore urges CMS to take the long view in designing and implementing this program, so that it can continue to work and reap benefits beyond the initial phases. Hoveround recommends that CMS incorporate a cap on each supplier's capacity when evaluating demand for any given CBA. This would go a long way to protect beneficiaries' interests and ensure that they continue to enjoy choice in the products furnished to meet their medical needs.

A cap may be structured to evaluate low bids from very large suppliers favorably, yet also to limit each bidding supplier's demand to 20% of anticipated demand. In this way, even if the supplier could provide 50% of the products needed, it would only get credit for 20% for purposes of determining winning bidders. Further, the formula used should incorporate a transparent methodology that can be easily understood and reproduced. To ensure the integrity of such a methodology, CMS should make available the list of all bidding and winning suppliers and should provide an explanation of the methodology used to determine the composite bid, pivotal bid and competitive bidding payment amounts for each product category.

V. TAILOR PROGRAM REQUIREMENTS TO ADDRESS BUSINESS CONSIDERATIONS OF THE DMEPOS INDUSTRY

[Terms of Contract; Physician Authorization/Treating Practitioner]

Hoveround believes that, as proposed, the program does not adequately address business considerations of the DMEPOS industry and that a number of changes should be made to the regulations to ensure that suppliers are able to participate as a practical matter. Together, these provisions could lead many current suppliers to exit the Medicare program—a result that would have a devastating impact on beneficiaries' ability to obtain needed items.

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

Proposed 42 C.F.R. § 414.422(c) requires contract suppliers to bear responsibility for repairs and maintenance of items that were previously furnished by non-contract suppliers. Hoveround requests that, in recognition of the fact that contract suppliers can only perform such services for products that they sell, CMS refrain from finalizing this proposal.

Hoveround opposes this proposal because it ignores practical realities of the DMEPOS industry. In many, if not most, instances, suppliers have no experience in repairing or performing maintenance on items that were supplied by other suppliers and will be unable to perform such work themselves. This proposal, in effect, will require the contract suppliers to pay for a sub-contractor to perform the service—a result that would impose significant costs on winning suppliers. Otherwise, suppliers will need to seek out manufacturers to obtain parts needed to make repairs and, particularly if the suppliers do not have an ongoing business relationship with particular manufacturers, may not be in a position to obtain favorable prices for these one-off situations. It is difficult to determine what these costs will be in advance of bid submission and, as a result, short of CMS providing the information as part of the Requests for Bids, there is no way for suppliers to weigh this cost in determining bid prices.

Even if CMS is able to offer this information prior to bid submission, the proposal is particularly onerous for manufacturer-suppliers that only carry their own products and suppliers that have arrangements only with certain manufacturers, as is often the case in the DMEPOS industry. It is these very entities (manufacturer-suppliers and suppliers with consolidated purchasing arrangements) that may be able to provide the lowest bid prices because standardization of their product lines enables them to keep costs down. CMS's proposal, then, could inadvertently cause suppliers to increase the bid amounts submitted and, in the aggregate, decrease savings from competitive bidding significantly.

Hoveround therefore recommends that CMS continue to make payments for repair and maintenance of DMEPOS items to the non-contract supplier, as it has done in the past.[15] There is no reason to shift this burden to another supplier, particularly one who is likely to be unequipped to perform the services itself. If, however, CMS decides to proceed with this proposal, at a minimum, the agency should exempt manufacturer-suppliers from the requirement. Under this approach, the following regulatory language would be appropriate. A new subsection (c)(3) may be incorporated into 414.422: "*Contract suppliers that are FDA-approved manufacturers and that only furnish their own products to beneficiaries in the competitive bidding area are exempt from the requirement in paragraph (c)(1) for purposes of items furnished by other suppliers.*"

Physician Authorization of Product Brand

Hoveround believes that revision is also warranted for proposed 42 C.F.R. § 414.420. This provision would oblige contract suppliers to make a reasonable effort to furnish a physician-specified brand (or mode of delivery). Under this provision, CMS notes that physicians and other treating practitioners could prescribe a particular product brand if they determine that it would avoid an adverse medical outcome for the beneficiary. If a treating practitioner specifies a particular product under these circumstances, the contract supplier would be required to "make a reasonable effort to furnish the particular brand." If the supplier is unable to furnish the

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15 Under existing Medicare Supplier Standard # 6, suppliers are required to provide maintenance and repairs for items furnished to beneficiaries under warranty at no charge. *See* 42 C.F.R. § 424.57(c)(6). There is no reason to alter this longstanding business requirement.

designated product, it would need to work with the practitioner to find an alternate item that is appropriate and obtain a revised order.[16]

Manufacturer-suppliers only maintain inventory that contains their own products and will never be able to furnish a brand other than their own. Hoveround believes that the regulation should be revised to make clear that the contract supplier need not be able to offer the item if it is not part of its inventory. This could be accomplished by adding a new subsection (b)(4) to 414.420, stating: "*The contract supplier is not required to furnish the particular brand or mode of delivery itself if such brand or mode of delivery is not in its inventory in order to be deemed to have made a reasonable effort under this paragraph (b).*"

Change In Ownership

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

Hoveround believes that this proposal is overly restrictive and penalizes business arrangements that may have no impact on the contract supplier's relationship with CMS. Further, the proposed regulation would needlessly devalue the monetary worth of a supplier. Critically, the existing Medicare supplier standards, as well as the soon-to-be-implemented quality standards, already provide all the necessary assurances needed to ensure that only high quality services are provided to beneficiaries. The new notice requirement does not add to these assurances in any meaningful way.

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

CMS could also borrow (as it has in the past) from the definition of "change of

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[16] *See* 71 Fed. Reg. at 25684.

ownership" in the provider context under 42 C.F.R. § 489.18(a). With respect to corporations, by way of example, this regulation provides that:

> The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.[17]

Hoveround thus suggests adopting this definition in the proposed regulation. This would notify contract suppliers of the types of transactions that would trigger the completion of a new Form CMS-855S, as well as the change that would trigger the examination by CMS that a contract supplier can continue to meet the obligations under the existing contract.

In addition, Hoveround asks that CMS finalize this proposal so that it is consistent with the existing notice requirements for DMEPOS suppliers. The current regulations do not require notice to CMS until *after a change of information or ownership has occurred* and adopt a 30-day timeframe. There is no reason to require advance notice in this context. CMS recently re-affirmed this approach in newly finalized supplier enrollment regulations, requiring DMEPOS suppliers to report changes of information and changes of ownership or control within 30 days of their occurrence.[18]

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

Furnishing Power Wheelchairs On a Rental Basis

In the preamble, CMS proposes to require contract suppliers of power wheelchairs to agree to give the beneficiary (or caregiver) the choice of renting or purchasing the item and to furnish the item on a rental or purchase basis, as specified.[19] This requirement would unnecessarily impose financial hardships with little gains. Beneficiaries requiring power mobility currently purchase these items in the vast majority of cases because they have chronic, progressive and lifelong need for the device. Based on its extensive experience in the industry, Hoveround has observed that 99% of the power wheelchairs the company delivers to the Medicare population are prescribed for use well beyond the current 13- (or prior 15-) month statutory rental periods for typical capped rental items.

Under the Medicare statute, suppliers are currently required to offer beneficiaries the

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17 42 C.F.R. § 489.18(a)(3).

18 42 C.F.R. § 424.530.

19 71 Fed. Reg. at 25681.

option to *purchase* the power wheelchair at the time it is initially furnished to them.[20] The statute is silent as to whether a rental option must be offered and whether items must be furnished on that basis, if requested. Early in the 2006 budget reconciliation process, there was a proposal to make power wheelchairs a mandatory rental item. This proposal met with serious objections from the industry and beneficiary advocacy groups alike and was ultimately, and for good reason, excluded from the bill that passed Congress. Indeed, Congress affirmatively reiterated its intent to keep in place the up-front option to purchase. There are sound reasons not to revive the rental requirement here.

Power wheelchairs are designed to preserve an individual's functional ability and, in the Medicare population (the elderly and disabled), are used by those suffering from chronic and degenerating ailments and severe and/or permanent injuries. These individuals for the most part do not have temporary mobility needs. While power wheelchairs are of varying sophistication, they are frequently modified to suit specific body types and functional needs of patients. When provided for those with severe limitations, they are even more likely to be customized and unsuitable for use by another individual.

For power wheelchair manufacturers and suppliers, providing power wheelchairs to Medicare beneficiaries is a considerable, capital-intensive investment, including steps from the point of development of and manufacturing the product to obtaining prescriptions and qualifying the beneficiary under Medicare requirements. Delays in full Medicare payment for each and every unit supplied—regardless of the individual's medical condition and unique circumstances—is an untenable position for all providers of this benefit, regardless of size. This has a particularly devastating impact on small suppliers who are unable to float a large volume of loans to subsidize rentals for a period of time. Such a policy would increase the costs of doing business considerably, which would in turn increase bid amounts—contrary to the goal of achieving savings through competitive bidding.

Furthermore, providing wheelchairs on a rental basis has not been shown to save the Medicare program money. When the equipment is automatically transferred to the beneficiary in the 13th month of the rental period, as is required by statute, Medicare will have paid 105% of the lump-sum payment made if the beneficiary had purchased the product when it was furnished. For these reasons, it is inappropriate and unnecessary for CMS to mandate that contract suppliers offer a rental option to beneficiaries, and Hoveround strongly urges that this proposal not be adopted.

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20 42 U.S.C. § 1395m(a)(7)(A)(iii).

VI. ADOPT AN APPROACH FOR SETTING PAYMENT AMOUNTS THAT REASONABLY REFLECTS ACTUAL BIDS

[Determining Single Payment Amounts for Individual Items]

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

Hoveround believes that alternative approaches would lead to a reasonable payment rate. Specifically, the Company supports the adjustment factor approach that was used in the demonstration projects and is discussed in the preamble to the proposed regulations.[21] Under this approach, CMS would calculate payment rates as follows:

(1) Calculate the average of the winning bids for each HCPCS code;

(2) Calculate the average of the composite bids for a product category;

(3) Establish an adjustment factor (*i.e.*, pivotal composite bid divided by average composite bid) that is intended to bring each winning supplier's overall bids for a product category up to the pivotal bid; and

(4) Multiply the amount from Step 1 by the amount from Step 3.

This approach ensures that the overall payment amount that contract suppliers receive is at least as much as their bid prices. As CMS observes in the preamble to the proposed regulations, suppliers may be less likely to leave the Medicare program if this approach were adopted because there is some assurance that payment rates will be sufficient. Hoveround thus recommends that 42 C.F.R. § 414.416 be amended to incorporate this methodology in lieu of the median approach.

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

VII. ENSURE PAYMENT RULES USED FOR HCPCS CODES REVISED MID-CYCLE RESULT IN REASONABLE PAYMENT AMOUNTS

[Gap-filling]

CMS proposes special payment rules in 42 C.F.R. § 414.426 for competitively bid HCPCS codes that are revised in the middle of a competitive bidding cycle. For the most part, Hoveround supports these rules. However, in certain circumstances, the Company believes that CMS should continue to use the codes that were competitively bid and not replace them with new codes until the next cycle.

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

(1) If a single code is split into multiple codes, the supplier would be paid the payment amount for the former code.[22] Therefore, the split into new codes would not impact payment. During the subsequent bidding cycle, suppliers would bid on the new separate and distinct codes.

(2) For codes for several components that are merged into a single new code, the payment policy would differ depending on whether the former codes described (a) components of a single product or (b) multiple products. If the former codes described components of a single product (scenario (a)), the supplier would be paid a rate equal to the total of the payment amounts under the former codes. If the former codes described multiple products (scenario (b)), the new payment amount would be the average (arithmetic mean) of the former payment amounts weighted by the frequency of payments for the former separate codes. For each of the two scenarios, during the subsequent bidding cycle, suppliers will bid on the new single code.[23]

As to the proposal under (2)(b), Hoveround is concerned about the use of a weighted arithmetic mean when a new code replaces multiple codes for similar products. First, it is unclear how the weighting would occur. For instance, would CMS review payments for all suppliers in all jurisdictions or only contract suppliers in CBAs? Furthermore, this formula could result in significantly different pricing in the middle of a bidding cycle. Using the new code would disrupt suppliers' expectations as to the payment levels they would receive for furnishing products to beneficiaries in the CBA. It could also create a disincentive to participate in the program.

One benefit to competitive bidding for suppliers is that, if selected, they are guaranteed a

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

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

certain price for products furnished to Medicare beneficiaries for a set period of time. Because this proposal injects a sufficient level of uncertainty, suppliers may opt not to participate in or, significantly, upon such a payment change, may choose to exit the program instead of continuing to service the CBA at a lower payment rate.

For this reason, Hoveround asks that, where multiple codes for similar items are merged to a single new code, CMS continue to use the former codes and payment rates for the remainder of the bidding cycle. This could be accomplished by revising 42 C.F.R. § 414.426(d) as follows: "If multiple codes for similar items are merged into a single code, *the codes that were competitively bid and the established payment amounts for those codes, with any adjustments provided under § 414.408(b), will remain in effect for the remainder of the competitive bidding program*."

VIII. CONSIDER SALES VOLUME ASSUMPTION WHEN USING COMPETITIVE BIDDING RATES TO ADJUST PAYMENT AMOUNTS IN NON-COMPETITIVE BIDDING AREAS

[Payment Basis]

CMS proposes to use its statutory authority to adjust payment in other areas based on payment information determined under the competitive bidding program. Such adjustments may not be made prior to 2009, and CMS did not provide a specific proposal as to how this authority would be used. Hoveround requests that stakeholders be given another opportunity to comment on how to implement this provision at a later date once CMS develops a particular proposal.

In the interim, Hoveround strongly cautions CMS to use this authority carefully. Hoveround is particularly concerned that, if competitive bidding payment amounts are applied nationwide in 2009 or later years, this would in effect move the Part B DMEPOS benefit toward an "any willing provider" model—which is not the intent of competitive bidding. Competitive bidding rates will be based on bid amounts that are calculated using an assumed increase in volume. Suppliers assume that there will be few suppliers in each CBA for competitively bid products and, accordingly, that they can offer lower prices because these prices will be offset by the higher volume of products they will furnish. It is inappropriate to apply competitive bidding rates to non-competitive bidding areas because, in non-competitive bidding areas, there would be no concomitant volume-upside to balance out the pricing-downside. At minimum, this means that CMS should not borrow directly from competitive bidding rates in setting fee schedule amounts for items in non-competitive bidding areas.

IX. DISCARD THE PROPOSED REBATE PROGRAM

[Determining Single Payment Amounts For Individual Items]

Under proposed 42 C.F.R. § 414.416(c), CMS proposes to allow contract suppliers that submitted bids for an item below the competitive bidding payment amount to provide rebates to beneficiaries. This rebate would be equal to the delta between the supplier's bid amount and the competitive bidding payment amount for the item. At the PAOC meeting, several committee

members, as well as members of the industry, objected to this proposal. Hoveround shares their concerns that this proposal implicates and may run afoul of the Federal Anti-Kickback Statute (the "AKS") and, for that reason, strongly urges that the proposal not be finalized.

The AKS is a criminal prohibition that provides punishment for any person who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."[24] Rebates intended to induce beneficiaries to purchase a particular Medicare-covered item are generally prohibited under the AKS. Hoveround is concerned that adoption of the rebate program would generate significant confusion in the industry as to what is permissible under the AKS and what continues to be prohibited. Hoveround asks that the rebate program not be finalized.

X. SAFEGUARD EXISTING APPEAL RIGHTS

[Administrative or Judicial Review]

The proposed regulation concerning appeal rights under the competitive bidding program (42 C.F.R. § 414.424) tracks closely the statutory provision and prohibits appeals on most decisions made regarding competitive bidding. This includes, for instance, which suppliers are awarded contracts, payment amounts established, and selection of items to be competitively bid.[25] As written, the proposed regulation does not make clear that existing rights of beneficiaries and suppliers to appeal denied claims are preserved.

In the preamble to the proposed regulations, CMS acknowledges that existing rights are undisturbed by competitive bidding. Hoveround requests that this be explicitly stated in the regulation itself, by adding the following subsection (c) to 414.424: "*All existing rights to appeal denied claims are unaffected by this provision.*" In addition, the statement in the regulation that "[a] denied claim is not appealable if CMS determines that a competitively bid item was furnished in a competitive bidding area in a manner not authorized by this subpart" is vague and should be removed and/or clarified. As written, it is not clear what is meant by this language.

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24 42 U.S.C. § 1320a-7b(b)(2).

25 71 Fed. Reg. at 25682.

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

[Gap-filling]

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

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

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

Substantive Criteria

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

on deflation factors that often result in drastic under-compensation for new products.[26] Hoveround believes, however, that the proposed criteria lack specificity sufficient to inform stakeholders as to the formula to be used.

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

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

As to the FTA, the notice states that there were three main areas studied in the FTA conducted in CMS's pilot study: (1) Functional Assessment, which evaluated the device's operations, safety and user documentation relative to the Medicare population; (2) Price Comparison Analysis, which involved a cost analysis comparing the product to similar products or alternative treatment modalities; and (3) Medical Benefit Assessment, which focused on the effectiveness of the product using scientific literature and interviews of providers to determine if the product does what it purports to do. Not only is this vague explanation insufficient information for meaningful comments, the FTA analysis oversteps congressional mandates on when the agency can adjust fee schedule amounts and identify alternative "realistic and equitable" amounts. It is improper for CMS to cast aside Congress's grant of IR authority. Further, CMS should not resort to incorporating a coverage analysis to establish pricing. Here, as well, Congress has prescribed how to evaluate coverage. Simply, CMS cannot exercise powers that contradict Congress's specific language in specific statutory grants of authority.[27]

Pricing should be established using objective criteria that can be applied to all products in the same way. A transparent formula, capable of being reproduced for all products must be used. To design FTA criteria that are objective and capable of being reproduced (and we believe that this likely cannot be achieved easily), extensive modifications must be made to incorporate IR

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

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

and coverage requirements. One approach might be to develop an algorithm with a sequential analysis. The FTA would be the last and final step taken. However, it should *only* be used when the median pricing information or pricing of comparable codes is not available. Most critically, it *should only be used as part of an exercise of CMS's IR authority.*

Procedural Requirements

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

As CMS describes in the preamble to the proposed regulations, the two FTAs that have previously been undertaken in its pilot study (the results of which have not been shared with stakeholders) involved evaluation of the device's safety and effectiveness in improving clinical outcomes. Both of these elements are considered in determining whether an item meets the Medicare statute's "reasonable and necessary" standard and will be covered under the Medicare program.[28] It is significant that over the years the coverage process has become more open. To that end, Congress recently mandated that CMS follow a defined process for making NCDs, including providing an opportunity to appeal the decisions.[29] There is now a fulsome appeals process available for aggrieved parties who believe an NCD provision is unreasonable.[30] Similar processes are available for challenges to local coverage determinations.[31] CMS must not and may not circumvent these procedural requirements by folding a coverage decision into the payment calculation process.

Perhaps most importantly, payment adjustments like those being proposed here are

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28 42 U.S.C. § 1395y(a)(1)(A); *see also* Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapt. 15, § 110.1 (stating that the necessity of equipment is determined based on "when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member" and that reasonableness is determined based on considerations such as whether the expense of the equipment would not be clearly disproportionate to the therapeutic benefits that could ordinarily be derived from it).

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

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

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

statutorily required to undergo a notice and comment process as well. Under the IR provisions, CMS must analyze a variety of factors and adjust pricing for an item or service upon a determination that the otherwise applicable payment amount is grossly excessive or grossly deficient, which is defined by its own regulations to include a threshold variance of fifteen percent.[32] Once CMS has determined that a payment amount is grossly excessive or deficient, it may establish a payment amount only by considering certain factors, including pricing information and the resources required to produce the products. There is no reason that the FTA should not require similar procedural safeguards. Significantly, CMS may not use its IR authority without first following the required procedural steps:

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

- For payment adjustments of greater than 15% in a single year, more rigorous reviews and procedures are to be undertaken. As to the procedures, CMS must consult with supplier representatives from the industry likely to be affected by the payment change. Notice of the proposed determination must also be published in the Federal Register, with a 60-day public comment period. The Federal Register Notice with the proposed determination must contain an explanation of the factors and data considered in determining that the payment amount is grossly excessive or deficient, list the proposed payment amount, and describe the factors and data used to set this adjusted rate. CMS is to consider any comments submitted prior to publication of a final determination, and discussion responsive to these comments is to be included in the Federal Register Notice announcing the finalized payment determination.[33]

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

As stated above, if the functional technology assessment is used—and Hoveround does not believe that it should be used—then CMS should incorporate the FTA expressly into its IR process so that the same procedural requirements are used. Use of this assessment tool as a means of justifying reductions in payment rates otherwise is impermissible. This means that CMS would be permitted to use FTAs only *as part of* the IR process, *i.e.*, to determine whether a payment rate is grossly excessive or deficient and to identify a realistic and equitable amount. This would ensure that fulsome notice and comment were provided prior to any reductions in

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

33 42 USC § 1395u(b)(8)-(9); 42 C.F.R. § 405.502(g)-(h).

payment levels based on a functional technology assessment. Accordingly, the proposed regulation must be revised in its entirety. Although Hoveround opposes the use of the FTA for the reasons stated here, out of an abundance of caution, suggested language is described in **Appendix A** to this comment letter.[34]

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

Truly yours,

Esther R. Scherb

Stuart S. Kurlander
Esther R. Scherb
Of LATHAM & WATKINS LLP

Cc: Hoveround Corporation
Rebecca L. Spain, Latham & Watkins LLP

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[34] Similar changes could be made to the proposed regulation for PEN items and services at 42 C.F.R. § 414.102(d).

Appendix A

Hoveround's Proposed Revisions to 42 C.F.R. § 414.210 (Gap-Filling)

(g) Establishing fee schedule amounts for new items and services.

(1) The DMERC or local carrier uses the process described in paragraph (g)(2) of this section to establish the fee schedule amounts for the items and services included in a new HCPCS code created for a category of items and services payable under this subpart, but only if reasonable charge data are not available to calculate a fee schedule amount.

(i) The fee schedule amounts are updated in accordance with this subpart.

(ii) Items described in Sec. 414.224 are not subject to paragraph (g)(1) of this section.

(2) CMS calculates the Medicare fee schedule amounts for the items and services described in paragraph (g)(1) of this section taking into account one or more of the following:

(i) The *weighted* median retail price for items and services classified under the new HCPCS code (CMS determines the retail price for an individual item and service based on supplier price lists and manufacturer suggested retail prices [delete: , or wholesale prices plus an appropriate mark-up)]; or

(ii) Existing fee schedule amounts for comparable items.

~~(iii) A functional technology assessment of the items or services classified under the new HCPCS code that takes into account one or more of the following factors:~~

~~(A) Functional assessment.~~
~~(B) Price comparison analysis.~~
~~(C) Medical benefit assessment.~~

~~(3): A functional technology assessment described in paragraph (g)(2)(iii) of this section is also used to adjust fee schedule amounts calculated under paragraph (g)(2) of this section if CMS determines that these amounts do not reflect the costs of furnishing the item or service.~~

(3) As used in paragraph (g)(2)(ii), "comparable items" means items that are similar in price, function and clinical application.

(4) If the fee schedule amount for a particular HCPCS code resulting from application of paragraph (g)(2)(i) and (ii) is to be adjusted because it is determined to be grossly excessive or grossly deficient, as described in 42 C.F.R. § 405.502(g), CMS shall use the

procedures required in 42 C.F.R. § 405.502(g).

(5) A functional technology assessment that takes into account one or more of the following factors: Functional assessment; Price comparison analysis; and Medical benefit assessment may be used in conjunction with the determination in paragraph (g)(4).

Submitter : **Dr. Hal Abrahamson** **Date: 06/29/2006**

Organization : **Long Island Podiatry Associates**

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:
This is a very critical and serious issue. Please read.
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.

Submitter : Ms. Lorrie Kline Kaplan **Date:** 06/29/2006

Organization : National Home Infusion Association (NHIA)

Category : Other Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attachment

CMS-1270-P-882-Attach-1.DOC

NHIA
National Home Infusion Association
Providing solutions for the infusion therapy community

June 28, 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:

The National Home Infusion Association ("NHIA") 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 as issued in the Federal Register on May 1, 2006.

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions. Currently, NHIA has approximately 1,800 members.

CMS has the unenviable task of developing and implementing within a limited time frame a nationwide competitive bidding program for a large portion of the Medicare program. The proposed rule reflects the hard work that CMS has devoted to this effort. We commend CMS for its efforts to translate the statute into a viable program.

That said, the proposed rule is unlike most proposed rules in that this rule lays out a number of unanswered questions. On a number of important issues, CMS has not committed to a concrete proposal. The preamble section regarding criteria for product selection, wherein CMS

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seeks comment on very general criteria for subsequent product selection, and the preamble discussion regarding the application of competitively bid rates in other areas of the country, are two examples of this practice. In addition, the Part B quality standards have not been issued yet, and thus our comments on the proposed rule cannot reflect the impact of the quality standards on the proposed competitive bidding program.

At this juncture, it is difficult to project what the final rule will look like on a number of important issues where CMS did not propose a specific course of action. For that reason, we suggest that CMS issue the final rule as an interim final rule with comment period, so that the public will see, for the first time, CMS' directions on an array of issues and thus will have an opportunity to comment on concrete proposals.

Quality Standards

At the outset, we want to address briefly an issue pertaining to the development of Part B quality standards for durable medical equipment, prosthetic and orthotic services and items (DMEPOS). Section 1847(a) of the Social Security Act (hereafter "Act") requires CMS to develop quality standards that would apply to the provision of most non-physician Part B items and services. We applaud this initiative, as these quality standards are important to the functioning of the competitive bidding program that is the subject of the proposed rule. Importantly, however, the quality standards are not limited to those items subject to competitive bidding. The standards will apply equally to those non-physician Part B items and services that are not subject to competitive bidding and which will continue to be reimbursed pursuant to the otherwise applicable payment methodologies.

There should be no argument with the principle that Medicare payments, whether determined by fee schedule or via competitive bidding, should be sufficient for efficient suppliers to comply with the quality standards. The standards will have little meaning or effect if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. This is, we believe, an important point that CMS should affirm in the final rule.

With the development of meaningful quality standards, we believe CMS and the OIG now are required to factor the costs of compliance with these standards into their assessments of adequacy of reimbursement. It would be a most illogical development if these assessments continue to be conducted as if the quality standards have no applicability, meaning or cost. We request that CMS acknowledge that the costs of compliance with applicable quality standards should be taken into account in future consideration of reimbursement issues, both within and outside the competitive bidding program.

Executive Summary

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. Home infusion therapy is one of the most service-intensive and invasive therapies covered under Part B of the Medicare program. Medicare Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is 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. 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.

3. 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 is misleading and incorrect. It includes expenditures made for insulin and insulin pumps for patients with diabetes, which are provided by entities *other* than infusion pharmacies and is largely a different market than infusion. It includes drugs that have sole or limited national distribution arrangements with particular pharmacies, so that there would continue to be a very limited number of infusion pharmacies that supply the drugs to Medicare beneficiaries. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs 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, which represents less than 0.8% of DMEPOS expenditures for that year.

4. Enteral nutrition is not a good candidate for inclusion in the first phase of the competitive bidding program. 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 within the scope of the competitive bidding program. It creates serious policy and operational issues for nursing homes as well as for CMS itself. 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.

5. 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.

6. If CMS ultimately subjects enteral nutrition to competitive bidding, it 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.

7. The competitive bidding areas should be limited to the geographic scope of the selected metropolitan statistical areas ("MSAs"), and should not encompass contiguous areas

8. The proposed gap-filling provisions are too vague and undefined, and appear to be in conflict with the limitations on CMS' authority to modify existing payment rates. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders as to how existing payment levels can and should be adjusted when existing codes are modified.

Criteria for Item Selection

We understand that competitive bidding is intended to be a far-reaching initiative that will achieve two important objectives: (1) improve the level of care for Medicare beneficiaries requiring Part B items and services, and (2) reduce Medicare expenditures, including the amount of beneficiary co-payments.

Both, obviously, are admirable goals. For the reasons described herein, however, we believe that infusion drugs, supplies and pumps covered under the DME benefit and e nteral formulas, supplies and equipment covered under the prosthetic device benefit are poor candidates for inclusion in the competitive acquisition program, particularly in the initial phase of the program.

DME-Covered Infusion Pumps and Related Drugs

Home infusion therapy involves the administration of medication through a needle or catheter. Typically, infusion therapy means that a drug is administered intravenously, but the term also may refer to situations where drugs are provided through other non-oral routes, such as intramuscular injections and epidural routes. Diagnoses requiring infusion therapy include infections that are unresponsive to oral antibiotics; cancer and cancer-related pain; and congestive heart failure. Common prescription drug therapies administered via home infusion include antibiotics, chemotherapy, and pain management. Home infusion therapy is indicated for patients with medical conditions that cannot be treated effectively with oral medications.

Policy Bases for Excluding Infusion Pumps and Related Drugs from Competitive Acquisition Program

Home infusion therapy is one of the most clinically complex areas within the scope of the competitive bidding program. Infusion therapy involves more than the delivery of infusion drugs to patients. Patients receiving home infusion therapy require an array of professional services, including the following:

- Initial patient evaluation and assessment
- Development and implementation of the patient care plan
- Compounding and dispensing of infusion medications and equipment
- Ongoing clinical monitoring and treatment plan oversight
- Care coordination
- Provision of on-call services and patient discharge services.

These services are provided by specialized home infusion pharmacies that must satisfy licensing and other regulatory requirements imposed by state pharmacy boards as well as accreditation standards required by most third-party payers. For a complete description of the necessary functions and costs associated with the safe and effective administration of home infusion drug therapy, see Appendix A.

Current Part B coverage of home infusion therapy is limited to what is covered under the DME benefit, wherein coverage is based on the use of an item of DME – in this case, an infusion pump – and extends only to a few designated drugs. Medicare Part B is unique in this approach to home infusion therapy coverage, as most other payers define and cover home infusion therapy as a professional service under a major medical benefit. While Part B coverage for infusion therapy is keyed to the involvement of an infusion pump, it should be noted that the infusion pump itself is just one component of care in the provision of home infusion therapy.

Instead, this is an area of therapy that is clinically possible in the home primarily because of the specialized professional services provided by home infusion pharmacies. These services require close contact between the infusion pharmacy and patient, and the effective and safe provision of home infusion therapy is dependent in large part of the development and maintenance of a trusting relationship between the infusion pharmacy and the patient (and the patient's family and caregivers).

No one has seriously suggested that competitive bidding should be applied to physician services, because the choice of a personal physician is a very personal one. While there are differences in degree, for infusion therapy the patient's choice of an infusion pharmacy also is very personal.

We suggest that as a starting point for the selection of items to be subject to the first phase of the competitive bidding program, CMS should focus first on those products that are not service-intensive. Certainly, home infusion therapy, which is perhaps the most service-intensive area under consideration, is a poor candidate for this phase of the program.

There are other important policy reasons why infusion drugs and pumps are not suitable at this time for competitive bidding. Home infusion therapy is unique in the DMEPOS category in that while 23 drugs can be covered in the home under limited circumstances under Part B, since January 1, 2006 hundreds of home infusion drugs are now coverable under Part D. Therefore, the implementation of competitive bidding for home infusion under Medicare Part B should not be considered without contemplating the effect this would have on the already extremely complicated Part B-Part D drug coverage issues.

It is easy to foresee that a patient may have a need for both a Part B-covered drug as well as a Part D-covered drug i.e., a Part B cancer drug and a Part D IV antibiotic drug. This would be a very likely occurrence because many infusion patients are receiving more than one therapy, and most infusion drugs are coverable under Part D. The patient, mostly likely a dual eligible beneficiary in the case of home infusion, may have to go to more than one pharmacy to obtain the needed drugs because the pharmacy that supplies the Part D drug may not be a contract supplier under the competitive bidding program for the Part B drug. At the very least, Medicare beneficiaries should be spared that ordeal. In addition, there would be important coordination of care concerns at issue here. The involvement of more than one pharmacy in the treatment of the patient increases the possibilities of mistakes and the prescription of several contra-indicated medications, which could have serious consequences for the patient and result in increased costs

of care. It also would create further confusion for discharge planners, who already are beset with a bewildering array of Part B – Part D coverage issues.

We believe that CMS should exclude from the first phase of the competitive acquisition program infusion pumps and related drugs, as well as any product category where, as here, coverage is divided up among multiple parts of the Medicare program. The Medicare program should avoid the illogical situation where it is encouraging infusion pharmacies to participate in Part D for the provision of home infusion therapy while limiting their participation in Part B for the provision of home infusion therapy. CMS should proceed very carefully with pharmacies that also are trying to participate in the Part D outpatient drug program. The Part B and Part D drug coverage issues must be resolved, or at least far better coordinated than they are now, before CMS subjects the Part B portion of the home infusion area to competitive bidding.

In addition, the application of CMS' factors for determining product selection for the 2007 phase makes it clear that Part B-covered infusion drugs and pumps are a poor candidate for inclusion in the competitive bidding program at this time, as described below:

I. Level of Medicare Expenditures

CMS proposes to use allowed charges at the product level and at the product category level for the purpose of selecting which items to phase in first under the competitive bidding program.

Infusion drugs, supplies and pumps comprise a very small part of the Part B expenditures. Most infusion drugs that are covered by commercial health plans are not covered under Part B. As indicated above, only 23 infusion drugs are covered under the Part B DME benefit, mostly anti-cancer drugs, inotropic, pulmonary hypertension and pain management drugs.[1]

Complicating this analysis is the fact that the Part B infusion pump and related drugs product category is far from homogenous. It should be noted that there are no single products used in home infusion drug therapy that fall within the list of high volume items found in Table 3 in the preamble to the proposed rule. In addition, we believe that the following products within the category should be excluded when attempting to quantify infusion-pump and related drug expenditures (2003 Part B allowed charges are shown in parentheses):

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[1] At a PAOC meeting in 2005, CMS circulated a document that indicated that Medicare expenditures for infusion pumps and related drugs amounted to $69,580,260 in 2002. By contrast, the proposed rule lists infusion drugs and pumps as the eighth largest area of expenditure in Part B in 2003, with over $149 million in allowed charges in 2003.

NHIA has been unable to determine precisely how these totals were derived. We believe the disparity in the amounts attributable to infusion pumps and related drugs underscores the confusion and ill-fitting coverage criteria that surrounds Medicare's policies pertaining to home infusion therapy. It is critical for CMS to understand fully what is involved in the home infusion product category before considering subjecting this area to the competitive bidding program.

a. **Insulin pumps and supplies** ($10,275,629)
b. **IVIG** (only $29,515 in 2003, but increasing thereafter)
c. **Limited distribution products** ($30,747,401 in 2003, but along with IVIG, the fastest growing product areas in this category)
d. **Inotropic Therapies** used to treat patients with Classes III and IV congestive heart failure – milrinone and dobutamine ($26,156,345)

Once these subcategories are excluded, the remaining allowed charges for home infusion therapy products totals $87.4 million, 14th on the list of product categories ranked by level of allowed charges. It must be noted however that this revised total still includes infusion pumps and supplies used to administer limited distribution products and inotropic therapies, since it is impossible to separately identify these expenditures.

For a more in-depth quantitative analysis of infusion pump-related expenditures in recent years highlighting these components of the infusion pump product category, we have prepared a chart that separates out these key subcategories of DME infusion pumps and related drugs. Additional information about the bases for excluding particular drugs and pumps from the infusion product category for the purposes of this analysis are provided on the following page.[2]

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[2] To understand the allowed charges for home infusion drug therapy reported in Table 4 in the preamble to the proposed rule, we obtained the Physician Supplier Procedure Summary Master File (PSPSMF) from CMS for 2003. We analyzed the DMERC medical policies for external infusion pumps and the relevant DMERC advisories from 2002, 2003 and 2004 to compile a comprehensive list of all alpha-numeric HCPCS codes for home infusion drug therapy (including external infusion pumps, infusion drugs and supplies) that could have been in effect at any time during calendar year 2003.

Many of these HCPCS codes can be used on claims submitted both by physician offices and home infusion pharmacies. To identify the aggregate allowed charges attributable to DME infusion pumps and related drugs, we calculated the total allowed charges for each code for claims processed by the four DMERCs in the 2003 data file. We aggregated these amounts, and the total allowed charges in 2003 based on our calculations was nearly identical to the total that CMS reported in the proposed rule for this broad category.

The PSPSMF for each calendar year includes procedure-specific billing data for all physician and supplier services provided to Medicare beneficiaries during the calendar year. To be included in the PSPSMF, a claim must be processed by the Medicare Part B carriers on or before June 30th of the subsequent year.

Using CMS' PSPSMF data from CY2003, we calculated that the total expenditures for home infusion drugs totaled $151,090,407. This total is within 1.3 percent of the number reported by CMS in the proposed rule for DME infusion pumps and related drugs ($149,208,088, see page 25671). As explained in this section, that number encompasses more than the home infusion therapy market, and thus it is larger than what can be attributed to traditional home infusion therapy provided by home infusion pharmacies.

Allowed Charges For DME Infusion Pumps and Related Drugs, 2002-2004							
	2002	2003	Dollar increase, 2002-03	Rate of increase, 2002-03	2004	Dollar increase, 2003-04	Rate of increase, 2003-04
Total all infusion pump-related expenditures	**$141,423,406**	**$155,017,887**	**$13,594,481**	**10%**	**$198,892,724**	**$43,874,837**	**28%**
Insulin Therapies							
J1817 – nsulin for insulin pump use	-	$ 1,201,390	$ 1,201,390	N/A	$ 3,732,449	$ 2,531,059	211%
E0784 – External ambulatory infusion pump insulin	$ 8,345,127	$ 9,524,239	$ 1,179,112	14%	$ 11,877,197	$ 2,352,958	25%
Total insulin related expenditures	**$ 8,345,12**	**$ 10,725,629**	**$ 2,380,502**	29%	**$ 15,609,646**	**$ 4,884,017**	46%
% of total infusion pump-related expenditures	*6%*	*7%*			*8%*		
IVIG Therapies							
J1563 – IG, intravenous, inj, 1 g		$ -	$ -	N/A	$ 5,268,677	$ 5,268,677	N/A
J1564 – Immune globulin, 10 mg	-	$ 29,515	$ 29,515	N/A	$ 110,000	$ 80,485	273%
Total IVIG-related expendtures				N/A	**$ 5,378,677**	**$ 5,378,677**	N/A
% of total infusion pump-related expenditures		*0%*			*3%*		
Pulmonary Hypertension (PH) Therapies							
J1325 – Epoprostenol, inj, 0.5 mg	$ 23,479,946	$ 25,751,157	$ 2,271,211	10%	$ 28,647,547	$ 2,896,390	11%
Q4077 – Treprostinil, inj, 1 mg	no data in file	$ 2,816,580	N/A	N/A	$ 27,358,283	$ 4,541,703	871%
K0455 – Infusion pump for uninterrupted epoprostenol admin.	$ 1,796,803	$ 2,179,664	$ 382,861	21%	$ 2,481,902	$ 302,238	14%
Total, PH-related expenditures	**$ 25,276,749**	**$ 30,747,401**	**$ 5,470,652**	22%	**$ 58,487,732**	**$27,740,331**	90%
% of total infusion pump-related expenditures	*18%*	*20%*			*29%*		
Inotropic Therapies							
J2260 – Milrinone lactate, inj, 5ml	$ 27,683,998	$ 25,743,270	$(1,940,728)	-7%	$ 29,397,882	$ 3,654,612	14%
J1250–Dobutamine HCL, inj, 50mg	$ 387,412	$ 413,075	$ 25,663	7%	$ 340,222	$ (72,853)	-18%
Total, inotropic therapies	**$ 28,071,410**	**$ 26,156,345**	**$(1,915,065)**	-7%	**$ 29,738,104**	**$ 3,581,759**	14%
% of total infusion pump-related expenditures	*20%*	*17%*			*15%*		
Total, Insulin, IVIG, PH, and Inotropic therapies	**$ 61,693,286**	**$ 67,658,890**	**$,965,604**	10%	**$ 103,945,482**	**$36,286,592**	54%
% of total infusion pump-related expenditures	*44%*	*44%*	*44%*		*52%*	*83%*	
Total infusion pump-related expenditures excluding these drugs	**$ 79,730,120**	**$ 87,358,997**	**$ 7,628,877**	10%	**$ 94,947,242**	**$ 7,588,245**	9%

Below is a more detailed explanation of why certain categories of products should be excluded from the infusion therapy product category.

1. Insulin and Insulin Infusion Pumps for Patients with Diabetes

Although insulin and insulin infusion pumps are covered under Medicare Part B under the same benefit as home infusion drug therapy, CMS should consider these products separate from the product category for traditional home infusion drug therapies.

In practice, the provision on infusion pumps for insulin is much less service-intensive than the provision of drug therapies used to treat cancer, intractable pain, congestive heart failure and other common indications for traditional home infusion therapy.

More importantly, the pharmacies that provide traditional home infusion therapy usually differ from the entities that typically provide infusion insulin pumps and supplies. Insulin and insulin infusion pumps typically are provided by the same suppliers that specialize in test strips, lancets and glucose monitors for patients with diabetes. As a result, when considering home infusion drug therapy as a product category, it is misleading and seriously inaccurate to include insulin and insulin pumps in that product category.

The PSPSMF data from 2003 reveals that Part B claims for insulin (J1817) and insulin pumps (E0784) accounted for $10,725,629 in allowed charges in 2003. This represents approximately seven percent of all Medicare Part B home infusion drug therapy expenditures in 2003.

2. Intravenous Immune Globulin ("IVIG")

In calculating the DME infusion pump and related drugs product category, CMS should exclude any amounts attributable to the provision of home IVIG. Home IVIG is not covered under the DME benefit and is not otherwise subject to the competitive bidding provisions of Section 1847(a) of the Act. Rather, home IVIG is covered under Medicare Part B under Section 1861(s)(2)(Z) of the Act, as of January 1, 2004.

3. Infusion Drugs Used to Treat Patients with Pulmonary Hypertension – Epoprostenol (Flolan®, Glaxo Smith Kline) and Treprostinil (Remodulin®, United Therapeutics Corporation).

Pulmonary hypertension is a rare and potentially life-threatening disorder of the lungs in which the pressure in the pulmonary artery (the blood vessel that leads from the heart to the lungs) rises above normal levels. Under the terms of the DMERC medical policies, to qualify for infusion therapy to treat pulmonary hypertension, the patients must have very severe symptoms such as severe shortness of breath with exertion, fatigabilty, angina or syncope.

For a number of unique clinical and practical reasons, competitive bidding would be unworkable for the two infusion drugs that are used to treat pulmonary hypertension in the home setting – epoprostenol (Flolan) and treprostinil (Remodulin).

It is important to note that there is no opportunity to achieve savings under competitive bidding for Flolan because the manufacturer (GlaxoSmithKline) recently entered into a five-year exclusive agreement with Accredo Health, Inc. to provide the drug in the U.S. marketplace. As a result, Accredo Health, Inc. is the only home infusion pharmacy that can provide Flolan to Medicare beneficiaries or other patients in the United States for the foreseeable future. This, then, is not a competitive market and will not be until at least 2010.

Similar threshold problems exist for the potential application of competitive bidding to Remodulin, an alternative treatment for pulmonary hypertension. Manufactured by United Therapeutics), Remodulin is subject to a limited distribution agreement wherein only Accredo Health, Inc., Curascript, Inc. and Caremark, Inc. distribute the drug in the United States. This arrangement will preclude a competitive market for the drug. Thus, Medicare expenditures for Remodulin overly inflate the level of expenditures attributable to infusion pumps and related drugs, since competitive bidding would not be possible for this drug.

With an overall incidence of pulmonary hypertension of only eight per 100,000 population, only a few Medicare beneficiaries in the United States receive Remodulin or Flolan therapy. It would be problematic to fashion a competitive bidding program for such a small number of patients.

The PSPSMF data from 2003 reveals that home infusion claims for epoprostenol (Flolan, J1325), treprostinil (Remodulin, Q4077) and infusion pumps for epoprostenol (K0455) accounted for $30,747,401 in allowed charges in 2003. This represents approximately 20 percent of all Medicare Part B home infusion drug therapy expenditures in 2003. This does not consider other charges incurred in administering these therapies, including the allowed charges for infusion supplies for these two drugs and the allowed charges for the pumps used to administer Remodulin therapy.

4. Infusion Drugs Used to Treat Patients with Classes III and IV Congestive Heart Failure – Milrinone and Dobutamine

Congestive heart failure is a debilitating and life-threatening disorder in which the heart muscle is unable to pump with sufficient force. The heart is unable to keep up with the flow of blood returning to the heart, resulting in fluids collecting in the body.

By the time that the infusion of inotropic drugs in the home setting is indicated (so-called Stage III and Stage IV congestive heart failure), the patient is severely debilitated. For example, under the terms of the DMERC medical policies and well-established standards of care, the infusion of these drugs is not indicated unless the patient becomes short of breath (called dyspnea) by merely performing activities of daily living.

Under the terms of the DMERC medical policy, these drugs are only covered for continuous infusion if the patient has been demonstrated to deteriorate in clinical status when the drug is tapered or discontinued when monitored in the hospital setting. Similarly, these drugs are only covered under DMERC policy for intermittent infusion if the patient has experienced repeated hospitalizations for congestive heart failure. In fact, the Medicare program has identified these patients as an extremely costly group of patients, and that significant cost savings are likely from ensuring access and adherence to their medication therapies.

The application of competitive bidding to the vulnerable population of patients receiving infusion drug therapies for advanced congestive heart failure is unwise. These patients are reliant on these drugs to remain outside of the hospital setting. In fact, the clinical literature includes numerous studies documenting the cost-effectiveness of this class of intravenous drugs to reduce emergency room visits and hospitalizations.

Especially in the early days of competitive bidding, the program could inadvertently (but easily) interfere with access to these drugs or to the level of clinical care associated with providing these therapies. Home infusion therapy is clearly more cost-effective than treatment for exacerbations (or worse) in the acute care setting, but driving the payment rates to significantly lower levels through competitive bidding could jeopardize patient safety and result in increased hospital expenditures.

The PSPSMF data from 2003 reveals that home infusion claims for milrinone (J2260) and dobutamine (J1250) accounted for $26,156,345 in allowed charges in 2003. This represents approximately 17 percent of all Medicare Part B home infusion drug therapy expenditures in 2003 without even accounting for other related charges included in the aggregate figure for home infusion therapy, including the allowed charges for infusion supplies and pumps.

Summary of Issues Regarding Medicare Expenditures for Home Infusion Therapy

Thus, to summarize, the administration of insulin to treat diabetes does not fit well within the product category of traditional infusion pumps and related drugs. Typically, the suppliers that provide insulin for infusion and related products are not the same pharmacies that specialize in traditional home infusion therapies. There also are drugs that are subject to limited distribution arrangements and thus do not present a potentially competitive market for Medicare. In addition, there are a handful of highly complex drug therapies that would be especially problematic, including infusion drugs used to treat pulmonary hypertension and congestive heart failure.

This leaves a potential grouping of less than $88 million for infusion pumps and drugs in the traditional home infusion product category based on 2003 data, a far cry from the $149 million listed in the preamble to the proposed rule.

II. Rate of Growth

The sizeable portion of the increases in allowed charges and payment amounts for infusion pumps and related drugs from 2002-2003, and the vast majority of the increases from 2003-2004, were attributable to the particular drugs described above that should not be considered as part of the infusion therapy product category: Flolan, Remodulin, milrinone, dobutamine, and insulin and insulin pumps. Together, these drugs accounted for $6 million (44 percent)of the $13.6 million increase in allowed charges for infusion pumps and drugs from 2002-2003, and for $36.3 million (83 percent) of the of $43.9 million increase in allowed charges from 2003-2004.[3] In fact, it appears that rate of increase in infusion pumps and related drugs *other* than these particular drugs decreased from 2003 to 2004. It also should be remembered that Flolan and Remodulin are subject to exclusive or limited distribution arrangements and would not contribute to savings via a competitive bidding process.

III. Demonstration Project Experience

Infusion drugs were not subject to either demonstration project conducted by CMS, and thus there is no evidence that competitive acquisition would be applied successfully to infusion therapy.

IV. Studies and Reports

Infusion therapy is an area that has attracted considerable attention recently because it has defied easy placement in the Medicare coverage scheme. As CMS is well aware, home infusion therapy is covered in the private sector as a medical benefit – not under a medical equipment benefit or as a drug benefit. Medicare coverage of home infusion therapy under the DME benefit is limited to the infusion pump, supplies, and the few infusion drugs covered under Part B. There is no explicit coverage for the professional services and other overhead associated with the safe and effective provision of home infusion therapy.

As a result of Congressional studies and other governmental reports, Congress made significant changes in 2003 in how Medicare Part B pays for outpatient prescription drugs. The MMA changed the general payment methodology from 95 percent of the average wholesale price to 106 percent of the average sales price for a drug. Importantly, however, the incomplete coverage definition under the DME benefit prompted Congress to exempt home infusion drugs from the average sales price payment methodology. Instead, infusion drugs continue to be reimbursed on the basis of average wholesale prices as of October 1, 2003. It was widely understood that the application of the average sales price methodology would have denied infusion pharmacies sufficient reimbursement to provide infusion therapy to Medicare beneficiaries. Payment for infusion drugs continue to subsidize the costs of the professional services and related overhead.

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[3] As described above and shown in the above chart, this figure excludes allowed charges related to insulin, insulin pumps and IVIG.

In addition, coverage of home infusion therapy has been a challenge for policymakers and infusion pharmacies alike. As indicated above, most infusion drugs are not covered under Part B; rather, they are coverable under Part D. However, CMS interprets Part D as covering only infusion drugs and retail drug-like dispensing functions. Consequently, most of the services are not covered under Part D, and none of the supplies or equipment are covered under Part D.

Currently, NHIA is working with CMS to resolve a wide spectrum of coverage, operational and logistical issues regarding home infusion therapy under Part D. While some progress has been made, the definitional issues continue to present significant problems. It is clear that adding to this muddled policy mix a new payment scheme would unnecessarily complicate an already complex and challenging situation.

Summary of Concerns and Issues regarding Home Infusion Therapy and Competitive Bidding

- Home infusion therapy is extremely service-intensive, and is perhaps the most invasive therapy covered by Medicare Part B; as such, it is a poor candidate for competitive bidding generally, and especially in the early stages of the competitive bidding program.
- Extremely complex definitional and coordination issues between Part B and Part D coverage for infusion therapy continue, and subjecting the Part B portion of infusion therapy coverage to competitive bidding would present needless logistical, operational and policy challenges for the Medicare program, the beneficiaries, physicians and discharge planners, and infusion pharmacies.
- The level of Medicare expenditures for DME infusion pumps and related drugs appears to be seriously over-inflated in the preamble to the proposed rule because CMS includes in the calculation (1) insulin and insulin pumps (2) drugs that are subject to exclusive [limited?] distribution agreements, and (3) drugs that are provided to the most severely compromised patients and which require a particular level of experience and expertise.
- The rate of growth of Medicare expenditures for DME pumps and related drugs was less than nine percent from 2003 to 2004, once we subtract the expenditures attributable to the three categories listed above.
- Home infusion therapy was never tested in the demonstration projects.
- There are no relevant studies and reports indicating that Medicare overpays for home infusion therapy under Part B; in fact, Congress exempted home infusion therapy from the average sales price methodology because of concerns that it would lower payment levels for home infusion therapy to a level that would impair access to quality care.

Necessary Steps Prior to Subjecting Home Infusion Therapy to the Competitive Acquisition Program

As indicated above, we believe Part B infusion therapy should not be subjected to competitive bidding until CMS can be confident that Medicare beneficiaries will have access to safe and quality care. Competitive bidding should be tested on less service-intensive areas before it is attempted with home infusion. In addition, the Part B and Part D coverage issues must be resolved. The best means of resolving these issues is to consolidate Medicare outpatient coverage of home infusion therapy under Part B.

Enteral Nutrition

Enteral nutrition involves the provision of nutrients by tube into the patient's stomach or intestine. It is appropriate for patients whose lower gastrointestinal tract functions normally but who are unable to swallow, who have a gastric obstruction or who cannot otherwise ingest adequate amounts of food and fluids by mouth. Medicare Part B covers enteral nutrition formulas, supplies and equipment under the prosthetic device benefit for patients for whom enteral nutrition is necessary to maintain weight and strength commensurate with their general condition..

At this point, we do not believe enteral nutrition's inclusion in the *first* phase of the competitive bidding program in 2007 would make significant progress towards CMS' goals, and instead would present costly and complicated administrative challenges for CMS and its contractors. As explained below, enteral nutrition presents some of the most challenging obstacles for inclusion in the competitive bidding program, and we believe it would be an odd selection for the competitive bidding program to begin with in light of CMS' objective of getting off to a successful start of this enormously complex program. We support the comments and the position of the National Alliance for Infusion Therapy on the issues pertaining to enteral nutrition, as set out below.

Factors Determining Product Selection

We will address each of these factors' application to enteral nutrition.

I. Level of Medicare Expenditures

Enteral nutrition is listed in the proposed rule as fourth in total Medicare expenditures for Part B items for 2003. That number, however, is seriously misleading, since enteral nutrition is not a monolithic therapy provided in one setting. Rather, enteral nutrition, for policy purposes, should be divided into three parts:

(1) Enteral nutrition provided to residents in long-term care (LTC) facilities ;
(2) Enteral nutrition provided in the home to patients who also qualify for the home health benefit; and
(3) Enteral nutrition provided in the home to patients who do not qualify for the home health benefit.

Historically, a clear majority of Medicare Part B enteral patients are residents of long term care facilities. The percentage of enteral patients who are in LTC facilities increased from 2003 to 2004 to approximately 56 percent, based on the data described below. This fact is extremely relevant to CMS' ultimate decision of whether to include enteral nutrition in the 2007 phase of competitive bidding. Based on our involvement with CMS in the development of the new Part B quality standards, we understand that the enteral-specific quality standards will not apply to these enteral patients, and thus will not apply to the majority of Part B enteral patients.

Thus, enteral patients in long term care facilities are and will continue to be treated pursuant to the nursing home conditions of participation, not the Part B standards on enteral nutrition.

Similarly, we understand that those enteral patients qualifying for the home health benefit are and will continue to be treated pursuant to the home health conditions of participation, not the enteral-specific Part B standards. Thus, the only segment of the enteral patient population who will be subject to the Part B enteral-specific quality standards are the home care patients who do not quality for the home health benefit, a distinct minority of the Medicare enteral patient population. That small segment of the population does not involve Medicare expenditures anywhere near the top ten items of Part B expenditures.

II. Rate of Growth

Our analysis of enteral claims data from the years 2002-2004 indicates that Medicare payments for enteral nutrition are far from skyrocketing. The rate of growth of Medicare allowed charges increased by 1.7% from 2002 to 2003, and actually decreased by approximately 5% from 2003 to 2004. Thus, Medicare allowed charges for enteral nutrition in 2004 were $20,624,897 less than they were in 2002. Clearly, this is not an area that requires immediate action and attention from CMS to restrain inexplicable increases in the rates of Medicare expenditures. If this factor truly is an important criterion in CMS' product selection, then enteral nutrition is a poor choice for inclusion in the 2007 phase of competitive bidding on that basis.

III. Demonstration Project Experience

Enteral nutrition was not tested successfully during the two demonstration projects and was categorized as not well suited for competitive acquisition by CMS. Enteral nutrition originally was included in CMS' Polk County, Florida demonstration project that tested competitive bidding for certain Part B items. Importantly, enteral nutrition was removed from that demonstration after the first phase of the project. CMS indicated that it was removed primarily because most enteral patients reside in long term care facilities, where the application of the competitive bidding regimen would be difficult and confusing. Thus, use of competitive acquisition to set prices and pay for enteral nutrition in Medicare has not been tested sufficiently or successfully.

In addition, based on its own analysis of the data from the DMEPOS competitive bidding demonstration projects, CMS concluded in its final report to Congress that enteral nutrition was not well suited for competitive acquisition. Recently, CMS staff echoed this perspective, indicating that certain products may not be suitable for competitive acquisition because Medicare will not realize sufficient savings to justify the administrative expense of the competitive acquisition program.

Importantly, enteral nutrition was the only therapy in the demonstrations where the majority of patients are in a setting other than the home. Competitive bidding clearly was designed by Congress with the home care patient in mind, a concept that the long term care

component of enteral nutrition would greatly complicate. We address this issue in greater detail in the section below about long term care facilities.

IV. Studies and Reports

The Office of Inspector General ("OIG") has issued many reports over the years about a wide array of product categories. A number of these studies were not written, or designed, to reflect all of the issues faced by policymakers on a particular subject. Instead, they were focused largely on a narrow issue or a small subset of issues, and as a result the reports often reflect a skewed perspective of (1) the particular problem and (2) the suggested solution to that problem.

This clearly has been the case with respect to OIG reports about enteral nutrition. A number of OIG reports about enteral nutrition contain estimates about supplier acquisition costs for enteral formulas, supplies and equipment, and compares those acquisition costs with Medicare payment rates. The OIG often describes the gap between the acquisition costs and payment rates as "waste" or "abuse", despite the fact that the OIG has never focused on -

- The services and functions required of enteral nutrition suppliers to provide good quality care,
- The costs associated with these services and functions, or
- If payment rates are limited to the acquisition costs of items and equipment, then no supplier will be able to remain in business to provide enteral nutrition to Medicare beneficiaries.

Since policymakers are aware that enteral nutrition involves more than the delivery of formulas, supplies and equipment to beneficiaries, as most recently evidenced by the issuance of quality standards in this area, OIG reports such as the ones described above have limited value to CMS as a foundation for decision-making. Despite the clear limitations of the OIG reports on enteral nutrition as well as their seriously misleading conclusions, CMS indicated in the proposed rule that it wants to include these type of reports in its analysis of what product categories are best suited for inclusion in the competitive bidding program. We understand that CMS cannot simply ignore OIG reports, but we do urge CMS to place such reports in the proper context and determine whether their findings are supported by other sources of information. In the case of enteral nutrition, we believe you will find that the reports are largely inaccurate portrayals of what is involved in the provision of enteral nutrition and the costs associated with such therapy.

If CMS wishes to use outside sources to gather information about enteral nutrition functions and costs, we urge CMS to consult with the American Society for Parenteral and Enteral Nutrition (ASPEN), the clinical society for physicians, nurses, dietitians and pharmacists involved in the provision of enteral nutrition. ASPEN has developed quality guidelines as to the functions and services required for enteral nutrition. Likewise, we suggest CMS consult with the Joint Commission on the Accreditation of Healthcare Organizations and other accrediting organizations as to their perspective on what is involved in the provision of enteral nutrition.

In addition, the OIG studies could not have reflected the costs associated with accreditation, either in terms of the administrative costs of seeking and maintaining accreditation or the costs of complying with the new Part B quality standards that are the bases of accreditation. In light of this clear discrepancy, we urge CMS not to rely heavily on OIG reports in determining product selection for the competitive bidding program.

The reasons for excluding enteral nutrition from the first phase of the competitive bidding program are not limited to the criteria set out above. There are important other bases for omitting enteral from the 2007 portion of competitive bidding, including the following:

Enteral Patients in Long Term Care Facilities

As indicated above, most enteral nutrition is provided in nursing facilities, which presents issues that go far beyond the scope of the competitive acquisition program. It is apparent that CMS and its contractors will be burdened with numerous complex issues to implement the competitive acquisition program even in the most basic manner possible. Attempting to use competitive acquisition for products used in long term care facilities raise a whole host of issues involving access and choice that are not easily resolvable, especially in the immediate timeframe.

Nursing facilities have a special relationship with their residents. In most instances, the facility is the resident's home. The nursing facilities are responsible for coordinating the work of an array of clinicians, providers and suppliers to meet patient health care needs, and they are held accountable for the quality of these services. Nursing homes must meet detailed conditions of participation to participate in the Medicare and Medicaid programs as well as a wide array of additional quality standards. Because of their multiple responsibilities in this regard, nursing facilities traditionally have established long-standing relationships with selected suppliers based on experience, trust and respect for their level of professionalism.

For these reasons, most nursing facilities will be extremely concerned if they are forced to admit unfamiliar suppliers into their facilities to provide services, supplies, and equipment to their residents. Nursing facilities must be able to select the suppliers that the facilities believe can best enable them to meet resident needs and comply with applicable standards. The competitive bidding program would interfere with their ability to make these decisions, and potentially interrupt ongoing relationships that have worked to the benefit of their residents.

CMS' demonstration projects did not test a model of competitive bidding that involved long-term care facilities. This is extremely important, because the proposed rule reflects an overly simplistic view of how long term care facilities operate and how they could fit into the competitive bidding program. We are concerned that the proposed rule appears to reflect a view that a nursing home is simply a supplier that does not have to travel to treat its patients. The only recognition that a nursing home is different in any respect is the provision that a nursing home can limit its participation in the competitive bidding program to treating its own residents. What is surprising is the clear implication that a nursing home actually has to be a winning bidder just to treat its own residents. Residents in nursing homes usually are more impaired than home care patients and require a different regimen of care. Primarily for that reason, it would not be a fair

or accurate process to combine nursing home bids with home care bids for a particular products category.

The proposed rule also does not account for Part B suppliers whose entire business is treating beneficiaries who are residents of nursing homes. Nursing home suppliers have very different businesses than home care suppliers. They are not interchangeable, and should not be combined into a single grouping to demonstrate that an area has a certain number of suppliers.

We do not understand how there can be fair and responsible competitive bidding when there are at play different quality standards, different settings of care, and different patient needs. As explained below in the section on competitive pricing principles, competitive bidding requires bidders to have to meet the same requirements in the same context. The nursing home component flies in the face of this principle. With all respect, we do not believe CMS has considered the differences and particular problems the nursing home setting brings to the competitive bidding program. We urge CMS to refrain from selecting products for inclusion in competitive bidding if, as with enteral nutrition, most of the Medicare market for those products is in the long term care setting.

Application of Quality Standards

The competitive bidding program is predicated in large part on the application of the Part B quality standards and the requirement that every participating supplier be accredited in accordance with the accreditation provisions of the proposed rule. This is an important component of the overall scheme of the competitive bidding program, wherein bidders will have similar costs and will benefit from a generally level playing field. That makes perfect sense – again, except with regard to enteral nutrition.

For the enteral patient population, there will not be one set of quality standards – there will be **three** sets of standards: the conditions of participation for long term care facilities; the conditions of participation for home health agencies; and the quality standards under development in connection with the competitive bidding program. This creates a unique problem for enteral nutrition.

As described above, most of the enteral patients are in long term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long term care market. Likewise, enteral nutrition is provided to homecare patients by suppliers that focus solely on the homecare market. In other words, the quality standards and the enteral suppliers in the homecare setting will be significantly different from the quality standards and enteral suppliers in the long term care setting. The application of the home health conditions of participation to those homecare enteral patients who qualify for the home health benefit only further complicates an already complicated situation..

Thus, it would be highly illogical to subject all of enteral nutrition to the competitive bidding program at this point, because of the involvement of the three different sets of quality standards. The costs of compliance with the standards differ, due in large part to the fact that the

settings of care differ. On the other hand, we do not believe it is a feasible option to simply limit the competitive bidding program to homecare enteral patients, since those patients make up less than half of the enteral patient population and thus CMS would not achieve the savings envisioned by the MMA. Regardless, the administrative costs of sorting out the various enteral patient populations and standards within the context of the competitive bidding program would be disproportionate to any value derived from applying competitive bidding to this area.

Payment Basis: Enteral Nutrition Pumps

Under current payment policy, monthly rental payments for enteral pumps were calculated originally on the basis of the purchase price for the particular type of pump. Once the purchase price was determined, the monthly rental payments were set at 10% of that purchase price up to a maximum of 15 months. This has been different from items in the DME capped rental category, wherein monthly rental reimbursement for capped rental items has been 10% of the purchase price for the first 3 months and then it is reduced to 7.5% of the purchase price for each of the remaining months of coverage.

However, the proposed rule would reduce monthly rental payments for enteral pumps under the competitive bidding program for the months 4-15 to 7.5% of the purchase price. In other words, under the competitive bidding program, rental payments for enteral pumps would be determined as if enteral pumps were capped rental items.

Enteral pumps are not capped rental items. Rather, they are covered under the prosthetic device benefit and reimbursed under a fee schedule specifically tailored for enteral nutrition. Further, Congress explicitly rejected an attempt by CMS in 1989 to put enteral pumps in the DME capped rental category. CMS' proposal for the competitive bidding program would effectively negate an explicit act of Congress. If enteral pumps ultimately are to be included in the competitive bidding program, they should be reimbursed on the same basis as they are now – 10% of the purchase price for up to 15 months.

There does not appear to be any policy basis for CMS' proposal regarding enteral pumps, other than simply to further reduce payments for these items. That objective alone, we submit, is not enough to counter Congress' intent in keeping enteral pumps separate from the DME regulatory scheme.

Payment Basis: Grandfathering

The proposed rule does not extend grandfathering provisions to enteral nutrition. Instead, it limits all grandfathering protections to DME and oxygen items. We understand that the statute requires grandfathering only for those items, but we believe the statute does not prohibit CMS from extending grandfathering protections to other products that are subject to the competitive acquisition program in the interests of program efficiency.

The policy bases for grandfathering DME and oxygen items apply with equal force to enteral nutrition. Beneficiaries already on service often develop trusting relationships with their

enteral suppliers, and many would prefer to continue that relationship for the entire course of their therapy. In addition, the responsibility for servicing and maintaining enteral pumps would be an important issue for the new contract enteral supplier. The contract supplier will be liable for the servicing and maintenance of enteral pumps which it did not provide to the beneficiaries.

Enteral pumps are not capped rental items, but the duration of the rental payments for such pumps is limited to 15 months. At the very least, it would be sensible to permit the "old" enteral supplier to continue with an enteral patient until the 15 month rental period elapses.

Necessary Steps Prior to Subjecting Enteral Nutrition to Competitive Bidding Program

As indicated above, we are strongly urging CMS to delay application of competitive bidding to enteral nutrition until a later phase of the program. The issues that we have raised regarding nursing homes, quality standards and operational issues peculiar to enteral nutrition make it clear to us that these issues cannot be resolved in the short timeframe leading up to the 2007 phase of the competitive bidding program. We recommend instead that CMS and representatives of the various enteral nutrition stakeholders work together to resolve the many issues that pertain to enteral nutrition.

In particular, we suggest the following actions:

- Clarify the different requirements and obligations specific to enteral suppliers regarding nursing homes and their residents
- Integrate the Part B product-specific standards applicable to enteral nutrition with the nursing home quality standards
- Clarify the different requirements and obligations specific to enteral suppliers regarding home health agencies and their patients
- Integrate the Part B enteral standards with the home health quality standards

Competitive Bidding Areas

The proposed rule provides CMS with the authority to designate competitive bidding areas in the initial phase of the competitive acquisition program as extending beyond the boundaries of the selected metropolitan statistical areas (MSAs). We do not believe this proposal is consistent with the statute.

Section 1847(a)(1)(B) of the Act specifically provides that CMS is to phase in the competitive bidding program so that competition occurs in the 10 largest MSAs in 2007 and 80 of the largest MSAs in 2009. The statute authorizes expansion of the competitive acquisition program to areas beyond MSAs only after 2009. Section 1847(a)(1)(B)(i)(III).

If Congress intended competitive bidding areas to include areas *outside* of the MSAs in 2007 and 2009, it would have authorized CMS to include those areas as it did for expansions occurring after 2009. It did not do so. The fact that Congress was so specific in its language on

this point makes it clear that CMS was not authorized to venture beyond the borders of MSAs in the 2007 phase of the program.

In addition to health policy issues raised above, we have several concerns regarding the application of basic federal procurement principles to the proposed competitive acquisition program, which we summarize below.

Competitive Pricing Issues

The Medicare Modernization Act ("MMA") reflects a clear Congressional intent that, to the maximum extent practicable, CMS is to utilize the concept of competitive pricing in its implementation of the competitive bidding program. The expression of this Congressional intent first appears in Section 302 (b) of the MMA which begins by changing the heading of Section 1847(a) of the Act to read: "COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES....(a) ESTABLISHMENT OF COMPETITIVE ACQUISITION PROGRAMS." The provision then directs the Secretary to "establish and implement programs under which competitive acquisition areas are established...for the furnishing...of *competitively priced* items and services..." (italics added) and provides that "[p]ayment under this part for *competitively priced items* and services...*shall be based on bids submitted and accepted* under this section for such items and services." (italics added.) Sections 1847 (a) (1) (A), (b) (5)

The term "competition" is defined as " a market condition in which a large number of independent buyers and sellers compete for *identical commodities*..." Webster's Third International Dictionary (1976) A price is "the amount of money given or set as the amount to be give as a consideration for the sale of a *specified thing*." Black's Law Dictionary, Sixth Edition (1991) at 1188. (italics added.) "Pricing means the process of establishing a reasonable amount or amounts to be paid for supplies or services." Federal Acquisition Regulation (FAR) 2.101. In light of these definitions, it appears that when Congress directed CMS to establish a program that entails "furnishing...of *competitively priced* items and services" it understood that the constituent elements of the program would include: a number of independent sellers who can furnish specified items or services that are identical as to function and who can offer to sell the items or services at a specified amount or price.

CMS has correctly chosen to characterize the Congressionally mandated use of competitive pricing as a program of "competitive bidding" for DMEPOS. The Government Accountability Office has long considered issues relating to competitive bids and, in doing so, has aptly described the characteristics of an invitation for bids, stating that it:

> "...must contain specifications that are sufficiently descriptive in language to permit full and open competition, and to permit evaluation of bids upon a common basis. ...the invitation must provide objectively determinable standards against which the bids can be evaluated on an equal basis to determine the acceptability of the low bid" McBride and Tuohy, Government Contracts, Section

10.10 citing *Science Management Corp,,* B-181281, 74-1 CPD 6 (1974) (emphasis added.)

Thus, competitive pricing a nd its fraternal twin c ompetitive bidding both require that those competing to sell an item or service to the government must be given the opportunity to make their bids, submit their offers or propose their prices on the same item or service and under conditions that allow evaluation of their bids, offers or prices on an equal basis whether the outcome is to a be a single award or, as is the case here, awards to multiple bidders.

With that as background, we believe the application of these competitive pricing principles raises important concerns regarding the proposed competitive bidding program.

First, in addition to the policy and fairness issues we described earlier in these comments, we believe the application of competitive bidding to enteral nutrition would be counter to basic competitive pricing principles. The application of different quality standards, and the existence of different markets within the enteral nutrition area, means that the competition for contracts could not be on an equal basis. Enteral nutrition suppliers that focus solely on the nursing home market will have a different business and cost structure from enteral nutrition suppliers that focus solely on the homecare market. A competitive bidding program that combines the two types of enteral suppliers into one bidding group clearly is inconsistent with competition on an equal basis.

Secondly, Section 414.414(h)(1) of the proposed rule provides that "Subsequent to the awarding of contracts under this subpart, CMS may award additional contracts if it determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program." In order to select additional contractors, CMS plans to use bids previously submitted by bidders in the specific product category for which additional contract suppliers are needed to make award. Id. CMS plans to offer award first to the disappointed bidder whose composite bid is the first composite bid above the pivotal bid for that product category. Id.

This is an inappropriate method for the acquisition of additional contractors following award. First, by awarding contracts after award without competition, CMS would violate the clear language of the statute, which requires that CMS conduct a competition for the award of any contracts for the items specified by the statute. The statute states: "[t]he Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services." Sec. 1847(b)(1) of the Act.) A post-award contract award to the next-in-line disappointed bidder who participated in the initial competition is not a competitive acquisition. It is not a continuation of the original competition. It is a sole-source acquisition. (See 41 U.S.C.A. § 253(a),(c) (West 1987 and Supp. 2006); see 48 C.F.R. 2.101 for the definition of sole source acquisition.) Sole-source awards to contractors for items and services within competitive acquisition areas are not authorized by the statute.

Gap-Filling Proposal

CMS proposes to modify its current gap-filling procedures and instead use far more subjective criteria in developing payment levels for new products and for new HCPCs. We agree that the current gap-filling practices should be revised – they are not well understood and probably result in payment levels that are significantly lower than the payment levels found in the private sector.

That said, we must strongly oppose the particular modification proposed by CMS. CMS simply listed a number of general factors for determining gap filling amounts, without any indication how they would be used. CMS is proposing to give itself what appears to be virtually unfettered authority to choose and apply payment criteria for any new product. Perhaps of greater concern is CMS' intention to apply this broad authority to new codes. It would appear that CMS could trigger this authority by simply modifying a HCPC for a product category, thus reorganizing and creating a new code. By doing so, CMS could set aside the existing fee schedule and substitute its own judgment as to what is a reasonable payment level based on the general factors listed in the proposed rule.

Congress has provided CMS with the specific authority to modify payment amounts if CMS determines after a prescribed analysis that the payment levels are grossly excessive or grossly deficient. Section 1842(b)(8) of the Act. This so-called "inherent reasonableness" authority is set out at 42 CFR 405.502 and includes a number of procedural and substantive safeguards to ensure that CMS and its contractors do not act arbitrarily. None of those safeguards is present in the CMS proposal on gap-filling. The scope and limitations of CMS' inherent reasonableness authority will be meaningless if CMS can use its gap-filling authority to change payment levels for existing products merely by first changing the HCPC codes for those products.

Inherent reasonableness may only be used if payment levels are determined to be grossly excessive (or grossly deficient), which CMS has defined by regulation as being at least 15 percent more or less than a reasonable level of payment. CMS must use valid and reliable data in its analysis and its calculation of new payment levels. Part B suppliers must have the opportunity to comment on the finding that payments are grossly excessive and on the new payment level determined by CMS or its carriers. In addition, if CMS seeks to make an adjustment that will have a significant effect on a substantial number of small suppliers, it must publish an analysis in the Federal Register pursuant to the Regulatory Flexibility Act.

Further, CMS has defined to some extent how it will interpret various factors in its application of inherent reasonableness. CMS and its carriers also must consider the effects on the Medicare program, including

1. The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

2. What entities would be affected, such as classes of providers or suppliers and beneficiaries.

3. How significantly would these entities be affected.

4. How would the adjustment affect beneficiary access to items or services.

In addition, the carriers must evaluate the comments received on the proposed notice. And, to ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

Additional factors apply if CMS seeks to modify payment levels by more than 15% in a given year. Yet, none of these processes and criteria, which result directly from several statutes and recommendations of the Government Accountability Office, will have any applicability if CMS chooses to use its gap-filling authority instead of its inherent reasonableness authority to

adjust payment rates. We do not believe CMS has the legal authority to modify payment levels for existing, covered products by manipulating the particular HCPCs for those products. Where Congress sought to provide CMS with the authority to modify payment levels, it did so in an explicit and structured manner. The proposed rule on this issue appears to be little more than a reach for additional authority to undertake actions that could be precluded under the inherent reasonableness authority or would be more time-consuming under that authority. Congress, by its actions on inherent reasonableness, effectively limited CMS to the scope of that authority.

Thus, the proposed rule would act to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS could create a new HCPCS category, use the vague "functional technology assessment" to compare older, similar products already on the market to newer products and bundle all of these into the new HCPCS codes. CMS could then use the revised "gap filling" process to reprice the existing products and new products establishing what amounts to a revised payment. Since there is already a statutory avenue for addressing excessive or deficient payment under the "inherent reasonableness" methodology, the new regulations would at best be duplicative of these provisions. At worst, they would act as a contravention of existing law.

There may well be a need for the development of new codes in the future, and we are not suggesting that the current coding structure is somehow untouchable. We strongly believe, however, that if and when coding modifications must occur there must be a far more formal, transparent and inclusive process for determining reimbursement for the items in the new codes than is proposed in this regulation.

Thank you for the opportunity to comment on the important proposed rule. If you have any questions or desire additional information from NHIA, please contact me at 703-838-2658 or lorrie.kaplan@nhianet.org.

Sincerely,

Lorrie Kline Kaplan
Executive Director

Attachment: Appendix A: Infusion Therapy Services

Appendix A

Infusion Therapy Services

There are a number of necessary functions and costs associated with the safe and effective administration of home infusion drug therapy. These important functions and costs, detailed below, are consistent with the well-established standards of care recognized by national accrediting organizations, as well as common practices for patients under both private and public health insurance plans. (See Appendices A, B, and C, summary statements provided by the three national accrediting organizations offering accreditation of home infusion therapy service providers, the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Commission for Health Care, and the Community Health Accreditation Program.

In addition, for a quick visual presentation of home infusion services and operations, see the National Home Infusion Association's online virtual tour which begins at http://www.nhianet.org/virtualtour/slide1.htm.

A. Direct Patient Services

- **Initial Patient Evaluation and Assessment.** Initial patient evaluation is an important component of infusion therapy. At initial intake, the pharmacy must collect information on the clinical status and medical history of the patient, examine the physician's orders and laboratory reports, gather information on the cognitive and psychosocial status of the patient, and determine the patient's appropriateness for home therapy.

  After the patient is accepted for service, comprehensive assessment activities include a complete physical assessment of the patient, an assessment of the appropriateness of the home environment for home infusion therapy, a review of concurrent oral prescription and over the counter medications, an evaluation of the patient's ability to learn self-administration, and a review of the medical history. Admission procedures include patient and family teaching for mechanical and disposable equipment use, medication storage and handling, emergency procedures, vascular device management and the recognition and reporting of adverse drug reactions and other infusion related complications.

- **Development and Implementation of the Patient Care Plan.** The home infusion pharmacy is the primary entity responsible for the development and implementation of the multidisciplinary care plan. Care planning activities consider actual or potential drug or equipment related problems, therapy monitoring with specific goals, coordination of activities with other providers and provide ongoing patient monitoring and reassessment activities to continually assess for response to treatment, drug complications, adverse reactions, and patient compliance. The infusion pharmacy must also communicate and coordinate the care plan with the physician, patient, patient's family, and other health care providers.

- **Compounding and Dispensing of Infusion Medications and Equipment.** Home infusion drugs and solutions must be prepared under environmentally controlled conditions, as mandated by various regulatory and accreditation agencies. Sterile admixtures are prepared in a clean air environment, using aseptic techniques. The compounding room must be designed and maintained appropriately to prevent contamination. The specifications of home infusion compounding rooms typically exceed those of hospital environments because the compounded products must be capable of remaining sterile for longer periods of time than is required in the inpatient setting whereas infusion therapies are usually administered within 24 hours of preparation. Final compounded products are subject to routine quality control procedures designed to ensure the accuracy of the preparations, product integrity, stability, and sterility. Depending on the pharmacy's volume of business and applicable legal restrictions, trained pharmacy technicians may prepare drugs under a pharmacist's supervision.

  Each patient's prescription is filled in quantities and at intervals sufficient for continuous service. Frequency of drug preparation depends on several factors, including expected duration of treatment, frequency of dose administration, home delivery schedules, drug stability or shelf-life, and the patient's clinical condition. The average time required to compound, dispense, assemble, and package a patient's order depends, in part, on the number of doses in an order, the quantity of each dose, the number of compounded doses per delivery, the volume and number of ingredients and the complexity of compounding. Time and motion studies conducted by the University of Texas College of Pharmacy document the variability of these activities by therapy.[11]

  The ancillary supplies and equipment necessary to administer the therapy must be selected and packaged for delivery to the patient's home. Infusion therapy-related supplies are uniquely tailored to the individual patient based on the patient's vascular access device, type of infusion delivery device and the patient's ability to perform self-administration.

- **Ongoing Clinical Monitoring.** Throughout the course of therapy, and particularly after a nursing visit, the pharmacist reviews an infusion patient's clinical information, discusses the findings with the attending physician, assesses the continuing appropriateness of the current medication schedule, participates in multidisciplinary patient care conferences to examine the patient's progress and to establish future goals, and communicates with the patient's other caregivers regarding the patient's compliance and progress.

- **On-Call Services.** Offering continuous, round-the-clock on-call services (24 hours a day, seven days a week) is a standard of practice for home infusion providers. This practice reflects the acute need for the continuous availability of a qualified home infusion pharmacist and nurse to support the complex therapies and infusion equipment that these patients require. Calls may include new or changed orders from the nurse or physician, questions about the medication from the patient or the nurse, troubleshooting the pump, concerns about why a delivery has not arrived, a possible adverse drug reaction, vascular access issues, or need for medication or supplies. The on-call pharmacist often triages the call, then addresses the problem or refers the call to the patient's physician or home care nurse.

- **Patient Discharge Services.** Patient discharge services include communication with all health care providers involved with the case and the closing of the medical record. Clinical outcome data, patient perception data, and the documentation of staff is reviewed and collected as part of the ongoing quality management activities required by state regulations and accreditation standards.

B. Administrative and Support Services

There are significant direct and indirect administrative and support services that impact the quality of patient care. Home infusion therapy cannot be coordinated and delivered effectively without adequate administrative and support personnel. Many of these requirements are established by licensing boards, accrediting bodies, private insurance plans, and federal and state health programs. Other activities are simply part of managing and operating any health care entity. Examples of administrative and support services include quality improvement programs, utilization review, medical records management, coordination of insurance benefits, claims processing and collections, medical waste management, personnel management, inventory control, orientation programs for new employees, and clinical development and education programs for management and staff.

Accreditation, for example, is an indirect cost that affects the quality of care delivered by home care pharmacies. Accredited companies must meet quality standards for patient care and business functions to maintain accreditation (see Appendices A, B, and C). Accreditation offers the public the assurance that an accredited entity meets or exceeds an objectively verifiable standard of care. It will be a setback for Medicare beneficiaries if Medicare reimbursement does not adequately reimburse providers and suppliers for the cost of meeting quality standards. In addition to accreditation, there are costs associated with complying with state licensure and professional board requirements.

Home care pharmacies also incur significant costs in complying with Medicare program rules, especially those pertaining to billing and documentation. These include, among others, the following:

- Accumulating documentation to support claims for services
- Preparation of claims
- Communication with physicians regarding completion of certificates of m edical necessity and other documents required by the program from physicians
- Communication with carriers regarding claims and documentation
- Participating in medical review process with carriers on particular claims
- Delays in payment from the program
- Preparing for and filing appeals to the carrier and Social Security Administration

Submitter : Mr. Mark Goodman **Date:** 06/29/2006

Organization : Home Medical Specialties, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 29, 2006

Dr. Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MS 21244-8013

Dear Dr. McClellan,

New York Medical Equipment Providers Association (NYMEP) appreciates the opportunity to provide comments on the Proposed Rule Making entitles Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues published in the Federal Registrar on 5/1/06

NYMEP is a state association comprised primarily of 140 durable medical equipment providers (DME) and manufactures employing over 5,000. NYMEP, on behalf of our membership, is submitting comments related to the documentation and procedural issues as they relate to the implementation of the proposed rule making for Competitive Bidding.

In general, NYMEP supports the implementation of the Quality Standards for the suppliers of DMEPOS equipment and the accreditation process. These are important components for the continuum and quality of care for the beneficiary. These standards will define a standard of quality within the DME industry. NYMEP s initial concern is providing comments on the Proposed Rule in the absence of the final Quality Standards, MSA and the product categories.

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

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

CMS Must Publish An Updated Implementation Timeline. CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulation; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. It is expected that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

Consider the Impact on the Patient
CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy. Product Selection Must Be Conducted With Beneficiary Welfare In Mind. (Criteria for Item Selection). How will savings be calculated; problems with beneficiaries having to deal with multiple suppliers; recognition of items that are custom and service oriented; incorporate Hobson-Tanner provisions.

All the Supplier Product Specific Services Requirements refer to products or equipment provided in the home setting. There were no standards for supplying products to patie

Submitter : **Dr. Henry Balboa** **Date: 06/29/2006**

Organization : **Plainview Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

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.

Submitter : Ms. Michelle Deininger **Date:** 06/29/2006

Organization : Arkansas Medical Supply

Category : Health Care Provider/Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Concerning the area of competitive bidding I have many concerns for our entire industry and our customers.For people that have never experienced using a HME/DME company for themselves or a loved one there is more than just being a number through a competitive bid. With competitive bidding the customer will not have the option of products that have always used or the products that work best for them. They will be forced to take the cheapest product.
Due to the nature of receiving the Medical products customers often need the human compassion on the other end of the phone or when walking into the store.With Competitive bidding this will not be possible. The customer will be put on hold and will again only be a number. Alot of times we deal with very uneducated customers and other
factors. A small DME/HME company can assist these people one on one or give more time. With Competitive bidding this whole process is lost. Who will Competitive bidding benefit?
Certainly not the customer or the small HME/DME company that helps the U.S economy by providing jobs for 10 plus employees.
Before Competitive bidding is forced upon us more options and other areas in the current system should be reviewed. The competitive bidding is not the answer for the customer or the HME/DME business.

Sincerely,

Mikki Deininger
Arkansas Medical Supply

Submitter : M Nell Bailey **Date:** 06/29/2006

Organization : RESNA

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-886-Attach-1.DOC

RESNA

National Office: Suite 1540, 1700 North Moore Street, Arlington, VA 22209-1903
703/524-6686, Fax: 703/524-6630, TTY: 703-524-6639, Website: www.resna.org

To be sent electronically to http://www.cms.hhs.gov/Rulemaking

June 27, 2006

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

Re: Proposed Rule to Improve Medicare's Payment for Certain DMEPOS

Providing **specialized** durable medical equipment (DME) products and services consists of highly individualized clinical services involving the design and development of individually configured devices, often from many different sources to meet the specific functional needs of the person with a disability. Many durable medical equipment products and services are provided by clinicians and suppliers with extensive training in working with clients requiring these products and services to meet a variety of needs including communication (both expressive and receptive), mobility, postural support, accommodation of sensory impairments as well as addressing issues related to transportation.

When price becomes the sole determining factor in securing products and services, the range and quality of professional services provided to the client is sacrificed in order to put forth a low bid. Many DME products and services are configured and selected for each client – they are not generic. They are configured and designed to address the specific medical and functional needs of each client.

Under the proposed rule published in the Federal Register on May 1, 2006, RESNA strongly encourages CMS to exclude high-tech rehabilitation and assistive technology[1] products from the initial implementation of the program. We believe that language contained in Section 302(b) of the Medicare Modernization and Prescription Drug Act of

[1] Assistive technology (AT) is any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve the functional capabilities of individuals with disabilities. (29 U.S.C. Sec 3002 (a)(3)).

2003 gives the Secretary the authority to exempt certain products when competitive acquisition "is not likely to result in significant savings."

Furthermore, because the nature of the injury or disease process (including but not limited to: spinal cord injury, amyotrophic lateral sclerosis, multiple sclerosis, traumatic brain injury; muscular dystrophy, cerebral palsy, etc.) for those individuals needing alternative control power wheelchairs; power seating options including tilt, recline, tilt/recline, etc.; high strength lightweight and ultralight manual wheelchairs; skin protection and positioning cushions, custom seat and back cushions and wheelchair accessories require individual attention, we request these items be excluded from the initial implementation of the competitive acquisition program. Proper provision of this equipment requires careful evaluation, often through a team effort, consideration for progression and complications affecting the condition, trial of equipment, proper fitting, training and follow-up. Though labor intensive, these activities are critical to minimizing greater complications that can result in further injuries, additional hospitalizations, loss of function and decreased independence. These therapeutic services are inconsistent with competitive bidding. In addition, RESNA feels it will be difficult to demonstrate significant cost savings on many of these products through competitive acquisition when there is yet to be a fee schedule for reimbursement that will be in alignment with these products under the new HCPCS codes planned for October 1, 2006.

RESNA also recommends the initial bid cycle be phased in gradually starting with perhaps 4 metropolitan statistical areas (MSAs) instead of the planned 10 MSAs as required. The rationale behind starting with 4 MSAs is to align the areas with the 4 DMERCs so that CMS and its approved accrediting organizations can ensure that quality standards are applied to all qualified suppliers.

Further, regarding the rebate program ("Submission of Bids Under the Competitive Bidding Program under H.2 Rebate Program"), RESNA strongly urges CMS to not implement a rebate program. We do not see an incentive in such a program but rather a disincentive in that quality and professionalism will be further compromised because this program would encourage beneficiaries to select a supplier solely based on the rebate price.

RESNA is an interdisciplinary association of people with a common interest in technology and disability. Its 1,500 members represent dozens of professional disciplines including physical therapists, occupational therapists, speech-language pathologists, rehabilitation and assistive technology suppliers, rehabilitation engineers, researchers, orthotists, prosthetists, special educators and consumers of rehabilitation and assistive technology (individuals with disabilities and their family representatives).

RESNA is an ANSI accredited standards organization with experience in developing standards through its Technical Standards Board and creating a professional credentialing program for assistive technology practitioners (ATP), assistive technology suppliers (ATS) and rehabilitation engineering technologists (RET) through its Professional Standards Board (PSB).

In summary, RESNA recommends:

1. Omitting mobility assistive equipment and seating technologies from the initial competitive acquisition program in 2007 until costs avoided with the new policy changes can be examined.
2. Gradually phasing in the MSAs, initially beginning with four until CMS can ensure that quality standards are applied to all qualified suppliers.
3. Eliminating the rebate program altogether.

If you need additional information or have any questions, please contact Nell Bailey, Governmental Affairs Coordinator at (703) 524-6686 ext. 305 or via email at nbailey@resna.org.

Respectfully Submitted,

RESNA Government Affairs Committee

Katherine D. Seelman, Ph.D.
Chair

Rory Cooper, Ph.D.
President

Submitter : **Dr. Donald Fedder** **Date: 06/29/2006**

Organization : **Board for Orthotist/Prosthetist Certification (BOC**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-887-Attach-1.PDF

Board for Orthotist/Prosthetist Certification
THE ADVANTAGE IS EXPERIENCE™

Board for Orthotist/Prosthetist Certification
100 Penn Street, Room 505
Baltimore, Maryland 21201
Phone: 1.877.776.2200
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June 13, 2006

Submitted electronically to www.cms.hhs.gov/eRulemaking

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

Dear CMS Colleagues:

On behalf of the BOC Board of Directors I am writing to address several critical practical and philosophical disparities found in the **Proposed Competitive Bidding Rule (pages 64 and 169-170)**. To better protect the public, these issues should be addressed and resolved to ensure continued access to certified practitioners, practicing in accredited facilities. At issue are: (1) the independent status of Certified Orthotic Fitters (COFs), and (2) privileging.

Off-the-Shelf (OTS) Orthotics (see p. 64):

The description– *"...which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit the individuals"* ... refers to only a small number of OTS devices. Increasingly, very complex OTS devices are being manufactured (sized small, medium, and large), boxed and sold. This area of practice had never been considered important to credential until BOC introduced the Certified Orthotic Fitter (COF) and the Certified Mastectomy Fitter (CMF) programs in 2000. This coincided with the development of more and more complex devices available as OTS. These now credentialed, independent practitioners are in place nationwide, able to provide professional service to patients in need of prefabricated/OTS devices, but that none-the-less require sophisticated or custom fitting to meet patients' individual needs.

Major points follow:

- The proposed "Fitted High" and "Fitted Low" delineations are artificial, impractical barriers to an independent practice. Orthotist supervision is, perhaps, an attempt to control the COF independent area of practice.
- BOC's Certified Orthotic Fitters (COFs) have been determined by National Commission for Certifying Agencies (NCCA) standards to be independent practitioners.

- The COF Scope of Practice includes *only prefabricated orthotic devices* -- also referred to as OTS. However, the Criteria for Item Selection (page 64 of Proposed Rule) omit the role of the COF entirely.
- The COF is able to assess the patient's condition, determine the appropriateness of the prescription and custom fit the OTS device as required. (For an overview/description of COF practice, see COF Content Outline – Appendix A).

Privileging

Appendix I: Customized Orthotics and Prosthetics, refers to a "process for privileging non-credentialed or non-licensed professional staff...." BOC strongly objects to this and would remove this entirely from the proposed standards. What this clause does is permit any credentialed practitioner to authorize an employee, for an indefinite time period, to perform any function based upon the employer's judgment only. Further, since there is no time limit to this authorization of privilege, neither the patient nor CMS can be assured that this privileged person will continue to maintain competence. All other certified or licensed practitioners must be re-credentialed periodically. The only possible validity of privileging is under the narrow constraints of a ***closely supervised training program***, and with supervisors available at all times on the premises.

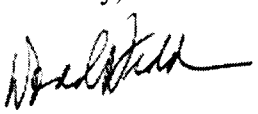
- BOC's position is that it is in the best interest of the public, at some point in the education and training of practitioners, every person *should be required* to pass comprehensive objectively developed examinations to demonstrate competence to practice, as a condition to provide continuous patient care. Further, each should periodically be re-certified as a measure of maintaining competency. Privileging provides a giant loophole and thus eliminates a major patient safeguard.
- The opportunity to become certified should be based on time-tested procedures and not be denied by artifice or non-job related requirements.

Every certificant is not necessarily competent to fit every device included under their scopes of practice. It is the responsibility of a professional to recognize that certification is just one step along the road to competence. Each credential is based upon the concept of "minimum competency" and it is required thatc ertificants will further hone their skills as they develop clinical experience. And of course, some will specialize in aspects of practice (e.g., pediatric scoliosis, halos, myo-electric arms, and therapeutic shoes) by taking specialized training.

Additionally, these are essential principles of a time-tested certification philosophy which has been accepted across numerous professions,national boundaries, and meets the directives of the National Commission for Certifying Agencies. In an effort to protect the public, Congress (BIPA 2000), insurance companies and other third party payers have shown a commitment to BOC national certification philosophy. In addition, these certification principles have been addressed and endorsed by the O&P profession.

BOC looks forward to receiving the final Rule. If I can provide any further information, please do not hesitate to contact me, 410-706-5044, or dfedder@bocusa.org.

Sincerely,



Donald O. Fedder, DrPH., MPH. FAPhA
Chief Executive Officer

Appendix A: COF Content Outline

Board for Orthotist/Prosthetist Certification THE ADVANTAGE IS EXPERIENCE **Certified Orthotic Fitter Detailed Content Outline**	Total	Recall	Application	Analysis
I. Facilities Management	**8**	**1**	**5**	**2**
A. Determine elements of the fitting room (e.g., adjustable stool, exam/fitting table, mirror, hard back chair, and parallel bars, or other appropriate ambulating device)				X
B. Determine required equipment, tools, and materials				
1. manufacturing/alteration equipment (e.g., heat gun, oven, bending irons, sewing machine, alignment device, anvil, grinding and carving tools, vise)				X
2. measuring devices (e.g., tape measures, goniometer, calipers, VAPC caliper, ML gauge, measuring chart, plumb bob, yard/meter stick)				X
3. casting equipment and materials (e.g., saws, spreaders, stockinette, indelible pencil, plaster of Paris, fiberglass, surgical gloves, water, bowls)			X	X
C. Comply with environmental safety regulations in all practice settings (e.g., pathogens, cross-infection, work place hazards)				X
D. Assure quality care by development and maintenance of policies and procedures regarding patients, prescribers, personnel, maintenance of records, etc.				
E. Comply with HIPAA regulations				
II. Perform Professional Practice/Ethics	**8**	**2**	**5**	**1**
A. Maintain patient confidentiality				X
B. Provide training, lectures and information to staff or other health care professionals on current orthotic information				X
C. Establish a quality assurance system that evaluates patient care				
D. Participate in orthotic clinics				X
E. Fulfill necessary continuing education requirements				X
III. Patient Assessment/Evaluation	**18**	**3**	**11**	**4**
A. Establish relationship with patient				
1. Patient intake				
a. Record all personal and insurance information about patient				X
b. Discuss financial matters for services/devices with patient				X

BOC Board for Orthotist/Prosthetist Certification

THE ADVANTAGE IS EXPERIENCE

Certified Orthotic Fitter Detailed Content Outline

	Total	Recall	Application	Analysis
c. Determine patient's expectations				
d. Interview patient and obtain history				X
e. Collect and evaluate patient records				
f. Identify the pathology of the disease to provide the proper orthosis or prosthesis				
g. Discuss any related medical treatment(s)				X
B. Evaluate and assess patient to determine				
1. skin condition				X
2. range of motion				X
3. muscle strength				X
4. manual dexterity				X
5. coordination				X
6. posture and gait				X
7. proprioception				X
8. sensation				X
C. Assess Prescription				
1. Determine elements of a valid prescription				
a. Verify validity of prescriber			X	X
b. Verify information contained on prescription				X
2. Determine relation of prescription to presenting problem				
3. Discuss prescription with patient (i.e., explain the patient's role/responsibilities)				X
4. Contact prescribing doctor and discuss/revise prescription				X
IV. Communication/Patient Education	**12**	**3**	**7**	**2**
A. Explain purpose/objective of orthosis				
1. Inform patient and/or caregiver of the various procedures to be performed				X
2. Explain advantages and disadvantages				X
3. Determine patient's expectations				
4. Explain patient's role/responsibilities				X
B. Provide initial instructions				
1. Instruct patient and/or caregiver in donning, doffing, care of orthosis/prosthesis				X
2. Demonstrate proper application, alignment and removal				X
3. Instruct patient and/or caregiver in fitting adjustments such as using prosthetic socks or tightening straps, etc.				X

Board for Orthotist/Prosthetist Certification THE ADVANTAGE IS EXPERIENCE **Certified Orthotic Fitter Detailed Content Outline**	Total	Recall	Application	Analysis
4. Explain how to recognize potential problems (e.g., pressure points, skin breakdown, numbness, contractures)				
5. Explain care and cleaning procedures			X	X
C. Evaluate psychological impact of devices on patient, family and others				
D. Establish procedures for patient follow-up				
1. Initiate and encourage on-going communication with patient and/or caregiver			X	X
2. Develop and maintain patient's records				X
3. Inform patient and/or caregiver of provisions for continued servicing of device (e.g., adjustments, consultation)			X	X
4. Communicate with the patient and/or caregiver verbally and in writing			X	X
E. Conduct inter-professional communications				X
V. Orthosis Application and Delivery	**17**	**6**	**10**	**1**
A. Finalize alignment and fit orthosis to patient				
1. Don orthosis to patient and finalize alignment, fit, and cosmetic appearance				X
2. Demonstrate proper application, alignment and removal				X
3. Demonstrate to patient and/or caregiver donning, doffing, fitting adjustments and care of orthosis				X
4. Explain how to recognize potential problems (e.g., pressure points, skin breakdown, numbness, contractures)				
5. Have patient and/or caregiver demonstrate proper application and removal				X
6. Have patient and/or caregiver sign receipts and acknowledgments			X	X
B. Explain follow-up procedures				X
C. Refer to physician for post-fitting follow-up			X	X
VI. Patient Follow-up	**7**	**1**	**5**	**1**
A. Evaluate fit and function of orthosis/prosthesis				
B. Perform necessary adjustments				X
C. Schedule follow-up visits			X	X

BOC Board for Orthotist/Prosthetist Certification

THE ADVANTAGE IS EXPERIENCE

Certified Orthotic Fitter Detailed Content Outline

	Total	Recall	Application	Analysis
VII. Patient Preparation/Measurements	**10**	**4**	**5**	**1**
A. Measure patient				
1. Select techniques (e.g., patient positioning, casting, tracing)				X
2. Identify anatomical landmarks			X	X
3. Use measuring devices				X
B. Perform casting procedures for foot only				X
C. Select materials for diabetic shoes and inserts				
VIII. Evaluation/Selection of Product/Model/Type of Orthoses	**20**	**4**	**12**	**4**
A. Cervical/Cervical Thoracic Orthoses (CO, CTO)				
1. soft foam collars				X
2. semi-rigid (e.g., Philadelphia)				X
3. rigid (e.g., multiple post)				X
B. Thoraco-Lumbo-Sacral Orthoses (TLSO)				
1. rigid (e.g., Taylor, Knight-Taylor, plastic, hyperextension)				X
2. flexible (e.g., with steel stays, thermal molded insert)				X
C. Lumbo-Sacral Orthoses (LSO)				
1. rigid (e.g., chairback, Knight, Harris, Williams flexion, plastic)				X
2. flexible (e.g., with steel stays, thermal molded insert)				X
D. Knee Orthoses (KO)				
1. rigid types (e.g., ACL, PCL, MCL, OA, multi-ligamentous, genu recurvatum, dynamic and adjustable R.O.M.)				
2. flexible (e.g., patella-stabilizer, elastic type knee supports with or without inserts/hinges/pads)				X
E. Knee Ankle Foot Orthoses (KAFO) (e.g., double or single upright, leather or plastic, dynamic and adjustable R.O.M., ischial weight bearing)				
F. Ankle Foot Orthoses (AFO) (e.g., double or single upright, leather or plastic, dynamic and adjustable R.O.M., posterior leaf spring (metal or plastic))				
G. Foot Orthoses (FO) (e.g., arch support, UCBL, straight/ reverse last shoes, shoe modifications, foot plate)				
H. Wrist/Hand/Finger Orthoses (WHFO, WHO (e.g., dynamic and adjustable R.O.M., resting, and functional orthoses)				X
I. Elbow Orthoses (EO) (e.g., dynamic and adjustable R.O.M., resting, and functional orthoses)				X
J. Shoulder Orthoses (SO) (e.g., dynamic and adjustable R.O.M.,				X

Board for Orthotist/Prosthetist Certification THE ADVANTAGE IS EXPERIENCE **Certified Orthotic Fitter Detailed Content Outline**	Total	Recall	Application	Analysis
resting, and functional orthoses)				
K. Functional Fracture Orthoses (e.g., upper extremity and lower extremity)				X
L. Abdominal and Pelvic				
1. trusses (e.g., flexible and rigid)				X
2. flexible supports				X
3. maternity supports				X
M. Compression Devices				
1. lymphedema garments				
2. compression garments				X
3. burn garments				
N. Breast Prosthesis and Ancillary Supplies				X
Totals	**100**	**24**	**60**	**16**

Submitter : Joyce Field **Date:** 06/29/2006

Organization : Joyce Field

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Competitive billing takes away a patient's choice. They will be forced to use the company with the lowest bid but will that company have the best service? If a patient is dissatisfied, where will they be able to go if they have limited choices? This program will put so many small businesses out of business that the next time a competitive bidding opportunity comes around, there won't be any small companies left to bid.

Patients are mainly elderly and infirm and hate change. They build up trusting relationships with the company that services their DME needs. They rely on that company to be there to answer their questions when they are sick and confused. Patients need the personal touch of a caring voice and the individual attention they receive from a small business. It is proven that this kind of service keeps patients from more costly hospital stays.

Businesses should be required to meet all quality standards before they are even allowed to bid. What is the point of putting in the lowest bid in the bidding process if the company is disqualified because they do not meet the required quality standards? That would just skew the result and could possibly eliminate a legitimate company from the pool.

Submitter : **Dr. Jan Tepper** **Date: 06/29/2006**

Organization : **Family Foot and Ankle Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician, for the past 29 years, 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. If this is a Diabetic patient the potential complications include infection, ulceration and possible loss of limb and/ or life. I frequently am the first to diagnose Diabetics with early onset of Charcot and delay of care can result in collapse of the foot, infection ulceration, loss of limb and / or life.

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,

Jan David Tepper, DPM, FACFS
Director, California Podiatric Medical Association

Submitter : **Ms. Joey Ryan** **Date: 06/29/2006**

Organization : **Air Products Healthcare**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-890-Attach-1.DOC

Air Products Healthcare
101 West Elm Street, Suite 210
Conshohocken, PA 19428

Tel 888-243-3456
Fax 860-668-5846

June 29, 2006

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

Dear Sir/Madam:

Attached are comments on behalf of Air Products Healthcare regarding the Department of Health and Human Services recently released Notice of Proposed Rule Making (NPRM) concerning Competitive Bidding.

Please note that Air Products Healthcare represents the following legal entities:

Air Products Healthcare Southeast, Inc.
dba American Homecare Supply, Georgia
MedSafety

Air Products Seating and Mobility, Inc.
dba Air Products Seating and Mobility

American Homecare Supply IV Georgia, Inc.
dba American Homecare Supply IV Georgia

American Homecare Supply Mid-Atlantic, LLC
dba Air Products Healthcare Pharmacy
MidAtlantic Healthcare
Young's Medical Equipment

American Homecare Supply New York, LLC
dba A & J Care
American Homecare Supply, Western New York

American Homecare Supply West Virginia, Inc.
dba Home Health Care Services

AmHealth Group, Inc
dba Collins I.V. Care, Inc.
Genox Homecare, Inc.

COPD Services, Inc.
dba COPD Services

Denmark's Inc.
dba Denmarks Home Medical Equipment
Vanguard Home Medical Equipment

Dependicare Home Health, Inc.
dba DependiCare

Lakeway Medical Rentals, Inc.
dba In Home Medical Equipment

Mosso's Medical Supply Company, Inc.
dba Mosso's Medical Supply Company
RX Pharmacy Services

Nightingale Medical of Indiana, LLC
dba Nightingale Medical

Ultra Care, Inc.
dba Ultra Care

We provide DMEPOS equipment and supplies along with infusion and custom rehab services to approximately 100,000 patients primarily on the East Coast with additional coverage in the Chicago, Indiana and Tennessee markets.

We appreciate the opportunity to review and comment on the proposed NPR. We would urge CMS to carefully review and consider our comments and recommendations. While we believe competitive bidding, if properly executed, would save money for the government, however, we are gravely concerned about how DRA will be incorporated into competitive bidding.

We would further urge CMS to publish an interim final review prior to the final rule to ensure all companies have an opportunity to review and comment one last time.

Questions may be directed to:

Joey Ryan
VP Compliance and Government Relations
Air Products Healthcare
101 West Elm Street, Suite 210
Conshohocken, PA 19428
Phone: 484-530-0880 Ext. 10224
Fax: 484-530-0888
Email: jryan@airproductshc.com

Thank you very much
Joey Ryan

General Comments

Supplier Standards and DRA Implementation

Our first overall comment relates to the information contained in the Competitive Bidding NPRM. We believe the NPRM does not provide enough information to adequately comment. We would urge CMS to publish an interim final review so that suppliers will have adequate time to review and provide comments before the final rule is published.

Section H Quality Standards for Suppliers of (DMEPOS)

We would further urge CMS to allow suppliers an opportunity to review the proposed quality standards prior to submitting comments on the NPRM. Without reviewing the final version of the standards we are unable to understand and incorporate into our comments reactions to the Quality Standards.

Accreditation for Suppliers of DMEPOS and Other Items

APH fully supports suppliers meeting accreditation standards. We would encourage CMS to identify quickly the MSAs to be included in the first round, so that the accrediting organizations can begin processing the applications and schedule the surveys necessary for the suppliers who are not presently accredited. We would recommend all suppliers who submit bids should be accredited; that there should be no transition period.

At the very minimum prior to CMS selecting and arranging winning bids, a supplier's credentialing (accreditation) should be reviewed and only those suppliers who are accredited should be considered for bid purposes by CMS.

Competitive Bidding Areas

While the MMA of 2003 requires that Competitive Bidding (CB) programs be established and implemented in areas throughout the United States, it also provides the Secretary with the authority to phase in competitive bidding programs.

We would recommend and urge CMS to begin the CB program in a phased approach for the first 10 MSAs. This will result in a program that will be able to be managed by CMS since CMS has only conducted two demonstration projects on a radically smaller basis prior to this implementation.

Our concern is that implementation in the 10 largest MSAs will be too large a program to implement, manage and monitor with no history of having successfully run or managed in the past. Our recommendation would be to implement 3 CBAs in October 2007; 3 CBAs in February 2008 and 4 CBAs in June 2008.

Our recommendation would be to exclude St. Louis, Kansas City, Baltimore, Washington DC, because of overlap with multiple DMERC regions or recent transition to a new DMERC MAC. Additionally, we would recommend that Orlando, and San Antonio be excluded since they were part of the demonstration projects.

Further we would recommend the exclusion of San Juan because of logistical and language concerns.

Our recommendation would be to implement the first round in 3 MSAs Miami, Houston and Dallas; allow these programs to transition through 120 days, then implement the next 3 MSAs in February and finally the last 4 MSAs. This will allow CMS to monitor programs and proactively make changes before full implementation in the 10 MSAs.

MSAs – 2007
We would request CMS define "combined rankings of DMEPOS allowed charges per FFS beneficiary." Do these represent the submitted allowed charges of suppliers to Medicare or the allowed payments. If this definition represents allowed payments (i.e. paid claims); we believe CMS will understate beneficiary need for a CBA.

Further, regarding the establishment of Competitive Bidding Areas, we do not believe that CMS has the authority to extend Competitive Bidding Areas outside an MSA either in 2007 or in the next round of bidding in 2009.

MMA 2003 states the competitive acquisition areas will be established in an MSA. We also believe this would be extremely confusing for beneficiaries. Third we do not believe the incremental administrative costs would be offset by the savings, and would request the data used by CMS to make this statement.

p.58
Finally regarding CMS' statement regarding the exclusion of "...an area within an urban area that has low population density is not competitive", we have a number of concerns. First, we do not believe CMS has the authority to exclude certain areas within an MSA from Competitive Bidding. Second, we do not understand how areas would be defined by CMS for exclusion, i.e. by zip code, by county, by street address. Third we believe not only would this be extremely confusing for beneficiaries who may be excluded but potentially have neighbors next door who are included; but inefficient to CMS in terms of administering and monitoring the program. We would urge CMS to reconsider this exclusion provision.

"Nationwide or Regional Mail Order Competitive Bidding Program" (§414.410(d)(2)
We request CMS define whether this would be a nationwide or regional program. We would further request CMS define a national vs. a regional mail order supplier. Many suppliers provide items to beneficiaries via multiple delivery methods, i.e. their own trucks, UPS or other delivery services or other personnel. We do not understand why CMS would dictate the delivery method to be used by a supplier. Further, many beneficiaries require in person demonstration and instruction on the use of products. We would question why CMS would want to restrict this in-home instruction to beneficiaries. We do not believe delivery methods should be stipulated by CMS. A competitive environment supported by a free market economy, drives businesses to choose the optimum delivery methods.

Limitation on Beneficiary Liability

Currently, Medicare allows a supplier to provide an item to a beneficiary for which the supplier believes Medicare may not pay, by executing an Advance Beneficiary Notice (ABN) with the beneficiary. Additionally, the MMA 2003 requires CMS to continue to allow use of ABNs by suppliers. However, it is indicated in the NPRM that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. However, it also states the beneficiary will have no financial liability to a non-contracted supplier for competitively bid items provided by that supplier. We would request clarification on this and the continued use of ABNs.

Authority to Adjust Payment in Other Areas

The NPRM indicates that CMS has the authority to adjust payments for items outside of competitive bidding areas based on information obtained from competitive bidding. We disagree with this statement by CMS and believe this statement only applies to prosthetics and orthotics as defined in §1834a(1)(F)(ii) and §1834(h)(l)(H)(ii).

We believe CMS has the authority to adjust payments via the inherent reasonableness (IR) methodology authorized under the Benefits Improvement and Patient Protection Act (BIPA)

We would recommend CMS issue a separate notice and provide the adequate comment period for suppliers to understand the business implications.

Substantial Savings

CMS has outlined in the CB NPRM that "...CB resulted in substantial savings to the program." Original results reported savings of 20.3% from the two demonstration projects in Polk County, FL and San Antonio, TX. However, the net savings were based on comparison to 2002 fee schedules and when compared to 2005 fee schedules (after the FEHB Predictions) resulted in only 8% savings. We would request definition of substantial savings.

Requirement to Obtain Items from a Contracted Supplier

While we understand the intent of CMS to ensure traveling beneficiaries are serviced by contracted suppliers our concerns are as follows:
How does CMS intend to inform traveling beneficiaries of contracted suppliers in a CBA? Currently there is coordination between suppliers to ensure beneficiaries' medical needs are not interrupted.

For beneficiaries traveling from a CBA to a non-CBA what process will be made available (i.e. access to common working file) to suppliers in the non-CBA to know the services rendered to their beneficiary will be reimbursed at a different fee schedule than the one currently set up in their system. Potentially in 2007 Suppliers will need to setup 14 Medicare fee schedules to accommodate 4 DMERC/MACs and 10 CBAs. By 2009 the number of these fee schedules will grow to 84. This will also require corresponding fee schedules to be set up by each DMERC/MAC which represents an operating burden on both. It likewise will be extremely confusing to Medicare beneficiaries who will potentially receive different coinsurance bills for the same item as the beneficiary travels to different CBAs.

Criteria for Item Selection

We would request clarification from CMS regarding the three categories subject to competitive bidding. Our interpretation of §1847(a)(2) would lead us to conclude that prosthetics and prosthetic devices along with ostomy products would be excluded.

We would request clarification from CMS regarding the methodology to determine an item's potential savings resulting from competitive bidding. Please define "greatest potential for savings".

Additionally, we would request clarification of the following:

Annual Medicare DMEPOS Allowed Charges – Does this reflect submitted allowed charges to Medicare or paid claims or some other measure? Are these charges by Competitive Bidding Area or in total for the nation?

Annual Growth in Expenditures – We would request definition of this.

Number of Suppliers – We would request definition of this. Is this the current (as of 2005) number of legal entities in total? The number of approved Medicare Supplier numbers issued in total? The number of legal entities for each competitive bidding area? The number of legal entities per competitive bidding area? Or some other measure?
Additionally, what methodology will be used by CMS to determine the number of suppliers needed for each competitive bidding area and will this information be released to suppliers prior to the bidding process?

Savings in DMEPOS demonstrations – we would request the methodology to be used by CMS to determine the savings for those items not included in the Demonstration Projects.

Reports and Studies – We would request CMS define the reports and studies to be used and provide access to them for suppliers.

We would also request that CMS provide the reference that quantifies the statement "we saw evidence in the competitive bidding demonstrations that products furnished by a large number of suppliers had large savings rates and fewer problems with quality". We would further request that CMS provide the measure to which the fewer problems with quality was compared to.

It appears from the numerous references to quality within the NPRM that CMS is concerned about preserving quality for beneficiaries, however, we could find no reference to a quality measure being used or considered in the selection of winning bidders. We could only identify references to cost and utilization of items. We would recommend that CMS develop an evaluation method that would include a quality measure as a portion of the overall score in determining a winning supplier.

Regarding product selection, we would recommend that power equipment, such as power wheelchairs and POVs along with "custom" cushioning equipment be excluded. We make this recommendation for three reasons:

- New changes to HCPCS codes along with the new LCD and fee schedules for these items will result in new utilization data from which CMS is relying to select items for competitive bidding
- Historical utilization data used by CMS may have included documented fraudulently billed items (operation wheeler dealer) which would distort reliance on this utilization data
- Power wheelchairs and "custom" cushioning equipment are complex items requiring significant involvement by specialized personnel and do not in our opinion, lend themselves to a competitive environment.

We would recommend that if CMS includes the wheelchair product category in competitive bidding that only low end wheelchairs (K0001 thru K0004) and one basic wheelchair cushion be included.

Additionally we would recommend that OTS orthotics and enteral products be excluded from the first round of competitive bidding. OTS orthotics because many physicians and large chain drugstores currently supply these items and would be unable to provide these to patients in an emergency. Enteral because currently many nursing homes provide enteral products to their patients and may be prevented because they would probably become a non-contracted supplier.

Our recommendation would be that CMS initiate competitive bidding using three product categories and that these product categories be the same across all competitive bidding areas. This will allow better management of the program in the initial rollout, comparison of cost savings across competitive bidding areas and consistency of products for beneficiaries.

Submission of Bids Under the Competitive Bidding Program

CMS has defined in the NPRM that suppliers must bid on all items within a product category. Which we understand the reasoning used for this proposal, suppliers need to know the product categories to determine if they would want to bid on all items in the category. If the product categories are defined too broadly, suppliers will not be able to rationally bid on the items.

The second largest policy group based on "Allowed Charges" in the NPRM is Wheelchairs/POVs. This category includes equipment ranging from manual wheelchairs (K0001) through highly specialized power wheelchairs (K0011).

This further supports our recommendation that CMS more narrowly define product categories to be used in competitive bidding.

Power wheelchairs are complex items requiring custom configuration to the patient along with special adaptations that would not easily be able to be competitively bid. Additionally, manual wheelchairs are scheduled to be recoded in 2007 which will affect the utilization data used by

CMS. Suppliers bidding in this category will still need to inventory many custom additions which will be difficult to bid competitively.

Further concern is that potentially a winning supplier for wheelchairs, may not be the winning supplier for any associated "add-ons", such as specialized seating or backs. Beneficiaries would then be required to use two different suppliers for one piece of equipment.

Regarding oxygen, we are unclear how the DRA would affect the implementation of competitive bidding and would request clarification. The requirement in the NPRM regarding oxygen and oxygen equipment indicates "... the single payment amounts for oxygen and oxygen equipment be calculated based on separate bids submitted and accepted for furnishing on a monthly basis of each of the oxygen and oxygen equipment categories of services described in §414.226(b)(l)(i) through (b)(l)(iv)." We are unclear as to how a rational bid can be made for oxygen and oxygen equipment under DRA.

Finally, the capped pricing, increased quality standards, requirement to service all beneficiaries (including travelers) and costs of servicing beneficiaries from grandfathered suppliers will increase the costs of suppliers. The DRA imposes a cap on the months of payment for oxygen and capped rental equipment. In view of this, allowance should be made to bid item prices above the existing fee level.

Product Categories for Bidding Purposes

Requirements to Bid on all Products in a Category
We would request clarification of the statement, "We believe that suppliers that are located outside of a competitive bidding area, but do business in the competitive bidding area and are able to service beneficiaries residing within the CBA should be permitted to submit bids and participate in the competitive bidding program for that area."

As an example if we have locations not far from a CBA and depots within the CBA would this presence allow us to bid and participate in competitive bidding? Additionally if we have desire to bid for a CBA which would be in our defined company geographic boundaries, but do not presently have a presence within that CBA would we be allowed to bid and participate in competitive bidding? What is CMS' definition of "do business in the competitive bidding area"? Would this include non-Medicare business? And what are the quantitative measures that will be used for evaluation purposes.

Conditions for Awarding Contracts

Quality Standards and Accreditation
The NPRM states "A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid." We are concerned with this recommendation because potentially suppliers could be chosen as winning bidders who are subsequently not accredited. This would result in CMS having to redetermine the pivotal bid or bids from suppliers who are disqualified having been considered in the determination of the pivotal bid.

We would therefore recommend that only accredited suppliers be allowed to bid and only accredited suppliers' bids be considered by CMS and used in the determination of pivotal bids.

To meet the expected demand from suppliers needing to become accredited we would urge CMS to quickly identify the criteria to be used in identifying the accrediting organizations and to expedite the accrediting process.

Financial Standards

We request clarification of the statement; "§1847(b)(2)(A)(ii) specifies that we may not award a contract to an entity unless the entity meets applicable financial standards specified by the Secretary." Please define the "applicable financial standards". We would request the objective, quantitative measures that will be used by CMS to assess the "expected quality of suppliers, estimating the total potential capacity of selected suppliers and ensuring that selected suppliers are able to continue to serve market demand for the duration of their contracts."

We are unclear and would request the methodology and quantitative measures and/or standards CMS will use to "maintain beneficiary access to quality services."

Regarding the request for bank information, we are concerned about the timeframe needed to obtain this information from the banks as well as the coordination needed by CMS to match the requested banking information (which is to be sent directly from the bank to CMS) to the RFB from the supplier. This potentially could involve ten (10) or more from each bidding supplier. While we understand the need to assure financial stability of winning suppliers we do not believe banking information (as outlined in the proposed RFB document OMB No. 0938-xxxx) will successfully demonstrate this.

Our recommendation regarding financial standards and evaluation is as follows:

CMS should define the financial standards and/or measures that will be required from suppliers to bid. Only those suppliers who meet those standards and/or measures should be allowed to bid. This will ensure only financially stable suppliers are chosen as winning bidders.

We would propose using the following

- Audited financial statements only.
  (Reviewed financial statements do not provide the same assurance that an organization is complying with GAAP and the cost is not prohibitive to small suppliers.)
  Audited financial statements should include those of the legal entity bidding in the CBA and those of the parent corporation if there is one. This request is made because some legal entities within a CBA may be relatively small because they are a start-up or small acquisition, but are financially supported by a very large profitable parent organization. These statements should include balance sheet, P&Ls, Statements of Cash Flows. Additionally trade references should be submitted along with Letters of Credit.
- Insurance Certificates and direct follow up with the underwriter
  (as is done now by the NSC)

An additional question concerns the RFB and whether the bidding would occur by legal entity or supplier number or parent corporation. Our recommendation would be that while bidding be submitted by legal entity, parent corporation financial stability and resources be factored into the financial considerations of the legal entity bidding and the capacity to meet the demand of the CBA.

Market Demand and Supplier Capacity

In determining the beneficiary demand, we would urge CMS to carefully consider how projected growth in a competitive bidding area is determined. Many "sunbelt" areas have experienced substantial increases in seniors over the past few years and the census bureau has projected this trend will continue. In determining the number of suppliers needed for a competitive bidding area, we would urge CMS to "over project" so there is no shortage.

Regarding CMS' approach to estimating supplier capacity to meet the projected demand in a CBA, we do not understand the necessity of comparing a supplier's current activity in a CBA with their projected capability unless it is to identify suppliers whose projected capability is less than current activity. To compare current activity to projected capability if used for exclusion purposes would defeat the purpose of competitive bidding, i.e. a large supplier may want to enter a new geographic area as part of their overall expansion plans. While they may not currently be providing many services (or none) to Medicare beneficiaries, they would have more than adequate financial resources available to service the CBA.

We would urge CMS not to disregard suppliers based on low or no current activity in a CBA if their financial statements reflect adequate capital to service an area.

Determine the Pivotal Bid

Our concern with the proposed methodology to determine the pivotal bid is there is no mechanism for excluding arbitrarily low bids. We would recommend some mechanism to exclude "radical outlier" bids.

We also would request clarification on whether bids will be in whole dollars or include cents. If bids are to include dents, will they then be rounded to the closest dollar?

We would also urge CMS to allow any willing supplier be accepted as a wining supplier if they agree to provide competitively bid items at the winning price.

Finally CMS has stated they plan to select at least two suppliers for each CBA. We would urge CMS to select more suppliers than it projects are needed to ensure beneficiary access throughout the contract period.

Assurance of Savings

The goal of competitive bidding is to reduce overall costs to the Medicare program but not necessarily item costs. We believe CMS should not limit bids by disqualifying bids above the current fee schedule amount for that item. There are items for which costs have risen above the current fee schedule because of BIPA and FEHBP reductions and no CPI increases for suppliers. By not allowing bids above the current fee schedules CMS is forcing suppliers into an artificial,

illogical pricing structure. Instead, CMS should continue to use the methodology used in both demonstration projects.

CMS should recognize that overall savings in a product category can be achieved even though one item may have a payment amount above the current fee schedule.

Selection of New Suppliers After Bidding

Our questions regarding the NPRM proposal for selecting new suppliers are as follows:

- Would all contract suppliers be contacted at the same time? By what method?
- How would CMS determine the allocation of beneficiaries? By Beneficiary zip code? Or some other arbitrary measure?
- What is the timeframe for "timely manner"?

We are also concerned with the time frame needed for the next supplier on the list to be able to provide updated information and the need to be able to quickly meet the beneficiary demand in the CBA. We believe the need for this procedure can be eliminated by CMS carefully evaluating the financial statements and viability of suppliers and selecting more suppliers than the projected demand of a CBA.

Setting Single Payment Amounts for Individual Items

The NPRM proposes setting the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". Use of median pricing is not in accord with the original third principle that contract suppliers will be paid at least as much as they have bid for an item. This principle was stated as necessary to "ensure fairness and access". [see PAOC presentation on Determining Payment Amounts]. Median pricing methodology is contrary to the objectives and results achieved through normal competitive bidding processes and does not follow the selection method used in both demonstration projects.

Our recommendation would be for CMS to set the pivotal bid at the highest price bid for a product category that will include enough suppliers to meet the projected demand for that CBA.

An alternative would be to determine the "mean" bid price for a product category.

Rebate Program

The NPRM proposes to allow contract suppliers to provide rebates to beneficiaries that equal the difference between the supplier's bid price and the single payment amount. Contract suppliers however could not advertise their rebate program directly to beneficiaries; rather CMS would provide information identifying rebate suppliers to beneficiaries in a CBA. The program is voluntary, however a supplier would need to identify whether they intend to offer rebates in their RFB.

We have very serious concerns about this and do not understand why a program such as this would be included in the NPRM when it is in direct contradiction with the statutory prohibition on beneficiary inducements in §1128A(a)(5) of the Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception. We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

The OIG has published guidance in the form of advisory opinions, fraud alerts and special advisory bulletins to assist providers and suppliers in understanding their obligations to comply with the statutory prohibition on beneficiary inducements. OIG guidance has consistently held that inducements distort beneficiary decision making, increase costs to the Medicare program, and undermine competition among providers. In a Special Advisory Bulletin, *Offering Gifts and Inducements to Beneficiaries*, published in August 2002 (Bulletin), the OIG took an uncompromising stance against the practice of offering *any* inducements, other than items of nominal value, to Medicare beneficiaries. The OIG provided the following rationale for its position:

> Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

Bulletin at 1.

CMS proposes two ways to ameliorate the fraud and abuse issues inherent in the rebate program. First, CMS would require any contract supplier that offers rebates to offer the rebate to all Medicare beneficiaries in the competitive bidding area. The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not offer the rebate only to patients with a specific chronic diagnosis requiring long-term rental equipment. Second, the supplier could not advertise the fact that it offers a rebate.

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

> The "inducement" element of the offense is met by *any offer* of valuable . . . goods and services as part of a marketing or promotional activity, *regardless of whether the marketing or promotional activity is active or passive.* For example, *even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.*

Bulletin at 5 (Emphasis supplied).

CMS' proposal to allow contract suppliers to offer rebates fundamentally conflicts with the longstanding rationale underlying the prohibitions on inducements and kickbacks in federal health care programs. This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote *exactly* what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) – competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Terms of Contract

The NPRM states "§1847(b)(3)(B) requires the Secretary to recompete contracts under the Medicare DMEPOS Competitive Bidding Program at least every 3 years. The length of the contracts may be different for different product categories…"

We are concerned that CMS could set the contract period at different lengths than 3 years, which would be extremely confusing to both suppliers and beneficiaries. We would urge CMS to standardize the contract terms for all competitive bidding areas and for all product categories.

Repair and Replacement of Equipment

The NPRM states "the contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding." The NPRM also will require contract suppliers to accept all beneficiaries within the competitive bidding area.

We would recommend that contract suppliers accepting new beneficiaries be entitled to a new rental period proportionate to the equipment, i.e. 13 months for capped rental items and 36 months for oxygen equipment.

This will ensure contract suppliers are not adversely affected financially when beneficiaries change suppliers. This will also ensure beneficiaries continue to have a wide variety of suppliers to choose from for their services.

We would recommend that CMS consider separately supplier bids to repair items.

We also request clarification regarding repairs:
Could a contract supplier sub-contract out the repairs needed on beneficiary owned equipment? We do not believe contract suppliers should be required to repair patient owned equipment.

Termination of Contract
CMS must define the process to be used in termination of a contract supplier including an opportunity and adequate timeframe to cure any identified breach of contract.

Information Collection from the Supplier
We do not understand and would request clarification on the following "conditions and information that we propose a supplier must agree to provide to CMS for purposes of assessment prior to becoming a contract supplier:"

- Information on product integrity
- Information on business integrity
- Organizational conflicts of interest
- Names of all owners
- Employee information
- Training and qualifications
- Customer Service protocol

We also suggest CMS consider requesting complete disclosure on CIA agreements, OIG convictions and consider conducting criminal background checks.

Change in Ownership
We are concerned with CMS' request that notification be provided in writing 60 days prior to any changes of ownership, merges or acquisitions being finalized. We understand and agree that CMS should be notified of ownership changes, however in our experience there are instances when this timeframe is unrealistic. We are additionally concerned that CMS could according to this rule, potentially be notified of numerous acquisitions that upon further due diligence are not consummated. We are concerned about the additional administrative costs and burden this rule would place on CMS. We are likewise concerned with the proposal that "the successor entity must agree to assume the contract supplier's contract including all contract obligations and liabilities that may have occurred after the awarding of the contract to the previous supplier." Our interpretation of this statement is that all future changes of ownership will take the form of stock acquisitions. We are very concerned that CMS would limit suppliers' ability to enact asset acquisitions. We are also concerned about the successor's liability for potentially fraudulent activities that could have occurred on the previous company's watch. Additionally, we are concerned about instances where the new company determines revised CMNs are needed and the physician is no longer in practice or refuses to execute new CMNs. And finally we are concerned about the accounting and tax implications by restricting change of ownership transactions to only stock transactions. There may be instances where sale of a company because of death of the owner would be prohibitively expensive if executed as a stock transition, leaving the widow with little money and no other recourse to dispose of the business.

Opportunity for Networks

Regarding CMS' proposal concerning networks we would request clarification on the legal structure that would allow a joint venture to be formed. Currently joint venture arrangements are not compliant or approved by the OIG. We are also concerned that there may not be enough time to form a network prior to submitting bids. We are also concerned about CMS' limitation on networks to 20% of the Medicare market and would request CMS disclose the basis for this limitation.

Further we request clarification regarding networks in a CBA. Could a supplier be part of or form a network for each CBA?

Finally we request clarification regarding liability regarding the billing arrangement for networks. CMS has stated "the legal entity would be responsible for billing Medicare and receiving payment on behalf of the network suppliers." Would the legal entity also have liability for actions related to network suppliers in post payment audits?

Education and Outreach

We are concerned with the enormity of communicating to all referral sources which include thousands of physicians and hospitals and range to sleep labs, outpatient facilities, ambulatory surgical centers, nursing homes, etc. We are likewise concerned about CMS' ability to effectively communicate this change to beneficiaries, particularly those traveling patients who will not initially be part of competitive bidding because their permanent residence is not one of the 10 MSAs selected, but who travel frequently or infrequently to one of the MSAs. We do not believe there exists an effective means for communicating this enormous change. We believe that despite a thorough, comprehensive communication plan, beneficiaries will be confused and not understand this program. Further we believe competitive bidding as outlined in the NPRM will force beneficiaries with multiple pieces of equipment to use multiple suppliers. This will be confusing for the beneficiaries who may contact the wrong supplier in an emergency and not receive the treatment needed timely, causing an emergency room visit and potentially a costly hospital stay.

CMS may considering partnering with AARP to enhance its outreach to beneficiaries, however, this will not prevent the multiple supplier issue that beneficiaries will have. CMS should also be mindful that these planned outreach activities are additional costs to the competitive bidding program.

Finally we are concerned about CMS' ability to communicate this change to suppliers, within one of the initial ten MSAs, and those that may have small operations in an MSA but may be part of a larger organization not in the MSA.

We would request CMS define and publish their plans for communicating these changes.

Monitoring and Complaint Services for the Competitive Bidding Program

We would request CMS define and publish the proposed "formal complaint monitoring system to address complaints in each competitive bidding area."

We applaud this measure by CMS but would urge careful examination and review of any complaints. We are concerned that disgruntled suppliers, referral sources or beneficiaries may file fictitious complaints about a winning supplier.

Physician Authorization/Treating Practitioner

CMS has proposed to allow physicians to prescribe a specific brand or type of equipment. This provision seeks to preserve beneficiary access to equipment. We do not believe this provision should be included in competitive bidding. A physician always has had the freedom to prescribe a particular brand or item and we believe this would continue under competitive bidding. Suppliers are always looking satisfy a physician's request for specific equipment particularly if the equipment requested is clinically superior. We would request that CMS establish a process to reimburse at a higher rate a specific piece of equipment requested by a physician if that physician can demonstrate the medical necessity and clinical superiority of the equipment. We believe that if a specific piece of equipment is requested by a physician, there should be documented medical need and clinical justification for the equipment. Suppliers should also be reimbursed at a higher rate to compensate them for the additional expenses associated with obtaining such an unique item. Further, we are concerned that there could be increased beneficiary risk of injury because supplies will be forced to repair brand specific items for which they are not knowledgeable of or qualified to repair. Finally, we are concerned that manufacturers could promote their expensive brands to physicians which could inappropriately drive up the requests for these types of equipment.

In conclusion, we would propose that this proposal to allow physicians to request brand specific items be removed in CMS' final rule.

Implementation Contractor

We would request CMS define the quantitative, objective measures and evaluation tools that the CBIC(s) will use in evaluating the bids submitted by suppliers.

Suppliers need to understand the data and information that will be reviewed by the CBIC(s) as well as the actual scoring and evaluation process to be used. Without this guidance, suppliers have no assurance that bid evaluations will be performed in a fair, objective and quantitative manner and not using qualitative, unmeasurable, judgment related methods.

We would agree that the evaluation process should not be performed by the DMERCs but would request that the actual scoring mechanism that will be used to evaluate bids be published with sufficient time for supplier review prior to the RFB.

Payment Basis

Inflation Update

We are concerned that there is no assurance in the competitive bidding NPRM to guarantee suppliers will receive the inflation update in years two and three of the contract period. We would request that CMS define its plan to guarantee that Congress will not override this price increase through subsequent legislation in any contract year.

Grandfathering Medicare Advantage Beneficiaries

CMS has not defined the process by which a contract supplier will service a Medicare Advantage beneficiary who chooses to become a Medicare fee-for-service beneficiary. These patients may have a supplier who is part of the Medicare Advantage plan network, but may not be a contract supplier. Will these beneficiaries be allowed to continue to receive services from their existing supplier? Or will they be forced to change suppliers? Our recommendation would be that these beneficiaries be allowed to remain with their existing supplier and excluded form competitive bidding.

Process for Grandfathering Suppliers

The DRA will cause a major change in the behavior of grandfathered suppliers when compared to their behavior in the demonstration areas. It will now be to the advantage of grandfathered suppliers to withdraw from providing the service when the peak of their beneficiary oxygen population approaches 36 months to recover and sell the equipment on the used market. Withdrawal could take two forms - formal withdrawal at the time of contract awards (i.e. the start of the contract period) or informal withdrawal sometime later by providing a poor service and encouraging beneficiaries to switch to a new supplier at 35 months. For the contract suppliers this would result in an uncontrolled transition of beneficiaries and, in the unfair situation where the contract supplier is paid little or nothing for equipment they are forced to supply. With the current draft rules there is a high risk that beneficiary service quality will decrease and there will be confusion in the market.

To avoid this situation we would propose that grandfathered suppliers should be required to phase out their beneficiaries within 6 months of the contract award and that contract suppliers who take over existing beneficiaries are permitted to bill for a new rental period not to exceed either 13 months for capped rental items or 36 months for oxygen beneficiaries (or until the beneficiary no longer requires the equipment whichever is sooner), at the contract rates.

This recommendation regarding a six-month transition will prevent the perpetual roll-over of non-contractual suppliers, who could potentially rebid for the next 36 month period. This will also ensure continued access to quality services for beneficiaries with contracted suppliers and an uncontrolled transition of beneficiaries.

Beneficiary Switch to Contract Suppliers

The NPRM indicates beneficiaries may choose to use a contract supplier at any time and that a contract supply must provide capped rental or oxygen equipment to the beneficiary in the competitive bidding area regardless of the remaining rental months. The NPRM also indicates that suppliers must factor these additional costs into the bids they submit.

Suppliers will not be able to forecast whether a beneficiary will choose to remain with a supplier or choose a new contracted supplier. Nor can they forecast the number of rental months remaining for capped rental or oxygen equipment for these beneficiaries.

This is why we are recommending a six-month transition period for all non-contracted suppliers and a new rental period for contracted suppliers.

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? As noted above, the implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Gap-Filling Methodology

Finally, we do not believe gap filling to determine Medicare fee schedule payments should be included in competitive bidding. We would recommend that CMS consider and address this separately from competitive bidding.

One final question that we have concerns the process for determining capacity in a competitive bidding area for a subsidiary supplier of a very large parent organization that is not located in the competitive bidding area. Our question concerns how the subsidiary supplier's ability to meet the projected demand for that CBA will be determined. We believe and would recommend that CMS heavily weight the parent organization's financial strength and capability to meet any demand projections and not rely solely on the subsidiary supplier's size. This will ensure that CMS selects financially stable suppliers who will be able to meet the demand projected for a CBA.

Submitter : Dr. Scott Gurwin **Date:** 06/29/2006

Organization : Foot & Ankle Specialists of Central Ohio

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

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

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

I am writing this letter to you today to request the Centers for Medicare & Medicaid Services to modify the physician definition which is being used in the proposed rule from 1860 (r) (1) to 1861 (r) (3). This proposed rule is going to establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

Podiatrists should not be discriminated against in this definition of physician and should be treated equal to MD and DO suppliers. I am a current supplier and adhere to all supplier standards. I am subject to the Stark laws, as well as other regulatory requirements that apply to MD and DO suppliers.

As a specialist in podiatry, treating my patients with needed durable medical equipment supplies is vital to patient care. If I am no longer able to be a supplier, especially in the case fractures and ankle instability, my patients will be forced to go elsewhere to obtain these medically necessary items. This will just risk further injury to my patient therefore lowering the quality of patient care.

I am strongly urging CMS to use the 1861 (r) (3) definition of physician in the final regulation.

Sincerely,

Dr. Scott D. Gurwin, D.P.M.

Submitter : **Date: 06/29/2006**

Organization : **RESNA**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-892-Attach-1.DOC

RESNA

National Office: Suite 1540, 1700 North Moore Street, Arlington, VA 22209-1903
703/524-6686, Fax: 703/524-6630, TTY: 703-524-6639, Website: www.resna.org

To be sent electronically to http://www.cms.hhs.gov/Rulemaking

June 27, 2006

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

Re: Proposed Rule to Improve Medicare's Payment for Certain DMEPOS

Providing **specialized** durable medical equipment (DME) products and services consists of highly individualized clinical services involving the design and development of individually configured devices, often from many different sources to meet the specific functional needs of the person with a disability. Many durable medical equipment products and services are provided by clinicians and suppliers with extensive training in working with clients requiring these products and services to meet a variety of needs including communication (both expressive and receptive), mobility, postural support, accommodation of sensory impairments as well as addressing issues related to transportation.

When price becomes the sole determining factor in securing products and services, the range and quality of professional services provided to the client is sacrificed in order to put forth a low bid. Many DME products and services are configured and selected for each client – they are not generic. They are configured and designed to address the specific medical and functional needs of each client.

Under the proposed rule published in the Federal Register on May 1, 2006, RESNA strongly encourages CMS to exclude high-tech rehabilitation and assistive technology[1] products from the initial implementation of the program. We believe that language contained in Section 302(b) of the Medicare Modernization and Prescription Drug Act of

[1] Assistive technology (AT) is any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve the functional capabilities of individuals with disabilities. (29 U.S.C. Sec 3002 (a)(3)).

2003 gives the Secretary the authority to exempt certain products when competitive acquisition "is not likely to result in significant savings."

Furthermore, because the nature of the injury or disease process (including but not limited to: spinal cord injury, amyotrophic lateral sclerosis, multiple sclerosis, traumatic brain injury; muscular dystrophy, cerebral palsy, etc.) for those individuals needing alternative control power wheelchairs; power seating options including tilt, recline, tilt/recline, etc.; high strength lightweight and ultralight manual wheelchairs; skin protection and positioning cushions, custom seat and back cushions and wheelchair accessories require individual attention, we request these items be excluded from the initial implementation of the competitive acquisition program. Proper provision of this equipment requires careful evaluation, often through a team effort, consideration for progression and complications affecting the condition, trial of equipment, proper fitting, training and follow-up. Though labor intensive, these activities are critical to minimizing greater complications that can result in further injuries, additional hospitalizations, loss of function and decreased independence. These therapeutic services are inconsistent with competitive bidding. In addition, RESNA feels it will be difficult to demonstrate significant cost savings on many of these products through competitive acquisition when there is yet to be a fee schedule for reimbursement that will be in alignment with these products under the new HCPCS codes planned for October 1, 2006.

RESNA also recommends the initial bid cycle be phased in gradually starting with perhaps 4 metropolitan statistical areas (MSAs) instead of the planned 10 MSAs as required. The rationale behind starting with 4 MSAs is to align the areas with the 4 DMERCs so that CMS and its approved accrediting organizations can ensure that quality standards are applied to all qualified suppliers.

Further, regarding the rebate program ("Submission of Bids Under the Competitive Bidding Program under H.2 Rebate Program"), RESNA strongly urges CMS to not implement a rebate program. We do not see an incentive in such a program but rather a disincentive in that quality and professionalism will be further compromised because this program would encourage beneficiaries to select a supplier solely based on the rebate price.

RESNA is an interdisciplinary association of people with a common interest in technology and disability. Its 1,500 members represent dozens of professional disciplines including physical therapists, occupational therapists, speech-language pathologists, rehabilitation and assistive technology suppliers, rehabilitation engineers, researchers, orthotists, prosthetists, special educators and consumers of rehabilitation and assistive technology (individuals with disabilities and their family representatives).

RESNA is an ANSI accredited standards organization with experience in developing standards through its Technical Standards Board and creating a professional credentialing program for assistive technology practitioners (ATP), assistive technology suppliers (ATS) and rehabilitation engineering technologists (RET) through its Professional Standards Board (PSB).

In summary, RESNA recommends:

1. Omitting mobility assistive equipment and seating technologies from the initial competitive acquisition program in 2007 until costs avoided with the new policy changes can be examined.
2. Gradually phasing in the MSAs, initially beginning with four until CMS can ensure that quality standards are applied to all qualified suppliers.
3. Eliminating the rebate program altogether.

If you need additional information or have any questions, please contact Nell Bailey, Governmental Affairs Coordinator at (703) 524-6686 ext. 305 or via email at nbailey@resna.org.

Respectfully Submitted,

RESNA Government Affairs Committee

Katherine D. Seelman, Ph.D.
Chair

Rory Cooper, Ph.D.
President

Submitter : **Dr. Daniel Logan** **Date: 06/29/2006**

Organization : **Foot & Ankle Specialists of Central Ohio**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 23, 2006

Mark B. McClellan, MD, PhD
Centers for Medicare & Medicaid Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

It has been brought to my attention that CMS believes it is required by statute to establish a competitive bidding program for all DMEPOS suppliers, including physicians. The physician definition appears to be problematic in that it is exclusive only MDs and DOs.

Similar to MD and DO suppliers, I am required to obtain a valid supplier # and must adhere to all of the current supplier standards including the Stark laws and all other Federal and State regulatory suppliers.

Excluding me from being a DMEPOS supplier in the new competitive acquisition program and just because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, my patient will have to go elsewhere to obtain the necessary medically items. As you well know, this will result in certain patients risking the existing injury into one that is more severe, with greater recovery time and increased risks for complications. My use of DMEPOS products is just as vital to my patient care and is no different than that of MDs and DOs.

I am requesting CMS to change the physician definition from 1861 (r) (1) to 1861 (r) (3) allowing the broader definition, which includes podiatric physicians. I want to be able to continue providing medically necessary items and quality care to my patients.

Sincerely,

Dr. Daniel B. Logan, D.P.M

Submitter : Dr. Timothy Musselman **Date:** 06/29/2006

Organization : Virginia Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

National or Regional Mail Order Program:

* If CMS creates a national or regional mail service program, beneficiaries must have the option to continue to obtain their DME supplies from their provider of choice - they should not be forced to use one provider over another.

* We strongly object to CMS' alternative proposal that would limit beneficiaries' choice of DME provider. This proposal would severely restrict beneficiaries' access to needed items and supplies. Limiting beneficiaries' access choice to mandatory mail service is not appropriate for DME such as lancets and glucose testing strips - items that beneficiaries need convenient and frequent access to.

* Program oversight - CMS must prohibit suppliers from automatically refilling and sending replacement supplies without receiving a refill request from the patient. This practice could lead to increased risk of fraud and abuse and may unnecessarily increase costs to the Medicare program and beneficiaries.

Criteria for Item Selection

Criteria for Item Selection

DMEPOS Items Included in the Program:

* The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies

* If CMS wants to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be more economically provided be a central supplier.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

Single Payment Amount:

* While we understand that CMS is required to set a single payment amount for each item, we are concerned that using the median bid will set an artificially low payment rate that many small suppliers will not be able to accept. CMS must review the process to determine the single payment amount and ensure that the payment rate is adequate to cover a supplier's costs to acquire and provide the product. The Agency must periodically examine the payment rate as it compares to supplier acquisition costs.

* We appreciate CMS' intention to update the single payment rate based on the consumer product index during the second and third years of the supplier contract; however, this proposal does not address situations in which the manufacturer or distributor raises the acquisition cost of the product. Suppliers would be required to continue providing the product at the single payment rate even if the reimbursement amount is significantly less than their acquisition cost. Suppliers will not be able to continue providing DMEPOS supplies in this situation. CMS must make provisions to increase the payment amount during the year if acquisition costs change.

Rebate Program:

* We are concerned with CMS' proposal to allow suppliers to provide a rebate to Medicare beneficiaries. Allowing suppliers to provide rebates to beneficiaries could give large suppliers an unfair competitive advantage.

* If suppliers are allowed to provide a rebate, the supplier and CMS should be prohibited from advertising the rebates to beneficiaries, prescribers, and other referral sources.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Small Suppliers:

* CMS must do more to ensure that small suppliers - which include the majority of pharmacy based suppliers - can participate in the competitive bidding program.

* Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to competitive in large metropolitan areas with large suppliers.

* After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should be allowed to join the competitive bidding program as a contracted supplier.

* We urge CMS to take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Terms of Contracts

Terms of Contracts

Furnishing Items to Beneficiaries:

* We believe that beneficiaries should be guaranteed prompt receipt of items within a specific period of time after the order is received if item is in stock. Delay in receiving items such as diabetic testing supplies could lead to adverse events for beneficiaries.

Submitter : Andrew Funk **Date:** 06/29/2006

Organization : Medicap Pharmacy

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

If CMS moves forward with competative bidding, some pharmacies will be unable to service their patients in the same manner as in the past. Pharmacies are already under fire and are expected to continue to accept decreased reimbursement from Medicare part-d plans. Scripts are continually being sold for UNDER cost due to lack of repayment from 3rd party payers. Now, CMS wishes to enforce a competative bid, which would force the elderly and indigent to go large pharmacy chains and or mail order facilities. Patients trust their small town pharmacists, and I know they would like to continue to be serviced by their pharmacies.

Submitter : Ms. Kelly Oday **Date:** 06/29/2006

Organization : Ultimate Mobility, inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-896-Attach-1.DOC

June 2006

Department of Health and Human Services
ATTN: CMS-1270-P
PO Box 8013
Baltimore, MD 21244-8013

RE: Comments regarding CMS-1270-P/Competitive Bidding

We are a small Rehab & Adaptive equipment company located in Massachusetts. Eighty-five percent of what our organization provides is customized wheelchairs & adaptive seating systems for individuals who have been diagnosed as having permanent loss of mobility. We work closely with the clinicians (physical therapists and physicians) to ensure that all therapeutic goals are met. The remaining 15% is standard dme & daily living aids. We do not provide oxygen or nutrition.

We employ 7 people in our organization, 2 of which are CRTS credentialed, combined years of employee experience in our industry is well over 50 years. In our organization 5th year of business we are focusing on becoming accredited. We will be having our site visit for CHAPS accreditation in the fall 2006. This has been an expensive undertaking and a true commitment to our business believes that we meet or exceed the accrediting bodies' standards.

I wanted to take time to voice our opinion on at least 2 topics within the document.

Elimination of providers
CMS should consult with the small business bureau- administration to better understand what the impact will be on small businesses. Ultimate Mobility, Inc. is part of the 90 % of the providers that this will impact. The implement date does not even allow us an opportunity to network with other providers to even try to compete against the national companies.

Criteria for item selection
CMS does not specify what products will be put up for bid, but it does say that selection will be based on high volume & potential savings. There needs be some attention paid to the equipment /service line (wheelchairs/POV's) that requires more than just purchase power but professionals that are working in conjunction with the medical community to improve the potential of people with disabilities.

There remains to be many areas that require further clarifications and I know our state and regional associations have also made formal comment back to CMS. We feel it's important for you to hear yet another voice, a small independent provider that takes pride in servicing Medicare beneficiaries in central Massachusetts.

Thank you for taking the time to review my comments.

Kelly O'Day
General Manager

Submitter : **Mrs. Sandra Canally, RN** **Date: 06/29/2006**

Organization : **The Compliance Team, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Comments and Recommendations regarding NPRM
DMEPOS accreditation grandfathering

Sandra Canally, RN
President
The Compliance Team, Inc.
Exemplary Provider" Accreditation Programs
USA 1 215 654 9110
www.exemplaryprovider.com

At the most recent Program Advisory and Oversight Committee meeting in Baltimore on May 22-23 there were numerous calls from members of the committee and concerned industry stakeholders for the Centers for Medicare and Medicaid Services to clarify its position on accreditation grandfathering ; for both providers who are currently accredited as well as for those who seek DMEPOS accreditation prior to the full implementation of the Medicare Modernization Act of 2003. In addition, it was also pointed out that there are tens of thousands of providers holding Medicare DMEPOS billing numbers who are presently not accredited.
It appears that the overwhelming majority of these unaccredited providers are electing not to enroll in any accreditation program until CMS announces the approved accrediting organizations or agrees to accept on an interim basis those providers that have been accredited by one of the identified DMEPOS accrediting bodies.
The nationally recognized accreditation organizations that were identified by the CMS at the first PAOC meeting in Fall 2004 are: ABC/BOC, ACHC, CHAP, JCAHO and The Compliance Team, Inc.
Based on our extensive conversations with prospective participants in the Compliance Team s Exemplary Provider" Accreditation Program for DMEPOS, and on reports from around the country from industry observers, providers are indeed fence sitting when it comes to choosing an accreditation program. Given the uncertainty surrounding the accreditation grandfathering issue, their hesitancy is understandable. It is our belief that with 2007 fast approaching it is imperative that CMS move forward on a ruling that protects providers who choose to enroll in one of the identified accreditation programs prior to the full implementation of the Medicare Modernization Act.
By removing the uncertainties that surround the accreditation grandfathering issue, providers will be more likely to get off the fence and start an accreditation process now without the concern that their choice of an accrediting body could jeopardize their Part B eligibility. Likewise, the Compliance Team and the other DMEPOS accrediting bodies could more quickly ramp up our capabilities to meet the looming accreditation logjam that lies ahead, and thereby help CMS facilitate a smoother implementation of the MMA.

Based on these observations, our recommendations are as follows:

(1) CMS needs to immediately announce that it will recognize, on an interim basis, the accreditation programs of the nationally recognized DMEPOS accrediting bodies that were identified at the first PAOC meeting in Fall 2004.

(2) Those providers holding a valid Certificate of Accreditation from any of the DMEPOS accrediting bodies that CMS identified in Fall 2004 should be permitted to continue its participation in Medicare until January 31, 2009. After that date, all providers must show evidence that they maintain a valid Certificate of Accreditation from an approved DMEPOS accrediting body.

(3) Providers not accredited as of the start of the MMA implementation (January 1, 2007) but who are working towards accreditation as evidenced by their active enrolment in one of the CMS identified DMEPOS accreditation programs will be permitted to continue their participation in Medicare programs for a grace period of one-year. Upon the end of the grace period, providers must produce a valid Certificate of Accreditation from the CMS identified DMEPOS accrediting body, or they risk losing their Part B eligibility.

(4) Starting February 1, 2009, all providers who wish to participate in Medicare programs must show evidence that they hold a valid Certificate of Accreditation from a CMS approved DMEPOS accrediting body.

CMS-1270-P-897-Attach-1.DOC

Submitter : Mr. James Potasiewicz **Date:** 06/29/2006

Organization : Direct Healthcare Supply

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-898-Attach-1.DOC

June 29, 2006

To: www.cms.hhs.gov/erulemaking
From: Direct Healthcare Supply PO Box 309 Hudson, OH 44236
RE: File Code CMS-1270-P

After reviewing Proposed Rule CMS-1270-P, we have concluded that Competitive Bidding cannot be efficiently implemented by Fall 2006 for the following reasons:

Impact on Beneficiaries:

- Medicare Beneficiaries deserve the opportunity to be made aware of the potential effects of Competitive Bidding on how they will have access to much needed life saving supplies. They should also be able to respond with comments prior to a final rule.

- The plans and processes by which they will be educated on the program need to be laid out in detail in the final rule. Medicare Part D is an example of a program where Beneficiaries felt uninformed prior to implementation.

- The impact of Competitive Bidding on Beneficiaries' quality of care should be a major concern. Also, will reducing access to DME products and decreasing time of benefit (such as oxygen coverage) reduce their Part B out of pocket costs but increase their Part A out of pocket costs through an increase in Emergency Room visits and hospitalizations?

Impact on Healthcare Professionals:

- There is no data in the proposed rule which considers the time and financial impact upon Healthcare Professionals. They will have patients who are in Competitive Bidding areas and patients who are not in Competitive Bidding areas. They will be concerned about quality of care and reasonable access to quality products as well as the paperwork and documentation burdens that will be placed upon them for new CMNs and physician orders because of Beneficiaries having to change suppliers or traveling and needing additional CMNs and written orders.

Impact on CMS:

- The infrastructure needed to implement this Program is enormous and the Implementation Contractors will need more than just a few months to design and implement the plans that will provide direction to the DMERCs. Additionally, the DMERCs will need adequate time to implement and test the directives from the Implementation Contractors.

- Competitive Bidding will significantly increase operating expenses to manage the DMEPOS program. Is the Program start-up and implementation fully funded by Congress or is it going to be funded through "potential savings"?

Impact on CMS, continued:

- There are proposals contained in the rule, such as the rebate option, the networking option, suppliers sub-contracting and sharing revenue which conflict with current Medicare policies and procedures. These conflicts will need to be resolved and implementation clearly defined prior to the final rule. Implementation of any one of these will be arduous and any unresolved problems will delay claim payment thereby affecting a supplier's viability and ultimately the Beneficiaries' access to life sustaining supplies.

Impact on Accreditation Agencies:

- The proposed time lines for Accreditation will swamp any of the Accreditation Agencies chosen by CMS to implement the quality standards. A "grace period" is an unrealistic solution. Allow adequate time for suppliers to become accredited before any initial bidding.

Impact on Suppliers:

- There is no adequate financial impact data on suppliers included in the proposed rule. The Florida and Texas Demonstration Projects showed a minimal impact based on a very limited local test.

- 90% of CMS suppliers are small businesses. The proposed rule mentions protecting small businesses but puts no provisions in place to do so. Some reasonable method to ensure the viability of a significant number of small business needs to be put in place prior to the final rule.

- What will be the impact of a net loss of supplier jobs and therefore a decrease in tax revenue on a local, state and national level?

- The proposal restricting a supplier's ability to sell their business needs to be defined very clearly so that it does not create an unfair restraint of trade. Additional infrastructure will be needed to evaluate all proposed supplier sales.

CMS-1270-P, as proposed, cannot be implemented by Fall 2006. We ask that CMS request an implementation extension from Congress and allow more time to develop a revamped proposed rule.

Additional Comments:

Section I. H. Quality Standards and Section I.I. Accreditation:

- The implementation of Supplier Quality Standards and Accreditation should enhance the quality of services provided to Beneficiaries if the Standards and Accreditation requirements are instituted and enforced on a uniform, nationwide basis.

- The phase in approach creates problems with the bid process itself. A provider could submit a winning bid but not become accredited by the time deadline. Their bid would unfairly be used to determine the pivotal price even though they never had to supply products.

Recommendation: Delay the initial implementation and require that all suppliers must be accredited PRIOR to submitting bids.

Section II.B. Competitive Bidding Implementation Contractor:

- A concern in this section is the statement that "...we believe that this approach would both lower costs and ensure regional consistency..."

- The current four DMERCs often have differing interpretations of the same requirements, such as what specific documentation is required for a power wheel chair or for testing blood glucose over the usual amounts.

Recommendation: Regional inconsistencies must be eliminated. The CBIC should be established, structured and managed to ensure national consistency.

Section II.C.3.a through c. Rental DME Items:

- The areas concerning both oxygen and other capped rentals should be changed to mandate that a Supplier providing an oxygen or capped rental item prior to any Competitive Bidding in an MSA must continue to furnish & service the capped rental item until the capped rental period is completed and title to the item is transferred to the beneficiary. These suppliers were willing to provide these rentals before Competitive Bidding and deserve the opportunity to finish recouping their investment.

- Conversely, no supplier should be required to begin renting capped rental items in the middle of a capped rental cycle. For example, if a supplier has to supply a capped rental item for the last 6 months of the rental cycle, the supplier receives only 45% of the single payment amount which does not cover the supplier's cost to acquire the rental item.

Recommendation: "Grandfathering" should be mandatory not optional.

Section II.4 Payment Adjustment to Account for Inflation:

- This has a significant impact on determining a bid submission.

Recommendation: Remove the current freeze on fee schedules and implement the suggested payment adjustments.

Section II.5. Authority to Adjust Payments in Other Areas:

- This section of the proposed rule creates a defacto national Competitive Bidding scenario effective January 1, 2009 for MSAs not included in Competitive Bidding.

- The lowest bid for a single item, anywhere in the country, could be used to establish the single payment amount for all areas not involved in Competitive Bidding without providers having the opportunity to bid.

Recommendation: This proposal should be eliminated.

Section II.6. Requirement to Obtain Competitively Bid Items from a Contract Supplier:

- The intent of this section to deal with summer/winter residence issues seems clear, it creates the need for clear process to inform beneficiaries of this requirement.

- A secure, accessible beneficiary database that suppliers with a valid Medicare supplier number could access to determine if a beneficiary falls into a particular CBA. These will now be zip code based instead of State of permanent residence based. Because of this suppliers must have an efficient electronic method to determine if a beneficiary falls within any given CBA.

- An area for potential problems is the statement "We propose that if a beneficiary is not visiting another area but is merely receiving competitively bid items from a supplier located outside but near the boundary of the competitive bidding area, the proposed travel exemption would not apply."

- What about beneficiaries with both summer and winter residences who change their "permanent residence" with Social Security every time they move between their two residences?

Recommendation: Clarify and simplify the explanation of this section, especially the definition of "outside but near".

Section II.D.1.a. Selection of MSA for 2007:

- Competition for market share among winning bidders will only happen if there is a sizable number of winning bidders.
- The proposed "capacity" determination is simply a guess provided by a supplier. For example, a supplier who in the previous year provided 500 units of a product in an MSA could state their capacity as 20,000 for the same MSA in the bidding process.

Recommendation: For the bidding process, an individual suppliers potential capacity should limited to a 20 percent increase over the number they supplied in the previous year.

Section II.D.2.c. National or Regional Mail Order Competitive Bidding Program:

- Are Beneficiaries being given any choice or is this designed to allow a small number of suppliers to drive everyone else out of competitive bidding for these products?
- This has the potential to severely restrict the number of potential winning bidders and create an anti-competitive situation since a small number of large suppliers dominate this market.
- If mail order CB must be included, the idea suggested in Section II.L. Opportunity for Networks that "We propose that the network member's market shares for competitive bid item(s) when added together, cannot exceed 20 percent of the Medicare market within a competitive bidding area." should also be applied to any regional or national mail order competitive bidding area. This would prevent a very small number of suppliers from creating an anti-competitive environment.
- Would suppliers who submit bids for a mail order competitive bid be allowed to submit bids in a "regular" CBA or would this not be allowed?
- How would "non-mail order" suppliers be differentiated from mail order suppliers? Would they have to physically deliver products versus using the Postal Service or UPS? How would this be verified or audited?

Recommendation: A national or regional mail order competitive bidding program should be totally deleted from this proposal.

- As to the alternative that all replacement supplies be mail order only.

Recommendation: This proposal should also be deleted because it creates the same anti-competitive scenario as mail order competitive bidding.

Section II.F.1. Providers:

- Clarification is needed for "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 appears to conflict with current Medicare policies and procedures.

Recommendation: Define how does a non-contract provider subcontract to use a contract provider to furnish supplies without violating current policies.

Section II.G.1. Quality Standards and Accreditation:

- The "grace period" provision of this section states "If a supplier does not then successfully attain accreditation, we will suspend or terminate the supplier contract." This can affect the pivotal bid determination in an unfair way since this supplier was never required to provide products at the bid price.

Recommendation: All suppliers should be required to meet the quality standards and to be accredited by one of the selected accrediting organizations PRIOR to submitting bids.

Section II.G.3. Financial Standards:

Recommendation: The financial standards should be modeled after the criteria used by the national accrediting organizations but who is going to audit their validity?

Section II.G.4.a. Market Demand and Supplier Capacity:

- Asking suppliers how many units they are willing and capable of supplying at the bid price has a great deal of impact on determining the pivotal bid.
- All suppliers who meet the quality standards and accreditation should be able to increase their total capacity.
- Please clarify if a supplier's stated capacity is a bid commitment to supply that volume or an estimate?
- Please clarify what happens if a given supplier states that they can supply more than the calculated demand for an item in a given CBA? Does this lock out all other suppliers and create a sole source scenario?

Recommendation: For the bidding process, an individual suppliers potential capacity should limited to a 20 percent increase over the number they supplied in the previous year.

Section II. G.4.c. Determine the Pivotal Bid:

- No supplier capacity should account for more than 20 percent of expected demand.
- ALL winning bidders at or below the pivotal bid price should be considered winning bidders regardless of "ties" at the pivotal bid level.

Recommendation: Create beneficiary choice and opportunity for multiple not several suppliers.

Section II. G.4.d. Assurance of Savings:

- This section states that any bid higher than the current fee schedule amount will not be accepted.
- There are current product categories and items being provided largely on an "unassigned claim basis" because the current fee schedule amounts are too low. This was the case in the demonstration projects for surgical dressings.
- Fee schedule amounts for ostomy items are almost always lower than a suppliers cost to acquire them.

Recommendation: Some provision needs to be put in place to correct such fee schedules.

Section II.H. Rebate Program:

- It is contrary to current CMS/DMERC policy whereby Medicare must be billed net of rebates.
- It creates a scenario where the beneficiary would actually profit from the rebate if Medicare paid 80%, a supplemental insurer paid the 20% and the rebate is sent to the beneficiary.
- Regardless of any restrictions on advertising, rebate availability will be communicated in other ways and creates rampant possibilities for fraud and abuse.
- The beneficiary benefits from the Competitive bidding process through stable or reduced co-pays which is contrary to rapidly rising product costs in the retail sector.

Recommendation: The proposal to allow rebates should be dropped completely.

Section II.I.4. Furnishing Items to Beneficiaries Whose Permanent Residence is Within a CBA.

- "…we are proposing that the contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented".
- If a supplier has to supply a capped rental item for the last 6 months of the rental cycle, the supplier receives only 45% of the single payment amount, which does not cover the supplier's cost to acquire the rental item.
- This clause is an incentive to use the lowest cost product available regardless of quality.

Recommendation: No supplier should be required to begin renting capped rental items in the middle of a capped rental cycle.

Section II.I.5. Furnishing Items to Beneficiaries Whose Permanent Residence is Outside the CBA.

- The main issue is how CMS/Medicare is going to communicate this requirement to the beneficiary.
- Many beneficiaries today believe that most of the regulations that a supplier tries to enforce are simply that individual supplier's policy not Medicare regulations.

Recommendation: Create and communicate a clear explanation of how this will be communicated to the Beneficiaries.

Section II.I.7. Change of Ownership:

- We are concerned that the proposed rule provides legal authority to prevent a supplier from selling their business through regulation rather than through law?

- We agree with the strategy of not allowing a supplier to circumvent the bidding process through merger or acquisition but the proposed rule creates a restraint of trade situation and/or devalues the business of a supplier who decides to sell the company.

Recommendation: Clear guidelines must be determined and communicated for comment.

Section II.L. Opportunity for Networks:

- This concept is contrary to all current CMS/Medicare regulations and may be illegal.

Recommendation: Delete this proposal. The Network idea creates opportunities for fraud and abuse.

Section II.M.2. Beneficiary Education:

- Competitive bidding drastically alters the way beneficiaries will receive needed medical products and supplies.
- Medicare Part D is a perfect example of the information the beneficiaries need and the confusion created when they are not comfortable with the changes taking place.

Recommendation: A comprehensive education process would need to be organized and put in place before implementation of the CB process.

Section II.N. Monitoring and Complaint Services for the Competitive Bidding Program:

- This section states that it would be considered a serious problem if "contract suppliers furnishing items of inferior quality than those that they bid to furnish".

Recommendation: Clearly state how quality of items is going to be determined on a bid submission.

Section V.B. Anticipated Effects:

- This section states that the first round of bidding will take place in the Fall of 2006 with prices taking effect in October 2007.
- Suppliers will be submitting bid pricing that will not take effect until a full year later.
- Suppliers are expected to anticipate any increase in costs and guarantee pricing for the year it takes to award bids plus the first full year of the bidding cycle. For example, if bidding had taken place in the Fall of 2005, who could have anticipated the dramatic increase in freight charges due to rising gasoline prices.

Recommendation: Delay implementation until bid dates and contract start dates are no longer than 90 days apart.

Conclusions:

We recommend that implementation of Competitive Bidding be delayed until the numerous unresolved issues in the proposed rules can be clarified, modified and corrected. We are aware that CMS is attempting to meet a deadline imposed by law but please consider the negative impact on CMS if Competitive Bidding is rushed to implementation and causes grave problems and health risks for Medicare Beneficiaries.

Submitter : Mr. Ray McClure **Date:** 06/29/2006

Organization : Mr. Ray McClure

Category : Individual

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

This is not a true competitive bidding program it is a reduction in reimbursement program. The program will not allow you to participate unless your bid is less that the 2006 allowable fee. The 2006 fee come for 1987 pricing that has been reduced or frozen from any increase for at least 7 years. Capped payments and transferred rental equipment away for providers and gave it to patients. Their is no other business that the government contracts with that takes equipment in this manner. The requirments and cost of so many regulations, plus the cost of accreditation which amounts to 10% of all revenue collected just to comply. The cost to administrate this program will be more than any saving possible gained.

Regulatory Impact Analysis

Competitive bidding

Submitter : **Julia McGlone** **Date: 06/29/2006**

Organization : **HomeReach, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

See attached Word Document.

CMS-1270-P-900-Attach-1.DOC

HomeReach
OhioHealth

June 29, 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:

HomeReach, 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.

HomeReach, Inc. is a comprehensive home health organization serving the needs of patients and families in Central Ohio. HomeReach is a wholly owned subsidiary of OhioHealth since 1983. OhioHealth is the largest employer in Central Ohio utilizing the skills and talents of approximately 17,000 individuals. HomeReach, Inc.'s mission is to "Improve the health of those we serve." In order to accomplish this mission, we need to have continued adequate funding to support the high level of services that we provide to our patients. HomeReach Pharmacy, Inc. annually provides services to over 1500 home infusion, enteral, and respiratory patients. The existence of our service line supports the mission of OhioHealth and brings our level of care full circle.

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 b ut a lso t o o ther D MEPOS it ems t hat w ill c ontinue t o b e r eimbursed 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 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 inf usion therapy is no w div ided between P art B and t he ne w P art D p rescription dr ug 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 require extraordinary expertise for safe and effective provision. These drugs 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 614-566-0850.

Sincerely,

Julia A. McGlone, R.Ph., M.S.
Pharmacist

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