Submitter : Dr. Paul Kesselman

Date: 06/29/2006

Organization : Dr Paul Kesselman

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-766-Attach-1.TXT

Paul Kesselman DPM FACFAS
980 East 12th Street
Brooklyn NY 11230
Tel 718-338-7878 Fax 718-338-7879

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS–1270–P,
Mail Stop C4–26–05,
7500 Security Boulevard,
Baltimore, MD 21244–1850.

June 26 2006

Re: COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, and SUPPLIES

Dear Sir/Madam:

After a thorough review of the proposed "Competitive Acquisition Program, I am significantly troubled about the impact this will have on my patient's ability to receive and my ability as a podiatric physician to deliver effective and quality health care. There are several major areas of concern:

1) Podiatric Patients to Receive Prejudicial Treatment by CMS

During a recent meeting, CMS officials confirmed that podiatric physicians will be eligible to participate in the competitive bidding program, but these officials also indicated that CMS **DID NOT** use the 1861(r) definition of physician, which includes podiatric physicians, in defining individuals who may bid to supply DMEPOS to only their patients. Instead, CMS officials used the more restrictive 1861(r)(1) definition of physician, which restricts its definition of physician to MDs or DO's.

This does not allow podiatrists the same abilities as MD and DO physicians to competitively bid in order to supply DMEPOS items to their patients, and has the real potential to be a real and present danger to podiatric patients.

As a result, of using1861(r)(1) definition of physician, podiatric physicians will be expected to bid to supply DMEPOS items to an entire metropolitan statistical area (MSA) rather than their own patients. This will necessitate podiatric physicians to compete with large, traditional DMEPOS suppliers for the right to supply items to Medicare beneficiaries.

This is clearly biased against podiatrists and our patients. It has the potential to cause significant harm to our patients, both those who may be acutely injured, and cannot tolerate delays in obtaining care, and those who with chronic disease processes.

A daily example in my office is that of an acutely injured patient with a foot or ankle fracture that has been reduced and now requires immobilization. Instead of the patient receiving a cam walker and crutches from my office, under the proposed competitive bidding system, they may now be required to go cross town to obtain these medically necessary services. That same patient seen by an MD or DO physician would not face the potential harm solely created by a proposed new system of reimbursement, and not due to my level of expertise as a podiatric physician.

Podiatrists just as MD and DO physicians, primarily supply DME supplies only to their current patients. As physicians we do not generally advertise ourselves as DME suppliers to the general public and only offer DME products as services which are integral to their medical services.

Under the proposed system, patients of podiatric physicians, many of whom are poor and elderly would be unduly punished. These patients will now be required to make several visits to both their podiatrist and another supplier in order to be furnished with needed medical supplies. These same patients seeking similar care from an MD would not be so punished. Since many podiatric patients suffer from multiple diseases this will be create significant problems in acquiring medically necessary products which they would otherwise have unfettered access to from the physician who is treating them. This will certainly create logistical problems for the patients and their families, potentially resulting in further medical complications.

Federally funded transportation assistance is now the only way many of our patients obtain medical care. Should the podiatric physician not be unable to deliver their acutely required care, patients will be required to go to other providers in order to receive their DME items. This will result in the federal government paying for additional trips to multiple providers in order for patients to obtain necessary supplies. As a result the total cost of furnishing DME products to podiatric patients under the proposed system may exceed the current fee for service system, and would actually higher than that when provided by an MD/DO supplier. I do not believe that any of these scenarios were the intent of the original authors of the competitive bid system.

As a result of this bias, the physician definition selected by CMS officials will negatively impact podiatrists' ability to render both effective and quality medical care to our patients. I am therefore urging you to change the definition of physician within the proposed competitive bidding program to include podiatrists.

2) Physician Need to Participate in Competitive Bidding

A recent review of the 2004 data on DMEPOS services reveals that all physician categories (MD DPM DO) are responsible for less than 4% of the DMEPOS services provided. Creating more restrictions and burdens on these physician categories, many of whom are small businesses, will result in most electing not to participate in the competitive bidding process. This will certainly be to the detriment of patient care and will most certainly not be an effective means of cost containment. I therefore question the efficacy of requiring any physician group in participating in competitive bidding s as a means of reducing expenditures on DMEPOS.

3) Cost of Travel to obtain DMEPOS

Patients who require acutely injured and/or have other urgent medical needs are often in no position to travel to another provider after being initially assessed and immobilized. In particular, the elderly often have multiple co-morbidities and may have required special arrangements for transportation to get to their doctors' offices. Requiring these frail patients to go to another provider for services which otherwise are readily obtained at my and many other physicians' offices will create an undue stress for them and increase the real costs of delivering their health care. Many may select to delay medically necessary treatment, others will elect to go to emergency rooms, and others will select to go to another provider to obtain the necessary DMEPOS service, via publicly funded transportation as per the proposed guidelines. Any of these possibilities will increase the real costs of delivering any given DMEPOS.

Should the patient elect to delay seeking care, this will ultimately allow their wounds, fractures and other disease states to progressively worsen. The potential escalation for an inexpensive minor problem into one which would require additional and more expensive sophisticated medical/surgical services is especially problematic to me as a podiatric physician. Having thoroughly read the proposed competitive bid program, I see no evidence that this has been factored into any theoretical cost savings postulated by CMS.

Particularly troublesome is what factoring in transportation costs may do to the real costs of delivering inexpensive off-the-shelf devices and/or dressings with present reimbursements at under a few hundred dollars. Adding in transportation and aide costs funded through the federal Medicaid programs, as well as municipally assisted transportation services through "Access A Ride Programs" would cause the real costs of providing these services, all paid for, or subsidized by the Federal Government to be exorbitantly higher that at present.
This would also create an undue financial stress on already strapped local and state government budgets to meet any additional costs not already paid for by the Federal Government.

4) Additional Expenses for Rural Patients

Patients who live in rural areas could be required to travel long distances in order to obtain necessary services, which up to this time could have been provided for locally in their doctor's office. This too would create long delays in delivering effective and timely patient care. There would also be a disproportionate increase in the financial costs necessary to transport patients' long distances in these areas.

5) The end of the small DMEPOS Supplier and easy patient access

Podiatrists and other small DMEPOS suppliers cannot afford retaining cost consultants employed by many large DMEPOS suppliers in order to determine what might be a winning bid. This will effectively eliminate the ability of small companies providing easy access to patients out of business.
This will in the long run result in large corporations rendering ineffective less accessible care to those who most need it.
Impeding access to any medically necessary service, will ultimately in the long run, cost Medicare more money as complications from lack of easy access multiply.

6) The cost of monitoring bids

A competitive bidding system would invite more fraud and abuse by large DME dealers who could get the "inside tract" on bidding, identical to what transpires with many other publicly funded works projects. The cost of monitoring this bidding system would also create another financial burden for the government significantly reducing any projected savings otherwise created.

7) Generic vs. Brand Name Supplies

The ability of the DME service provider to provide a generic device due to cost/profit restrictions on bids, rather than what was originally prescribed for by the physician, may cause significant problems for patients.

In the case of specially required off the shelf devices for patients who would not fit into a generic device (i.e. an obese patient with a fracture would not be able to fit into most commercially available CAM walkers, and requires a more expensive type such as one of the Bledsoe devices). It is already almost impossible to fit patients like this at today's current rates, without the supplier taking an economic loss. Further rate reductions will either force suppliers to refuse supplying this type of patient, or force the supplier to ask for a prescription for a custom fracture brace, costing hundreds if not thousands of dollars more.

This will expose the patient to an increased risk of functional limb loss if they cannot find a suitable supplier as well as increased costs for those previously outlined in paragraphs 1-5 not yet factored in.

8. Therapeutic Foot Wear and Surgical Dressings.

Upon reviewing the proposal it appears that these two items are exempt from competitive bidding, I cannot find an exact resource which would specifically state these items are exempt. Despite assurances from Dr. Edwards the SADMERC director, to their exclusion, I would urge CMS to specifically state which product items, by category, are exempt. This should be posted not only in the Federal Register, but on a website which would be updated on a regular routine basis.

Therapeutic Shoes for diabetics require fitting by professionals who have an intimate knowledge of foot anatomy and diabetic foot pathology. Doctors of Podiatric Medicine treat millions of patients with diabetic foot pathology and have intimate knowledge of their patient's medical histories, pathologies far superior to medical suppliers. Doctors of Podiatric Medicine are in a unique position to determine which shoe would be most suitable for their patients' individual needs. Many podiatrists have unfortunately been witness to the devastating effects a poorly fitting shoe has caused by medical suppliers who are untrained in proper shoe fitting techniques. These often result in significant ulcerations, infections and limb loss, at a substantial cost to the Medicare program. Simultaneously we are aware of the significant preventative benefits appropriately fitted shoes can provide, and the millions of dollars in costs savings that this type of preventative care provides to the Medicare program. The American Podiatric Medical Association and I along with other professional organizations have been working for the last several years with SADMERC's medical director, Dr. Edwards to revamp the Medicare Therapeutic Shoe Bill to insure that patients receive shoes from qualified providers (such as podiatrists). The result to diabetic patients could be catastrophic if podiatrists were unable to continue to service these patients with appropriate therapeutic shoes and would certainly result in much higher financial expenditures for the Medicare program.

Surgical Dressings:
Similarly because of our ongoing treatment of diabetic foot ulcers, patients need to have easy access to dressings which are most efficacious for their specific wounds, and not driven solely by the profit motives of a large medical/surgical supplier. Doctors of Podiatric Medicine are in a unique position to understand the needs of their patients' wounds, and should be able to continue to provide their patients with the best surgical dressings available.

By allowing podiatrists, who generally have long term relationships with a higher level of responsibility level to their patients than paraprofessional DMEPOS suppliers, to continue to function as their patients' DMEPOS suppliers, patients can be assured that they are receiving the correct products based on medically necessity, and not motivated purely by profit.

Summary and Suggested Changes:

A) Summary

For the above stated reasons the competitive bidding process, particularly as it would apply to podiatric physicians is flawed. It is therefore my opinion that the proposed competitive system will most certainly result in a system which:

1) Will not realize the savings projected;
2) May result in higher expenditures than through the current system for many services;
3) Unduly interferes with the doctor patient relationship, particularly for podiatrists' and our patients;
4) Places patients in harms way solely based on a system of reimbursement, and not based on provider licensure or expertise.

Suggested Changes:

I am therefore urging you to implement the following changes to the competitive bidding system:

1) Podiatrists should be included in your definition of physician with regards to participation in the competitive bidding system, and all physician specialty types should be exempt from the requirement in participating in the competitive bidding process so long as they are only supplying their own patients.
2) Some safe harbor should be created for small suppliers in order to assure patients easy access in obtaining DMEPOS supplies.
3) An any willing provider ruling stipulating that any provider, so long as they have submitted a bid, may choose to accept the winning bid fee schedule in their area.
4) Podiatrists and other physicians should be exempt from the inventory, toll free and other high cost requirements of quality standards proposals and proposed competitive bidding system. The APMA AMA and other physician specialty societies should be entrusted with setting up standards in mutual cooperation with CMS that would be unique for physicians.
5) Insure that podiatrists and other physicians have the ability to provide necessary DME services within the legal scopes of their practices.
6) Exclude off the shelf devices such as therapeutic shoes, surgical dressings orthopedic immobilization devices including CAM Walkers, crutches, canes from the competitive bidding proposal.

I look forward to continuing this dialogue and am prepared to answer any further questions you may have.

Sincerely,

Paul Kesselman DPM FACFAS

Paul Kesselman DPM FACFAS

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

I am 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 regularly treat conditions requiring ankle walkers, splints and braces which allow direction and continuity in 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.

This patient s regularly rely on family or public transportation for appointments. If I am forced to send the patient elsewhere this treatment process can be prolonged due to further transport needed. Fracture, ulcers and sprains should be addressed with proper immobilization during the visit. Further injury or exasperation of injury may occur secondary to the delay in treatment.

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,

Lora Baker, DPM

Submitter : Ms. Margaret Antoine **Date:** 06/29/2006

Organization : West End Orthopaedic Clinic

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

My name is Margaret Antoine. I am an occupational therapist as well as a certified hand therapist (CHT.) The latter requires passing a certification examination that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience. I have 30 years experience treating upper extremity disorders. I continue to treat both Medicare and Medicaid beneficiaries who frequently require custom and/or off the shelf orthoses, especially thumb splints which are required for the treatment of osteoarthritis in an effort to reduce pain and try to prevent surgery.

As a hand therapist, Ilook at the needs of the patient. As a provider and supplier I evaluate the appropriateness of hand splints and fit them accordingly. I simultaneously address functional and ADL needs, precautions, wearing schedules etc. As opposed to other suppliers of DMEPOS, I incorporate splints into an entire treatment plan.

I am asking that you revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries without additional constraints. The proposed regulation can interfere with patient care. We have already found that splints provided by a supplier often do not fit appropriately or not the one specified by a physician. We have had to send them back to either get the appropriate one or they choose to avoid the inconvenience and are left unprotected. We have found that if we charge the patient what we pay for an item, they are often willing to pay for it. Therefore the profit margin on these items are about nil. This is contrary to what suppliers do.

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

Sincerely,

Margaret Antoine, MS, OTL, CHT

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

Organization : The RRT Group

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment for comments

CMS-1270-P-769-Attach-1.DOC

The RRT Group, Inc.
81 South Terminal Drive
Plainview, NY 11803
Phone 516-256-0008 Fax 516-256-0009

June 29, 2006

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

Dear Dr. McClellan,

The RRT Group is a small DME company that employs 20 people. The impact of the Competitive Bidding on this company will be severe. If the implementation is not done thoughtfully and with understanding of the consequences it will be devastating to us and all the other small DME providers in the area. We are asking that you (CMS) role this process out appropriately by considering the following.

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 patients in a Skilled Nursing Facility (SNF). If there are no standards to apply to a company that only services the SNF community how they can be included in the accreditation process. CMS has to either issue standards or exclude SNF residents from consolidated billing.

Conditions for Awarding Contracts

An Appropriate Screening Process Must Be Developed To Determine Which Submitted Bids Will Qualify For Consideration. (Proposed §414.414) CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid is processed for further review and consideration as to pricing.

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

Do Not Make It Harder For Providers To Sell Their Businesses. (Proposed §414.414(e)) The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement that contracted supplier and its new ownership should retain its contract.

Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts. (Proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.

Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid. (Proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required.

Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a

"compilation", "review", or "audit" report from an independent Certified Public Accountant. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship and the potential borrowing capacity of the company. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Total Debt to Total Asset Ratio" (should be no higher than ___ and "Current Assets to Current Liabilities" (should be no lower than ___).

Use A Factor Of 130% In Calculating Supplier Capacity Needed In An MSA. (Proposed §414.414(e)) In determining the number of suppliers needed, CMS should apply a factor of 130% to the identified Market Demand. This would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payors, and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies. (Proposed §414.414(e)) Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of products provided to Medicare beneficiaries the previous year.

Company Should Be Able To Bid For Only A Portion Of An MSA. The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.

Do Not Restrict Submitted Bid Amounts. (Proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical need.

Terms of Contracts

Eliminate Requirement That Winning Supplier Must Repair Patient-Owned Equipment. (Proposed §414.422(c)) The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these costs into their bids.

Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment. (Proposed §414.422(c))

Restrictions On What Products Can Be Supplied To Individuals Outside The Medicare Program Must Be Eliminated. (Proposed §414.422) The terms and conditions section states "non-discrimination- meaning that beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier provides to other customers". This is unrealistic. In order for suppliers to bid lower prices they must either provide lower cost products or reduced services. Competitive bidding should be more like a contract with managed care where formularies are used. Medicare will be fully aware of what Medicare beneficiaries will receive, but it should not limit what customers outside of the competitive biding program receive.

Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier. (Proposed §414.422(c)) Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

Opportunity to Participate by Small Supplies Opportunity for Networks

Require That A Minimum Number Of Small Suppliers Be Included In The Wining Contract Suppliers. ("Opportunity for Participation by Small Suppliers) At a minimum, small business suppliers in an amount equal to the number of winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount.

Clarify Network Regulations. (Proposed §414.418) What are structural requirements? Who can do billing and collection?

Do Not Place Limitations On Formation Of Networks. (Proposed §414.418) Market share limitations should be removed (these do not apply to single entities that bid). Network members should be able to also bid through other means.

Payment Basis

Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowable. (Proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in non-bid area, CMS should pay the traditional Medicare allowable amount that corresponds with the beneficiary's permanent residence for up to five months.

Provide Details On How Pricing Will Be Used After January 1, 2009. CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to use the payment information determined under that competitive bidding programs to adjust payments amount for the same DMEPOS in areas not included in the competitive bidding program. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

Different Alternatives To Gap Filling Must Be Used. (Proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the gap filling pricing methodology. The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process.

Develop More Equitable System To Price HCPCs Changes. CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. This is not equitable solution and a more appropriate procedure must be developed.

Rebate Provisions Must Be Eliminated. (Proposed §414.416(c)) The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

Provide More Details On The "Composite Bid" Calculation. The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should provide suppliers with the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

Please truly consider the issues presented here, this is my livelihood

Respectfully Submitted

James L Cooke RRT
VP Patient Services
The RRT Group, Inc.

Submitter : Ms. Sira Botess

Date: 06/29/2006

Organization : Healthsouth

Category : Comprehensive Outpatient Rehabilitation Facility

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

As an Certified Hand therapist/Occupational therapist with 12 yrs of experience, I am convinced that my patients would suffer if this proposal should be approved. I work with acutely injured/traumatized hands in need of custom splints to immobilize injuries but also maximize function. As a clinician I need to be able to asses and manufacture a clinically appropriate device for each individual hand that I treat.
My patients can not be placed on hold 1)for a bid to be submitted, and 2) would generally not benefit from an off-the-shelve device.
As an experienced, and extensively trained therapist I am one of a select group of qualified professionals that are able to provide custom splinting for any type of upper extremity disability. This proposition would be infringing on my clinical reasoning,and judgement, and ability to provide my patients with qualitative appropriate intervention. I strongly oppose this proposition.

Submitter : Mrs. Maribeth Brinton

Date: 06/29/2006

Organization : Mrs. Maribeth Brinton

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : Mr. Kline Miller **Date:** 06/29/2006

Organization : Capital Medical and Surgical, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

Since the goal of this Competitive bid process is to reduce the amount of money spent on Medicare, all providers, whether they are the lowest bidder or not. The new low bid amount will be the new fee schedule, and if a company wants to participate at the fee schedule, they can choose to do so.

GENERAL

GENERAL

I feel the best way for the competitive bidding to work, and be fair to all, is use the lowest bid price as the "new" fee schedule. There are too many small providers, like my company, that might be put out of business if we are not the low bidder. So, with the "new" fee schedule, and all providers are able to provide products and services, this will enable business to stay in business and adjust to the new pricing structure. The market will adjust to this change in the way of lower product cost from the manufactures and competition between the manufactures.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

I feel that Accreditation is an unnessary financial burden for a very small provider like my company. The large companies think being accrediated is a godd thisng because thay can afford it, and it reduces the compititon.

Submitter : Ms. alice platt **Date:** 06/29/2006

Organization : Ms. alice platt

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

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

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Freedom of Choice? I think not. The proposed bidding takes away choices for Medicare reciepients by decreasing the number of providers. With competitive bidding a winning bid can put many providers out of business if a provider can't accept the winning bid amount. Free Enterprise? The competitive bidding is going to put the small business owner out of business because they will not be able to compete with the large national companies.

All business should have to meet the quality standards before they are included in the competitive bidding process. This then sets the standards for all businesses and does not let a sub-par business skew the process for legitimate provider bids.

Offering rebates goes against the integrity Medicare has set by alliviating kickbacks and inducements.

CMS already controls the pricing for Medicare why spend additional money to come full circle just to lower allowables.

Capitalism or Communism, I have to wonder. I thought we still had the freedom to make our own choices to whom we give our business.

Submitter : Mrs. Maribeth Brinton **Date:** 06/29/2006

Organization : Mrs. Maribeth Brinton

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Re: Medicare proposed Rule on Competitive Bidding System for Certain Durable Medical Equipment, including Prefabricated Orthoses (splints)

Attention: CMS-1270-P

Opposed to Definition of Prefabricated Orthoses

Opposed to Competitive Bidding for Prefabricated Orthoses

Dear Administrator:

I would like to take this opportunity to comment on the proposed rule CMS-1270-P. I am currently receiving occupational therapy at a hand therapy facility. I can see that orthoses are a large part of the treatment for these patients. While most are custom fabricated, prefabricated orthoses are also supplied. When a therapist supplies a prefabricated orthoses, they also instruct the patient in precautions, use, timetables for changes, wound care, disease process, etc. They frequently change the angle of the orthoses, add custom components, adapt these orthoses for wounds, and otherwise customize these prefabricated orthoses for the patient s individual needs. I do not feel that this type of customization could be preformed by a non-therapist that was not aware of all the aspects of my care.

In addition, my therapist expresses doubt about her ability to win a competitive bid. She has a small facility, and stocks only those items needed in her practice. While she has a variety of orthoses specific to her practice, I have been told that she would be unable to stock large amounts of goods outside of her expertise. As she stocks the devices that she feels will work best (not necessarily the most inexpensive), she has a very small profit margin with these goods and will be unable to bid significantly under the current reimbursement. I am concerned that a supply facility will stock the most inexpensive orthoses in order to ensure a margin of profit, regardless of my needs.

I also have concerns re: the need to go to another facility for my prefabricated orthoses. Hand therapists work with very acute patients, who frequently need immediate protection. Are these patients supposed to get in their car and drive to another facility unprotected, and then possibly have to wait for an appropriate device that may or may not be stocked? And what about the instruction that a therapist typically gives when a splint is placed? It goes beyond how to put on and take off the device. Will I have to go back to the therapist, possibly incurring another charge for evaluation and treatment, in order to get the advice that would have been given to me for free if I had received the orthosis in the therapist s office?

Finally, under the definition of custom orthoses, you did not mention occupational and physical therapists. Since they are currently supplying these orthoses, I strongly disagree with the wording of this definition. These therapists routinely supply custom orthoses that are critical to the effective treatment of the upper extremity patient.

Please consider exempting therapists from the competitive bidding program. I fear that you will loose a very valuable professional in the distribution of prefabricated orthoses through this program, the hand therapist that has an in depth and intimate understanding of my injury and orthotic needs.

Thank you for your consideration.

Submitter : Mrs. Alice Platt **Date:** 06/29/2006

Organization : Mrs. Alice Platt

Category : Individual

Issue Areas/Comments

GENERAL

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Thank you for your consideration.

Submitter : **Ms. Eline Haukenes** **Date: 06/29/2006**

Organization : **Cortland Regional Medical Center Home Health Servi**

Category : **Home Health Facility**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I manage a small DME and Oxygen service company in a rural county in Upstate NY. We are JCAHO certified and are affiliated with the local hospital in this area. Our mission is to provide quality service and equipment to our community. It seems that the proposed legislation will eventually undermine this effort. The network solution remains very unclear and the costs associated with a network startup are unknown. Certainly, our ability to provide and control our supplier service to Medicare patients in our community will be compromised. I would suggest continued support of small providers by allowing us to continue to provided equipment and supplies to patients utilizing the accepted bid amount for our area.

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 28, 2006

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

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the Centers for Medicare and 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 believe that excluding podiatric physicians from the list of physicians that you are allowing to competitively bid to supply DMEPOS for their own patients undermines the purpose and spirit of your own regulation. As a current supplier, we have been following the exact regulatory requirements as all other DMEPOS suppliers, and would, of course, continue to do so in the future. The proper selection and timely application of these supplies is at least as much, if not more, a part of our daily treatment for patients as that which goes on in the offices of our counterparts.

If you believe that allowing this particular bidding process is a sound practice for MD s and DO s, then certainly this same rationale would apply for podiatric physicians.

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

Sincerely,

Brad A. Toll, D.P.M.

BAT/vk

Submitter : Mrs. JUDITH CHAIRES **Date:** 06/29/2006

Organization : Mrs. JUDITH CHAIRES

Category : Individual

Issue Areas/Comments

GENERAL

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Thank you for your consideration.

Submitter : Mrs. TERESA KEANE **Date:** 06/29/2006

Organization : Mrs. TERESA KEANE

Category : Individual

Issue Areas/Comments

GENERAL

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Thank you for your consideration.

Submitter : Mr. Dennis Trach **Date:** 06/29/2006

Organization : Associated Healthcare Systems Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-781-Attach-1.DOC

COMMENTS ON NPRM FOR COMPETITIVE BIDDING OF DEMPOS

SUBMITTED BY: Dennis Trach, Associated Healthcare Systems, Inc.

DATE DUE: June 29, 2006

General Comments

1. **Implementation Timeline.** The preparation a supplier has to do in order to bid is enormous. Smaller companies, including Small Businesses as defined by the SBA, do not have the personnel assets to prepare for the requirements identified in the NPRM and announced at the public PAOC meetings.
   Suppliers need a timeline to prepare their organization for each of the requirements. Preparing the bid documents are the least of the concerns. Accreditation, and preparation for it, cannot be done in a few months – the process, at a minimum, takes six months as any of the accreditation bodies requires proof that the processes it requires have been in place for a minimum of four months. There is no magic formula; accreditation is an involved process requiring a makeover of the entire organization and its processes. Identification of the "deeming" accreditation bodies has not even begun. How can you expect an organization to commit to accreditation without a list?
   CMS stated at the PAOC meeting that they do not recommend suppliers "suppose" that a long time accreditation agency will be selected.

   When you finally publish a timeline only the national companies and those lucky enough to have guessed right will be ready and qualified to bid. It almost seems CMS wants to exclude smaller suppliers even though they could meet the arduous requirements if given sufficient time to make themselves eligible to bid.

   Recommendation: Slow down, get it right, and let's have a fair bidding process. Rushing implementation hurts everyone. CMS saving my tax dollars does not mean I want to see the billions the Small Business Administration spends each year to promote small businesses should be squandered by putting them out of business. The impact of this program will have lasting effects on the industry which is the most economical of all the services CMS pays for – Homecare.

2. **Accreditation and Medicare Supplier Standards.** Both must be in place before the bidding begins. Suppliers have to be given **time** to meet the standards. The process is not accomplished overnight. Don't rush to implementation by wiping out the chance for competition.

3. **Accreditation.** In order to bid a supplier must first be accredited – to accept anything less violates the intent of the MMA and its insistence on quality standards. Promises to become accredited or a "grace period" are unacceptable. You either meet the standards or you don't.

4. **Qualified Bidder.** To bid in an MSA a supplier has have a location in or near (within 30 air miles of the border of the defined MSA or portion thereof). There are facts associated with this recommended requirement to bid:

   a. One of the requirements for accreditation is demonstrated compliance with State and Local laws. No supplier from outside the state containing an MSA or portion thereof can readily demonstrate that compliance. They surely cannot demonstrate it at a yet to be opened location.

   b. Accreditation agencies "accredit" a specific location – there is no such thing as a blanket granting of accreditation with the assumption that every location operates the same or will operate the same upon opening. The fact is it takes time to find and train a staff to ensure daily compliance with the standards of accreditation and to the Medicare Quality Standards – it should be recognized it is a process of education and compliance monitoring, not of assumptions and past history. Locations and branches must be trained and guided to compliance. Time is an important ingredient and any company would have a hard time to open and become accredited at a new location within a short period of time.

   c. A "qualified bidder" should be able to demonstrate it is serving beneficiaries within the MSA or portions thereof. Any accredited company/location within a reasonable service distance of the defined boundaries of an MSA should be eligible to bid if they can demonstrate they are currently serving beneficiaries within the MSA or portion thereof on which they are proposing to bid. Out of state companies should not be allowed to skew the pivotal bid when they don't yet have an investment in the area.

   d. Medicare numbers granted by the NSC are **by location** based on a visit and observation of Medicare standards (soon Quality Standards). The process of obtaining a new Medicare Supplier number is not short. When accreditation becomes mandatory, the process becomes longer – even with the assistance of a "corporate" compliance staff who attempt to export the corporate culture to a new location and staff.

5. **Financial Statements.** Small businesses and regional companies are usually privately owned. They operated on different accounting systems then do large and very large companies. There is no need for them to have either reviewed or audited financial statements. The expense of reviewed statements is in the $12,000 to $20,000 range for a small company; audited financial statements rise drastically. What do you hope to gain by insisting on audited statements? What are you really going to see that you cannot see on a combination of other documents?
   Again, this expense, with no guarantee of a successful bid, does not help small businesses – it hinders their ability to compete.
   Suggested alternatives: Past two years of company Tax Returns; Bank Letters attesting to the company's lines of credit; Credit reports; Dun and Bradstreet ratings; Year end and recent company Bank Statements; any other outside proof of the company's financial viability. I'm sure there are other verifiable documents that a qualified CPA could identify that would demonstrate the financial viability of a company if reviewed or audited financials are not practical. Companies who have not completed audited

financials would have to do so retroactively in order to bid in the first round. How can you add more expenses and expect a bid to save money for CMS?
If small businesses are small now, with the current fee schedule, how can you expect them to survive with the added expenses of audited financials and accreditation. **The audited financials will do nothing to increase or guarantee the quality of care when they will cost more than the cost of obtaining accreditation.**
Please find another way to determine financial viability.

6. **Qualifying Bids.** Develop and publish in the final rule a system for determining which bids are qualified for consideration. Create a list of reasonable and practical wickets that a bid must successfully pass through and eliminate those failing each **before they have any influence on the bidding process and pivotal bid.**

7. **Final Rule Review.** Give the PAOC a chance to comment to CMS before the final rule is published – that is why the MMA formed the committee – industry input.

8. **Small Business Opportunity.** The presumption that simply providing small businesses an *opportunity* to form networks meets the MMA mandate to include small businesses in the competitive bidding process is outright prejudice against the majority of businesses in the country.
Recommendation: Determine the total capacity required in an MSA or portion thereof then add 30 to 50 percent. Designate the 'excess' for a small business set aside.
Note: Small Businesses who elect to participate in this program must bid but not be part of the equation to determine the pivotal bid. Have them designate themselves upfront as applying for the set side and separate them from the other bids.
When the number of required contract providers is determined to meet 100% of the total capacity, provide for an equal number of small businesses to cover the 'excess' capacity. As long as a small business is otherwise qualified to bid, even though they have bid at or above the pivotal bid, rank them according to a separate set of standards amongst themselves and offer the required number a contract at the final bid price. The SBA would probably applaud this methodology – ask them.
You would also guarantee the survival of some companies for the next round – without them here will be no real competition in subsequent processes; only national companies will prevail.

9. **Contract Suppliers.** Do not presume to limit any winning Contract Supplier's right to his own property by imposing CMS between those suppliers and the free market right to sell their company. Although CMS should require 45 days advance notice of such transactions in order to obtain written guarantees that the new owners will continue to meet the requirements for bidders and the provisions of the contract it should not intervene unless or until the new owners fail in their obligations to the contract. A new contract signed by the new owners for the remaining period would be reasonable due diligence.

10. **Traveling Beneficiaries.** Beneficiaries who travel should be able to obtain services at the local rate, whether at the local competitive bid rate or the fee schedule whichever is less.

The present determination for "permanent residence" does not fit beneficiaries who relocate due to climate. Six months and one day determines permanent residence yet one day equals one month for rental payments. A beneficiary who remains for five months and one day into the sixth month has spent six months away by the Medicare counter. Climate relocation beneficiaries more than not do so from November to April. It is not reasonable to tie payments to an arbitrary "permanent residence" – the local rate should prevail because it is based on actual costs of the services provided within that area and not the costs from any other area's costs. That is why the Fee Schedules are broken down by states in the first place.

The proposed price fixing based on "permanent residence" creates an administrative burden on beneficiaries, suppliers, and the DMERCs as they try to sort it out.

Recommendation: Keep it simple – pay the local fee where the services are provided. If the beneficiary stays over six months, can the provider now bill for the local rate in the seventh month? The problem is obvious.

11. **Formation of Networks.** The restrictions on networks in the NPRM do not apply to individual bidders. Is this really a fair opportunity for smaller businesses?
Recommendation: Remove restrictions on networks and increase competition and the ability to participate in the process.

12. **Network Bidding.** Allow the members of a network to also bid as an individual company. Somehow, you have to allow smaller businesses a chance against the national corporations.
Recommendation: Businesses should be able to designate themselves as small businesses concerns and be considered both in the small business category (see 8. above) and as part of a network in regular consideration with other bidders. You want competition; prove it.

13. **Grandfathering.** Grandfathered suppliers must not be allowed to "dump" beneficiaries near the end of a capped rental period for any competitively bid item. Any logical business person can figure out that they can retain title to their rental equipment if they dump patients as they approach the end of their capped rental period.
Requiring a winning Contract Supplier to have to provide services to beneficiaries then give up title to their equipment without any hope of retrieving the cost of the equipment and attendant delivery costs is unreasonable. **Nobody** can come up with a formula to predict if or how many beneficiaries will fall into this category and calculate it into their bid. It is beyond comprehension to expect that CMS would get "significant savings" if this were not addressed in the final rule and could actually be accounted for in a bid price.
Recommendation: Require Grandfathered Suppliers to sign a "Stop/Loss Agreement" which requires them to **either** give up all their current patients using competitively bid capped rental equipment **during the month prior to the implementation date** for the MSA **OR** agree to continue services and receive the standard fee until the equipment is capped per the draft NPRM.
Grandfathered suppliers should provide some assurances to get the standard fee which is above the fee to be paid to the Contract Providers.
To protect the Contract Providers against such dumping, guarantee them 6 or more months of rental at the competitive bid price when accepting any beneficiary with less than six months of rental left on a capped item. The NPRM method of attaching a 'designator' to the Medicare provider number would facilitate recognition of those

Contract Providers and allow a systematic revision to the capped rental period. Of course, if medical necessity is terminated so are the payments.

14. **Service and Repair.** It is unreasonable to expect a winning bidder to have to service and repair any and all manufacturer models even if they have never carried that model in their inventory. – repairs are not priority services and take time to quote, price, and get prior approval to perform.
What will the beneficiary do while their own equipment is being evaluated for repair?
Will CMS pay for "temporary" equipment while repairs are being approved?
If not, what will the beneficiary use to meet their medical necessity while waiting for a quote, prior approval and repair? Who pays for pickup and delivery?
How are you going to put that into the evaluation of potential bidders?
What standards are you going to have to include in the final rule and grade bidders on?
Will documentation of repair authorizations or certifications now be part of the " requirements for bidders?"
Suppliers are without historical data on repairs and maintenance, because Medicare has rented equipment for years and the suppliers serviced their own equipment. Beneficiaries are known not to do even basic preventative maintenance (like change filters) most capped items cannot be adequately accounted for in submitting a bid price.
Recommendation: Let the beneficiary shop for a qualified Medicare provider who can service their equipment.
The grandfathered supplier who originally provided the equipment should be allowed to service and repair the capped equipment as an incentive against dumping. They have the equipment maintenance records and a relationship with the beneficiary so there is little shopping around inconvenience for the beneficiary.
Requiring Contact Providers to establish a relationship with the beneficiary after the item has been capped will not promote timely service – there's no profit in service and repair of other providers' equipment.
In most areas there are companies who specialize in service and repair and are certified by the manufacturers and who do not provide the items for rental.
Don't make service and repair part of the competitive bid – leave it out and develop a separate system of evaluation, quotes, prior approval and payments.
If the intention is to let the beneficiary take responsibility for service and maintenance – leave it there.

15. **Rebate Proposal.** The proposal invites abuse. The current practice is to bill CMS the lowest price offered. Allowing rebates as proposed cuts Medicare short and gives the beneficiary the entire rebate when CMS should only be paying 80% of the actual charge.
Recommendation: Follow the industry and PAOC recommendation and delete this provision from the final rule.
Allowing contract providers who bid below the single payment to offer rebates while those who bid in good faith to establish the final single payment amount gives them unfair advantage and will skew the pivotal bid amounts.
The proposal is wrought with probable abuse.

16. **Subcontracting.** The difference between networks and subcontractors is not clearly defined in the NPRM.
Do subcontractors have to be identified and vetted during the evaluation process?

It seems there is no difference between a Network and a Company who intends to use subcontractors.

Bids from outside of the MSA invite subcontracting if those subcontractors are not initially identified – the winning bid has no requirement to even be present in the state, they can administer the contract and rake in fees without doing the work.

Can an individual company bid in its own right and be a subcontractor for another company?

If a contract provider finds after entering into the contract that they need more capacity then anticipated, then they should be allowed to find subcontractors – otherwise it is a network from the beginning.

17. **Administrative or Judicial Review.** There is no provision in the NPRM to challenge the outcome of the evaluation process and selection of the winning bids. This is a basic flaw in the normal process of bids. There needs to be some remedy to actual or perceived injustice in the selection process. The MMA may provide that there will be no administrative or judicial review but in the interests of fair play, there has got to be an opportunity to review the process and challenge decisions. The final process documentation has to be made available under the Freedom of Information Act and a period of time set aside to allow review. Decisions to offer contracts to some providers and exclude others has to be proven as fair. Submitting a challenge against a selected provider for cause has to be defined in the final rule. CMS needs to be squeaky clean in the process of selection or lose any credibility that the selection process was fair and open.

18. **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.

19. **Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts.** (Proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.

20. **Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies.** (Proposed §414.414(e)) Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 20% over the number of products provided to Medicare beneficiaries in the previous year.

Comments for Specific Topics within the NPRM

"Use of Terms"

Competitive Bidding Area (CBA)

Re-defining this term does not seem logical in the face of the MMA. A CBA is actually defined in the MMA as, "in ten of the largest Metropolitan Statistical Areas". The word, "in" defines the area that can be considered. The way the MMA reads, there is no provision for the Secretary to expand the MSA defined area beyond the area defined as an MSA by OMB. Certainly, what could be proposed is that the bidding does not have to encompass the entire MSA but only portions thereof to remain "in" the MSA. The term CBA should not be included as it defies the intent of the MMA to conduct the bidding inside an MSA as define by OMB. See the definition of MSA in the Use of Terms portion of the NPRM.

Composite Bid

This definition is incomplete as it does not define the "weights" to be applied to a supplier's bid. It does not set forth the exact methodology for weighting item elements of the bid. Without a specific definition for each product class, this term could become arbitrary and welcomes abuse and personal definition.

Define the term completely for each product group or discard it.

Item Weight

Without a specific number, item weight becomes arbitrary. To be a complete definition this term needs a defined methodology. There is nothing wrong with developing a formula by assigning weights to items but the weights need to listed to guide bidders to accurate submission.

Weighted Bid

Without an accurate "Item Weight" definition, a weighted bid is meaningless and cannot be adequately understood from this definition.

"Implementation Contractor"

Does waiving the FAR mean that Implementation Contractors will not have to undergo a bidding process themselves?

A CBIC candidate should undergo **at least** as rigorous a scrutiny as is proposed for the "suppliers" they are going to evaluate.

No candidate for becoming a CBIC should have had any part of designing the system that they are to administer on behalf of the Secretary. If an outside agency has had any part in the design of a system, including choosing a CBIC, or developing and defining its duties and responsibilities it should be precluded from becoming a CBIC.
Through bid, or outright appointment by suspension of the FAR, appointment of such outside agencies would be a breach of public trust.
It is tantamount to writing your own job description so that no others can meet the requirements. The OIG needs to look closer at this process of sidestepping the FAR and CFR. We either have Federal Regulations or we do not.

If RTI International becomes the only, or one of, the selected CBICs the process of sidestepping the CFR reeks of abuse and cronyism.

Payment basis

The proposal to pay only at the rate of the permanent residence if the permanent residence rate is in a competitively bid area is contrary to common sense. Different areas have different costs and therefore the rate in Miami could be much higher than in Podunk. To limit a supplier from billing the local fee schedule or the local competitively bid price is not logical. The opposite is also true. The local rate should prevail regardless of the beneficiary's permanent residence.

Additionally, knowledge of all the rates in all areas of the country puts an immeasurable burden on the supplier and on the DMERC to which the item is billed. This provision invites abuse and unintentional billing errors.
Recommend you establish the rate to be where the beneficiary is receiving the service(s).

Grandfathering of Suppliers

The proposal to "grandfather" suppliers currently providing services to beneficiaries is sound only under certain conditions which are should be stated in the NPRM.

Recommendation:

1. Suppliers who accept grandfathering must agree to do so for the entire remaining period of the rental.
   If a supplier bills for a competitively bid item after the implementation date they must provide the service for the entire remaining period. This precludes a "grandfathered" supplier from *dumping* rental beneficiaries onto the winning contractors in the next to last month of the rental limit. Without such an agreement, the winning suppliers become losers because they then must provide an item and lose its ownership to the beneficiary without a chance to regain the value of the item. On the other hand, the grandfathered supplier has recovered his costs and gets to keep his equipment.
   There is no method to compute these types of loses into a bid. If it were possible, there would be no savings to CMS due to the prices which would have to be bid. Any logical person (from either side of the equation: bidder or grandfathered supplier) they will come to the same conclusion. **Stop it now** by writing in a stop/ loss clause for "grandfathered" suppliers to protect those who will attempt to give you an honest effort bid.

2. "Grandfathered" Suppliers who break the stop/loss provision should lose their Medicare Supplier numbers and ability to bill Medicare for any item.

3. Contracted Suppliers should be protected against incalculable losses by guaranteeing them a minimum of months of rental payments should they have to take on *dumped* beneficiaries. Give them the opportunity to recoup the cost of equipment that would otherwise be a total loss, *ie.* Start rentals in the 6th month.

4. Grandfathered suppliers should be required to retain ALL the beneficiaries for a competitively bid item currently served **OR** give them ALL up to the Contracted Providers in the month **before** the date of implementation – no exceptions. Grandfathered suppliers must not be allowed to pick and choose which beneficiaries they want to keep. (This is where the guarantee to the Contracted Provider would come into play.) If you do not do this, access and patient safety are endangered. Also the financial viability of your contracted suppliers is in jeopardy – no matter how large they are.

5. Define what constitutes the break period between when a piece of equipment becomes "not medically necessary" then later again becomes "medically necessary" so the rental can begin again with the contracted supplier from month one.

6. No grandfathered supplier should be allowed to retain a beneficiary once the medical necessity period is broken.

7. Grandfathered suppliers must be accredited to retain patients.

Grandfathering of Suppliers (continued)

Grandfathered suppliers must also be permitted and/or required to service and repair equipment which has capped while they provided and billed for the item. Of course if they go out of business or give up their Medicare number, service and repair would have to move to some one who can legitimately service the item (it may not necessarily be a Contracted Provider but one who has a Medicare number).

Requiring a Contracted Supplier to service any make and model on the market is ludicrous. The item may not have been in the Contracted Supplier's inventory and they are not qualified to repair and service items for which they are not certified by the manufacturer.

Recommendation: Let the beneficiary shop for a qualified Medicare provider who can service their equipment. In most cases there are companies who specialize in service and repair and are certified by the manufacturers who do not provide the items for rental. Don't make service and repair part of the competitive bid – leave it the professionals.

Requirement to Obtain Competitively Bid Items from a Contract Supplier

This requirement is a burden on the beneficiary. Most beneficiaries who temporarily relocate are not equipped (mentally or physically) to shop around **before traveling** to find and chose a Contracted Provider so there is no interruption of their medical need. Further, many beneficiaries later decide to permanently relocate due to the hassle of moving from one location for part of the year. How do they and the Supplier determine what fee is now appropriate? What happens if they later decide to move back?

The present determination for "permanent residence" does not fit beneficiaries who relocate due to climate. Six months and one day determines permanent residence yet one day equals one month for rental payments. A beneficiary who remains for five months and one day into the sixth month has spent six months away by the Medicare counter. Climate relocation beneficiaries, more than not, do so from November to April. It is not reasonable to tie payments to an arbitrary "permanent residence."

Current Fee Schedules are broken down by states for the very reason that costs in each state are different. Saying the costs from the home state remain constant even when moving/traveling to a new state because of the "permanent residence" provision reflects a basic lack of knowledge of business or a convenient disregard of CMS's own historical recognition that prices and costs vary by location.

This proposed requirement is an undue burden upon the beneficiary and the supplier and invites erroneous billing which then becomes a burden on the DMERCs trying to sort it out.

Recommendation: Let the local rate, whether Competitively Bid rate or Fee schedule rate prevail for patients who relocate for parts of a year. Set the rate to the local rate where the service is provided. Eliminate the "permanent residence" provision across the board. Apply the KISS rule and reduce the administrative burden for all concerned – there are too many ifs, buts, and exceptions in the NPRM to enable anyone to make sense of the payment rules.

Competitive Bidding Areas

Please note that the MMA and your own NPRM both state that competitive bidding be conducted "in" (meaning within) a Metropolitan Statistical Area (MSA) as defined by OMB. There is no provision in the MMA to expand beyond the commonly defined area of an MSA. The law is specific and I cannot find any provision in it to allow the Secretary to expand the definition.

One could argue, however, that competitively bidding does not have to include the entire MSA. This would have prevented the exceptions for New York, Chicago, and Los Angeles. Phasing in those larger MSAs by dividing them up seems to be permitted by the MMA. It would also allow those MSAs which cross DMERC boundaries.

By the example given in the NPRM, the first 10 MSAs are still very large and finding smaller, not national companies, to compete for the entire MSA limits many providers from bidding. There is something wrong with inhibiting otherwise qualified companies who are larger and smaller than $6 million (SBA definition) but not multi million dollar companies from bidding because they could not possibly provide service to an entire MSA.

If you really want to give the quality and otherwise qualified "little guy" a chance to compete, large market MSAs should be divided into CBA "regions" delineated by county or zip code boundaries. In some of the MSAs there may be only one or two counties so zip codes may be a better alternative.

Recommendation: Divide the MSA's up by some easily recognized boundaries as proposed in the alternative proposed in the NPRM.

Data Use

Using the data for 2005 from the Census Bureau and data for utilization from 2004 is inconsistent. By the time you get this program published, it is inconceivable that you would not have the data on utilization available to use the most up-to-date information. It is available; ask for it.

The methodology for selection of the first 10 MSAs to be competitively bid appears rational and sound as long it is strictly applied. Also, the decision to exempt the largest 3 MSAs makes sense.

MSAs for 2007 and 2009

The NPRM is inconsistent with the MMA. The MMA says "80 of the largest in 2009" not 70 as stated on page 56 of the NPRM. Page 46 conflicts with page 56.

Recommendation: Use the same criteria for selection of the next 80 MSAs that were used for the first 10 with the most current available data.

Exempting rural areas where competition is already slim is reasonable and prudent.

Including areas "outside an MSA" goes against the intent and definition defined by the MMA. There is no provision to arbitrarily "expand" and MSA as defined by OMB. The MSAs are already defined by boundaries. If an MSA is "expanded to include adjacent areas, it is no longer an MSA, it is something else not defined by the MMA or OMB. It is my contention that to expand the area defined as an MSA is a violation of the intent of the MMA. CMS will open themselves to legal action should it attempt to redefine the term Metropolitan Statistical Area.

Recommendation: Stick to the OMB definition and stop trying to do more than the law allows.

Establishment of a competitively bid national bid for mail order supplies after 2010 makes sense but not if it includes items previously bid in the 2007 and 2009 programs.

Recommendation: If the intent is to nationally bid certain supplies in 2010 do not include those same items in MSA bidding. If CMS believes they can save money now, then launch the national competitively bid for mail order items in 2008 and get it over with but allow the beneficiary the opportunity not to participate in mail order purchasing. – set a fee schedule for the items nationally and let the beneficiary choose where they want to obtain their supplies as long as it is from a qualified Medicare provider. Having a local Contract Provider and a mail order supplier does provide choice but not enough and may not be convenient to the beneficiary – give them a break.

Supply of the initial diabetic monitor with attendant teaching and education for the beneficiary does not reflect the actual cost of doing so for the small provider. They get their payback with the re-supply of the necessary lancets and strips. Removing them from the equation after they did all the work is not fair. If CMS institutes a program which limits the ability of the provider to retrieve his cost through long term provision of supplies, the real benefit of education and compliance will be lost as those providers get out of the market.

Recommendation: Reconsider the inclusion of diabetic supplies in local MSA competitive bidding. Establish a fee schedule after national mail order bidding is complete.

Market Demand and Supplier Capacity

The NPRM considers the previous two years of data in determining "expected demand". The problem with using past data is that it does not consider the potential for expected demand based on Census data projecting beneficiaries who will turn 65 and be eligible for Part B benefits. I find no mention of the expected growth in the beneficiary pool due to the "baby boomer" group reaching age 65. By the time the first MSAs are put out for bid, the US population will be two years into the explosion the experts have identified. Population analysis from the Census data would provide a more accurate projection for growth than analysis of the past two years data.
Projecting market demand based on historical growth by percentage of eligible beneficiaries is only part of the necessary equation – first you have to project the number of eligible beneficiaries in the pool.

Capacity. Analysis of each bidders current billing will give a good indicator of current capability to supply Medicare beneficiaries but each provider does not only provide items and services to ONLY Medicare beneficiaries. The average supplier reports Medicare at or below 40% of their current business. This indicates their capacity is at least double what your billing analysis will show. The most successful (profitable) companies have a payor mix with low Medicare and Medicaid percentages.
If you are using current billings to Medicare as your indicator of capacity you need to determine the totals item by item (HCPCS code) not just total billings.
As far as each supplier stating his own capacity, those numbers will likely be high simply because a provider who is selected to be a Contracted Provider will have almost unlimited capacity for growth based on the government contract alone – available lines of credit will be raised considerably. Excessive growth by the Contracted Providers will drive others out of business.

No one supplier should be initially allotted to provide more than 20% of the projected capacity needed in any MSA or portion thereof. After the bidding process, if a contracted supplier can compete within the selected group and achieve more than 20% it will because of good patient care and smart business practices. Enough providers need to allocated within each CBA to provide for competition within the group.

No MSA or portion thereof should have less than enough contracted providers to provide 150% of the projected capacity required to meet market demand. Too few contracted providers will create a lack of competitors during the re-bid in three years – instead of competition you will create a monopoly and prices will rise significantly.

Composite Bids and Weighting

The final rule needs to identify expected usage data (projected market demand) within the MSA item by item so bidders have the knowledge to bid individual items. The more the usage the more likely the item can be bulk purchased or enable the supplier to negotiate individual item pricing based on estimated quantity guarantees.

Knowing the quantities a successful bidder might expect to deliver will make bidding a science rather than a systematic guess. Accurate bids ensure the ability to fulfill the provisions of the contract. Guesstimates endanger the supplier's ability to make an acceptable profit or, on the other hand, forces themselves out of the bidding process through over estimating purchasing power and over/under pricing.

Usage data combined with the knowledge of the number of contracts to be awarded facilitates better estimates of actual sales from the contract. Both these pieces of information are essential to accurate bidding and must be provided to bidders at the beginning of the process for each MSA.

Rebate Program

The proposal to allow contract suppliers to provide a rebate flies in the face of anti kickback laws.
Would a contract supplier actually bill a lesser amount to CMS so they can pay only 80% of submitted charges or will the rebate all go to the beneficiary?
Current CMS requirements are to bill the lowest of Provider's Standard and Usual Fee or the lowest fee billed to any other customer. I suppose that rule goes by the wayside.
There is a problem with any program that invites abuse to gain market share amongst the bid winners.
The entire industry sees rebates as a problem – delete the provision.
Check with the OIG and you will find holes in this proposal.

Submitter : Mrs. Tanya Ward **Date:** 06/29/2006

Organization : Criticare Home Health Services, Inc.

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-782-Attach-1.DOC

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

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

Re: Written Comments file code CMS-1270-P

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Beneficiaries will not have access to newer technology for competitively bid products.
The conclusion that "*...Competitive bidding provides a way to harness marketplace dynamics to create incentives for suppliers to provide quality items in an efficient manner and at a reasonable cost...*" is flawed.

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

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

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

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

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

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

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

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

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

SUMMARY:

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

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

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

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

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

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

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

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

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

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

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

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

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

Submitter : Dr. David P. Rosenzweig **Date:** 06/29/2006

Organization : The Advanced Footcare Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I urge CMS to change the definition from 1861(r) (1) to 1861(r).

Submitter : **Dr. Christine Weikert** **Date: 06/29/2006**

Organization : **Nittany Valley Ankle & Foot Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Christine E. Weikert, DPM
2505 Green Tech Drive, Suite A
State College, PA 16803
814-231-1451

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Christine E. Weikert, DPM

Submitter : Dr. Stathis Poulakidas **Date:** 06/29/2006

Organization : Cook County Hospital (Stroger)

Category : Physician

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attachment

CMS-1270-P-785-Attach-1.TXT

June 29, 2006

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

To Whom It May Concern:

My name is Stathis Poulakidas, M.D., and I am the recently hired Burn Director at Cook County Hospital, Chicago, IL. Up until this time, I have been an Assistant Professor of Surgery at Loyola University Medical Center, Maywood, Il, where I have specialized in the management of critically ill Trauma and Burn patients. I see some of the most horrific disease processes and have had wonderful outcomes based on use of the V.A.C. device by a company called KCI from San Antonio, TX. Having used this device for about 6 years now, I have seen a significant improvement in patient care from the standpoint of more rapid and complete wound healing. Along with this, I have cared for patients who likely would have died had it not been for this device prolonging their life, if not saving their lives, by its modality of action. Volume of literature exist in support of the V.A.C. and its ability to (1) improve blood flow to a wound, (2) remove bacteria from a wound, and (3) improve the rates of closure of wounds by improving the granulation tissue to the bed of any wound. It is these 3 concepts that allow for wounds that I care for in Trauma/Burn patients to heal. It is this device that allows these patients to survive their devastating injuries.

On the other hand, there is a device called the Versatile One, by the Blue Sky co., based out of San Diego, CA. Having seen and used this device, I have found it to be not only an inferior product, but I have seen outcomes which are detrimental to patient care. This company utilizes anecdotal data from V.A.C. (KCI) studies and infers their device is similar. This could not be further from the truth. The Blue Sky device has no data to support it and has no safety monitors to protect patients from adverse consequences, should the device fail to function properly. This is not the case with the KCI device as it does have such safety measures programmed into its CPU.

With this prelude, I am writing this letter in response to the CMS file code CMS-1270-P, for the proposal of competitive bidding with regards to use of devices which allow for negative pressure wound healing. This proposal, in my estimation, is potentially going to restrict and eliminate physician choice in regards to which of the above devices can be used based on cost. I feel this will be harmful to patient care, as the use of a potentially inferior device may be mandated for use in Medicare patients. By limiting the ability to use the KCI device, I caution that the only persons to suffer with this decision will be our patients, as their ability to heal will be compromised by using an unsafe device. Caring for critically ill patients, I have seen enormous success with the use of the V.A.C, as I eluded to above. More importantly, in this day and age of internet accessibility, my

patients are more educated and in many instances they can interpret data and identify which modalities of care will benefit them. With this, I have seen huge support from my patients with regards to use of the V.A.C. (KCI) in order to manage their wounds.

More importantly, as a physician, I find it difficult to understand why I should be mandated to use an inferior product, which can compromise my patient care, when I know based on data that a superior device (the KCI V.A.C.) is available which will allow for an overall improvement in patient outcome . If such an action is undertaken, I feel physicians who manage critically ill patients will be put at a huge disadvantage. By allowing this to occur, a device which has only limited use and experience (the Blue Sky apparatus) will be thrown into patient care only to display detrimental outcomes.

With this, I champion the powers that be at the CMS offices to closely look at this issue so as to allow for the ability of the physicians to choose which modality of treatment they wish to administer. Please do not remove this decision from the hands of those of us who fight the battle everyday to try to keep our patients alive. By supplying us with only inferior modalities of care, such as the Versatile One device, I only see patients having adverse outcomes in the future.

Thank you for your time and support.

Stathis Poulakidas, M.D.
Director, Burn Unit
Cook County Hospital
Chicago, IL

Submitter : Mr. Tom Gates **Date:** 06/29/2006

Organization : Mr. Tom Gates

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Seniors have been completely left out of this decision making process. Their voice should be heard. They require a great deal of assistance or in other words SERVICE to ensure the correct item and proper usage is occuring. Without the free market forces in place we will create a two tier system. One for the haves and the other for the have nots. If a bidding process takes place the ultimate winner will be forced to use cheap equipment and sacrafice service to make a profit. More costly accidents are on the horizon if the service aspect fades away. Given that the overall spending of Medicare on HME is a small portion of the overall budget and the fact that boomer are coming of age fast, I feel a gradual fee reduction would achieve the same result with minimal disruption to seniors. Thank you.

Submitter : **Dr. Philip Baldinger** **Date: 06/29/2006**

Organization : **Cortez Foot & Ankle Specialists**

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:

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 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.

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.

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.

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

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

Sincerely,

Philip J. Baldinger, DPM
3304 65th Street E
Bradenton FL 34208

Submitter : **Dr. Garrett Harte** **Date: 06/29/2006**

Organization : **Cotez Foot & Ankle Specialists**

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

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

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

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

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.

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.

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.

Sincerely,
Garrett L. Harte, DPM
9223 19th Drive NW
Bradenton FL 34209

Submitter : **Dr. Richard Berkun** **Date: 06/29/2006**

Organization : **Cortez Foot and Ankle Specialists**

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

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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.

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.

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

Sincerely,

Richard N. Berkun, DPM
1645 Quail Drive
Sarasota, FL 34231

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

Organization : Kaye Hapshe

Category : Social Worker

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

My concern is that the competitive bidding process would produce a single authorized provider thereby reducing the controls on the level of service beyond that of mere material supplies. A list of authorized vendors would be better in my estimation as it would allow the natural market forces to winnow suppliers out that don't meet the public expectations.

Submitter : **Dr. Alan Katz** **Date: 06/29/2006**

Organization : **Cortez Foot & Ankle Specialists**

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

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

Sincerely,

Alan Katz, DPM
1525 Mallard Lane
Sarasota FL 34239

Submitter : Dr. C J Addison **Date:** 06/29/2006

Organization : Cortez Foot and Ankle Specialists

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

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Sincerely,

C. J. Addison, DPM
1403 WaterOak Way N
Bradenton FL 34209

Submitter : **Mrs. Mitzi Zeno** **Date: 06/29/2006**

Organization : **The University of Tennessee Health Science Center**

Category : **Physical Therapist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Dear Dr. McClellan,

I would like to voice my objections to the proposed rule for competitive acquisition of certain DME. As a physical therapist working in an out-patient muscular dystrophy clinic, this idea of providing certain DME to the lowest bidder would be harmful to many of the patients I see on a weekly basis - especially those with ALS and other degenerative diseases who are on Medicare and need a variety of devices to remain mobile, independent and safe for as long as possible. Please let me explain why I feel this would be injurious to them and many of the patients seen by physical therapists in other settings:

1. Each patient, even with the same diagnosis, has his own unique problems.
Therefore, each needs to be evaluated and treated on an individual basis.
Frequently, PTs and OTs must try different devices to see which works best for each patient. Just because an "inexpensive" wheelchair or foot/hand brace can be obtained at a cheaper price, doesn't mean it will be beneficial for that particular patient. People who sell DME are not necessarily trained to determine which device a person needs or even if the one that's ordered fits appropriately and is doing what it's supposed to do. Physicians usually rely on therapists (as well as orthotists, etc.) to guide them in ordering specific types of devices rather than a "one size fits all" brace or chair that may be less expensive in the short run, but not provide the patient with what he really needs.

2. There is potential for greater costs to Medicare if a device obtained through the lowest bidder isn't appropriate or fitting correctly and therefore has to be replaced or supplemented with something else. In the case of patients with diagnoses like ALS, spinal cord injury or brain injury who often need many different pieces of equipment, this could end up being very costly to Medicare.

3. The most important adverse medical outcome is the potential for patients to develop secondary problems from inappropriate and/or poorly fitting devices. This again, could end up costing Medicare even more money, not to mention the injury/pain/suffering to the patients themselves. For example, if a physician orders a wheelchair cushion for a patient who has no sensation from the waist down and doesn't specify the exact type of cushion the patient needs (likely because he isn't familiar with the different types and their advantages/disadvantages), then the patient could end up with a 2 inch foam cushion provided by the lowest DME bidder. If the patient then develops pressure sores or skin breakdown, his subsequent medical care for the pressure sore problem will be very costly for Medicare.

4. DME providers DO NOT provide follow-up evaluations, care or consultation. Any problems that occur in the future as a result of inappropriate or poorly fitting equipment, will have to be addressed and funded by Medicare after being notified by the patient, therapist or physician.

Purchasing some equipment, like walkers or bedside commodes, certainly doesn't require the input of a therapist or other health professional. However, any orthosis, prosthesis, wheelchair or wheelchair cushion needs to be carefully considered by a trained professional before purchase.

Please consider these comments carefully before this proposed rule is implemented. Thank you for your time and attention to this matter.

Sincerely,

Mitzi Zeno, PT, MS, NCS
Associate Professor of Physical Therapy
MDA Staff Physical Therapist

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

Organization : Cortez Foot & Ankle Specialists

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:

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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,

Scott Handley, DPM
221 111th Street E
Bradenton FL 34212

Submitter : Ms. alyce crossman **Date:** 06/29/2006

Organization : upstate homecare

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-795-Attach-1.PDF

June 29, 2006

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

Dear Dr. McClellan,

Upstate HomeCare 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

Upstate HomeCare is a regional company, with five branches across New York State. We provide home medical equipment, oxygen, and home infusion services. We service well over 8000 patients annually and at least half of these on a continuing basis. We employ eight two of which a third are medical professionals (nurses, pharmacists and respiratory therapists). We have been accredited for the last twelve years.

In general, Upstate HomeCare 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. The first problem is providing comments on a Proposed Rule in the absence of the everything that affects it (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. Cost shifting to increased "facility" care must be included in the "savings" when that facility care results from the effects of Competitive bidding.

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 patients in a Skilled Nursing Facility (SNF). If there are no standards to apply to a company that only services the SNF community how they can be included in the accreditation process. CMS has to either issue standards or exclude SNF residents from consolidated billing.

Conditions for Awarding Contracts

An Appropriate Screening Process Must Be Developed To Determine Which Submitted Bids Will Qualify For Consideration. (Proposed §414.414) CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid is processed for further review and consideration as to pricing.

Competitive Bidding Must Be Competitive And Sustainable. CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either.
Do Not Make It Harder For Providers To Sell Their Businesses. (Proposed §414.414(e)) The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement that contracted supplier and its new ownership should retain its contract.

Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts. (Proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.

Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid. (Proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required.

Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "compilation", "review", or "audit" report from an independent Certified Public Accountant. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship and the potential borrowing capacity of the company. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Total Debt to Total Asset Ratio" (should be no higher than ___ and "Current Assets to Current Liabilities" (should be no lower than ___).

Use A Factor Of 130% In Calculating Supplier Capacity Needed In An MSA. (Proposed §414.414(e)) In determining the number of suppliers needed, CMS should apply a factor of 130% to the identified Market Demand. This would promote more competition in the market, ensure more suppliers remain in the market to serve non-Medicare payors, and ensure better competition for any future bidding rounds. In addition, this minimizes the need to recruit more suppliers (that bid above the pivotal bid) if one of the contracted suppliers is terminated or elects to drop out of the competitive bidding program.

Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies. (Proposed §414.414(e)) Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of products provided to Medicare beneficiaries the previous year.

Company Should Be Able To Bid For Only A Portion Of An MSA. The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.

Do Not Restrict Submitted Bid Amounts. (Proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical need.

Terms of Contracts

Eliminate Requirement That Winning Supplier Must Repair Patient-Owned Equipment. (Proposed §414.422(c)) The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these costs into their bids.

Eliminate Limitation That Only Winning Suppliers May Repair Patient-Owned Equipment. (Proposed §414.422(c))

Restrictions On What Products Can Be Supplied To Individuals Outside The Medicare Program Must Be Eliminated. (Proposed §414.422) The terms and conditions section states "non-discrimination- meaning that beneficiaries inside and outside of a competitive bidding area receive the same products that the contract supplier provides to other customers". This is unrealistic. In order for suppliers to bid lower prices they must either provide lower cost products or reduced services. Competitive bidding should be more like a contract with managed care where formularies are used. Medicare will be fully aware of what Medicare beneficiaries will receive, but it should not limit what customers outside of the competitive biding program receive.

Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier. (Proposed §414.422(c)) Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

Opportunity to Participate by Small Supplies
Opportunity for Networks

Require That A Minimum Number Of Small Suppliers Be Included In The Wining Contract Suppliers. ("Opportunity for Participation by Small Suppliers) At a minimum, small business suppliers in an amount equal to the number of winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount.

Clarify Network Regulations. (Proposed §414.418) What are structural requirements? Who can do billing and collection?

Do Not Place Limitations On Formation Of Networks. (Proposed §414.418) Market share limitations should be removed (these do not apply to single entities that bid). Network members should be able to also bid through other means.

Payment Basis

Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowable. (Proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in non-bid area, CMS should pay the traditional Medicare allowable amount that corresponds with the beneficiary's permanent residence for up to five months.

Provide Details On How Pricing Will Be Used After January 1, 2009. CMS has the authority to use payment information for covered items furnished on or after January 1, 2009 that are included in a competitive bidding program, to use the payment information determined under that competitive bidding programs to adjust payments amount for the same DMEPOS in areas not included in the competitive bidding program. CMS needs to issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

Different Alternatives To Gap Filling Must Be Used. (Proposed §414.210(g)) It is good to see the acknowledgement of the problems and inappropriateness of the gap filling pricing methodology. The provision for replacing the Gap Filling methodology for setting fees for new DMEPOS items is inappropriate for inclusion in the Competitive Acquisition NPRM. The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, the proposed rule calls for functional and medical benefit assessments to be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer and other knowledgeable entities in the process.

Develop More Equitable System To Price HCPCs Changes. CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. This is not equitable solution and a more appropriate procedure must be developed.

Rebate Provisions Must Be Eliminated. (Proposed §414.416(c)) The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

Provide More Details On The "Composite Bid" Calculation. The NPRM describes a methodology of creating a "composite" score to compare suppliers' bids in a category using weighting factors to reflect the relative market importance of each item. CMS should provide suppliers with the weighting factors it will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS item within a category.

Upstate HomeCare appreciated the opportunity to submit these comments.

Respectfully Submitted

Alyce Crossman

Alyce Crossman, RT, MPS
Vice President
Chief Information Officer
Innovative Service, Inc.
aba Upstate HomeCare
315.853.1280 X245

Submitter : Mr. LEO COLLISON **Date:** 06/29/2006

Organization : IAMES

Category : Health Care Provider/Association

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

tHE SMALL BUSINESS PROVIDER IS THE CORE FOUNDATION BUSINESS IN AMERICA. IT DRIVES ALL THAT WE VALUE IN OUR COUNTRY:FREEDOM OF CHOICE,INDIVIDUAL TREATMENT AND ATTENTION,CUSTOMER SERVICE .

WHY WOULD THE GOVERNMENT WANT TO ELIMINATE THAT?

WHY CAN'T THE GOVERNMENT SIMPLY SET THE REIMBURSEMENT RATE AT WHATEVER RATE IS NECESSARY,DETERMINED BY COMPETITIVE BIDDING ,ETC. AND THAN ALLOW THE ANY WILLING PROVIDER PROVISION. LET THE MARKETPLACE DETERMINE WHO SURVIVES-NOT THE DELIBERATE SUBJECTIVE OF A GOVERNMENTAL COMMITTEE.

IF THIS IS TRULY ABOUT SAVING THE GOVERNMENT HEALTHCARE DOLLARS, AND NOT ANTI-SMALL SMALL PROVIDER, WHY IS THERE NO COMPETITIVE BIDDING FOR DOCTORS AND DRUG COMPANIES WHERE HUGE SAVINGS COULD BE MADE IN HEALTHCARE SPENDING? TO ME, IT IS A UNBALANCED,UNFAIR,SELECTIVE APPROACH TO HEALTHCARE REFORM THAT CLEARLY FAVORS BIG BUSINESS.IT IS EXCLUSIONARY AND IT DOENN'T HAVE TO BE.

THANK YOU

LEO COLLISON

HEALTH LINK SERVICES
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Submitter : Mr. CORLISS STOXEN **Date:** 06/29/2006

Organization : STOXEN PROFESSIONAL PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern,

The competitive bidding program suggested would effectively put all small independent pharmacies out of the medicare supply business. Pharmacy is the one healthcare supplier that patients see on a regular basis. Purchasing a healthcare supply like BG strips, is not the same as buying a new lamp or couch. There is more involved in the purchase eg. training. I don't think I will be submitting a big under the p proposed program. We don't make that much as it is on the medicare strips & supplies we do sell. Our gross margin is less than 20% as it is.

Sincerely,
Corliss J Stoxen R.Ph.

Submitter : **Miss. Juliana Reed** **Date: 06/29/2006**

Organization : **Hospira Worldwide, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

see attachment

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

see attachment

Education and Outreach

Education and Outreach

see attachment

Gap-filling

Gap-filling

see attachment

CMS-1270-P-798-Attach-1.PDF

Hon. Mark B. McClellan, M.D., PhD.
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, MD 21244

June 29, 2006 Delivered Electronically

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

Dear Dr. McClellan:

Hospira Worldwide, Inc. (Hospira) is pleased to provide this comment letter to the CMS-1270, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Proposed Rule).

Hospira is a global specialty medication delivery company dedicated to Advancing Wellness™ by developing, manufacturing and marketing products that improve the productivity, safety and efficacy of patient care. Created from the core global hospital products business of Abbott Laboratories in April 2004, Hospira has a 70-year history of service to the hospital industry and is building its future from a strong foundation as one of the largest manufacturers of hospital products in the United States. Hospira has established long-standing customer relationships that span the "continuum of care" (hospitals, alternate site facilities, home healthcare providers and long-term care facilities). Hospira has a leading position in the manufacture and supply of a broad range of hospital products including:

- Specialty injectables
- Medication delivery systems (including electronic infusion pumps)
- Infusion therapy solutions/supplies
- Critical care devices

Hospira thanks CMS for the opportunity to comment on the CMS-1270-Proposed Rulemaking re: Competitive Acquisition for Certain Durable Medical Equipment, Orthotics and Supplies (DMEPOS) and Other Issues (May 1, 2006). As a manufacturer

of medical technologies, and in particular, infusion devices and their related drugs, Hospira is deeply concerned in regards to several components as outlined in CMS-1270 Proposed Rulemaking. Our comments will focus on the reasons why CMS should EXCLUDE infusion pumps and their related drugs from the CMS DMEPOS Competitive Bidding Program as outlined in CMS-1270-P and on the areas of gap filling that appear to set precedence for CMS to limit beneficiary access to new technologies in the future.

To ensure beneficiary safety, positive health outcomes, access to new technologies and potential reduction in overall costs to the Medicare program, Hospira recommends to CMS the following:

Recommendation #1: CMS should EXCLUDE the product category "Infusion Pumps and drugs" from the competitive bidding program.

Recommendation #2: CMS should require that the "composite bid" and the 'single payment amount for the individual items" within each product category reflect ALL the costs associated with safe administration of a piece of DMEPOS in a beneficiary's home.

Recommendation #3: CMS should REMOVE all references to the technology assessment as part of gap filling from the Final Rule and that a separate proposed rule, with specific procedural requirements, be published for comment.

Specifically, our comments will support these recommendations as we address the areas of:

- **Criteria of Item Selection**
- **Determining Single Payment Amounts for Individual Items –(proposed 414.416)**
- **Education and Outreach**
- **Gap Filling**

I. Criteria for Item Selection:

Our comments in this area will outline two conclusions: 1) why the product category or policy group, "Infusion Pumps & Related Drugs" should be EXCLUDED from the CMS DMEPOS Competitive Bidding Program, and 2) why CMS should exercise its authority to subdivide product categories by HCPCS code for bidding purposes.

Hospira

Recommendation #1): Infusion Pumps & Related Drugs should be EXCLUDED from DMEPOS Competitive Bidding:

A) Competitive bidding of such a broad group of medical devices that deliver critical therapies to Medicare beneficiaries could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

The broad spectrum of infusion technologies and drugs represented in this category represent very different beneficiary medical needs, lengths of treatment time and have no medical relationship to each other, other than the mode of delivery for the medication is infusion. For example, within the American Medical Association's HCPCS 2006 handbook, the infusion pumps listed under "Infusion Supplies" range from "Mechanical reusable pumps (E0780)", to "Ambulatory infusion pumps, single or multiple channels, electric or battery operated (E0781)" to "External ambulatory infusion pump, insulin (E0784), "Infusion pump, implantable, nonprogrammable (E0782) and finally "Infusion pump system, implantable, programmable (E0783)". These infusion devices vary in: the critical drug therapies they administer to Medicare beneficiaries, the infusion technology required within the different devices to deliver each medication safely, the length of time these treatments are required and the site of care where Medicare beneficiaries obtain these infusion devices. The therapies administered by the infusion technologies outlined in this category range from the critical acute care medical infusions such as the administration of Dobutamine for a cardiac patient, to the administration of narcotic painkillers to control the pain of cancer or to the chronic infusion of insulin through a small implanted infusion device. Each of these critical therapies has its own unique clinical requirements creating a significant variance in the way the therapies need to be administered. The only similarity in the product category is in the description of the devices is the word "infusion". The methods for the infusion of the different drugs vary greatly; the supplies necessary for the safe operation of the devices vary from device to device, from manufacturer to manufacturer and from drug to drug.

In addition, where the beneficiary obtains each device varies. For example, Medicare beneficiaries receive their implantable pumps (E0783) surgically in the hospital while on the other hand, another beneficiary may receive their ambulatory infusion pump (E0781) in their home from a home infusion company. Each type of these infusion devices is obtained from very different clinically specialized suppliers with their own unique requirements and regulations, patient education requirements, and monitoring. For clinical reasons, such as the surgical requirement to implant an implantable pump into a beneficiary, an implantable pump would not be an infusion device that could be safely supplied to a beneficiary in their home by a home infusion pump supplier, the provision

of these pumps should be part of the hospital surgical procedure. Vice versa, requiring a beneficiary to obtain their home infusion pump and related drugs from the hospital versus the home infusion supplier is neither medically necessary nor cost-effective alternative.

Each of the individual devices varies from manufacturer to manufacturer and the supplies used to operate the pumps, such as the intravenous solution sets, are not swappable with differing pumps. Different medical drug therapies require different intravenous lines. Chemotherapy drug intravenous sets are manufactured from different materials than general-purpose intravenous sets, yet both intravenous sets would be categorized as "supplies" under a competitive bid of the product category or policy group. A competitive bid of such a broad policy group that would fail to recognize the unique clinical parameters of each of the products contained within the group or category could result in unqualified suppliers providing beneficiaries with infusion devices, drugs and their related supplies in an unsafe manner. Therefore, Hospira recommends in recognition of the variability and unique clinical requirements associated with various types of infusion therapies and devices, Infusion Pumps & Related Drugs should be excluded from the CMS competitive bidding program.

Hospira notes that CMS has already recognized this variability by choosing to exclude Infusion Devices for Parenteral Nutrition from competitive bidding. We recommend that CMS expand this exclusion to all other infusion pumps and related drugs.

B) Infusion Pumps & Related Drugs were not part of either the Polk County, Florida or the San Antonio, Texas DMEPOS Competitive Bidding Demonstration Projects.

Throughout the proposed rules, CMS refers to initially choosing product categories and/or policy groups that a) create savings for the Medicare program and b) were part of the initial demonstration projects. As outlined above, the technologies and therapies contained under the overly broad category of Infusion Pumps & Related Drugs are not compatible with competitive bidding. Furthermore, the fact that CMS has no demonstration project experience with this category supports the need to exclude Infusion Pumps & Related Drugs from competitive bidding projects. As a result, we believe it would be most prudent for CMS not to attempt to add new product categories early in the life of a competitive bidding program. A delay for these devices would give the Agency time to assess what fine tuning is needed in the competitive bidding methodology and related policies (for example, with respect to physician authorization,

beneficiary travel and transition issues) before deciding whether the program is ready to be expanded to include additional DMEPOS products.

C) Infusion Pumps & Related Drugs as part of a DMEPOS competitive bidding program may demonstrate limited savings the Medicare program.

CMS proposes to use HCPCS codes individually or grouped together in "Product Categories" as the basis for competitive bidding. Because there are significant inconsistencies in the specificity of existing codes included in the product groups listed in the Proposed Rule, we are concerned that use of poorly defined HCPCS codes in competitive bidding could reduce beneficiary access to medically necessary products and adversely impact the quality of care.

An inappropriate lack of code specificity exists when products with a limited set of basic features and benefits are assigned to the same code with related products that have advanced features. This is true of the Infusion Pump & Related Drugs Policy Group as outlined above and even within the E0781 Ambulatory Infusion Pump HCPCS Code.

For example, as a leading manufacturer of infusion pumps, Hospira manufacturers a wide range of pump technologies varying from multi-therapy infusion pumps with medication safety software most commonly used in hospitals and the intensive care setting, to patient controlled analgesia infusion pumps that have specific mechanisms to administer narcotics in a safe, controlled manner, to smaller portable ambulatory multi-therapy pumps that can deliver a range of drugs in the home. In each of these devices, there are different technological features that provide different therapeutic benefits and/or support the special needs of each beneficiary. All these technologies can safely administer drugs to patients, but due to the lack of specificity within the HCPCS coding system each device currently would qualify for reimbursement under the same HCPCS code: E0781. Because of the additional provider costs associated with advanced features when required for beneficiaries, the advanced products would exceed the price range for general-purpose devices. Current fee schedules do not allow for separate payment for the advanced products. Given the proposed bid methodology, there is a real risk that suppliers may choose to provide only the less-advanced, less-costly products classified in the code in order to win the bid and be selected as a contracted supplier. If this occurs, we are concerned that there could be such significant reductions in payments that the advanced products, even though medically necessary, would no longer be available to Medicare beneficiaries. Competitive bidding should not restrict or reduce beneficiary and/or clinician access to the most appropriate, medically necessary products. We believe that that the bid process must ensure Medicare

beneficiaries receive the critical therapies they require in the safest manner with the medically correct device. To achieve this objective, CMS should work with manufacturers to evaluate the wide range of technologies available within the Infusion Pump & Related Drugs Product Category and each individual applicable HCPCS code.

CMS has the authority to establish separate subcategories for items within a given category if there is differential clinical benefit and or value for specific items within the category. Therefore, Hospira recommends that before any of the infusion device codes listed above are included in any stage of competitive bidding, CMS should exercise its authority to subdivide the product category Infusion Pumps & Related Drugs and establish a separate cost for each subdivided category. For example, the National Home Infusion Association has found that Infusion drugs, supplies and pumps comprise a very small part of the Part B expenditures. In it's analysis, the National Home Infusion Association (NHIA) found that when divided into subcategories, and the subcategories outlined below 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. (NHIA, 2006)

Subcategories of Infusion Devices & Related Drugs: (NHIA, 2006)

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)

As can be seen from this information, no single product used in home infusion drug therapy falls within the list of high volume items found in Table 3 in the preamble to the proposed rule per the NHIA analysis. (NHIA, 2006)

Therefore, Hospira recommends that CMS exclude Infusion Pumps & Related Drugs from the DMEPOS Competitive Bidding Program for the following reasons:

A) Competitive bidding of such a broad group of medical devices that deliver critical therapies in different ways to Medicare beneficiaries could reduce beneficiary access to the medically necessary products and adversely impact the overall quality of care.

B) Infusion Pumps & Related Drugs were not part of either the Polk County or Texas DMEPOS Competitive Bidding Demonstration Projects. As such, CMS has no experience in bidding this technology.

C) Infusion Pumps & Related Drugs as part of a DMEPOS competitive bidding program may demonstrate limited savings to the Medicare program.

Hospira recommends that CMS consider product categories other than Infusion Devices & Related Drugs for the initial round of DMEPOS Competitive Bidding. In later competitive bidding cycles, Hospira recommends that CMS start gradually with these devices by only bidding one Infusion Device subcategory and a gradual phase-in of subcategories of infusion devices to allow CMS and suppliers to gain experience and learn about applications in this area.

II. "Determining Single Payment Amounts for Individual Items" -- (proposed §414.416)

Under this section, Hospira encourages CMS to work with physicians, beneficiaries, manufacturers and suppliers to ensure that all of the necessary components for administering certain items considered DMEPOS are considered in "determining single payment amounts for individual items" as part of the bid and resulting payment amount. For example, to safely administer home infusion therapy in a beneficiary's home, the home infusion DMEPOS supplier must provide the following minimum items:

- Medically required infusion pump technology,
- Supplies medically necessary to safely administer the drug;
- The drug compounded and/or packaged in a fashion in which it can be safely administered to the beneficiary;
- The facilities to safely compound the infusion drug as required by FDA standards and state laws;
- The beneficiary education and training on the device and the therapy;
- 24-hour monitoring services necessary to safely supervise beneficiary care;
- The clinical services necessary to ensure that the technology is working properly in the beneficiary's home (An infusion pump cannot be checked for proper drug administration and safety by an unqualified or non-licensed professional, such as a delivery person. The supplier must provide licensed professionals, such as nurses to the beneficiary's home to ensure safety.);
- A program that meets accreditation standards per Medicare regulations;
- All necessary physician communication;
- All necessary documentation per state and federal regulations; and

- All necessary program functions to adhere to the yet released CMS Home Infusion Quality Standards.

In considering all the necessary components required for the safe administration of home infusion in a beneficiary's home, CMS should include the Temporary National Home Infusion codes used by the Blue Cross / Blue Shield Association and the Health Insurance Association to report drugs, services and supplies as published in the 2006 Healthcare Procedural Code System (HCPCS) manual. The "S" codes for home infusion serve as an excellent tool for suppliers for defining the clinical services component of home infusion. CMS should instruct suppliers to list the "S" codes as one of the components and necessary costs to included as part of the composite bid. Hospira envisions that as suppliers submit bids for DMEPOS, CMS will only consider bids that address all the necessary components required for safe administration of the equipment and the drug in the beneficiary's home. Hospira recommends that CMS consider the home infusion scenario outlined above as a model for other equipment bids and for how the single payment amount for an item must include all the necessary factors as outlined above.

III. Education and Outreach

In the 'Education and Outreach" section, CMS outlines some of the early education that the Competitive Bidding Implementation Contractors (CBICs) will provide to potential suppliers. We urge CMS to include specific educational requirements that address each of the components included in the composite bids that will create the single payment amount for each item. For example, Hospira is concerned that a supplier may not address all the clinically required components that make up the safe operation of a piece of durable medical equipment in a beneficiary's home. If a supplier does not include the costs for the equipment, the supplies, the beneficiary's education in the safe use of the equipment, the training of the supplier's staff, the transportation of the device, the monitoring of the beneficiary's safe utilization of the device, the maintenance of the device and the supplier's compliance with the yet to be released CMS Supplier Quality Standards, to name a few components, the successful bidder could greatly under bid the true cost to safely supply equipment to beneficiaries in their homes.

Hospira points CMS to the experiences of Medicare beneficiaries who were dual eligibles transitioned from their Medicaid drug benefit to the Medicare Part D drug benefit earlier this year. Many of these dual eligibles were safely receiving injectable drugs and infusion therapies in their homes under a Medicaid benefit that accounted for the costs of the supplies and other components necessary for the safe administration of

these drugs. When these dual eligibles were transitioned to the Medicare Part D program, many experienced difficulties with obtaining their drugs and supplies in the formats necessary to safely continue their therapies at home. Under Medicare Part D, the Prescription Drug Programs (PDPs) did not plan for the coverage of these drugs and their necessary supplies when these patients transitioned to Medicare Part D. Prior to the January 1, 2006 start date, Hospira contacted each of the 10 National PDPs to inquire on their preparations for the dual eligibles who required infusion drugs and supplies and each of the 10 Part D PDPs reported they were unaware of the dual eligible requirements for injectable and infusion drugs under the Medicare Part D program.

We urge CMS to work with physicians, patient advocacy groups, suppliers and manufacturers to outline all the components required to safely utilize DMEPOS in a beneficiary's home, and to require that education and outreach of this part of the bid be included for suppliers.

Recommendation #2: CMS should require that the "composite bid" and the single payment amount for the individual items within each product category reflect a composite bid that includes not only the cost of the DME item by HCPCS code and related supplies, but also the cost for all the other necessary components, such as the clinical services, beneficiary education and adherence to the yet unpublished quality standards for DMEPOS suppliers.

IV. Gap Filling

CMS proposes to amend its current gap filling methodology for establishing fee schedule amounts for certain items of new DMEPOS and for readjusting fee schedules for some items of DMEPOS which had been previously established using gap filling. The proposed new procedure would include a technology assessment based on a comparison of three areas: function, price and medical benefit. CMS contends that the Council on Technology and Innovation has endorsed this initiative in order to coordinate the activities of coverage, coding and payment and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

While we agree that it is important to coordinate communication of technology information among different sections of CMS and between CMS and its contractors, the administration and review of a comparative technology assessment is a comprehensive effort that raises many important procedural questions, such as:

- What would trigger such an assessment?
- Which of the three areas (function, price and medical benefit) of the assessment would be the first area of comparison?
- Which criteria would be used for assessment in each of the three areas (function, price and medical benefit)?
- Which entities within CMS would participate and at what level?
- What is the role of the FDA?
- When and how would outside contractors be used?
- When and how would outside stakeholder opinions be solicited?

Because of the complexity, comprehensive nature and serious implication for this type of initiative, CMS's use of the comparative technology assessment should be held to at least the same level of procedural predictability and transparency as the process for development of a National Coverage Determination, which has recently been defined in a guidance document published by the CMS Coverage and Analysis Group.

Moreover, this new initiative is not required as part of the implementation for competitive bidding and is not mandated by either the MMA or the DRA.

Recommendation #3: Hospira recommends that all references to the technology assessment as a part of gap filling should be removed from the Final Rule and that a separate proposed rule, with specific procedural requirements, be published for comment.

Summary:

In conclusion, as the manufacturer of Infusion Pumps & Related Drugs, Hospira recommends to CMS that this product category and policy group not be included in a DMEPOS Competitive Bidding Program. Overall the safety of the Medicare beneficiary may be compromised under such an approach. In addition, we recommend that CMS carefully consider all the necessary service components required to safely utilize piece of DMEPOS into a beneficiary's home and only consider bids that address all of these components. Finally, we strongly suggest CMS provide significant education and outreach to suppliers on the requirements of the competitive bid program to ensure beneficiary safety and seamless transition of Medicare beneficiaries without disruption of their medically necessary therapies.

As CMS considers adding Infusion Devices & Related Drugs to later rounds of competitive bidding, Hospira recommends that CMS start gradually with this broad category by only bidding one Infusion Device subcategory. A gradual phase-in of subcategories of Infusion Devices would allow CMS and suppliers to gain experience in this highly specialized area of devices without taking on all varieties of Infusion Devices at once.

Hospira Worldwide Inc. thanks CMS for the opportunity to comment on the CMS-1270, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" (Proposed Rule). We applaud CMS in reaching out to manufacturers throughout the process, including the creation of the yet-to-be released Quality Standards for Infusion Suppliers and Total Parenteral Nutrition Suppliers. We invite CMS to contact us in the future for any additional information or feedback.

Respectfully submitted,

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

Organization : Surgimed Corporation

Category : Health Care Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

First and foremost, I am against the idea of bidding on products that require a significent amount of service such as medical equipment. As you know, service is the most expensive component to the DME business so naturally it will be the first thing to suffer when cost cutting is the primary goal. With that said, and given that this passed regardless of the warnings and problems associated with it, I will address what I think is in need of further discussion and review. Like all industries, there are a few companies out there whose soul ambition is to make money, not to care for people. Having the accreditation piece in place is crucial for the integrity of the program. No bidding should even commence without a proven, defined criteria for DME companies to adhere to when being considered for participation. Leaders of the DME industry should be heavily involved in the process and accreditation should only be granted to companies that fall under these proposed rules and regulations. Another concern I have is the pace this program is to be implemented. There seems to be a push to get this in place without the proper time frame to assure its success. Let's face it, this is an enormous undertaking with a multitude of seen and unforeseen problems just around the corner. Getting into the middle of this mega project without all precautions being considered is just a disaster waiting to happen. I propose you slow the implementation down and be ready to evaluate precisely the fallout from this so a quick resolution can be administered. But by keeping it small and controlled initially, you will be able to "stop the bleeding" more quickly with less casualties, pardon the expression. Let me reiterate, competitive bidding is a bad idea, but if it is going to happen let's be smart about it. We are a pharmacy as well and when January 1st came around this year, it was chaos. The Medicare Prescription program was thrown down the throats of the American public who was obviously not ready for its complexities. My advice is the same advice I'd give a friend building a house. Expect delays. If you think it will take 6 months before you move in, plan on a year. If you budgeted so much money to complete the project, multiply that by one and a half times that number. And first and foremost, be very cautious of the people that say they can do the same job for a lot less money. There is no truer statement than "you get what you pay for". Does anybody really want the company that was "cheaper" to be the company responsible for their mothers oxygen needs? If you were having heart surgery, would you want the surgeon that submitted the "winning bid" to perform the procedure? My point is clear. If you are going to make saving money the primary objective in the DME industry, be prepared to safeguard the system and protect our seniors. This is a huge undertaking that you must take the proper time to implement. My final point is this: Pass HR 3559. This important legislation builds in some of the important safeguards I have discussed. It includes an amendment that allows smaller providers to be able to continue in the Medicare program at the winning bid amount, as long as they meet all other criteria. I support this. In conclusion, I am reminded of a letter that circulated around office e-mails a few years back. It was a letter, written by a seven year old girl to the airline pilot of the plane she was riding on. It read something like this: Hi! My name is Nicole and I am seven years old. This is the first time on an airplane. The clouds and sky are beautiful up here. Mommy says we will have a snack soon. Everyone is really nice and I am having so much fun. Thank you for being such a good pilot, you are so brave. Have a good day. By the way, please don't fuck up the landing. Love, Nicole. A smiley face was drawn at the bottom. Competitive Bidding has been up in the air for years. Just remember what Nicole said.

Submitter : **Dr. Harold Goldstein** **Date: 06/29/2006**

Organization : **Dr. Harold Goldstein**

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

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

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

Sincerely,

Harold L. Goldstein, DPM, FACFAS

Submitter : Dr. Harry Goldsmith

Date: 06/29/2006

Organization : Dr. Harry Goldsmith

Category : Health Care Professional or Association

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I am commenting on the classification separation of podiatrist DMEPOS suppliers from MD/DO DMEPOS suppliers and how it potentially effects patient care.

CMS-1270-P-801-Attach-1.DOC

Harry Goldsmith, DPM

13337 E. South St. #325
Cerritos, CA 90703
562 402-0789 hgfca@gte.net

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

To Whom It May Concern:

Having reviewed the Medicare proposed rule regarding competitive acquisition for DMEPOS, I am at a loss to understand why podiatrists were classified separate from MD and DO physicians in terms of supplier requirements. Other than being arbitrary (at best) or discriminatory (at worst), what defining differences exist between the DPM, MD, and DO as provider-suppliers? When considering the process of competitive acquisition, how is the cause of competitiveness served by developing two classes of physician-suppliers – one class that deals specifically supplying patients within their practice, and one placed into a more complex category that deals with the community at large? When a patient with a fracture metatarsal is diagnosed and treatment is initiated in a doctor's office, MD/DO DMEPOS "physician-suppliers" are able to dispense, on the spot, crutches for patients to leave the office, while, if the proposed classification of podiatrists is accepted, DPM "physician-suppliers" (if they are not the community "crutches" supplier) will need to give the patient with a fractured metatarsal a prescription to take to the supplier to get their crutches. This is inefficient, and bad medicine. Essentially, the patient is the one that suffers having to go elsewhere for a supply that could be (and should be) otherwise dispensed "on the spot."

I would ask that CMS reconsider its proposal to not include podiatrists (DPMs) in the same physician category as MDs and DOs. Nothing has been included in the proposal by CMS to explain the logic behind not including DPMs in the same category as MDs and DOs in the competitive bidding process for suppying certain DMEPOS.

Thank you for the opportunity to comment.

Harry Goldsmith, DPM

Submitter : Mr. Alex Lapp **Date:** 06/29/2006

Organization : Highline Hand Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

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

My Position: I request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care. Although I applaud your effort to look for ways to save money. However, this proposal, for many reasons, will compromise care and in many case cost more due to compromised care.

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

My name is Alex Lapp, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in an outpatient facility and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses.

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

Organization : **Cook County Hospital**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attachment (I am resending this attachment as I recieved an error on a prior transmission)

CMS-1270-P-803-Attach-1.DOC

June 29, 2006

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

To Whom It May Concern:

My name is Stathis Poulakidas, M.D., and I am the recently hired Burn Director at Cook County Hospital, Chicago, IL. Up until this time, I have been an Assistant Professor of Surgery at Loyola University Medical Center, Maywood, Il, where I have specialized in the management of critically ill Trauma and Burn patients. I see some of the most horrific disease processes and have had wonderful outcomes based on use of the V.A.C. device by a company called KCI from San Antonio, TX. Having used this device for about 6 years now, I have seen a significant improvement in patient care from the standpoint of more rapid and complete wound healing. Along with this, I have cared for patients who likely would have died had it not been for this device prolonging their life, if not saving their lives, by its modality of action. Volume of literature exist in support of the V.A.C. and its ability to (1) improve blood flow to a wound, (2) remove bacteria from a wound, and (3) improve the rates of closure of wounds by improving the granulation tissue to the bed of any wound. It is these 3 concepts that allow for wounds that I care for in Trauma/Burn patients to heal. It is this device that allows these patients to survive their devastating injuries.

On the other hand, there is a device called the Versatile One, by the Blue Sky co., based out of San Diego, CA. Having seen and used this device, I have found it to be not only an inferior product, but I have seen outcomes which are detrimental to patient care. This company utilizes anecdotal data from V.A.C. (KCI) studies and infers their device is similar. This could not be further from the truth. The Blue Sky device has no data to support it and has no safety monitors to protect patients from adverse consequences, should the device fail to function properly. This is not the case with the KCI device as it does have such safety measures programmed into its CPU.

With this prelude, I am writing this letter in response to the CMS file code CMS-1270-P, for the proposal of competitive bidding with regards to use of devices which allow for negative pressure wound healing. This proposal, in my estimation, is potentially going to restrict and eliminate physician choice in regards to which of the above devices can be used based on cost. I feel this will be harmful to patient care, as the use of a potentially inferior device may be mandated for use in Medicare patients. By limiting the ability to use the KCI device, I caution that the only persons to suffer with this decision will be our patients, as their ability to heal will be compromised by using an unsafe device. Caring for critically ill patients, I have seen enormous success with the use of the V.A.C, as I eluded to above. More importantly, in this day and age of internet accessibility, my

patients are more educated and in many instances they can interpret data and identify which modalities of care will benefit them. With this, I have seen huge support from my patients with regards to use of the V.A.C. (KCI) in order to manage their wounds.

More importantly, as a physician, I find it difficult to understand why I should be mandated to use an inferior product, which can compromise my patient care, when I know based on data that a superior device (the KCI V.A.C.) is available which will allow for an overall improvement in patient outcome . If such an action is undertaken, I feel physicians who manage critically ill patients will be put at a huge disadvantage. By allowing this to occur, a device which has only limited use and experience (the Blue Sky apparatus) will be thrown into patient care only to display detrimental outcomes.

With this, I champion the powers that be at the CMS offices to closely look at this issue so as to allow for the ability of the physicians to choose which modality of treatment they wish to administer. Please do not remove this decision from the hands of those of us who fight the battle everyday to try to keep our patients alive. By supplying us with only inferior modalities of care, such as the Versatile One device, I only see patients having adverse outcomes in the future.

Thank you for your time and support.

Stathis Poulakidas, M.D.
Director, Burn Unit
Cook County Hospital
Chicago, IL

Date: 06/29/2006

Submitter :

Organization : New York and New Jersey Carrier Advisory Committee

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-804-Attach-1.DOC

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

MEDICARE
Part B Carrier

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:

At yesterday's joint New York and New Jersey Carrier Advisory Committee meeting, the committee voted and approved sending this letter to CMS as their comment regarding certain provisions of the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS.)

I am forwarding that letter to you on page 2, in the role of their facilitator, so it will be received before the close of comments. The Co-Chairpersons of the New York and New Jersey Carrier Advisory Committee are:

New York
Robert Goldberg, D.O.
Medical Society of the State of New York
314 West 14th Street
New York, NY 10014
E-mail <drrobertg@aol.com

New Jersey
Clifford M. Sales, MD
45 Farbrook Drive
Short Hills, NJ 07078
E-mail <CMSDAD@comcast.net

Sincerely,

Gail Rounds

Gail Rounds
Senior LPET Coordinator

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:

We are writing in opposition to certain provisions of the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

As the New Jersey and New York Carrier Advisory Committee we recognize there are physicians that dispense DME as an integral part of their management of patients. For example, patients with acute injuries are dispensed splints or walkers at the time of diagnosis. To delay this process in order for a patient to find a qualified DME supplier would gravely impair the quality of care we have worked so hard to achieve for our patients.

It is our understanding that physicians represent 3.1% of all allowed dollars for DME. We feel to exclude them from competitive bidding would have little impact on the overall cost savings anticipated by competitive bidding. A competitive acquisition program that requires physicians to bid to in order to supply items to their patients will surely result in the elimination of the vast majority of physician suppliers from the program. Even if physicians are allowed to organize a network to provide DME as suggested by CMS, it is very unlikely they will be able to provide all the various selection of items required by the proposal. Again, if physicians can not directly supply DMEPOS items to their patients it is their health that will suffer.

We urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

Members of the New York and New Jersey Carrier Advisory Committees