

Submitter :

Date: 06/12/2006

Organization :

Category : Individual

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please do not place "lowest price" as the criteria for selecting items needed for continued health of our elderly. People want choice and need choice and will do far better with choice. If cost is the single most important issue, establish a REASONABLE Not to Exceed cost where any cost in excess can be paid by the individual. That will allow choice.

Submitter : Mrs. Ann Peterson
Organization : Keystone Blind Association
Category : Other Association

Date: 06/12/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

I am addressing Section 414.15, the exclusion of payment for CCTV's (closed circuit TV's) provided by CMS. For many of the individuals who are visually impaired, a simple refractive correction in glasses or contact lenses is inadequate to enable that person to use his/her vision to the best of his capabilities. Quite often, even low vision glasses may be too heavy, cumbersome or too strenuous for that individual to wear. I have been working with visually impaired individuals for almost 30 years and can verify that CCTV's have opened up a new world for many people who have struggled with glasses or magnifiers for years. If a doctor or low vision specialist recommends a CCTV for an individual, I would hope that Medicare or Medicaid would continue to cover this much-needed equipment.

Submitter : Mr. David Plum

Date: 06/12/2006

Organization : Mr. David Plum

Category : Individual

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I think the companies research and attention toward prevention and treatment of diabetes should be considered rather than the cost of the diabetes monitoring equipment. In our competitive capitalistic economy, if buyers judge only by price then there is little hope for medical equipment and supply companies to generate revenue for research into prevention and treatment, which are more important in controlling or reducing the spread of diabetes.

Submitter : Mr. jon konrad

Date: 06/12/2006

Organization : abbott

Category : Device Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Re: Blood Glucose Monitoring- please consider keeping all glucose meters available to pts with diabetes. Choice is an important aspect in getting the best diabetes control. If you defer to a limited technology you are going to increase cost even further in diabetes related spending. Pts with diabetes rely on superior technology in specific brands to help reduce micro/macro complications.

Thank you,

JK

Submitter : Gail Mapes

Date: 06/12/2006

Organization : Gail Mapes

Category : Individual

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As a patient using an insulin pump, I want want and need choice in my use of pumps, glucose monitors and testing strips (there really is a difference). Without it my health will suffer and Medicare will end up paying out much more in medical bills. That problem is with lack of attention toward prevention and treatment, not the price of diabetes technology.

Submitter : Linette Corwin
Organization : Schaeper's Pharmacy
Category : Pharmacist

Date: 06/12/2006

Issue Areas/Comments

GENERAL

GENERAL

Although I understand the need for standardization & simplification where Medicare DME billing is concerned, removing the ability of community pharmacists to serve their diabetic patients is ludicrous. Diabetes is the fastest growing health care crisis this country & the world in general is facing. How can pharmacists help this population if they can't even fill their diabetic supply prescriptions? In attempting to limit the amount of qualified Medicare DME billing entities, you will also limit the quality of care diabetic patients receive. If easy access to strips, meters, shoes, etc. isn't afforded the diabetic patient, their health care will be compromised leading to increased doctor visits & hospital admissions. How can this competitive bidding program possibly be a step towards cost containment??? Please rethink the care of the diabetic patient when formulating who will be able to participate as a DME supplier. A couple of million diabetic patients are counting on you!!!

Submitter :

Date: 06/12/2006

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am told that determining what diabetic blood glucose meter and strips medicare will pay for will be determined by cost/price and not accuracy/reliability or the ability to communicate information to treating physican. My insurance company last year determined that all of their diabetic clients were to use the cheapest meter they could find (True Track) because the strips were cheaper, results were faster and blood sample was smaller, none of these reasons played a role in the patient gaining and/or maintaining tight bg control in an effect to forestall complications, which would be more costly than strips/meter. My meter (accucheck) held 1,000 events, d/l data from meter to computer so that analysis could be effectively read by my doctor so he could make informed decisions re: my care & well being. My meter was more accurate and consistant than the stripped down meters. It required a slightly larger blood sample and took about 30 seconds more to report results but the results were needed to determine accurate insulin dosage (am type I) using pre meal readings, correction factor re: hypos or hyper readings and whether each insulin (basal and bolus) was acting effectively. The cheaper meters/strips afford none of these necessary features.

My insurance company allows me to use the more accrate meter/strips and I am grateful for that and would hate to find out that my government does not have the same concern and consideration as to my welfare and prolonging my life.

Submitter : Ms. cynthia kotlicky
Organization : AdVance Mrdical Equipment, Inc.
Category : Other Health Care Professional

Date: 06/12/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

To Whom It May Concern:

Within the next 7 months your organization will launch a competitive bidding program in 10 large MSA's. CMS has a huge responsibility to Medicare beneficiaries as well as to the tax payors of this country. You must provide the ability for beneficiaries to obtain quality medical equipment and service for a reasonable fee. This is not an easy task and I do not believe that any reputable DME would want their equipment and services offered to beneficiaries in any other manner. I do feel, however, that you are not allowing these companies the ability to work with you to their full potential.

First, you are allowing information from unqualified bidders to calculate the single payment amount. I believe only qualified bidders should be included in determining these bid amounts.

DME's who are not willing to invest the time and the money to become a qualified accredited organization should not be involved in determining the reimbursement allowance for equipment and servicing.

Second, you have not yet established what products will be included in the program. The providers of these products and services need time to evaluate the costs associated with purchasing delivering and servicing these products. Look at the price of gasoline right now. Are DME's supped to eat these costs while they pay higher shipping and delivery costs to their suppliers? Suppliers need to know which products are on your bid list so they are able to purchase the quality coded products at a reasonable rate.

Third, the cities where the bidding will be introduced should have been chosen months ago. The suppliers in those cities will need preparation time. They will need to accumulate data to submit realistic bids. They may need to hire additional personnel to service beneficiaries properly.

Fourth, you have not yet published, in final form, the quality standards you require for the accrediting agencies. How can you expect all of the providers in the 10 MSA's to become accredited before the bidding process begins if you have not set up standards and you have not chosen the MSA's? Do you not want providers to participate in the bidding process?

Fifth you have passed the capped rental for oxygen equipment but have you given any thought to how your beneficiaries will be serviced after the 36 months are over? Have you determined how providers, who win bids, will be compensated, for accepting beneficiaries who are in the final months of their 36 month rental period? How can providers factor in these unknown costs without enough information and notice?

Finally you have introduced the concept of "consumer rebates." I do not believe any reputable provider would want to be accused of fraud or abuse. Is Medicare that wealthy that they can afford to offer inducements to beneficiaries? If so, then why are they instituting a bidding process to save money?

It appears that some of the people involved in the decision making process have not thoroughly thought the process through. The beneficiary should be the most important part of this equation. When the capped rental on oxygen was passed no guidelines for servicing were set forth. Although no beneficiaries will reach the capped rental until 2009 many of them are worried about who to call when a unit malfunctions or a bottle needs to be replaced. If a beneficiary needs to visit an emergency room of a hospital instead of calling their provider how much money will Medicare spend? Will you be saving money or spending more for higher cost services?

Please spend the time necessary to institute a bidding process that will benefit the beneficiaries, taxpayers and providers. Allow your beneficiaries to continue to receive quality service from their providers. Thank you.

Cynthia Kotlicky
AdVance Medical Equipment, Inc.

Submitter : Mr. Steve Thompson

Date: 06/12/2006

Organization : n/a

Category : Individual

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

I am a diabetes 2 patient, and have recently retired. I am concerned that the results of CMS-1270-P will be to select the least expensive equipment and strips to support diabetes patients. It has been my experience that the cheapest is not always the most accurate and consistent for glucose monitoring, by comparison with what is used in labs and at my endocrinologist's office. To me the issue is the quality of the device/strip combination to provide accurate and consistent results.

I also think it is important in the selection process to give due consideration to those suppliers who will continue to invest in research to improve their device/strip products. Also we need to be sure that we do not simply concentrate our spending on monitoring activities, but that we also encourage investment in diabetes prevention and treatment (such as Byetta).

Thank you for your consideration of these comments.

Submitter : Susan
Organization : Susan
Category : Individual

Date: 06/12/2006

Issue Areas/Comments

Issue

Issue

In order to ensure that Medicare can consider other (read: non-price) considerations in awarding bids for glucose testing supplies (this means, in order to ensure companies will still be able to invest in patient and provider education, innovation, customer service, etc, I feel compelled to add comments about choices for medical testing supplies (meters and strips). One size does NOT fill all for a diabetic. I have two meters, one purchased on my own. It does not read my blood sugar accurately. According to my A1c readings, the other meter gives great, though slower, accurate readings. Each person and doctor must decide what is right for that person. Less choice means less control, thus more problems and higher medical expenses in the long run.

Submitter : Mr. Randy Freeman
Organization : Mediwell Inc
Category : Health Care Industry

Date: 06/13/2006

Issue Areas/Comments

GENERAL

GENERAL

I am a medical equipment dealer from Texas. I would like to express my dismay with the process of selecting dealers for the comp.bidding areas. It seems ridiculous for winning dealers to not be able to participate across the board in all the products.If we win a bid for beds, but lose on wheelchairs,another company will have to be called.This is a waste of staff time and money for the referral sources and patients.The patient is then required to have 2 separate deliveries from different companies.I know cms used this approach in the demonstration areas, however, that was a tempoary situation and the dealers knew they could wait for the end of the project.According to my information, it became difficult to obtain a bed in the san antonio project. Across the board, weighted average bids for all products is imperative to save time money and resources(especially gasoline).

The issue of rebates is also ludicrous.Aren't we tring to combat fraud with competitve bidding? I am very concerned for the bureaucratic genius who conceived this idea!

CMS needs to get on the ball in this process and give the dealers some solid information.The fate of our companies are sitting in this quagmire. We do not have enough time to formulate a strategic bid, while this murky bureaucracy attempts to attach the engine to the bow of this ship.

Submitter : Ms. Helen Mueller
Organization : Ms. Helen Mueller
Category : Individual

Date: 06/13/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I refer to strips and meters to check blood glucose in diabetics. As a patient and a member of a medicare HMO, I am being forced to change to a strip and meter that are not my preference and away from a strip and meter that are both more precise and accurate. As I use insulin, these features are important to me. However, the strip the insurance prefers is probably more profitable for them. If medicare confines itself to only that equipment which costs the least, my situation may worsen and others will be stuck along with me. I would like to see the opposite, medicare forcing plus policy providers to offer a better selection of strips.

Because I cannot trust the strips I am using, I cannot attain the tight control I need to avoid diabetic complications. When five tests range from a low of about 80 to a high of 134, how is one to choose the best amount of insulin? You wind up choosing the most conservative, and then chasing high numbers all day with corrections, using more needles and strips in the long run.

Submitter : Bruce Lenich
Organization : Bruce Lenich
Category : Individual

Date: 06/13/2006

Issue Areas/Comments

GENERAL

GENERAL

Diabetes testing is one of the critical aspects of managing the major threat to my continued well-being. If Medicare payment for test strips is determined by low bidder, and all Medicare participants are required to use one test strip, the accuracy of the test results may be in jeopardy. Competitive bidding usually results in putting cost before quality, therefore the test strips on the approved Medicare payment schedule may not provide the most accurate information regarding blood glucose levels. Secondly, and equally important, I have spent significant time with my diabetes care team becoming familiar with all aspects of my meter and test strips as they integrate into a total plan which has kept my blood glucose well controlled, my HbA1c consistently at 6.0, and has been responsible for enabling me to avoid any of the complications which usually occur in persons with insulin dependent diabetes for over 20 years. To change that regimen of care by requiring a different meter and test strips would be opening the possibility for some major complications in my diabetes care, resulting in costs far in excess of the costs presently being invested in me by Medicare. Please give consideration to continuing the present system of allowing the medical team and the patient to determine which meter and test strips best suit their needs for optimal results in the management of their diabetes. Thanks. Bruce Lenich

Submitter : Mrs. Linda Pearce
Organization : Montgomery Regional Hospital
Category : Nurse

Date: 06/13/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Why allow competitive bidding for low cost items when help individuals with diabetes attain and maintain blood glucose control and help avoid costly problems like dialysis, heart transplants, cardiovascular surgery, amputations, etc. The cost of the best technology for control is only a small drop in the bucket compared to the costly surgeries and other items that result from poorly controlled diabetes. Thank you.

Submitter : Mrs. Annette Grotz
Organization : Mrs. Annette Grotz
Category : Individual

Date: 06/13/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The problem is with lack of attention toward prevention and treatment, not the price of diabetes technology. Please provide choices for medicare patients needing to buy diabetes products.

Submitter : Mrs. Kathryn Patterson
Organization : Reston Hospital Center
Category : Nurse

Date: 06/13/2006

Issue Areas/Comments

Education and Outreach

Education and Outreach

Promote lifestyle changes in the government. Walking trails, education campaigns, encourage walking in cities by building redesign, change tax structure in favor of food establishments and companies that promote healthy eating. In low income areas designate plots of ground for community gardens so that these people can have access to expensive fresh fruits and vegetables. Leave some playing fields in the cities for sports. We'll pay more in the end if we don't.

**Submission of Bids Under the
Competitive Bidding Program**

Submission of Bids Under the Competitive Bidding Program

People deserve the ability to choose the blood glucose meter that will work best for them. Not all meters have the same capability. Some will not give accurate results with a hematocrit less than 30%; not good for anemic patients. Some can be used easily by stroke victims, others can't. Some have displays that allow people with poor vision to see the displays easily. Some use a tiny droplet of blood and are good for those with tender fingers. Don't limit choice and access.

Submitter : Mr. Larry Parrish
Organization : SHOP RITE DRUGS, INC
Category : Pharmacist

Date: 06/13/2006

Issue Areas/Comments

GENERAL

GENERAL

I STRONGLY OBJECT TO CMS' ALTERNATIVE PROPOSAL THAT WOULD REQUIRE BENEFICIARIES TO OBTAIN REPLACEMENT SUPPLIES OF CERTAIN ITEMS THROUGH DESIGNATED PROVIDERS AS THIS WOULD RESTRICT BENEFICIARIES CHOICE. THIS MAY SEVERLY COMPROMISE PATIENT HEALTH OUTCOMES. FURTHERMORE, I FEEL THAT COMP. BIDDING PROGRAM SHOULD NOT INCLUDE COMMON DMEPOS SUPPLIES SUCH AS DIABETIC SUPPLIES.
CMS MUST TAKE THESE STEPS TO PRESERVE BENEFICIARIES CONVENIENT ACCESS TO DMEPOS SUPPLIES AND TO MAINTAIN ESTABLISHED PROVIDER/PATIENT RELATIONSHIPS

Submitter : Mrs. Jeannie Hickey
Organization : Kaiser Permanente
Category : Nurse

Date: 06/13/2006

Issue Areas/Comments

GENERAL

GENERAL

I am concerned you may choose just one meter for diabetics to use for glucose readings. You well know the cost of diabetes complications to society. To reduce those complications, good glucose control is vital. Saving money on strips & meters will only save the Gov. money if the choice is for a reliable company. Choose well, not cheep.

Low cost strips could have a higher error rate so that patients must use more strips.

Submitter : Mr. FREDERICK NAYOR
Organization : Mr. FREDERICK NAYOR
Category : Consumer Group

Date: 06/13/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

PLEASE, 'PRICE' CANNOT BE THE ONLY, NOR PRIMARY FACTOR FOR COMPETITIVE AWARDS. I DEPEND ON ACCURATE AND RELIABLE (CONSISTENT FROM TEST TO TEST) READINGS FROM MY GLUCOSE TEST UNIT (TESTER AND TEST STRIPS) FOR CONTROL OF MY TYPE 1 DIABETES.

Criteria for Item Selection

Criteria for Item Selection

PLEASE, "PRICE" CANNOT BE THE ONLY, NOR PRIMARY FACTOR FOR ITEM SELECTION. I DEPEND ON ACCURATE AND RELIABLE (CONSISTENT FROM TEST TO TEST) READINGS FROM MY GLUCOSE TEST UNIT (TESTER AND TEST STRIPS) FOR CONTROL OF MY TYPE 1 DIABETES.

Submitter : Bruce Harvey
Organization : Bruce Harvey
Category : Individual

Date: 06/13/2006

Issue Areas/Comments

GENERAL

GENERAL

As a Type-2 Diabetic and fast approaching Medicare eligibility, I am concerned that you are considering covering only testing devices and strips from the lowest bidder. Meters that store data, track trends, and interface with personal computers allow diabetics to better manage their blood sugar levels, resulting in less complications and lower claims. It is better to spend a few cents in prevention than several dollars in treating complications. I urge you to compare other capabilities other than price when making a determination on what diabetic testing devices Medicare will cover.

Thank you very much,
Bruce Harvey

Submitter : Dr. Andrea Tiktin-Fanti

Date: 06/13/2006

Organization : Dr. Andrea Tiktin-Fanti

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please give patients access to a variety of diabetes testing supplies. It is very cost effective as frequent testing keeps people from getting complications which cost Medicare much more.

Submitter : Dr. Jeffrey Frederick
Organization : Dr. Jeffrey Frederick
Category : Health Care Provider/Association

Date: 06/13/2006

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I request that the Centers for Medicare & Medicaid Services (CMS) exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I believe that the proposal, if finalized in its current form, could interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients. This proposal would have a negative effect on patient outcomes, eventually costing the program more money in the long run and contributing to poor patient care.

Submitter : Dr. Joseph Gonzalez
Organization : American Podiatric Medical Association
Category : Physician

Date: 06/13/2006

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner
please see attached letter.

thank you

CMS-1270-P-161-Attach-1.DOC

Submitter : Dr. Donald Fedder

Date: 06/13/2006

Organization : Board for Orthotist/Prosthetist Certification (BOC)

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1270-P-162-Attach-1.DOC



**Board for
Orthotist/Prosthetist
Certification**
THE ADVANTAGE IS EXPERIENCE™

Board for Orthotist/Prosthetist Certification
100 Penn Street, Room 505
Baltimore, Maryland 21201
Phone: 1.877.776.2200
FAX: 410.706.0869
Email: info@bocusa.org
Website: www.bocusa.org

June 13, 2006

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

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

Dear CMS Colleagues:

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

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

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

Major points follow:

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

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

Privileging

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

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

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

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


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

Sincerely,

A handwritten signature in black ink, appearing to read "Donald O. Fedder", with a long horizontal flourish extending to the right.

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

Appendix A: COF Content Outline

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



Board for
Orthotist/Prosthetist
Certification

THE ADVANTAGE IS EXPERIENCE

Certified Orthotic Fitter Detailed Content Outline

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



Board for
Orthotist/Prosthetist
Certification

THE ADVANTAGE IS EXPERIENCE

Certified Orthotic Fitter Detailed Content Outline

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



Board for
Orthotists/Prosthetists
Certification

THE ADVANTAGE IS EXPERIENCE

Certified Orthotic Fitter Detailed Content Outline

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



Board for
Orthotist/Prosthetist
Certification

THE ADVANTAGE IS EXPERIENCE

Certified Orthotic Fitter Detailed Content Outline

	Total	Recall	Application	Analysis
J. Shoulder Orthoses (SO) (e.g., dynamic and adjustable R.O.M., resting, and functional orthoses)				X
K. Functional Fracture Orthoses (e.g., upper extremity and lower extremity)				X
L. Abdominal and Pelvic				
1. trusses (e.g., flexible and rigid)				X
2. flexible supports				X
3. maternity supports				X
M. Compression Devices				
1. lymphedema garments				
2. compression garments				X
3. burn garments				
N. Breast Prosthesis and Ancillary Supplies				X
Totals	100	24	60	16

Submitter : Ms. Patricia Dibblee
Organization : Skyview Medical Supply
Category : Other Health Care Provider

Date: 06/13/2006

Issue Areas/Comments

**Submission of Bids Under the
Competitive Bidding Program**

Submission of Bids Under the Competitive Bidding Program

Attached are comments expressing some of my specific concerns regarding the implementation of competitive bidding particularly in regard to:

F. Submission of Bids Under the Competitive Bidding Program 414.412

CMS-1270-P-163-Attach-1.DOC



June 16, 2005

CMS
Department of Health & Human Services
PO Box 8013
Baltimore MD, 21244-8013

Re: CMS-1270-P

Below are comments expressing some of my specific concerns regarding the implementation of competitive bidding particularly in regard to:

F. Submission of Bids Under the Competitive Bidding Program 414.412

For background, we are a small medical supply company (\$1 million annual revenue) serving a unique niche market. We supply Part B covered items and handle third party billing for beneficiaries residing in nursing facilities. Our business model is to contract with groups of nursing homes to provide this service so that nursing staff do not waste valuable time ordering and trying to manage supplies for patients from a myriad of suppliers. (Obviously some patients opt for a different supplier and some are forced by managed care plans to use a particular supplier, but we simplify the caregivers' jobs as much as possible.)

Because of this unique specialty we have a limited product line of Part B covered items that include:

- Enteral food, supplies & pumps
- Ostomy supplies
- Urological supplies
- Surgical dressings
- OTS orthotics

We are concerned with the potential disruption in beneficiary care and possible quality risks if this group of Part B covered services are split between bidding suppliers. While we might win the bid to continue supplying enteral food, the bid for urological and ostomy might go to two

other suppliers. This would mean that the already overworked caregivers have to remember and take time to order each category of supply used by a patient from a different vendor. Deliveries will be made at different times and not together increasing the workload on central supply staff to properly identify product to patient. Juggling re-orders will require additional staff management.

All these factors create additional system costs in labor, gas, paperwork, etc. for everyone involved. The risk to the patient of not receiving the proper supplies at the proper time is increased. And nothing is improved by this process. So for the benefit of a small decrease in payment by CMS, every other participant in the care delivery process loses financially through direct and/or administrative cost in addition to the reduced fee. And out of all this the beneficiaries' service and caregiver time decreases.

I do not see how this fits with the purported intent of the legislation which seemed to be to protect beneficiaries who are at home and at risk of being taken advantage of. Since the supplies we provide are all ordered and approved by a licensed facility's clinical staff and the patient's physician, they are highly supervised and controlled.

I would recommend CMS exempt Part B supplies to nursing facilities from these regulations whether they are billed by a supply company such as ourselves or by the nursing home with a DMERC number. If the bottom line is achieving dollar savings, this can be achieved by simply lowering the fee schedule payment for these items without adding all the administrative costs. If the quality of the products is somehow deficient, the facility will simply change suppliers. So both quality and cost are controllable in the absence of competitive bidding.

I respectfully request your re-consideration of this issue.

Sincerely,
Patricia Dibblee
President
Skyview Medical Supply
tdibblee@skyviewmed.com
Direct 971-224-2019

Submitter : Ms. Patricia Dibblee
Organization : Skyview Medical Supply
Category : Other Health Care Provider

Date: 06/13/2006

Issue Areas/Comments

**Submission of Bids Under the
Competitive Bidding Program**

Submission of Bids Under the Competitive Bidding Program

Below are comments expressing some of my specific concerns regarding the implementation of competitive bidding particularly in regard to:

F. Submission of Bids Under the Competitive Bidding Program 414.412

For background, we are a small medical supply company (\$1 million annual revenue) serving a unique niche market. We supply Part B covered items and handle third party billing for beneficiaries residing in nursing facilities.

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- " Enteral food, supplies & pumps
- " Ostomy supplies
- " Urological supplies
- " Surgical dressings
- " OTS orthotics

We are concerned with the potential disruption in beneficiary care and possible quality risks if this group of Part B covered services are split between bidding suppliers. While we might win the bid to continue supplying enteral food, the bid for urological and ostomy might go to two other suppliers. This would mean that the already overworked caregivers have to remember and take time to order each category of supply used by a patient from a different vendor. Deliveries will be made at different times and not together increasing the workload on central supply staff to properly identify product to patient. Juggling re-orders will require additional staff management.

All these factors create additional system costs in labor, gas, paperwork, etc. for everyone involved. The risk to the patient of not receiving the proper supplies at the proper time is increased. And nothing is improved by this process. So for the benefit of a small decrease in payment by CMS, every other participant in the care delivery process loses financially through direct and/or administrative cost in addition to the reduced fee. And out of all this the beneficiaries service and caregiver time decreases.

I do not see how this fits with the purported intent of the legislation which seemed to be to protect beneficiaries who are at home and at risk of being taken advantage of. Since the supplies we provide are all ordered and approved by a licensed facility's clinical staff and the patient's physician, they are highly supervised and controlled.

I would recommend CMS exempt Part B supplies to nursing facilities from these regulations whether they are billed by a supply company such as ourselves or by the nursing home with a DMERC number. If the bottom line is achieving dollar savings, this can be achieved by simply lowering the fee schedule payment for these items without adding all the administrative costs. If the quality of the products is somehow deficient, the facility will simply change suppliers. So both quality and cost are controllable in the absence of competitive bidding.

I respectfully request your re-consideration of this issue.

Sincerely,
Patricia Dibblee
President
Skyview Medical Supply
tdibblee@skyviewmed.com
Direct 971-224-2019

Submitter : Dr. John Parmelee
Organization : Covington Foot & Ankle Clinic
Category : Physician

Date: 06/14/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-165-Attach-1.DOC

CMS-1270-P-165-Attach-2.DOC

June 5, 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 a podiatric physician that has been in practice since 1991. I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I use items including walking boots for foot fractures and ankle braces for acute ankle injuries and night splints for plantar fasciitis. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result and it is inconvenient for them as most of them are older and have a hard time getting around. I cannot imagine telling a Medicare beneficiary that he or she must travel somewhere else to obtain an item that is both medically necessary and appropriate.

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

Sincerely,

John Parmelee, DPM

June 5, 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 a podiatric physician that has been in practice since 1991. I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I use items including walking boots for foot fractures and ankle braces for acute ankle injuries and night splints for plantar fasciitis. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result and it is inconvenient for them as most of them are older and have a hard time getting around. I cannot imagine telling a Medicare beneficiary that he or she must travel somewhere else to obtain an item that is both medically necessary and appropriate.

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

Sincerely,

John Parmelee, DPM

Submitter : Mrs. Kathryn Patterson

Date: 06/14/2006

Organization : Reston Hospital Center

Category : Nurse

Issue Areas/Comments

Education and Outreach

Education and Outreach

Diabetes Education Self Management training needs continued funding. Patients have no idea about the impact that this disease can have on their health. African American individuals, are much more at risk for end stage renal disease with costly dialysis to follow. In 2001 a total of 142,963 people with ESRD were on dialysis or had a kidney transplant from diabetes. Education can have a positive impact on decreasing costly complications by helping to improve blood glucose control. Other complications that can occur from uncontrolled diabetes include cardiovascular disease, blindness, nerve damage and amputation. 95% of diabetes care is self-care. People must be educated. A 15 minutes doctor's appointment does not provide the time required to do this.

Submitter : Dr. William Ofrichter
Organization : Dr. William Ofrichter
Category : Physician

Date: 06/14/2006

Issue Areas/Comments

GENERAL

GENERAL

June 13, 2006

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

Dear Dr. McClellan:

As a podiatric physician who has been in practice for more than 22 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. I use a wide range of DMEPOS items, including walking boots for foot fractures and ankle braces for acute ankle injuries. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury could result. I cannot imagine telling a Medicare beneficiary that I am unable to supply an ankle brace to treat an ankle injury and he or she must travel across town to obtain an item that is both medically necessary and appropriate.

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

Sincerely,
William Ofrichter DPM

Submitter : Ms. Jo Prang
Organization : Medicap Pharmacy
Category : Pharmacist

Date: 06/14/2006

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

We are a small franchise group of pharmacies in a town of 50,000. We provide glucose monitors, test strips & supplies to hundreds of patients between our four stores. I am writing to appeal to you to exempt diabetic supplies from your proposed regulation. It is critical for the diabetic to have easy access to supplies. Pharmacists have for years been the trainers and advisors on how to use the machine, how to prick your fingers/arms and how to change batteries. If you prevent us from selling the machines to our Medicare Part B patients, you effectively shut them out from this free assistance. There is no way that our small business can compete with the big mail-order companies in your competitive bidding process. The expense to get accredited alone is outrageous for the volume that we do. And though that volume may be relatively small in the big picture of CMS, it is important to those who receive our help and transmit those claims to Part B. CMS has stripped small-town pharmacy of so much that it seems our only option is to go out-of-business. Is this truly the goal CMS had in mind?? Good patient care involves face-to-face involvement of a professional- if mail-order prevails in the bidding process, patient care will deteriorate over the next decade. Is it then that CMS will say, gee- we should have exempted diabetic products from that bill long ago- by then it will be too late to bring us back! Please rethink this process, contact retail pharmacies in America, and consider the care your Part B diabetics get EVERY DAY in small town pharmacies across the nation. Believe me, it is actually worth more than the money the government is currently paying for it! Thank you, Sincerely, Jo Prang, RPH, VP of Operations, Medicap Pharmacies of the Black Hills
339 St. Patrick St. Rapid City, SD 57701 605-388-3622

Submitter : Mr. CHHAGAN VASOYA
Organization : EXPRESS PHARMACY, INC
Category : Pharmacist

Date: 06/14/2006

Issue Areas/Comments

GENERAL

GENERAL

CMS MUST DO MORE TO ENSURE THAT SMALL SUPPLIERS LIKE PHARMACY-DME CAN PARTICIPATE IN THE COMPETITIVE BIDDING PROGRAM, SMALL SUPPLIER SHOULE BE ALLOWED TO DEISGNATE A SMALLER MARKET IN WHICH TO PROIVE DMEPOS, IT WOULD BE DIFFICULT FOR SMALL SUPPLIERS TO BE COMPETITIVE IN LARGE METRO AREAS, ANY SMALL SUPPLIER WILLING TO ACCEPT CMS SINGLE PAYMENT AMOUNT SHOULD BE ALLOWED TO JOIN THE COMPETITIVE BIDDING PROGRAM AS A CONTRACTED SUPPLIER, I URGE CMS TO TAKE THESE STEPS TO PRESERVE BENEFICIARIES CONVENIENT ACCESS TO DMEPOS SUPPLIES AND TO MAINTAIN ESTABLISHED PROVIDER/ PATIENT RELATIONSHIP

Submitter : Dr. Ira Kraus

Date: 06/14/2006

Organization : American Podiatric Medical Association

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-170-Attach-1.DOC

Advanced Foot Care, LLP

**Ira Kraus, DPM *Palmer Branch, DPM, Aaron Solomon, DPM Clair Bello III, DPM
Diplomate, American Board of Podiatric Surgery

June 14,2006

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 a podiatric physician who has been in practice for 17+ years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, or ankle braces used for acute ankle injuries. . I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. If my patients have to obtain these items from another supplier as a result of the new program, additional injury could result. I cannot imagine telling a Medicare beneficiary that I am unable to supply an ankle brace to treat an ankle injury and he or she must travel across town to obtain an item that is both medically necessary and appropriate.

Consider a patient who presents with the chief complaint of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot is necessary to treat the fracture. If I no longer function as a supplier, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to the foot. If the patient is unable to bear full weight on the injured extremity, a fall could result, which could result in other additional injuries.

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

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries. I urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric

2368 Battlefield Pkwy
Ft Oglethorpe, GA 30742
(706) 861-6200

4308 Brainerd Rd
Chattanooga, TN 37411
(423) 698-1966

5741 Highway 153
Hixson, TN 37343
(423) 875-9211

8142B E Brainerd Rd
Chattanooga, TN 37412
(423) 553-8556

12978-B North Main St
Trenton, GA 30752
(706) 657-2467

"We, Advanced Foot Care, LLP, are pledged to improve the quality of life through treatment of foot and ankle disorders. Our team is committed to a relationship based upon care, concern, and compassion. We will always strive to enjoy what we do."

physicians, from the requirement to competitively bid. Instead, continue to allow physicians to supply appropriate DMEPOS items used in the care of patients without being forced to competitively bid for that privilege.

Thanking you in advance for your time and consideration.

Professionally,

Ira H Kraus, DPM, FACFAS
APMA Board of Trustees

Submitter : Dr. RICHARD LOGAN

Date: 06/14/2006

Organization : Dr. RICHARD LOGAN

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Competitive bidding on small ticket, much utilized items such as diabetic supplies will severely limit needed access to supplies and providers. It will adversely affect the health of diabetic and increase overall medicare spending.

Submitter :

Date: 06/14/2006

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
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: 06/14/2006

Organization :

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I understand the need to save money. I admire CMS's goal to save money. Consider however, my objections to competitive bidding. Competitive bidding could force smaller providers out of business. All that would be left is the Wal-marts of CMS. When they are gone, there won't be anyone to compete with, thus costs will go up. Competitive bidding will become just "bidding".

Smaller providers provide more than just product. They provide service and education. They are around when a patient has a question. They provide personal attention which improves compliance and decreases hospital admissions. Larger suppliers typically hire as many non-professionals as they can often using dishonest tactics just to increase sales. Many send out supplies the recipient did not want or need. They do not have a license they are trying to protect. They have no connection to the health care profession. They have not taken an oath to protect public health. Costs are not contained nor is money saved when patients are being mailed health care items and services they do not need nor do they know how to use.

Unregulated, I know of a lot of providers who will find the cheapest, ineffective products they can find only to upcode them and make a large profit. Competitive bidding will make this worse. There will be fewer local providers. Mail order will be the rule. Mail order companies can not be held accountable by their patrons from thousands of miles away. Products will be unreliable, requiring additional unnecessary visits to the hospital. Increasing healing time and increasing costs to CMS.

Please consider putting healthcare items in the hands of licenced professionals. I have been to too many 1 day seminars, sitting next to literally butchers and tatoos artists. Surprized by this, I asked why they were there. Their response, "Just wanted to make some quick money." I do not think this is the way healthcare items should be treated. Grant you I do not have a problem with butchers nor tatoos artists, yet when not regulated by licensure, you risk dishonest behavior and risk public health.

Health care products should be dispensed by licensed personnel. They have an understanding of the products and most have the integrity to not sell an item if they feel it is not suitable for the patient. They are local residents who have to live in the communities that they serve and must exercise good honest business practices for fear being forced out of business by the democratic public they serve.

Please let the democratic public serve the public. Let people choose their provider, let democracy serve the people. Do not force people to use mail-order. Medicare recipients are retired individuals who do not understand mail-order. They have questions that cannot be answered over the phone. They have established a relationship with their community pharmacist and trust them to provide trusted advice.

Submitter : Mrs. Pamela Kennedy
Organization : Brashears Pharmacy
Category : Nurse

Date: 06/14/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Brashears Pharmacy strongly objects to any regulation that would limit beneficiaries' ability to choose their own DME provider. Many of our elderly clients have been coming to our pharmacy for years because of service, care and convenience. This regulation would destroy that relationship. Beneficiaries should not be forced to use one provider over another. The mandatory use of a national mail order provider for such items as diabetic supplies is not appropriate since beneficiaries may need these diabetic items more frequently than on a monthly mail basis.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include diabetic supplies. Limit the DME in this regulation to highly specialized and unique items that are not normally handled by a local pharmacy.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

This regulation would set an abnormally low payment schedule that most small pharmacies cannot accept and still stay in business. The Agency must set a payment rate that adequately covers the cost of acquisition and providing the DME and then periodically examine the reimbursement payment as it compares to the provider's acquisition cost.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Brashears Pharmacy is a small privately-owned pharmacy serving many Medicare recipients in the state of Florida. We must be allowed to participate in a bidding program that should be specified for a small area, as it would be difficult to be competitive in large metropolitan areas. Our clients deserve the right to obtain their DME from their local pharmacy with an established provider/patient relationship.

Submitter : Dr. Mary Crane
Organization : Foot & Ankle Associates of North Texas
Category : Physician

Date: 06/14/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-175-Attach-1.DOC

June 14, 2006

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

Dear Dr. McClellan:

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

I am concerned that if physicians, including podiatric physicians, are not excluded from the new program, patient care will suffer. I provide certain DMEPOS items to my patients as part of the normal course of quality care and have been for the last 10 years. If I am no longer able to supply those items as a result of not being selected as a DMEPOS supplier under the new program, my patients will suffer.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS item when I am the one treating the patient just makes sense and is better medicine. I want to make sure the product fits the patient and functions as it should. I want the patient to receive exactly what they need without someone else making that decision for me. Patients should be able to get from me the full range of care they require for a particular problem, yet with this proposal that may no longer occur. Although we are in the Dallas/Ft Worth metroplex, the nearest qualified supplier is in either Dallas or Ft. Worth which are almost 30 miles away in a traffic nightmare for the patients.

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

Sincerely,

Mary E Crane, DPM, FACFAS, CWS
Foot & Ankle Associates of North Texas, LLP
2421 Ira E Woods Ave Ste 100
Grapevine, TX
crane@faant.com
(817)416-6155

Submitter : Dr. Michael Dixon
Organization : Barrett Parkway Foot and Leg Specialists PC
Category : Physician

Date: 06/14/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-176-Attach-1.PDF

There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. Again, I urge CMS to exclude all physicians, including podiatric physicians, from this program and to continue to allow physicians to supply DMEPOS items used in the treatment of Medicare beneficiaries.

Sincerely,

Michael W Dixon DPM, AACFAS, FACFAOM, CWS
Barrett Parkway Foot and Leg Specialists PC
425 Ernest Barrett Parkway Suite C2
Kennesaw, GA 30144
770.422.0280
fax 770.426.5388
email michaeldixon@pol.net

Submitter : Mr. Jody A. Spencer
Organization : Fairview Health Services
Category : Occupational Therapist

Date: 06/14/2006

Issue Areas/Comments

GENERAL

GENERAL

CMS's Proposed Rule on Competitive Acquisition for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies: I urge you to reconsider implementation of this rule as it will negatively impact the care and quality outcomes that occupational therapists have with their patients. OT's are in a unique position where we frequently need to provide "off the shelf" equipment/splints for patients. These items may be utilized for rehabilitative, habilitative or adaptive equipment needs. Sending a patient to another vendor may prevent the patient from obtaining the equipment because they may not have the means/transportation etc. This could also create additional costs as the patient will now 1) be evaled by an OT, 2) Need to make another stop or appointment to see a vendor and then 3) Return to the OT to be trained in/discuss the intended use of the piece of equipment obtained. Please don't restrict our practice by limiting our ability to issue "off the shelf/pre-fab splints" equipment/items which benefit our patients and their therapeutic outcomes.

Submitter :

Date: 06/14/2006

Organization : Center Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I strongly object to the CMS' alternative proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers-this restricts beneficiaries choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should NOT include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be provided by a central supplier.

GENERAL

GENERAL

Thank you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I offer my comments for consideration as CMS develops the final regulation. Thank you for considering my view.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I urge CMS to take steps to ensure that small suppliers-which include the majority of pharmacy-based suppliers-can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas. After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier. CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships. I currently provide the following types of DMEPOS in my practice and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients. The services I provide are: diabetic supplies (meters, strips, lancets, syringes, insulin, pumps, reservoirs, infusion sets, etc), aids to daily living, canes, walkers, wheelchairs (all types), hospital beds, seat lift mechanisms, nebulizers, tubing and medication, immunosuppressive medications and Power Operated Vehicles.

Submitter : Dr. Paul Kinberg
Organization : Dr. Paul Kinberg
Category : Physician

Date: 06/14/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 14, 2006

Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I believe that the proposal, if finalized in its current form, could interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

I am a podiatric physician who has been in practice for 32+ years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of DME items they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, and ankle braces and stirrups used for acute ankle injuries. I realize that CMS is still determining which items will be subject to competitive bidding but I believe that if an item is medically necessary in caring for a patient, a physician should be able to supply it.

I respectfully request that CMS modify its proposal and exclude all physicians, including podiatric physicians, from the competitive acquisition program. Instead, allow physician DMEPOS suppliers to continue to provide appropriate and medically necessary items that are used for patient care.

Sincerely,

Paul Kinberg, DPM

Submitter : Mr. Allen Goodall
Organization : Allen Goodall P.T.
Category : Congressional

Date: 06/14/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I want to register my opposition to the bidding out DME, it would severely slow our practice down by with unwarranted nepotism by big companies and getting equipment to our clients/patients.

Submitter : Mr. Evan Prost
Organization : University of Missouri Physical Therapy
Category : Physical Therapist

Date: 06/15/2006

Issue Areas/Comments

**Quality Standards and
Accreditation for Supplies of
DMEPOS**

Quality Standards and Accreditation for Supplies of DMEPOS

re: Proposed Rule for Competitive Acquisition of Certain DMEPOS

Hello,

I have been a physical therapist for 18 years, and have practiced in hospital settings and in home health.

The most cost efficient and productive arrangement for fitting assistive devices and orthotics is in the clinical setting while the physical therapist can observe the patient performing functional activities, to determine the impact of the assistive device or orthotic and to make appropriate modifications.

The goal of properly prescribed and fitted assistive devices and orthotics is to decrease functional limitation and disability. Physical therapists are the experts in screening, examining, and designing a comprehensive plan of care to alleviate movement impairment, whereas commercial suppliers who sell DMEPOS have a much more limited scope of knowledge and insight into this aspect of rehabilitation.

Please reconsider the your Proposed Rule for Competitive Acquisition of Certain DMEPOS.

Patients will be the ones to benefit!<p>

Sincerely,

Evan Prost PT

CMS-1270-P-181-Attach-1.DOC

Submitter : AuraLee Pitt
Organization : AuraLee Pitt
Category : Health Care Professional or Association

Date: 06/15/2006

Issue Areas/Comments

**Quality Standards and
Accreditation for Supplies of
DMEPOS**

Quality Standards and Accreditation for Supplies of DMEPOS

It has come to my attention that there is a competitive bidding program in DMEPOS that could significantly affect the practice of physical therapist. If the bid is being implemented because it would be in the best interest of the patient, then I think it is providing the opposite. Physical therapists have the education and professionalism to implement durable medical equipment such as wheelchairs, orthotics, and other ambulatory devices. It is in their scope of practice to assess and intervene in the patient's functional limitations to improve upon their quality of life. This includes providing the aforementioned assistive devices to improve the patient's function. They are not just handing these devices like candy. They use their education and expertise to provide these devices judiciously and with the intention to ameliorate the functional limitations that are discussed with the patient.

The elimination of this service from the physical therapist's scope of practice will be a disservice to the patient/client and will impede the ability of the therapist to provide quality care.

Regards - AuraLee Pitt

Submitter : Mrs. Denise Overlock
Organization : Life Care Center of America
Category : Physical Therapist

Date: 06/15/2006

Issue Areas/Comments

GENERAL

GENERAL

I am a Physical Therapist Assistant that treats in a SNF that treats both part A and part B. In our dept we treat many diagnosis and CVA is a common one. While treating the CVA patient many times the patient will need a brace (AFO ankle foot orthotic) which is off the shelf and we have available to use for patient-use to assist in a quicker return to walking and safer transfers. With this brace, which I can modify and adjust by trimming and adding steps for patient comfort on a daily basis if needed. By making this change I would not be able to work with the stroke patient as soon on walking because I would need to make sure the brace is what I want and then find someone to come and provide it for the patient which could be costly in the patients recover, in length of days. Every day that the patient is not working on becoming more independent they are costing more mone to the system in length of days.

As a Physical therapist assistant I work under the care of the Physican that the physical therapist has set up. During the care of the patient, we often time will need to furnish an orthotic or splint that is needed. With this change, I understand I will not be able to supply or adjust a minimal adjustable device. Thos restriction will severly limit/decrease my ability to progress patients in a timely manner. I was trained to make adjustments to many different types of orthotics and equipment that we use with different diagnosis so please think about how this may cost more visits in physical therapy because of the number of days waiting to recieve the equipment/brace.

Submitter : Dr. Joshua Bailey
Organization : Rehabilitation Associates of Central Virginia
Category : Physical Therapist

Date: 06/15/2006

Issue Areas/Comments

**Quality Standards and
Accreditation for Supplies of
DMEPOS**

Quality Standards and Accreditation for Supplies of DMEPOS

As a Physical Therapist and a Certified Pedorthist who cares for patients primarily with foot and ankle disorders I have been concerned with the language regarding competitive acquisition of durable medical supplies. I feel that it would be nearly impossible for an outside entity to understand the needs, risks, and desires of my patients like I would. Subsequently, it seems to me that allowing a bidding process would remove the focus from quality of care and heavily shift the focus to saving healthcare dollars. I think that this process will eventually lead to poor healthcare and in the long run additional healthcare dollars spent. I am comfortable in saying that when acting judical each practioner should provide durable medical supplies as medically necessary to their own patients. This would be for the good of the patient, practioner, and CMS. I realize this docket exists as an attempt to minimize expenses. As a business owner I certainly understand that need. Minimizing the expense at the risk of decreased quality of care is malpractice in any other forum.

Submitter : Ms. Kay Scanlon
Organization : Ms. Kay Scanlon
Category : Physical Therapist

Date: 06/15/2006

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

I am asking CMS to reconsider the proposed rule change regarding competitive bidding for the ability to supply Medicare patients with durable medical equipment. As an orthopedic specialist, I have the expertise and training to evaluate, fit and supply my patients with orthotic devices. Many of my patients have benefitted from this service over the years. I believe awarding this only to the most competitive bidder will decrease the quality and integrity of this program and result in further costs to correct a simple biomechanical problem. Please reconsider this rule change to protect Medicare recipients.

Submitter : Mr. Lawrence LoDico III
 Organization : Vastech, Inc. / Atlantic Medical Supply
 Category : Home Health Facility

Date: 06/15/2006

Issue Areas/Comments

**Opportunity for Participation by
 Small Suppliers**

Opportunity for Participation by Small Suppliers

Atlantic Medical Supply / Lawrence R. LoDico III is a DME company who is part of a community which Medicare beneficiaries depend on. Our services are diversified excluding respiratory and oxygen. We are concerned that we will no longer be able to do business with the government (Medicare) should Competitive Acquisition commence as the law is written currently. Most importantly the patients (Medicare Beneficiaries) have the most to be concerned about regarding Competitive Acquisition. The vague description and information regarding the implementation of this legislation is simply unfair and represents tactics which we feel follow socialism and capitalism which not only is bad for the country's economy regarding small business but is down right unAmerican going against democratic values. We're not saying that maybe changes are not necessary in the Medicare program as it relates to DMEPOS, however this law appears to be a ploy to rid our local communities and our society as a whole of small DMEPOS suppliers. We have a passion for what we do in the health care industry and we are willing to comply with whatever is necessary for the better of the majority. The MMA with specifically the Competitive Acquisition clause must be rethought and provisions must be made in order to protect the rights of our fellow country men and women who are in need and depend on our local community based DMEPOS. Simply, the home medical equipment industry as a whole has much to suffer including jobs lost, services to beneficiaries diminished, increased acute care visits (i.e. emergency room visits) overall putting a strain on the economical structure of our delivery of health care services, specifically home medical equipment. We believe it is our government's responsibility to protect and serve the people. Competitive Acquisition is wrong and unfair. Chaos will be the result should this legislation be implemented as written. On behalf of my staff, my clients / patients who receive our services, we ask you to take a moment and think if you would like it if for example a loved one who you were directly involved in was told he or she could no longer receive services from their community based DMEPOS. This would mean if this loved one was in need in wheelchair modification, incontinence supplies (ostomy) wound care supplies, and or immediate service regarding an air mattress replacement system, your loved one would have wait till the supplier could actually arrive, that may mean 24 hours or more or days depending on the work load. That scenario is only one of many that will occur. Furthermore, we believe, that community based business is important to the infrastructure of our society and more importantly to the quality of life to elderly individuals who may be sick at home or to the young disabled person who may be paralyzed in need of frequent wheelchair modifications in order to keep active in the community. We ask that our elected officials rethink what could be devastating to our Medicare Beneficiaries and to small business owners and make a law that works for everyone just as our fore fathers did in the Constitution and the Declaration of Independence. Thank You Lawrence R. LoDico III

Submitter : Mr. Christopher Hairie
Organization : Twin Lakes Physical Therapy
Category : Other Health Care Professional

Date: 06/15/2006

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

If CMS moves to a competitive acquisition for DMEPOS, this could seriously harm physical therapists and physical therapy clinics from issuing durable medical equipment. This rule could significantly impact the ability to furnish canes, walkers, wheelchairs, or other off the shelf orthotics that can be easily dispensed by a physical therapist. This rule could lead to wrong equipment being dispensed as one company approved through the competitive acquisition will want to dispense the the equipment that it deems necessary or in substitution or the actual equipment needed.

Regulatory Impact Analysis

By imposing this rule it could harm the bottom line of small businesses. Some small organizations will likely have to cut staff for the potential loss of income, if this rule is imposed. Each clinic needs to have the ability to dispense the appropriate equipment to their patients with no delay.

Regulatory Impact Analysis

Regulatory Impact Analysis

I understand the need to drive down healthcare costs, but by imposing this rule will harm physical therapists and small physical therapy clinics around the country. We need to protect small clinics and not force Medicare patients to drive long distances to get the equipment that is needed.

Submitter : Dr. Glenn Huggins
 Organization : CMC-Home Infusion
 Category : Pharmacist

Date: 06/15/2006

Issue Areas/Comments

**Submission of Bids Under the
 Competitive Bidding Program**

Submission of Bids Under the Competitive Bidding Program

We are a large Non-profit hospital system providing HME and pharmacy services to indigent/under insured patients for this county (our dept donates over \$200,000/yr with no reimbursement). We use the proceeds from paying patients (Medicare) to cover a significant portion of this expense. If our services are restricted or eliminated from Medicare participation, we could no longer afford to operate this department and will not be able to support indigent care patients. Since these patients are ineligible for Medicaid (many are aliens) who will become responsible for their home medical needs? Very Few of the for-profit DME companies contribute anything to this burden. What small contribution is made is driven solely for marketing purposes. With a contracted Medicare provider, no incentive would be available to encourage any support. Competitive bidding will remove any necessity of offering community care. The impact of excluding providers from Medicare will eliminate the majority of providers, thereby eliminating the competitive force that drives businesses to improve patient satisfaction and donate services back to the community. Examine the impact of ASP + 6% on pharmaceutical reimbursement to physician offices and outpatient facilities. The result is a significant increase in rehospitalization for INPATIENT services covered under Part-A; Most physicians no longer administer IVIG in their office because the Medicare allowable is below acquisition cost - (we know because we have the invoices) -- Hence, the less expensive, convenient method is lost and the total expense increased because no viable alternative is encouraged.

As a JCAHO accredited provider, we are SEVERELY regulated for quality standards. Is CMS allowing bids from NON-Accredited providers? This would be a great disservice to providers who do not understand the expense of obtaining and maintaining accreditation. These providers may win an award and be unable to participate due to inability to pay the cost of accreditation standards. Inappropriately low bids would reduce reimbursement to facilities submitting higher bids due to the expense of accreditation.

CONSUMER REBATES: 1. who would monitor 2. Who would administer? Low bids mean low number of staff. thereby becoming Unable to hire more financial staff to process this additional paperwork burden. Rebated in what form (gift certificate to my wife's store, a money order, cash)?? Rebated when (first day of service, last day of service or when we have received payment from Medicare or when forced to)?? If claims are denied later and a rebate already paid, who collects from the patient? Aren't INDUCEMENTS against the law?? - Just ask ANY Medicare attorney.

If a provider is unable to provide adequate services after 2 years due to bankruptcy from bidding to low, how will oxygen patients be serviced since a 36 month cap is now law (the equipment would be returned to the bankrupt provider). Any remaining provider cannot afford to provide free services if no reimbursement after 36 months.

What standards for accreditation are required? Do you bid for a car to purchase without knowing if it runs?

Please delay the implementation of this process until ALL questions can be addressed. I can always find a job, but can patients always find a caring provider? No, not if they are not required to be.

By excluding a provider for 3 years without Medicare reimbursement, there will become very few providers available to even bid for the 2nd 3 year period because no one would desire to continue a money losing business.

I expect CMS to PUBLISH a list of products subject to bidding at least 12 MONTHS in advance of bid dates. Why are current laws being ignored with this proposed bidding concept.

We provide many HME items with little or no profit because it helps our patients, What incentive is there for any provider to offer low profit items if no other source is available to offset its expense?

Submitter : Dr. CARLA J PORTER

Date: 06/15/2006

Organization : L S GERBER

Category : Physician

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner
PLEASE SEE ATTACHMENT

CMS-1270-P-189-Attach-1.DOC

June 11, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, "**Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**", that would establish a competitive acquisition program for DMEPOS.

I am a podiatric physician who has been in practice for over 5 years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities, or ankle braces used for acute ankle injuries. I realize that CMS is still determining which items will be subject to competitive bidding but I believe that if an item is medically necessary in caring for a patient, a physician should be able to supply it.

The proposed rule, if implemented, would significantly reduce the quality of health care that I can deliver to my patients. These are medically necessary items. Take, for example, a CAM walker type of device. In the last month alone, I had 3 patients on Medicare who sustained serious foot fractures during a fall. A CAM walker is necessary for these patients as they are generally too frail to use crutches. If I had had to send these patients to a third party to pick up the device, I would have had to send them out of the office walking on a fractured foot. This would likely have led to a more severe injury than the original. Also, I would be concerned that the patient did not

receive the device I prescribed. The patient only stands to lose from such an action.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. **I respectfully request that 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 quality, appropriate patient care.**

Sincerely,

Carla J. Porter, DPM
22 Fairmont Ave
Poughkeepsie, NY 12603

Submitter : Dr. LEONARD S GERBER

Date: 06/15/2006

Organization : L S GERBER DPM

Category : Physician

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner
SEE FILE ATTACHMENT

CMS-1270-P-190-Attach-1.DOC

June 11, 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,

LEONARD S GERBER, DPM
22 Fairmont Ave
Poughkeepsie, NY 12603

Submitter : Dr. CHRISTOPHER K BROMLEY
Organization : L S GERBER DPM
Category : Physician

Date: 06/15/2006

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner
SEE FILE ATTACHMENT

CMS-1270-P-191-Attach-1.WPD

June 11, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, "**Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**", that would establish a competitive acquisition program for DMEPOS.

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Sincerely,

CHRISTOPHER K. BROMLEY DPM
22 Fairmont Ave
Poughkeepsie, NY 12603

Submitter : Dr. AUDRA R SIEGEL

Date: 06/15/2006

Organization : L S GERBER DPM

Category : Physician

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner
SEE FILE ATTACHMENT

CMS-1270-P-192-Attach-1.DOC

June 11, 2006

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Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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Electronic Comments

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Sincerely,

AUDRA R SIEGEL, DPM
22 Fairmont Ave
Poughkeepsie, NY 12603

Submitter : Dr. FLORENCE G SUMMERS

Date: 06/15/2006

Organization : L S GERBER

Category : Physician

Issue Areas/Comments

**Physician Authorization/Treating
Practitioner**

Physician Authorization/Treating Practitioner

SEE FILE ATTACHMENT

CMS-1270-P-193-Attach-1.DOC

June 11, 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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The proposed rule, if implemented, would significantly reduce the quality of health care that I can deliver to my patients. These are medically necessary items. Take, for example, a CAM walker type of device. In the last month alone, I had 3 patients on Medicare who sustained serious foot fractures during a fall. A CAM walker is necessary for these patients as they are generally too frail to use crutches. If I had had to send these patients to a third party to pick up the device, I would have had to send them out of the office walking on a fractured foot. This would likely have led to a more severe injury than the original. Also, I would be concerned that the patient did not

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Sincerely,

AUDRA R SIEGEL, DPM
22 Fairmont Ave
Poughkeepsie, NY 12603

Submitter : Dr. CARL PURVIS
Organization : CARL G PURVIS, DPM PA
Category : Physician

Date: 06/15/2006

Issue Areas/Comments

GENERAL

GENERAL

June 15, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I believe that the proposal, if finalized in its current form, could interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

I am a podiatric physician who has been in practice for 30 years. I routinely treat Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If the new program results in my elimination as a supplier, I may no longer be able to supply medically necessary items, such as walking boots used for fractures or other structural instabilities. There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. I realize that CMS is still determining which items will be subject to competitive bidding but I believe that if an item is medically necessary in caring for a patient, a physician should be able to supply it.

I respectfully request that CMS modify its proposal and exclude all physicians, including podiatric physicians, from the competitive acquisition program. Instead, allow physician DMEPOS suppliers to continue to provide appropriate and medically necessary items that are used for patient care.

Sincerely,

Carl G. Purvis, DPM, FACFAS

Submitter : Dr. Jennifer Zimmermann
Organization : Kensington Physical Therapy
Category : Physical Therapist

Date: 06/15/2006

Issue Areas/Comments

GENERAL

GENERAL

This proposal could potentially impact the ability of physical therapists in hospitals or private practice to furnish off-the shelf orthotics, wheelchairs, ambulatory assistive devices, and other medical equipment to our patients. Durable medical equipment such a orthotics are a service we are able to provide our patients for cost of the equipment only, and if this passes we will need to send our patients out for this equipment. I strongly urge Medicare to reconsider this proposal.

Submitter : Dr. Robert Siwicki
Organization : Emerald Coast Podiatry Center
Category : Physician

Date: 06/15/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES
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.