

Submitter : Mrs. Fran Marasow
Organization : Professional Medical Corp.
Category : Health Care Industry

Date: 06/15/2006

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

I would like to comment on few issues with regards to the Competitive Bidding process.

1. Consumer Rebates- coming out of left field, this proposal goes against the prohibition of offering inducements for business- if we are not allowed as a company to write off the 20% copay across the board- how can offering a beneficiary a rebate be legal?
2. Products included- as of now there is no clear list of the products that will be included in the competitive acquisition program- companies hoping to bid on these products will need a minimum of 12 months to accurately evaluate all of the costs associated with providing a product to a client in order to prepare a cost that is sustainable and appropriate.
3. Quality Standards- ever since I have first read of the competitive acquisition program I have been trying to find out how I can become accredited. As of now CMS has not published their standards, nor have they chosen agencies to conduct the accreditation. How can I even begin this process, and as a result, what will my chances of submitting a bid be?? Before CMS identifies its first MSA to begin this process shouldn't they be required to publish the standards that the companies in those locations will be required to adhere to if they chose to undergo this process. This is putting the cart before the horse and makes little sense all the way around.

These are just a few of my concerns and from what I am reading and hearing they are national concerns. While the government is looking to save money on its future needs, this process is unclear, not properly thought out and ultimately will affect the very people that we are all attempting to help!

Submitter : Mr. James Drechsel
Organization : Atlantic Medical Supply
Category : Other Technician

Date: 06/15/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Competitive bidding is not good for anyone, but if it must go through there should be provision for small DME Providers to accept the lowest bid and still provide services. The equipment put up for bid should be very limited for example either wheelchairs or Hospital Beds, not both. The multi million dollar companies can't deliver the level of service that a small provider can. Our company and other small providers have a integral place in the community and people count on us because they have access to us and can relate to us on a personal level. With the Competitive Bidding Act, equipment set up and education will be a thing of the past. The level of service will go way down and the only way a beneficiary will get educated on their DME equipment will be from their owners manual. Further more the company who gets the winning bid will never be able to handle the work load of calls for maintainence and service for every beneficiary. In the coming years more and more baby boomers are going to be retiring and enrolling in Medicare services. The way I look at it the more providers the better. No one benefits from this Competitive Bidding and ultimatly the beneficiaries are going to suffer in the long run. Please have the wisdom and intuition to not make a vital error that future generations will have to live with.

Submitter : Gary Franks
Organization : Ability Physical Therapy, PS
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

6-15-2006

The Issue: The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule May 1 to implement a competitive bidding (also known as competitive acquisition) program for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) in the Medicare program.

Greetings,

My name is Gary Franks and I am a physical therapist (PT) and the owner of a private practice specializing in outpatient orthopedics. As a clinician I utilize my training and expertise to evaluate the need, supply, create and/or make recommendations, for orthotics and other assistive devices. I am of the opinion that PT's are best equipped to provide this service subsequent to their evaluation and their specific plan of care for the individual patient. Here also, PT's possess an intimate knowledge of their patients' history and their specific needs. This is of paramount importance for the ultimate benefit of the patient. This approach would preclude the need for a prosthetics or orthotics specialist to re-invent the wheel regarding patients who are unfamiliar to them. Nevertheless, please note that I believe there is a definite need for these specialties.

There are numerous occasions whereby a patient may require an assistive or stabilizing device sooner rather than later, i.e. patient access. As we house an inventory of the most commonly needed DME, I am readily able to provide the necessary item without delay. This translates into the immediate safety for our patients. Furthermore, since I have prescribed and fitted the patient with a device or orthotic, and due to familiarity with it, I would be better able to make any necessary, on-the-spot adjustments. This practice would likely represent a savings for the Medicare program.

I thank you for your consideration in this matter. I invite you to contact me should you have questions and/or concerns.

Respectfully,

Gary Franks, PT

Submitter : Diane Mason
Organization : Providence Medical Equipment
Category : Home Health Facility

Date: 06/15/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Allowing only national mail order suppliers to provide diabetic supplies certainly removes the competitiveness in the market. Additionally, many of the elderly are not comfortable with mail order or would prefer coming in to pick up their supplies. Diabetic supplies are a vital part of our business and are often a lead-in for customers for our other services.

Submitter : Mr. Daniel Karant
Organization : Medicine Shoppe Pharmacy #1065
Category : Pharmacist

Date: 06/15/2006

Issue Areas/Comments

GENERAL

GENERAL

Patients in need of medical supplies should not be forced into a mail order situation. We as suppliers should not have to participate in a competitive bidding scenario with large companies with huge buying power. The patient will suffer due to lack of access to qualified and convenient sources of supplies, such as diabetic test strips and lancets. The small suppliers will suffer and some will certainly go out of business due to the inability to compete in the bidding or by having their patients access to them cut off. We need providers that will be able to do a hands on training and troubleshooting from convenient locations for these patients. Many are handicapped and others are elderly and unable to adequately fathom the mail order and how to get service on some medical device that they need. Limiting the patient's access to qualified providers will drop prices initially because the patients won't be getting their supplies as easily as they have in the past. After that initial drop, patients will have greater hospitalizations and complication from inappropriate monitoring of their disease states. We as small providers, and pharmacists especially, have a great impact on the success of a patient's therapy due to our greater ability to encourage them to care for themselves in face to face encounters. I could go on, but, the point is that these services should not be limited to just the big providers in a few locations. As it is, CMS already sets the prices. Why do you now need to further get bid prices if you already control them?

Submitter : Dr. Stephen Bennett
Organization : Dr. Stephen Bennett
Category : Physician

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

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 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 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. This would delay proper treatment and put the patient at risk for further injury and discomfort.

I feel that I am best qualified to dispense the correct medically necessary DMEPOS item for my patients individual needs. Often, I have been force to write prescriptions for items I would normally dispense from my office, due to the maze like rules of private insurers. Under such circumstances, the patient often comes back to my office with an item that is ill fitting, inadequate and inappropriate. This situation has often led to increased distress of my patients, and an impediment to our doctor-patient relationship, for there has been a delay in their medical treatment and they still need to go back to the supplier and reattempt to get the correct device. I have seen this event played out again and again, with ankle braces, fracture walkers, support stocking, diabetic shoes, canes, etc. . Furthermore, I have seen advertised more than 20 types of ankle brace, for example, and I have come to know which ones are appropriate for a specific injury and which ones aren t worth the cost of packaging. When I have been forced to outsource these items, it has always been at the discretion of the supplier as to which item they dispense.

DMEPOS items are not like medications that are easily dispensed by prescription by a trained and licensed pharmacist. These items are uniquely fitted to each individual and when dispensed by an untrained supplier they could and do put a patients well being at risk.

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,

Dr Stephen J Bennett

Submitter : Karl Gibson
Organization : River Valley Rehabilitation Associates
Category : Physical Therapist

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-203-Attach-1.DOC

**RIVER VALLEY
REHABILITATION
ASSOCIATES, PC
815 FREEPORT ROAD D
PITTSBURGH, PA 15215
(412) 784-4750**



**PHYSICAL THERAPY
SERVICES**

**Karl R. Gibson, PT, MS Walter Garcia, PT, MS
Mike Calabrese, PT, ATC Christine Dolnick, PT, MS**

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

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS

Dr. McClellan,

As a practicing physical therapist I am writing to express my concerns with the proposed CMS regulations regarding the provision of orthotics to our patients. This service is an integral part of our plan of care for a significant number of patients, and I urge CMS to revise the proposed regulations and establish a process that will enable physical therapists to continue to furnish orthotics that are critical to the care of patients.

One of the reasons for my concern is that the proposed competitive bidding program poses a serious threat to timely patient access to medically necessary DMEPOS, proposing a system that could obstruct the way clinicians currently furnish DMEPOS to their patients. It is not uncommon for us to provide an orthotic on a given patient visit to avoid aggravation of an injury, and delaying the provision of this process through contact with another provider may delay the service and potentially increase the degree of the patient's impairments or delay their recovery, both at a cost to Medicare.

You may or may not be aware that PTs also routinely make adjustments to orthotics, and these adjustments are within the scope of physical therapy practice and do not require consultation with an orthotist, although in some circumstances we may consult them to improve the quality of the care provided through our collaborative management of the patient. I encourage you to revise the regulations to recognize that physical therapists perform adjustments to orthotics.

Lastly I would request that you revise the regulations to recognize the need for physical therapists to be able to specify brands to prevent adverse medical outcomes. While there is an allowance for allowing physicians to specify certain brands if there would be an adverse medical outcome for the patient, the physician commonly consults the physical therapist for examination and management of the patient and expects the PT to make the decisions that are in the best interest of the patient.

Sincerely,

Karl R. Gibson, PT, MS

Submitter : Diane Mason
Organization : Providence Medical Equipment
Category : Home Health Facility

Date: 06/16/2006

Issue Areas/Comments

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

Submission of Bids Under the Competitive Bidding Program

With regards to convenience to the Medicare beneficiary, the ability to get all of their equipment and supplies at a "one-stop shop" is a greater benefit than only getting equipment within a certain product category. The majority of our clients do not need items from only one product category but rather from several. For example, if they have oxygen from us, they will end up getting a wheelchair through us also when they develop a need for that. We have had several ostomy and urological clients who have seen their conditions worsen to needing oxygen or a bed or a wheelchair. In these cases, we have been able to provide the continuous care with familiar faces and quality service since we can supply all their needs. Specialization - sending clients from one supplier to another as their needs change - would not be favorable to beneficiaries.

Submitter : Mr. Carlos Villahermosa
Organization : CIV Biomedical Services
Category : Other Health Care Provider

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-205-Attach-1.DOC

Center of Medicare and Medicare Services
Department of Health and Human Services

Attention: CMS 1270-P

The primary objective of the Competitive Bidding Program is to reduce the amount Medicare pays for DMEPOS and bring the reimbursement amount more in line with that for a competitive market. With the implementation of the Medicare Advantage (MA) program in Puerto Rico, this objective has been achieved. According to information provided by the CMS Director of Puerto Rico, Ms. Delia Lasanta, more than 50% of beneficiaries in Puerto Rico are presently enrolled in an MA program as May 9, 2006. Currently in Puerto Rico there are twelve Medicare Advantage Organizations providing services to beneficiaries across the island. Therefore, upon considering the total amount of MA organizations that cover Puerto Rico, the small size of the island, the aggressive marketing and reach-in programs used by these MA Organizations, and the steady increment of enrollment by beneficiaries, it is strongly believed that by 2007 the number of MA enrollees could come close to cover all beneficiaries on the island. Therefore there is no need for a Competitive Bidding Program in Puerto Rico.

Sincerely,

Carlos I Villahermosa
CIV Biomedical Services

Submitter : Mr. Juan Valentin
Organization : Tu Equipo Medico Isla
Category : Other Health Care Professional

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-206-Attach-1.DOC

The primary objective of the Competitive Bidding Program is to reduce the amount Medicare pays for DMEPOS and bring the reimbursement amount more in line with that for a competitive market. With the implementation of the Medicare Advantage (MA) program in Puerto Rico, this objective has been achieved. According to information provided by the CMS Director of Puerto Rico, Ms. Delia Lasanta, more than 50% of beneficiaries in Puerto Rico are presently enrolled in an MA program as May 9, 2006. Currently in Puerto Rico there are twelve Medicare Advantage Organizations providing services to beneficiaries across the island. Therefore, upon considering the total amount of MA organizations that cover Puerto Rico, the small size of the island, the aggressive marketing and reach-in programs used by these MA Organizations, and the steady increment of enrollment by beneficiaries, it is strongly believed that by 2007 the number of MA enrollees could come close to cover all beneficiaries on the island. Therefore there is no need for a Competitive Bidding Program in Puerto Rico.

Submitter : Mr. Bernard Natt
Organization : Shelbourn Chemists
Category : Pharmacist

Date: 06/16/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Shelbourn Chemists
3918 18th Avenue
Brooklyn, NY 11218
718-853-9349

Dear CMS representative

I have a number of questions concerning blood glucose strips and diabetic supplies within the Competitive Bidding Program. Can you please assist us?

1. Will only 1 type of strip be covered?
2. Will it be a generic strip or one of the major brands?
3. If it is just one type of strip how do we convert members using a different meter to the one covered by the Competitive Bidding Program (CMP)? Currently the member is allowed 1 meter every 5 years.
4. Is the cost of in-home teaching covered?
5. Has CMS determined which accreditation programs will be approved?
6. Will Medicaid automatically follow program?
7. Not all meters are equal in quality or accuracy. Is that a concern?
8. Will the program be universal for all DMERCs?
9. If a member moves from one area to another is the original supplier allowed to continue billing if they are in the competitive bidding program?
10. Will there be competitive bidding for meters?
11. There is only 1 recognized meter for the legally blind member- the Voice-Mate. Will that be continued to be supplied even if the strip for it- the Comfort Curve- is not low enough in price for competitive bidding?
12. Will we be able to verify whether or not a member received the product from a different approved supplier? Will the Lifetime prescription still be honored if the member is within guidelines?
13. How often will there be bids for the same product?
14. Is the program definite or a trial program to determine if the logistics of providing prompt provision of supplies being met?
15. How will the determination be made as to the number of suppliers per geographic area?
16. Will the bidders be mandated to be in that area?
17. If a patient who resides in NJ and the CMP is already in effect in that state will we be able to provide the patient with his/her supplies since we are a NY base facility. Note: We are a licensed NJ MM provider as well. Will the patient be obligated to receive supplies from a provider that is within the state of NJ.

Thank you.

Bernard Natt

Submitter : Mr. Oscar Pabon
Organization : REHABILITATION MEDICAL SUPPLY
Category : Health Care Professional or Association

Date: 06/16/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The Primary reason for the Competitive Bidding is to reduce the payment of Medicare for DMEPOS. This objective has been achieved with the implementation of the Medicare Advantage program along with the reduction of the Medicare Fee Schedule year 2005. On May 9, 2006 more than 50% of the beneficiaries were enrolled in one of the eleven Medicare Advantage Companies. This information was provided for Ms. Delia Lasanta, CMS Director of Puerto Rico. This fact allows us to strongly believe that for the year 2007 the Medicare Advantages enrollees could come close to cover all beneficiaries on the island. Another important fact is that Puerto Rico is yearly impacted for hurricanes or tropical storms making it impossible for distance suppliers to provide the service needed such as oxygen because of sudden flooding.

In conclusion if we already achieve the goal of reducing the payments, the Competitive bidding will only bring disadvantage to Medicare Beneficiaries.

Submitter : Dr. Cristie Pellegrini
Organization : Sonoma County Indian Health Project
Category : Pharmacist

Date: 06/16/2006

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

I would like to comment on the proposed competitive bidding program for DMEPOS and its potential impact on small suppliers if implemented as proposed.

I strongly object to 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.

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. Even this is not without risks, as evidenced by other organization's attempts to use a single supplier. More often than not, the organization pays higher prices to a central supplier than would be paid to individual 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 compete 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 recently applied for and was approved to provide supplies through Medicare. What I noticed in the application process was a concern for fraud. While this is a valid concern, I don't think fraud is an issue with the majority of small suppliers, and I don't think a central supplier is the answer. Our government shouldn't be putting even more power into the hands of the Rite Aids and Walgreens of the world.

I currently provide test strips, lancets, and unit dose nebulizer products in my practice, and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

Thank you for considering my view.

Sincerely,

Cristie Pellegrini

Submitter : Dr. Harvey Lekowitz
Organization : Dr. Harvey Lefkowitz D.P.M.,P.C.
Category : Physician

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-210-Attach-1.DOC

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

June 16, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician of 24 years, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge that Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care, which is both good medicine and good business for CMS.

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

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

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications, and in turn more expense to the system for treatment. This is not only bad medicine, it is bad business for CMS.

There are many other examples that could be provided to demonstrate how including physicians in the competitive acquisition program can be detrimental to patient care. Again I 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,

Dr. Harvey Lefkowitz, D.P.M.

Submitter : Dr. Anthony Giordano
Organization : Dr. Harvey Lefkowitz D.P.M, P.C
Category : Physician

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-211-Attach-1.DOC

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

June 16, 2006

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

Dear Dr. McClellan:

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

Dr. Anthony Giordano

Submitter : Dr. Michelle Jupin
Organization : Dr Harvey Lefkowitz D.P.M., P.C.
Category : Physician

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-212-Attach-1.DOC

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

June 16, 2006

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

Dear Dr. McClellan:

As a podiatric physician who has been in practice for 3 years, I am concerned with the recent proposal from the Centers of Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, for the new program.

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

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,

Dr. Michelle Jupin D.P.M

Submitter : Dr. James Ioli
Organization : Dr. James Ioli
Category : Physician

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

June 16, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

James P. Ioli, D.P.M., F.A.C.F.A.S.
Clinical Instructor of Orthopedic Surgery
Harvard Medical School
Chief, Division of Podiatry
Brigham and Women's Hospital

Submitter : Steve Hornbeck
Organization : SEAPT
Category : Physical Therapist

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

I must voice my opinion for You to NOT implement the competitive bidding program for suppliers of DMEPOS. Patient's should have their choice from whom they receive their equipment or supplies, including items they can receive from their rehabilitation providers. I urge You to not pass this program as it will have wide-ranging impact on senior's ability to receive the proper equipment and rehabilitation devices they may need.

Submitter : Mr. John Krug
Organization : ProCare Physical Therapy, PC
Category : Physical Therapist

Date: 06/16/2006

Issue Areas/Comments

Issue

Issue

I believe the Proposed Rule for Competitive Acquisition of Certain DMEPOS will unfairly prohibit physical therapists in private practice from dispensing and being reimbursed for equipment and supplies that are routinely handled by a PT office. This includes pre-made and custom-made orthotics, splints, ambulatory assistive devices, and others. This is wrong, and should not happen.

Submitter : Dr. Alan Schram
Organization : Northwest Podiatry, PC
Category : Physician

Date: 06/16/2006

Issue Areas/Comments

GENERAL

GENERAL

June 15, 2006

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

Dear Dr. McClellan:

We are writing in opposition to the proposed rule, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. As written, this rule would include physicians in a competitive acquisition program for certain DMEPOS items. We do not believe that the majority of physicians, including podiatric physicians, dispense such an overwhelming amount of DMEPOS so as to be in an equitable position when bidding competitively. We urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

By providing DMEPOS items to our patients at the time of service, we are able to correctly evaluate and fit the patient, if necessary, for the required supply. This also alleviates possible further discomfort or complication, as the patient would need to obtain the items from another source. If we are no longer able to supply those items as a result of not being selected as a DMEPOS supplier under the new program, our patients will suffer.

Our primary concern is for our patients. We want to ensure that patients receive appropriate care for their particular problem. Dispensing a medically necessary DMEPOS item for patients we treat just makes sense.

We do not believe that the Centers for Medicare & Medicaid Services (CMS) intent is to interfere with patient care or to make it inconvenient for Medicare recipients to obtain required supplies. We hope that the CMS will give consideration to this input and reconsider the original proposal and to exclude all physicians from the requirement to participate in the competitive bid process.

Respectfully,

Lee M. Hoffman, DPM
Alan J. Schram, DPM
Hilary Rosenthal, DPM

Submitter : Mr. Brad Maurer
Organization : Freedom Medical Supply
Category : Individual

Date: 06/17/2006

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the Notice of Proposed Rule Making on Competitive Acquisitions.

I am concerned that CMS will be including information from unqualified bidders in calculating the single payment amount. This will allow businesses that are incapable of meeting the financial and quality standards to be a provider under the competitive acquisition program can submit a lowball bid that will fundamentally taint the calculation of the final amount.

The NPRM mentions the concept of 'consumer rebates'. This seems to run counter to CMS rules that prohibit suppliers from offering inducements to beneficiaries. This seems that it could lead to inappropriate Medicare expenditures. The lack of specificity could leave providers open to allegations of fraud and abuse.

Without identifying the specific products that will be included in the competitive acquisition program, how can we accurately evaluate all the costs associated with procuring, delivering, and servicing those products? This will allow providers that have not evaluated the cost, to submit flawed bids that will not be sustainable over time. The products that are subject to competitive acquisition should be published at least 12 months in advance of the date that bids are due.

We also need to know 12 months in advance the geographic regions where the competitive acquisition programs become effective in 2007. By waiting until the final rule is published, CMS makes it impossible for providers to begin gathering the necessary data to submit educated bids.

The NPRM references quality standards, yet has not published the standards. CMS needs to give providers sufficient time to be accredited, once accreditation organizations have received 'deemed status' from CMS.

The grandfathering and transition policies are both unworkable and unfair. The NPRM says that while losing suppliers may continue to service their oxygen patients at the new single payment amount, if they choose not to, 'winning bidders' will have to serve these patients. A winning bidder could inherit an unknown number of patients who have been receiving home oxygen therapy for 20-30 months. The Deficit Reduction Act caps oxygen payments at 36 months when ownership of the equipment transfers to the beneficiary. How can a provider factor in these unknowable costs?

Submitter : Mrs. bindu sundar
Organization : None
Category : Physical Therapist

Date: 06/17/2006

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Proposed Rule for Competitive Acquisition of Certain DMEPOS'

I am a physical therapist currently practicing in an out-patient setting and have had background in both skilled nursing and acute care settings.

As part of providing care to my patients,I have to analyse patients overall posture, gait and mecahnics of various joints to treat patients effectively. Routinely I have used several different kinds of orthotics devices and made necessary adjustments to cater to patients needs ,for example, I had to mold a hand splint for a patient with nerve laceration to avoid pressure points due to the splint. Patients often require an item to be available to them during their visit to assist with mobility or to stabilize an injured body part.'competitive Bidding' will cause delay and interruption to normal patient care.

I urge CMS to enable the regulations to recognize the need for physical therapists to be able to specify brands to prevent adverse medical outcomes. For example , there are various types of walkers available but only few are safe for patients and as a physical therapists I have the knowledge and first hand experience with my patients to make a educated decision on selecting proper brands.

The work I do as a therapist providing orthotics to my patients is an integral part of my plan of care Vs commercial suppliers who sell DMEPOSAs. Hence, I Urge CMS to revise the proposed regulations and establish a process that will enable physical therapists like me to continue to furnish orthotics that are critical to the care of my patients.

I thank you for your kind consideration of my comments.

Sincerely
Bindu Sundar P.T

Submitter : Mr. Kevin Maloney
Organization : Hanover Hospital & Hanover Rehab Centers
Category : Hospital

Date: 06/17/2006

Issue Areas/Comments

GENERAL

GENERAL

I am a Physical Therapist with over 10 years specialization in biomechanics and orthotics and would like to comment on the "Proposed Rule for Competitive Acquisition of Certain DMEPOS". Providing orthotic devices to my patients is an integral part of my treatment plan and having direct access to these devices is of paramount importance. I routinely have to modify these devices; they are very patient/diagnosis specific, and not having access to these directly would greatly interrupt my plan of care. Knowing the various brands/styles of orthotics and having the ability to choose these for my patients based on their biomechanical problems is also very important; knowing what style/brand that works is very much a learned science and cannot be provided by a commercial supplier who sells DMEPOS. I routinely encounter patients who have had over the counter orthotic devices provided by "foot specialists" in these commercial settings, only to find that they are totally mismanaged because these individuals have no background in biomechanics or no history in treating foot problems or conditions. These patients are simply told they need a "good arch support" by these suppliers, charged an insanely large amount of money, and sent on their way, never having any scheduled follow-up visits. Physical therapists like myself are not only able to provide devices we know that work, but also are able to modify these devices and monitor patient tolerance on a regular basis.

Additionally, the footwear these over the counter devices are put into is very seldomly addressed by these commercial suppliers - as I tell my patients "the orthotic is only as good as the shoe it is in". Or these suppliers will talk the unknowing patient into a "shoe and orthotic" package which sometimes may cost upward of \$300 for the unsuspecting patient. Physical therapists are able to provide information on appropriate footwear at more reasonable costs for these patients.

Lastly, patients managed by suppliers without experience can sometimes be significantly adverse. I have routinely experienced patients who have been orthotically mismanaged by unexperienced suppliers who have ended up with problems that have worsened or new problems have developed. This is especially important with diabetes patients with insensate foot problems; this is a very large population that could be effected by these changes. Pressure ulcers are significantly mismanaged by unknowing commercial suppliers of DMEPOS.

I urge you to strongly consider my above contribution toward your decision on this matter. If you have any further questions regarding my viewpoint on this subject, please contact me.

Kevin Maloney PT
Director, Physical Medicine and Rehabilitation
Hanover Hospital & Hanover Rehab Centers
maloneyk@hanoverhospital.org
717.633.8986

Submitter : Dr. Walter Zelasko
Organization : Dr. Walter Zelasko
Category : Physician

Date: 06/17/2006

Issue Areas/Comments

GENERAL

GENERAL

June 17, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) 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 24+ 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.

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,

Walter Zelasko, D.P.M.

Submitter : Mr. Quinn Millington
Organization : PT Solutions
Category : Physical Therapist

Date: 06/17/2006

Issue Areas/Comments

GENERAL

GENERAL

My name is Quinn Millington. I am a physical therapist practicing in Montgomery, Alabama.

As part of my practice I routinely work with Medicare recipients who are in need of OTC orthotics. In most cases the needs are straight forward and because the application of the orthotic is part of the treatment it is important to assess the patient's response to a given intervention (i.e. application of an orthotic).

An example will help illustrate. A patient with knee or hip pain will often have a corresponding change in the way in which the foot and ankle function. With the application of a simple orthotic we are able to alter the position and function of the knee and hip. The application of the orthotic often requires mild alterations to "fine tune" the position of the foot and ankle in order to optimize the treatment response.

If orthotics are delivered through select DME providers my ability to respond immediately to a patient's need is limited. Imagine the difficulty in coordinating schedules with a DME provider, the therapist and the patient. The other issue is how to handle to adjustments that are inevitable whenever orthotics are applied.

As you can see, I am opposed to this proposed change in procedure. It will limit patient access and treatment time will be prolonged (which will ultimately cost more money).

Sincerely,

Quinn Millington

Submitter : Dr. Margo Sobol
Organization : Fox Hills Pharmacy
Category : Pharmacist

Date: 06/17/2006

Issue Areas/Comments

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

Submitter : Dr. Margo Sobol
Organization : Fox Hills Pharmacy
Category : Pharmacist

Date: 06/17/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

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

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

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

Criteria for Item Selection

Criteria for Item Selection

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

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

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

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

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

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

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

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

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

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

Submitter :

Date: 06/18/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. Mark McClellan:

I oppose 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 exclude all physicians, including podiatric physicians, from the requirement to competitively bid.

If physicians, including podiatric physicians, are not excluded from the new program, patient care will probably suffer.

Allowing physicians to dispense a medically necessary DMEPOS item when we are the ones treating the patient makes sense. I want the patient to receive exactly what they need. I want to make sure the product fits the patient and functions as it should. This way, Medicare will also save money from inappropriate equipment, extra adjustments, and additional physician encounters.

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.

Submitter : Dr. Timothy Tillo
Organization : American Podiatric Medical Association
Category : Physician

Date: 06/18/2006

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Dr. McClellan

I would like to voice my strong objection to 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). In my opinion, all physicians, including podiatric physicians, should be excluded from the new program.

In order to adhere to the standard of care for acute injuries such as a foot fracture, I must be able to dispense items such as walker boots to protect the injured area. Many of my patients are not candidates for cast immobilization because of peripheral neuropathy or variable peripheral edema. In such cases, a removable brace is of paramount importance. These patients must be able to obtain this brace at the time of evaluation or further injury may result. Furthermore, it is considered malpractice to not provide such treatment.

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,

Timothy H. Tillo, DPM

Submitter : William Nelson
Organization : The Medicine Shoppe Pharmacy
Category : Pharmacist

Date: 06/18/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Choice of suppliers by beneficiaries should not be restricted as would happen with requiring the use of mailorder for certain supplies including glucose testing supplies--items for which beneficiaries need quick, convenient and frequent access. Also, CMS should exercise oversight to prevent the possibility of fraud and abuse by mailorder providers by prohibiting the automatic refilling of supplies without a specific refill request from the beneficiary.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies which are relatively inexpensive such as diabetic supplies, walkers and canes. Centralized provision of DMEPOS items with competitive bidding should be limited to those unique products that could more economically be provided by a central supplier

GENERAL

GENERAL

The danger in large metropolitan areas is that existing small-business suppliers will be completely shut-out of the DMEPOS program with Medicare because of the disproportionate advantages of large corporations in the bidding process. Once CMS has established the single payment price for each item, any supplier who is willing to meet that price should be allowed to participate.

Independent pharmacies across the country went to extraordinary lengths to insure that the Medicare-D drug benefit worked smoothly upon its introduction earlier this year. As small DMEPOS suppliers, many of the same independent pharmacies wish to be allowed to continue their role as DME suppliers to their patients and customers as well. Our expertise, integrity, and ability to spend the one-on-one time required with our patients is a great asset that should not be lost in the competitive bidding requirements.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

It is important that CMS does more to ensure that small suppliers including the nation's independent pharmacies can participate in the DMEPOS supplier program. To do this, smaller suppliers must be allowed to designate a smaller market area to service. The smaller supplier should be allowed to accept the approved single payment amount AFTER CMS establishes it and be allowed become a contracted supplier at that time. I urge CMS to take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established and trusted provider/patient relationships with the small supplier.

Submitter : Mr. Henry Claypool
Organization : Independence Care System
Category : Consumer Group

Date: 06/18/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-227-Attach-1.DOC

June 19, 2006

Center for Medicare and Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1270-P,
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments on the Proposed Rule Regarding Medicare's Competitive Acquisition for
Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Comments submitted by:

Independence Care System
257 Park Ave. South, 2nd Floor
New York, NY 10010

Criteria for Item Selection

Independence Care System is a managed long term care Medicaid program. Our membership is comprised of persons with long term disabilities who are Medicaid eligible. Over 40% of our 850 members are dually eligible, Medicare and Medicaid beneficiaries.

We do not believe that the competitive acquisition of items covered by Medicare as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies is beneficial to Medicare beneficiaries. This approach will no doubt have a negative effect on access to certain items that people with Medicare currently rely upon to maintain or improve their health status. We are particularly concerned about those with Medicare that live with a chronic health conditions and/or disability.

We understand that the proposed rule is in response to Congressional action that requires CMS to implement this unfortunate purchasing practice. In light of this reality, we urge CMS to advise the Secretary of the U.S. Department of Health and Human Services (HHS) to exempt items considered to be Rehab equipment and assistive technology devices for the requirements of this proposed regulation. For purposes of these comments we use the following definition of rehab equipment:

- wheeled mobility for persons who rely on wheeled mobility as their only form of mobility; or seating and positioning support to use the wheeled mobility device; or speech generating device are provided under at least one of the following situations:

- the consumer has a primary diagnosis which results from childhood or adult onset disease, injury or trauma; or
- the consumer has a primary diagnosis or symptomatology that is neuromuscular in nature and prevents ambulation as a primary means of mobility; or
- the consumer requires adaptive seating to operate the mobility device or to maintain skin integrity; or
- the consumer has a diagnosis that indicates a need for other assistive technology including, but not limited to, speech generating devices,

For a definition of assistive technology, we recommend the federal definition of an assistive technology device from the Assistive Technology Act of 1998.

The term 'assistive technology device' means any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain, or improve functional capabilities of individuals with disabilities

CMS should identify codes in HCPCS that are used exclusively for items that are considered rehab equipment or assistive technology that correspond to these two definitions. Once the agency has identified the appropriate codes, all items in these codes should be exempt from competitive bidding. (example, K0005 wheelchairs would be exempt as this code includes wheelchairs that are always consider Rehab equipment).

Quality Standards and Accreditation for Supplies of DMEPOS

Before this proposed regulation is finalized, CMS should provide the revised version of the quality standards to the Program Oversight and Advisory Committee (POAC) for review and comment. Once the POAC has made comments on the quality standards, CMS should use the final quality standards to identify appropriate accreditation for suppliers of DMEPOS. If CMS does not follow this sequence of activities, it will be impossible for the competitive acquisition process to conform to the statutory requirement that calls for DMEPOS suppliers to receive accreditation based on specific quality standards developed during this process.

The grandfather of accreditation received prior to the release the DMEPOS quality standards should not be allowed. Only those entities that receive accreditation that addresses the specific quality standards currently under development by CMS should be awarded a contract under this regulation.

Determining Single Payment Amounts for Individual Items

While we support the efforts of CMS to lower the cost of DMEPOS to Medicare beneficiaries, the proposed rebate program is significantly flawed. The process for providing beneficiaries with rebates outlined in the NPRM is convoluted and confusing. Offering this type of "kickback" to Medicare beneficiaries only increases the probability of fraudulent behavior or at a minimum the appearance of fraud on the part of suppliers. Alternatively we recommend that the HHS Secretary use his authority to allow all beneficiaries to opt-out of the competitively bid network and select the provider of their choice at the Medicare DMEPOS fee schedule amount

Submitter : Mr. Mark Hobbs

Date: 06/19/2006

Organization : Hobbs Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Restriction of DME services, especially access to diabetic supplies, to a single provider will increase overall health costs. There is an epidemic of diabetes in the US, and all health care professional must rally to prevent massive costs to the system. Monitoring diabetic blood glucose is essential to proper therapy.

Submitter : Ms. Cathy Yi
Organization : Ms. Cathy Yi
Category : Physical Therapist

Date: 06/19/2006

Issue Areas/Comments

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

Quality Standards and Accreditation for Supplies of DMEPOS
comments contained in the attachment

CMS-1270-P-229-Attach-1.DOC

My name is Cathy Yi and I work in an outpatient orthopedic setting. We treat anywhere from post MVA's (C/S, T/S, L/S pains) to post surgical to overuse/strain/sprain syndromes to degenerative changes (up to the geriatric-age population). In this setting, the issue of providing, fitting, and recommending orthotics is a common affair.

In regards to the "Proposed Rule for Competitive Acquisition of Certain DMEPOS", quality patient care is a concept that must be reminded to those who are creating this "bidding war". It is also more efficient to avoid this "extra step" when it comes to providing a patient what he/she needs. This proposition will only create extra "hoops" to leap through and can significantly limit the broad spectrum of DME's that is impossible to predict when it comes to providing all that a patient may require. Inevitably, the longer a patient has to wait for orthotics/assistive devices, the further their quality of life is limited, their "-itis" worsens, symptoms spread from affected areas due to compensatory motions, and their recovery period is considerably lengthened.

Physical therapists are the ones who most frequently see/reassess/treat the patients. We spend an hour, on average, observing their functional levels, abilities, limitations, compensatory tactics, etc. Therefore, it is only customary that we are better able to identify a patient's need for orthotics/assistive devices, evaluate and measure what would best support them, and fit them to best improve their function/mobility. Yet, the process does not end there as any patient's reaction to such DME's is unpredictable and take time to appear. Again, as the treating professionals that not only have background on the patient's diagnoses, status, and level of function, but also their present level and state of mobility; we are also able to assess what aspect of the orthotics/assistive devices are causing negative effects. In so doing, the physical therapists that are skilled in identifying what adjustments must be made (that surpass the "minimum adjustments" stated in the proposed rule) are practiced in executing the modification in a timely manner in order to prevent further skin deterioration, increase of symptoms, or prevent creating another compensatory motion.

In the end, one must picture their own parents, grandparents, children regarding these matters. In seeking care, anyone would want the best. If orthotics/assistive device were recommended for your grandmother, for example, would you want her to have to wait for paperwork, find a carrier, wait to set an appointment, wait to receive them, etc. Then when she finally receives them, she develops pain elsewhere or blisters in contact areas and then has to send them off, go through more paperwork, wait to receive them, and wait to see if anything more could happen. When, all the while, she could have all the assessment, fitting, information she could possibly require through her physical therapy visits and benefit from their expertise.

Submitter : Dr. Mark Zeleat
Organization : Dr. Mark Zeleat
Category : Physician

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

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

As a podiatric physician, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

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.

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

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,

Mark Zeleat, DPM

Submitter : Ms. B Martin
Organization : Ms. B Martin
Category : Occupational Therapist

Date: 06/19/2006

Issue Areas/Comments

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

Quality Standards and Accreditation for Supplies of DMEPOS

Please consider allowing Physical Therapist's to continue fabricating custom splints for their patients. The background and training Physical Therapist's have separates them from other DME orthodic providers. Their unique understanding of the biomechanics of the human body puts them at an advantage when fabricating splints.

Thank you for your consideration.

Sincerely,
Beth Martin

Submitter : Dr. Dan Meisenhelder
Organization : Martin Foot and Ankle
Category : Physician

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

June 19, 2006

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

Dear Dr. McClellan,

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

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 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,

Dan Meisenhelder
Martin Foot and Ankle
1203 S. Queen St.
York, Pa 17403
717.757.3537

Submitter : Dr. Craig Martin
Organization : Martin Foot and Ankle
Category : Physician

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

June 19, 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 a podiatric physician who has been in practice for more than 27 years. Through these years, I have always tried to provide the highest quality of care to all of my patients. I believe that the proposed rule will impact my ability to provide the patients with the immediate care they need and they will suffer

I use a wide range of DMEPOS items, including walking boots for foot fractures and ankle braces for acute ankle injuries. If I am no longer able to supply these items due to the competitive acquisition program, my patients will be required to obtain these items from another supplier away from my office, and additional injury could result. 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 urge CMS to reconsider its original proposal and to exclude all physicians, including podiatric physicians, from the requirement to competitively bid. Instead, allow me as a qualified supplier to continue to directly supply items to Medicare beneficiaries.

Sincerely,

R. Craig Martin, DPM
Martin Foot and Ankle
1203 S. Queen St.
York, Pa 17403
717-757-3537
martinfootandankle.com

Submitter : Dr. Rick Martin
Organization : Martin Foot and Ankle
Category : Physician

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

June 19, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment and I am requesting that the Centers for Medicare and Medicaid Services exclude all physicians, including podiatric physicians from the new competitive acquisition program. I believe that the proposal could interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

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 occur, which could result in other additional injuries. I cannot imagine telling a Medicare patient 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. This would be a set back in quality patient care that our practice is known for.

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

Sincerely,

Rick Martin
Martin Foot and Ankle
1203 S. Queen St.
York, Pa 17403
717.757.3537
martinfootandankle.com

Submitter : Mr. David Streng
Organization : Mercy Family Pharmacy
Category : Pharmacist

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

There is nothing competitive about this new mail order rule that the CMS is considering. I believe this will result in a significant reduction in competition and to a significant decrease in services to Medicare beneficiaries.

One of the assumptions of this rule is that patients do not need any face-to-face attention after the first visit. Studies have shown that many patients need constant reminders to continue proper technique when using health care devices. Many times patients do not even know that there is a problem. The community health care is best positioned to provide this service. The mail order supplier has no personal or time commitment to the patient and cannot provide the level of personal service to patients.

With this rule the community health care provider would take time to do all the counseling for the product the first time, and after that the mail order provider could then supply the with a minimal time commitment and little or no personal counseling commitment to the patient, as the patient would punch their order into a telephone answering system. Studies have shown that patients need constant reminders to continue proper technique when using health care devices. The patient may not even know that he/she needs attention. When a patient has a problem, they are more likely to contact their hometown health care provider and have the problem resolved than if mail order is used. Because of a higher incidence of age related impairments including hearing, site, cognitive, and other physical problems, this group of patients benefits from face-to-face. How can a telephone answering system or telephone counselor notice these problems.

What if the patient forgets to order her/his supplies? While many Medicare beneficiaries are more than able to take care of themselves, some have cognitive deficiencies, which limit abilities to plan ahead and therefore will run out of supplies. If this problem was solved by automatic filling, some people will end up with lots of supplies in the home that they would not need because of non-adherence to treatment plans. This will result in more costs to Medicare, not less. Also, the supplies would in many cases have to travel hundreds of miles through the postal-delivery system which does not guarantee that manufacturer recommended temperature storage requirements are met while in transit.

At the same time, the reimbursement for these items should also be increased to a level to what the community health care provider actually has to pay for these supplies. These companies are able to obtain product at a reduced price because of tiered drug pricing. The community pharmacy provider is discriminated against because he/she has to pay more. The carriers mail order program will keep the extra money and Medicare will not save anything. There is no transparency requirement for these carriers.

In conclusion, this rule will not only decrease competition, it will result in more costs to the Medicare health care system. The CMS proposal sounds more like an attempt to monopolize health care sourcing into the hands of a small number of insurance mail order carriers. More importantly, I urge you to reconsider and reject this proposal as a needless and reckless disregard for patient safety that would endanger the health of one of this country's most vulnerable patient populations.

Submitter :

Date: 06/19/2006

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-236-Attach-1.DOC

June 16, 2006

There are many issues in the recently released CMS NPRM for competitive bidding of DME that are of grave concern: A few of the more pernicious are:

1. Unqualified Bidders:

CMS intends to include information from unqualified bidders in calculating the "single payment amount" (the winning bid amount). This will result in bidders who are incapable of meeting the financial and quality standards of the program submitting "lowball bids" that will not be representative of the bids submitted by firms whose cost structure enables them to meet these requirements.

This will skew the bid results to a point where genuine providers will be driven from the marketplace due to unfair pricing. This will result in a devolution of the industry to the point where the word 'quality' is meaningless and beneficiaries suffer at the hands of unqualified and incompetent 'low bidders' who should never have been allowed to submit a bid in the first place.

Why allow bidders who can't support their bid to have any part at all in the process of setting prices – especially when beneficiaries' lives are at stake?

This policy of using quotes from unqualified bidders to set prices for qualified bidders is unethical. It is in direct opposition to CMS's stated goal of producing a fair market driven cost structure.

2. Inducements for Referrals:

The NPRM runs counter to decades of health care law by allowing providers to offer inducements to beneficiaries in the form of consumer rebates. CMS is promoting the very fraud and abuse that it claims to be fighting.

This policy is in direct opposition to CMS's long held prohibition against providing inducements for referrals.

3. Insufficient Information:

The products subject to competitive bidding and the geographic areas where bidding will take place should be published a minimum of 12 months in advance of bids being accepted. Quickly pushing such sweeping policy changes through will result in poorly conceived plans, the NPRM is a good example, and the resulting unintended consequences.

This lack of information runs counter to CMS's stated goal of producing an orderly transition to its competitive bid model.

4. Lack of Standards:

Quality standards should be based on current industry standard accreditation protocols as established by ACHC, CHAPS and JCAHO and should be published a minimum of 12 months in advance of bids being accepted. Only bidders in full compliance with the standards at the time of bid should be allowed to bid.

Not enforcing this policy will produce bidders who do not understand the cost of such quality standards and are therefore incapable of accurately factoring them into a bid price. The result will be unrealistically low bids that winning bidders cannot sustain, which will lead to bankruptcies, which will lead to disruptions in patient care and egg on CMS's face for accepting bids from providers who were not qualified at the time of bid.

The lack of timely published standards is in direct opposition to CMS's stated goal of maintaining the beneficiaries' quality of care.

5. Poorly Conceived Grandfathering and Transition Plan:

The grandfathering and transition policies are going to produce severe negative consequences that are contrary to CMS stated goals. For example; if losing suppliers choose not to continue servicing their existing patients, winning suppliers will be forced to inherit an untold number of patients who have been receiving services that are near the end of the capped rental period. The winning supplier would have to buy new equipment to meet the beneficiary's needs, receive a few rental payments that are insufficient to cover the cost of the equipment, and then lose title to the DME or oxygen equipment after only a few months.

CMS's stated goal is to deal with financially stable companies but this policy will result in the opposite effect, namely:

- a) Creating financially unstable companies and
- b) Make it impossible for firms to produce a bid that covers the cost of transitioning patients since the winning bidders have no control over how the losing bidders choose to conduct, or not conduct, their business.

6. Price Fixing = Non-competitive Bidding:

If CMS wants market dynamics to set prices then why does it mandate price caps? This CMS policy is diametrically opposed to its stated goal of achieving market dynamics.

Some DME items have already been set by the government at a price below what the market would set. If a provider cannot bid above a mandated below-market fee ceiling established by CMS then the resulting bids are not based on market dynamics but rather upon a bureaucrat's decree.

Furthermore, the methodology for determining the winning bid is not competitive. CMS is basically predetermining the bid it wants to achieve by its 'pivotal bid' methodology which is in direct contradiction of its stated 'competitive' bid goals.

7. Beneficiaries that Relocate:

What of beneficiaries that move from one location to another. Winning bidders will be required to accept patients who are at the end of the capped rental period or the 36 month oxygen period. This means a provider will have to provide a patient with equipment, only receive a few rental payments, and then hand over the equipment to the patient.

CMS would argue this would not be a problem if the beneficiary would choose a provider with a national presence. However, this argument is in direct opposition to CMS's stated objective of not driving small businesses out of business.

In Conclusion:

The most troubling aspect of the NPRM is its persistent direct contradiction of CMS's stated goals.

This leaves the conclusion that the NPRM is poorly conceived and seriously flawed or that CMS's stated goals are nothing more than rhetoric designed to obfuscate CMS's true intentions and goals.

Whichever conclusion is correct, the results are the same - tens of millions of Medicare beneficiaries are going to be placed at risk and many will incur direct and specific injury or loss due to implementation of policy that is in direct contradiction of CMS's 'stated' goals.

Submitter : Mr. Bill Bishop
Organization : Advantage Home Medical Company
Category : Other Health Care Provider

Date: 06/19/2006

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

Instead of applying competitive bidding to 20 items, why not select the top 5 items that have the greatest potential for cost savings and apply it only to them? If cost savings is really the issue, these items will provide CMS with a great picture of how serious cost savings will be. To "nickel and dime" the entire DME list of items is an example of shooting an elephant with a scatter gun. You'll probably hit the target, but can you bring the big boy down? Probably not.

Also, having the oxygen equipment revert to the patient after 36 months is fine and good, but what about the portable tanks they have? How many do they get? Who fills the tanks once they are empty? Do they get paid for re-filling the tanks? How much? All these and more questions like them MUST be addressed for the patient's welfare to be maintained while they are on oxygen.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

As a small supplier, we don't make a lot of money doing DME business. The reason I stay in business is to meet my expenses and to serve my patients. If I was in this business to make money, I'd have left it long ago. If the regulators and legislators are REALLY CONCERNED about saving money through this process, why not make it applicable to those DME business who are doing the bulk of the DME business, and not the "little man", who simply is trying to stay in business. There ought to be some reasonableness put to which suppliers are being targeted for cost savings. I can tell you as a small supplier, whatever you cut from me, even if I am a qualified supplier, will be "peanuts" compared to what you might realize from the "big boys". Somebody with some real insight ought to realize what I'm saying is true.

There needs to be some immediate criteria for allowing small providers to combine their efforts and bids in order to compete again with the large chain operated DME companies. Without the small providers this process cannot be successful.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

As a small home medical equipment owner and operator, I think that competitive bidding will do nothing more than put myself and other businesses like me - OUT OF BUSINESS. Specifically to the issue of accreditation, I think it is absolutely absurd that you would expect DME suppliers to become accredited when other health care suppliers (home health agencies, nursing homes, hospice organizations etc.) are NOT required to be accredited. It is discrimination in the highest order.

Why should I have to pay \$7,000-\$9,000 to become accredited when I may not be able to recover any of these costs due to the fact that I may not be a "qualified supplier" after the bidding process has ended? What purpose will that serve me and my company then?

Furthermore, even if I elected to be accredited, with the schedule being set for competitive bidding implementation, I may not have an opportunity to become accredited even if I could afford it. To make a small business, who has less than 1 million in gross revenue in a year to have to compete with the national chains who realize many, many more millions of dollars from doing business with the Federal government is a slap in the face of those companies who are doing their best to supply needed equipment and services to elderly patients, with a watchful eye on customer service. The chain operations don't care what kind of service the patient gets - all they want is the money from the transaction. If you people continue on with this absurdity, customer service - which is what the patient want just as much as the equipment, will be totally down the drain.

If you do make us get accredited, how about reimbursing us for the expense if we don't get the bid to put out the equipment? At least their would be some sort of incentive to get and stay accredited.

Regulatory Impact Analysis

Regulatory Impact Analysis

Would think that if CMS or the government is really interested in saving money through the Medicare program, it would take a SERIOUS look at:

1. Hospitals and the related cost of doing business there
2. Physician's costs, relative to the service they provide and
3. Drug and prescription costs.

HERE'S WHERE THE BIG BUCKS ARE, NOT IN SOME SMALL ANCILLARY BUSINESS LIKE HOME MEDICAL EQUIPMENT!!!!

It makes all of us wonder when you talk saving money are you really interested in saving money or simply protecting the ones who ring up the highest charges?? Think about it ladies and gentlemen. It's robbing the poor and giving it to the rich.

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

As a strong supporter of the Hobson-Tanner Bill (HR 3559), it should be considered for ALL BIDDERS to be given the opportunity to participate in the servicing of their market area.

What's going to happen if only a few providers are selected is:

1. They will be unable to meet the growing need, due to expanding "baby boomers" entering the market for DME goods AND
2. Customer service will go down the tubes. Equipment will be "pushed in the door" with little or no attention given to whether the patient knows how to use it or whether it will do them any good to have it.

You need to carefully consider supply and demand issues before through the bidding process you go and decrease the market capability by getting rid of businesses who are willing an able to supply needed items.

Submitter : Mr. GARY McCRORY
Organization : McCRORY'S PHARMACY
Category : Pharmacist

Date: 06/19/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I STRONGLY OBJECT TO CMS' ALTERNATIVE PROPOSAL THAT WOULD REQUIRE BENEFICIARIES TO OBTAIN REPLACEMENT SUPPLIES OF CERTAIN ITEMS THROUGH DESIGNATED PROVIDERS. THIS RESTRICTS THE BENEFICIARIES' CHOICE AND EXPOSES THEM TO THE POTENTIAL OF NON COMPLIANCE DUE TO SHIPPING ERRORS. THIS PROPOSAL SEVERELY RESTRICTS BENEFICIARIES' TIMELY ACCESS TO NEEDED SUPPLIES AND ITEMS AND COULD COMPROMISE PATIENT HEALTH OUTCOMES. PLEASE RECONSIDER THE IMPLEMENTATION OF THIS PROPOSAL.

Submitter : Dr. Christian Valcke

Date: 06/19/2006

Organization : Dr. Christian Valcke

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The field of glucose home monitoring has made an enormous improvement in diabetes care and represents the most cost-effective patient management possible. Although not enough effort is spent in reversing the risk factors towards diabetes (obesity, exercise, diet, etc.), it would be unwise to control or restrict the access to strip-based sensing. A lot of research is spent in optimizing the technology (smaller blood volume sampling, faster and more accurate readouts, etc) which would be stalled if competitiveness is taken out of this market, resulting in long-term harm to patient welfare.

Thank you for your consideration in this matter.

Submitter : Mr. GARY McCrory
Organization : McCrory's Pharmacy
Category : Pharmacist

Date: 06/19/2006

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

THE COMPETITIVE BIDDING PROGRAM SHOULD NOT INCLUDE COMMON DMEPOS SUPPLIES SUCH AS NEBULIZER MEDICATION, DIABETIC TEST STRIPS AND IMMUNOSUPPRESSIVE MEDICATIONS. IF CMS INTENDS TO CENTRALIZE AND CONSOLIDATE THE PROVISIONS OF DMEPOS ITEMS AND SUPPLIES THE AGENCY SHOULD LIMIT THE COMPETITIVE BIDDING PROGRAM TO THOSE UNIQUE ITEMS THAT COULD BE PROVIDED BY A CENTRAL SUPPLIER.

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 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; IMMUNOSUPPRESSIVE DRUGS, NEBULIZER MEDICATION AND DIABETIC SUPPLIES AND WITHOUT THESE REVISIONS TO THE FINAL REGULATION, I WILL BE UNABLE TO CONTINUE PROVIDING THESE VALUABLE SERVICES TO MY PATIENTS.

IN CONCLUSION, I URGE CMS TO REVISE THE REGULATION TO NOT INCLUDE COMMON DMEPOS SUPPLIES IN THE COMPETITIVE BIDDING PROGRAM AND TO INCLUDE STEPS TO ENSURE THAT SMALL SUPPLIERS CAN PARTICIPATE IN THE COMPETITIVE BIDDING PROGRAM. THANK YOU FOR CONSIDERING MY VIEW.

Submitter :**Date: 06/19/2006****Organization :****Category : Pharmacist****Issue Areas/Comments****Quality Standards and Accreditation for Supplies of DMEPOS****Quality Standards and Accreditation for Supplies of DMEPOS**

The quality standards, accreditation implementation and competitive bidding, which would include independent pharmacies, would restrict access to beneficiaries for DME equipment. Our customers have voiced their concerns to us regarding this implementation. The "full service" they currently receive when their prescriptions are filled is a great convenience. Independent pharmacies should be exempt from this process. The bottom line is to provide unfettered access to beneficiaries for DME equipment they need and this additional layer is a leviathan for them. Why insert an additional layer of bureaucracy? There are other ways to streamline the process and make it more accountable without impeding access to beneficiaries.

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

The competitive bidding process will negatively affect beneficiaries regarding access to DME and moreover servicing of equipment issues. A better process for CMS to save money (which I am sure is the main reason for the competitive bidding program) is to close the issuing of DME provider numbers (those current providers who comply with CMS regulations who do not have a record of inspection failures would remain as providers) and revise the current fee schedule for DMEPOS to fall fairly inline with the current market. Limiting access to beneficiaries regarding equipment and service is unacceptable. Additionally, existing DME companies contribute to the payroll tax roles of the Federal Government. Eliminating DME providers through competitive bidding would have a detrimental effect on small business thereby increased business closings and decrease collection of payroll taxes.

Submitter : Dr. Ronald Pate
Organization : Mer-Rob Pharmacy
Category : Pharmacist

Date: 06/19/2006

Issue Areas/Comments

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

Submission of Bids Under the Competitive Bidding Program

Allowing individual pharmacist or independent pharmacies to provide a services is a convience and service for medicare patients. Some can not read or write and depend on the trust and loyalty of local pharmacist.

Bid price submitted for 50 count diabetic strips is \$89.00

lancets 100 count box \$12.00, blood sugar monitor quantity of 1 \$112.50

Submitter :

Date: 06/19/2006

Organization :

Category : Home Health Facility

Issue Areas/Comments

**Determining Single Payment
Amounts for Individual Items**

Determining Single Payment Amounts for Individual Items

The rebate program is ripe with opportunity for fraud. There isn't any part of the proposal for rebates that is a good idea.

Submitter : Mrs. LAURA FITZPATRICK
Organization : MERCY FAMILY PHARMACY
Category : Pharmacist

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

Thank-you for the opportunity to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. I am concerned with the following areas of your proposal.

1. Competitive Bidding Areas

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

2. Criteria for Item Selection

Including items such as diabetic testing supplies under a centralized, consolidated supplier would not only affect access to these very important products, but would also affect local suppliers of these products. The community pharmacies would most certainly be those most affected when patients forget to order their supplies or become confused with the process. People are so confused already with all the Medicare changes, we do not need to add to this confusion.

3. Opportunity for Participation by small Suppliers

I urge CMS to take steps to ensure that small suppliers-including community pharmacies-can compete in the competitive bidding program. CMS should establish a single payment amount for each item of DMEPOS and any small supplier willing to accept that payment amount should be allowed to participate. I currently provide the diabetic supplies as well as wound care and respiratory care products. I will be unable to continue providing these valuable service to my patients with the current proposal.

In conclusion, I urge you to reconsider your proposal to require beneficiaries to obtain replacement supplies through designated providers, to not include common DMEPOS supplies such as diabetic supplies, and to take steps to make sure the small suppliers such as community pharmacies are allowed to participate.

Thank-you for considering my view.

Sincerely,

Laura FitzPatrick R.Ph.
Mercy Family Pharmacy
250 Mercy Dr.
Dubuque, IA 52001

Submitter : Mrs. Stephanie Brackett
Organization : Westlake Hospital
Category : Physical Therapist

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-1270-P-245-Attach-1.DOC

Tuesday, June 20, 2006

To: Mark B. McClellan, MD, PhD

From: Stephanie Brackett
Physical Therapist
Westlake Hospital
1225 W. Lake Street
Melrose Park, IL 60160

Subject: ***NOT in support of the current draft language re: qualified providers & accreditation standards for orthotics. NOT in support of competitive bidding for prefabricated orthoses.***

In compliance with the Medicare Modernization Act of 2003, I understand that the Secretary of Health and Human Services is responsible for establishing a competitive bidding system and quality standards for certain durable medical equipment, prosthetics and orthotics (DMEPOS). Furthermore, I understand the quality standards, which include the professionals recognized as qualified suppliers are being developed for approval by your Program Advisory Oversight Committee.

As a therapist, I have great concern for the language regarding who is qualified to provide orthoses to beneficiaries. The current draft language specifically indicates orthotics and prosthetics "require the qualifications and expertise of a certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". This ***language does not include occupational therapists and physical therapists. The language does not correspond with the existing language outlined in the Social Security Act, Section 1834(a)(20).***

I cannot understand why CMS would consider restricting providers to orthotists and prosthetists and mandate accreditation standards through the O & P boards. The omission of therapists does not correspond with current CMS regulations. TODAY, occupational therapists and physical therapists are recognized as qualified CMS providers for evaluating patients, designing, fabricating, and dispensing the appropriate orthosis, along with educating the patient (e.g. applying/removing the orthosis, understanding the wearing schedule and precautions). ***Occupational therapists and physical therapists are specifically identified as qualified practitioners in the Social Security Act, Section 1834(a)(20), and our status as a practitioner also qualifies us as suppliers for these devices.*** TODAY, there are thousands of therapists throughout the country fabricating customized orthoses and issuing prefabricated orthoses to patients. We are highly trained and highly qualified professionals who have a long-standing history of fabricating orthoses in this country.

It is important to know the minimal educational standards for occupational therapists and physical therapists are either a bachelor or master's degree. Orthotics is included in our academic curriculum. Both occupational therapists and physical therapists must successfully pass national boards at the completion of the academic experience before applying for licensure or certification at a state level. These examinations are administered through national testing companies accredited by NOCA and ANSI, which are recognized by CMS today. This academic background is complemented with clinical experience and ongoing medical education. We serve as authors for peer-review journals, manuals and books on

orthoses, and have lectured to our profession and others on the subject. In addition, beyond our high academic standards, many therapists choose to have additional certifications, one example being the certified hand therapist (CHT). CHTs have a minimum of five years of practice experience and have successfully passed an examination specific to the upper quarter (shoulder, elbow, wrist and hand). Specific questions related to orthotics are included in the examination. Once certified, recertification is mandated each five years to retain the CHT designation. This is accomplished through medical education requirements and practice involvement (i.e. clinical practice, research or education) related to the upper extremity. The Hand Therapy Certification Commission (HTCC), is responsible for the administration process for becoming a certified hand therapist and subsequently recertifying. Their website can be accessed at www.htcc.org.

We are sought out by patients, businesses, industry, case managers, referring physicians and therapists to treat patients with special medical problems. There are lofty expectations and demands placed on us to provide the highest level of patient care and remedy their medical condition. Often, we are the last opportunity to improve the patient's medical condition and quality of life. The physicians and therapists communicate closely about the patients and their medical condition or surgery. As therapists, we have a strong working knowledge of the medical conditions/surgeries and anatomy of the affected area. With this expertise we can carefully craft the proper rehabilitation program and determine the necessary orthosis. I cannot begin to imagine that my patients would receive an initial evaluation and treatment by the physician/surgeon, subsequently be referred to therapy for a portion of the therapy services and then go to another facility to receive the orthosis or orthoses they need. Evaluating the patient, fabricating and dispensing the orthosis, determining the wearing schedule and educating the patient about their orthosis is an integral part of hand therapy. Often it is the orthosis that is key to a successful outcome! It is those frequent, little adjustments that can result in terrific functional outcomes!

It is equally important to understand that sending patients to another provider fragments and disrupts the continuity of patient care. It is difficult enough for our Medicare and Medicaid patients to drive to office visits and therapy, let alone requiring them to drive to another location for additional services. During the course of therapy most of the patients require a number of adjustments to their orthoses, which would result in multiple trips to the DME distributor. These adjustments are necessary due to frequent dressing changes, fluctuation in edema, progression of the treatment plan, and patient progress. I can only imagine the burden and confusion this would cause for the patient and family.

With respect to competitive bidding for prefabricated orthoses, how could therapy providers possibly participate in the competitive bidding process? We are at a huge disadvantage. Therapists are not in the business of manufacturing and supplying high volumes of medical equipment. Individually, each therapist and/or therapy facility dispenses small volumes of medical supplies to their patients. There is no way therapists could compete with respect to wholesale pricing, volume warehousing, and having the business infrastructure for wide-scale distribution within their medical model today. The small amount of profit generated from these prefabricated orthoses serves, at best, as a very small source of revenue.

I must believe there has been an accidental oversight on behalf of the committee as the quality standards and accreditation process for orthotics and prosthetics has evolved. It is strongly recommended the language state: "orthotics and prosthetics require the qualifications and expertise of **a licensed, certified or registered occupational therapist, physical therapist OR** certified or licensed orthotist, prosthetist, and/or staff certified by the American Board for Certification in Orthotics and Prosthetics (ABC) or the Board for Orthotist/Prosthetist Certification (BOC)". In addition, I do not believe there can be a genuine interest in the small volume suppliers (i.e. therapists) participating in competitive bidding. **Therapists should be exempt from the competitive bidding process.**

It is so important for the committee to understand how instrumental occupational therapists and physical therapists are in providing both custom-made and prefabricated orthoses to patients, your beneficiaries. Respectfully, I ask that you give this letter full consideration and act on these major concerns.

Submitter : Sharon Cashman
Organization : Waverly Health Center
Category : Pharmacist

Date: 06/19/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

In some things you get what you pay for, lowest bidder sells the most quantity and you end up lacking on quality. Our pharmacy staff works with the patients to ensure they understand and are properly trained. They are asked regularly about their medical needs and are monitored. Our patients will end up utilizing less resources due to better care and control of their medical condition, costing less to medicare, reducing hospitalizations and emergent care. If you want to control DMEPOS costs, look to pharmacies/suppliers that provide high quality care not bottom dollar pricing.

Submitter : Dr. Trevor Ling
Organization : Rapid Rehabilitation
Category : Physical Therapist

Date: 06/19/2006

Issue Areas/Comments

GENERAL

GENERAL

This is in regards to the Proposed Rule for Competitive Acquisition of Certain DMEPOS

CMS-1270-P-247-Attach-1.DOC

CMS-1270-P-247-Attach-2.WPD

To Whom It May Concern:

My name is Trevor Ling and I am a physical therapist and athletic trainer. I am currently working in an outpatient physical therapy clinic. In this setting certain types of medical equipment are needed to be dispensed to patients. This includes off the self orthotics, both full and partial. By dispensing these items myself I am able to assess the specific type of orthotic that would best fit the patient's need and complaint. Depending on the patient's impairments a more flexible vs. rigid full off the self orthotic may be the most beneficial or the patient may only need an arch support or metatarsal pad placed in their existing shoe insert. I do not feel this type of specificity can be achieved through the use of commercial suppliers who do not have the knowledge or time to evaluate the individual patient's needs before dispensing orthotics of any kind. This is also pertinent with issuing assistive devices such as canes and walkers that need to be sized and personalized to each individual. I feel that if this facet of physical therapy is not able to continue that it will prove as a disservice to our patients and future patient population.

Sincerely,

Trevor Ling, DPT, ATC/L

Submitter : Mr. Steve Treinen
 Organization : Banner Home Care
 Category : Home Health Facility

Date: 06/19/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

File CMS-1270-P

Comments on Competitive Bidding Area

We propose that selection of MSA s for 2007 implementation of competitive bidding be based on the total expenditure of the aggregate totals of the selected MSA s total allowed charges as documented in the CMS chart in the proposed rule. Additionally, we suggest that at least one of the top three MSA s noted, New York, Los Angeles or Chicago be included in the 2007 selection.

The argument made by CMS that the San Antonio demonstration project only had a population base of 1.7 million people and therefore did not provide the experience necessary to ensure the maintenance of quality and beneficiary access to care, is weak at best. CMS by the 2007 date will have had seven years to evaluate data and study and implement a plan based on that experience. San Antonio while not a large population center ranks 21st on the CMS list of Allowed Charges. Are we to believe that after seven years CMS is not able to include even one of the 3 largest MSA s? Somehow it is suggested that Chicago number 4 on the list is too large but Houston number 5 is not. Are Houston beneficiaries any less deserving of quality or beneficiary access? To an outside observer it seems that the top three are probably more politically sensitive.

Include at least one of the top three MSA s and gain the experience of working with a large MSA. The top three represent the Allowed Charges of 14 other MSA s on the top 25 list. The proposal that CMS in two years will gain enough experience to handle the largest MSA s when after seven years of study it is unwilling to tackle the challenge of a large population center, does not speak well of it.

The mandate is savings. If that truly is the intention, how could CMS not consider where it could maximize savings?

Submitter : Carol Bylone
Organization : Redner's Pharmacy #21
Category : Pharmacist

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

There is a limit as to how inexpensively we can purchase glucometer supplies for our patients who rely on us for help in using these products. We train people to use glucometer and get paid nothing now. It appears that the federal government along with the state governments would prefer community pharmacies that truly help their patients would prefer them not to exist, however, the patient population that uses these pharmacies would prefer to have them rather than mailorder which your competitive bidding process would force them to use because history being what it has been where payment to community pharmacy is concerned, it's only a matter of time until the people in power like CMS along with all of our elected officials who are supposed to represent even the community pharmacist put the community pharmacies that care & take care of patients out of business with their Draconian reimbursement rates. All this will be is another nail in the coffin. It is questionable if we make anything now with the current rates & you want to lower them even more with competitive bidding. The small business person can't compete with big mail order operations that advertise on television & provide no face to face service. The geriatric & low income populations of the world which comprise the bulk of healthcare need face to face contact if they are to have the best quality of life they can while at the same time reducing unnecessary expensive care post community pharmacy when they know how to utilize equipment along with medications properly. Institutional care costs lots more than community pharmacy care. Don't do this to the community we serve.

Submitter :

Date: 06/20/2006

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

We need to care for our patients..keep things the way they have been..

Submitter : Dr. Thomas Azzolini
Organization : Dr. Thomas Azzolini
Category : Physician

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

June 20, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer.

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.

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace and crutches are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

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.

Respectfully,

Thomas J Azzolini, DPM
Director of Podiatric Medical Education, BSNJHS
Chief, Podiatry Service, St Mary Hospital

Submitter : Dr. Dana Giacalone
Organization : Foot and Ankle Associates of North Texas
Category : Physician

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

Sec Attachment

CMS-1270-P-252-Attach-1.DOC

foot and ankle associates
of north texas, LLP

Grapevine

Lewisville

Bedford

Denton

June 20, 2006

1.866.490.FOOT(3668)

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

Dear Dr. McClellan:

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

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

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,

Dana Giacalone, DPM

Submitter : Ms. Karen Cook

Date: 06/20/2006

Organization : none

Category : Individual

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

I have just today lost my job at (EBI in Marlow OK- Bio tech facility.) Due to the fact that I was a new hire on 90 days probation period and found out that I need cataract surgery to correct my vision problems that were impairing my ability to do my job. I have no insurance and am 40 years old. My vision problems have just begun and No hope in sight. How can you let pocples cys go when you have the power and ability to keep the person needing help productive an vital in life. What we don't NEED OUR SIGHY?

Submitter : Mr. TIMOTHY SCHELL
Organization : TMS PHYSICAL THERAPY
Category : Other Health Care Provider

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

My name is Timothy M. Schell and I am a practicing Physical Therapist in a rural setting, Grove City PA. I have been in practice for 30 years, owning my own outpatient clinic for 25 years. During this time I have supplied patients, as an integral part of the plan of care, with medical supplies including wrist braces, tens units, back braces and orthotics.

The proposed competitive bidding program poses a serious threat to timely patient access to medically necessary DMEPOS, proposing a system that could obstruct the way clinicians currently furnish DMEPOS to their patients. Patients come to us for therapy and as we evaluate the patient we may notice the patient's need for some type of medical supply to facilitate their rehabilitation. In consultation with their referring physician, we are easily and conveniently able to supply the appropriate items for our patients.

As professionals, we appreciate the fact that as of now, we can distribute to our patients supplies that we feel are most appropriate for the patient's condition. TMS Physical Therapy does not choose an item because of a 'name brand', we choose the item we feel would be most beneficial to our patients.

Since we are in a rural setting, receiving supplies at the same place as therapy makes it more convenient for our patients. Some of our patients are elderly and appreciate the service we provide.

Thank you for your time in this matter. Sincerely yours, Timothy M. Schell, P.T. TMS Physical Therapy

Submitter : Mr. Robert Ledbetter
Organization : Dahlongea Pharmacy, Inc
Category : Pharmacist

Date: 06/20/2006

Issue Areas/Comments

**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 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 nebulizer machines, wheelchairs, crutches, and other types of DMEPOS supplies in my practice and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients. I am also currently the only Pharmacy in Dahlongea Georgia that provides these services. In conclusion, I urge CMS to revise the regulation to allow the opportunity for participation by small suppliers. Thank you for considering my view.

Sincerely,
Robert A Ledbetter
Dahlongea Pharmacy, Inc.
70 Memorial Drive
Dahlongea, GA 30533
706-864-2522

Submitter : Dr. Richard Altwerger
Organization : PondView Podiatry
Category : Physician

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

June 20, 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 25 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I recognize the importance of being able to supply DMEPOS items to patients as part of the quality care I provide. If I am no longer able to supply these items due to the competitive acquisition program, my patients will suffer. 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 directly supplying items to Medicare beneficiaries.

Sincerely,

Richard Altwerger, D.P.M., F.A.C.F.A.S.
77 Miller Road, Suite 202
Castleton, New York 12033
(518) 479-3338

Submitter : Mr. STAN HOGAN
Organization : JACKSON DRUG COMPANY
Category : Pharmacist

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

Stan Hogan, Pharmacist, Jackson Drug Company
 May 20th 2006

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

Ref CMS 1270 P

There are several comments that I wish to make concerning the proposed competitive bidding process for durable medical supplies and equipment.

I truly believe that the government should seek fair and equitable cost for the products provided through Medicaid and Medicare services to the benefit of both the US taxpayers and beneficiaries of these products and services.

True competitive bidding can be a good thing as long as, in the end, all willing providers who are able and willing to accept the payment amount allowed for the product are allowed to participate in the program. No provider, who is capable and willing to participate should be excluded from the program. Just because a company or corporation is large does not usually mean that they provide the best service and sales. In fact, I submit that the opposite is often true. In a DMEC region is given to one or two providers, who do they have to answer to when they have no competition.

Jackson Georgia is far removed from metro Atlanta, I know that many patients do not have the means to go to a central supplies and get their equipment. With gas prices the way they are now, most Durable Medical suppliers only make 1 trip a week to deliver (or pick up) equipment. A good example of this is BCBS supplier located in north Atlanta, has 1 pick up/delivery a week to our area. If you need it now come up and pick it up yourself or wait until the next scheduled delivery to the Jackson Area. We deliver 6 days a week and in an emergency anyway.

The competitive bidding process should not include common DMEPOS supplies such as diabetic testing supplies. Someone with a little sense should also realize that not all testing strips cost the same. There is a large difference in range of cost for these strips and 1 flat fee for 50 or 100 strips no long is feasible. What you are now getting, especially from these mail order supplies, is the cheapest generic meters and strips available. Some are not even FDA approved. but you pay for them anyway and the patient has to rely on the test results to live another day. A wrong dose of insulin based on these cheap units can be deadly.

Small independent pharmacies and DME suppliers have always been the best answer to product quality and service. It is important that all supplies to be treated with equal rules and regulations. Larger is not often better, for the taxpayer or the patient.

We currently supply a number of DME items to many of our patients and others in our area. We supply walkers, commode chairs, bath benches, wheelchairs, electric wheelchairs, personal mobility options, diabetic testing supplies, canes, quad canes, diabetic shoes, many types of braces and support hose. Some items are covered by Medicaid or Medicare or both. Some are personal purchases. Our customers and patients depend on our personal care and quality equipment to aid them in everyday life.

Let us continue to help those in need.

Thank you,

Stan Hogan, RPH
 Jackson Drug Company

Submitter : Michael Scribner
 Organization : COLLIER NORTH HILLS PHARMACY
 Category : Pharmacist

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

AS A COMMUNITY PHARMACIST, I DEAL WITH A LOT OF PATIENTS WHO HAVE DIABETES. THIS IS NOT ONLY TO SUPPLY THEM WITH TESTING SUPPLIES, BUT ALSO TO ANSWER THEIR QUESTIONS ABOUT THE DISEASE, THEIR MEDICATIONS, DIET, AND EXERCISE. THESE PATIENTS WILL NOT GET THIS INFORMATION IF THEY ARE FORCED TO GO TO A "MAIL ORDER" SUPPLIER FOR DIABETIC SUPPLIES.

REGARDING A SINGLE PAYMENT AMOUNT FOR ALL SUPPLIERS, THIS WILL BE IMPOSSIBLE FOR A SMALL COMMUNITY PHARMACY TO DO WITH DIABETIC SUPPLIES. AS YOU SHOULD KNOW, MOST OF THE MANUFACTURERS WILL PROVIDE A "DISCOUNT" OR "REBATE" IF THE PHARMACY OR PROVIDER CAN SELL ENOUGH UNITS (EXAMPLE 5000 UNITS/YEAR). THE COMMUNITY PHARMACY CANNOT HAVE A CONTRACT WITH EACH MANUFACTURER AND THEREFORE THE SUPPLIER WOULD BE FORCED TO SWITCH THE PATIENT TO WHATEVER THEY HAVE CONTRACTS WITH. THIS IS WHAT THE MAIL ORDER COMPANIES ARE DOING TODAY. CHECK AND SEE HOW MANY COMPLAINTS DO YOU HAVE WHERE THE PATIENT HAS BEEN "SWITCHED" TO A DIFFERENT METER THAN WHAT THEY ARE USED TO, AND DO NOT TEST BECAUSE THEY DO NOT KNOW HOW TO USE THE MACHINE. THE NUMBER SHOULD SURPRISE YOU. YOU NEED TO KEEP THE LOCAL PROVIDERS IN THE NETWORK. GOING TO A COMPETITIVE BID SYSTEM WILL TRULY ALLOW ONLY THE LARGE (MAIL ORDER) SUPPLIERS TO COMPETE, AND THEREFORE DECREASE THE EFFECTIVENESS OF THE DIABETES HOME MONITORING PROGRAM.

REGARDING THE REBATE PROPOSAL; I DO NOT AGREE WITH ALLOWING A SUPPLIER TO GIVE A REBATE TO THE PATIENT; MEDICARE HAS ALWAYS SAID THAT THE PATIENT HAS A DEDUCTIBLE AND A 20% CO-PAY RESPONSIBILITY. THIS WAS INTENDED TO REDUCE THE CHANCE OF FRAUD/ABUSE IN THE PROGRAM. WHY WOULD YOU LOOK TO REMOVE THIS FRAUD DETERRENT?. WHY WOULD ANY PROVIDER LOOK AT GIVING MONEY BACK, IF THERE WAS NOT SOME OPPORTUNITY TO MAKE EVEN MORE MONEY FROM SUCH ACTIVITY.

IF CMS INCLUDES DIABETES TESTING SUPPLIES IN THE COMPETITIVE BID PROGRAM, MANY LOCAL PHARMACIES WILL NOT BE ABLE TO PARTICIPATE, AND AS A RESULT MANY OF OUR CUSTOMERS WILL NOT HAVE ACCESS TO THE INFORMATION THAT WE CURRENTLY PROVIDE. I SUGGEST THAT YOU DO A POLL OF THE PATIENTS, SEE WHERE THEY FEEL MORE COMFORTABLE GETTING THEIR SUPPLIES, LOCAL PHARMACY OR MAIL ORDER?

I STRONGLY OBJECT TO MEDICARE GOING TO A COMPETITIVE SYSTEM AS I FEEL IT WILL LIMIT THE PATIENTS ABILITY TO RECEIVE QUALITY CARE IN THEIR LOCAL AREA.

SINCERELY;

MICHAEL D. SCRIBNER
 COLLIER NORTH HILLS PHARMACY
 3380 N. FUTRALL DR. #2
 FAYETTEVILLE, AR. 72703
 PH. 479 443-9200
 E-MAIL north_hills@collicdrug.com

Submitter : Mr. Stan Hogan
Organization : Jackson Drug Company-Jackson Ga
Category : Pharmacist

Date: 06/20/2006

Issue Areas/Comments

**Determining Single Payment
Amounts for Individual Items**

Determining Single Payment Amounts for Individual Items

Stan Hogan, Pharmacist, Jackson Drug Company
May 20th 2006

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

Ref CMS 1270 P

There are several comments that I wish to make concerning the proposed competitive bidding process for durable medical supplies and equipment.

I truly believe that the government should seek fair and equitable cost for the products provided through medicaid and medicare services to the benefit of both the US taxpayers and beneficiaries of these products and services.

Please remember that all products are not created equal, much less when constructed, or designed by man.

When DME sets a price for a walker for example, many different models are available for the supplier to sell the taxpayer. Some are much better than others. Some are heavier for larger patients, some are made of lighter materials for the weak or smaller patient. Some have wheels that lock, some don't lock. Some are supposed to lock but don't do a good job presenting a safety issue for the patient. Some basic models can be converted to a wheeled walker, some can not.

When Medicare/Medicaid set a single average price for a "walker, basic" or "walker, wheeled" or even "walker heavy duty" they seldom get the best item for the patient to use for whatever "time of use before replacement." I have seen some suppliers who tend to use the cheapest equipment available to increase their profit margin and some who really try to provide the best equipment to the patient for the allowed price and still stay in business. What group do you think does the best at taking care of these needy patients, large corporations or the local independent supplier.

Progress is actually being made in many areas, one of which is diabetic testing supplies. One price for 50 or 100 strips for all brands, and capabilities is no longer practical. What you are getting by most mail order companies is the cheapest generic meter and strips they can find. The patient is then required to depend on these cheap units and strips to determine their insulin needs.

Common sense must prevail when the new system is presented to the public and the suppliers.

Thank you,

Stan Hogan, RPH

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

Stan Hogan, Pharmacist, Jackson Drug Company
May 20th 2006

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

Ref CMS 1270 P

There are several comments that I wish to make concerning the proposed competitive bidding process for durable medical supplies and equipment.

I truly believe that the government should seek fair and equitable cost for the products provided through medicaid and medicare services to the benefit of both the

US taxpayers and beneficiaries of these products and services.

True competitive bidding can be a good thing as long as, in the end, all willing providers who are able and willing to accept the payment amount allowed for the product are allowed to participate in the program. No provider, who is capable and willing to participate should be excluded from the program. Just because a company or corporation is large does not usually mean that they provide the best service and sales. In fact, I submit that the opposite is often true. In a DMEC region is given to one or two providers, who do they have to answer to when they have no competition.

Jackson Georgia is far removed from metro Atlanta, I know that many patients do have the means to go to a central supplies and get their equipment. With gas prices the way they are now, most Durable Medical suppliers only make 1 trip a week to deliver (or pick up) equipment. A good example of this is BCBS supplier located in north Atlanta, has 1 pick up/delivery a week to our area. If you need in now come up and pick it up yourself or wait until the next scheduled delivery to the Jackson Area. We deliver 6 days a week and in an emergency anyway.

We currently supply a number of dme items to many of our patient and others in our area. We supply walkers, commode chairs, bath benches, wheelchairs, electric wheelchairs, personal mobility options, diabetic testing supplies, canes, quad canes, diabetic shoes, many types of braces and support hose. Some items are covered by Medicaid or Medicare or both. Some are personal purchases. Our customer and patients depend on our personal care and quality equipment to aid them in everyday life.

Let us continue to help those in need.

Thank you,

Stan Hogan, RPH

Submitter : Mrs. Rebecca Erickson
Organization : Trinity Health Enterprises
Category : Health Care Professional or Association

Date: 06/20/2006

Issue Areas/Comments

**Determining Single Payment
Amounts for Individual Items**

Determining Single Payment Amounts for Individual Items

In response to the idea of rebates, I would like to address a couple of concerns. Rebates are very difficult to track and monitor. I would imagine that initiating such would require CMS to hire a large number of additional staff just to monitor and enforce the regulations set forth for the rebates. Also, more importantly, rebates would not benefit ALL Medicare Beneficiaries, as rebates would not be available in all areas. I feel it is the responsibility of CMS to monitor and enforce rules and regulations that benefit ALL Medicare Beneficiaries equally. Many Medicare Beneficiaries are struggling financially and using enticements for service, such as rebates, should be considered a violation of "their" rights. It is our responsibility as health care providers to ensure that all of our customers/patients are treated equally, honestly and charitably. This charity comes from our care, compassion and service, not from giving them "money back" if they choose us over our competition! Thank you for your time and consideration.

Submitter :
Organization : Rankos Pharmacy
Category : Pharmacist

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

Regarding CMS-1270-P

If CMS creates a national or regional mail service program, beneficiaries must have the option to continue to obtain their DME supplies through the provider of their choice. They should not be required or mandated to use a specific provider over another.

We strongly object to CMS' alternative proposal that would restrict beneficiaries choice of DME provider. This would profoundly impact beneficiaries choices and limit thcir access to frequent and convenient medical supplies. This would restrict patients access to essential and life-quality sustaining medical supplies that they must have frequent and reliable immediate access to.

A major oversight--CMS must prohibit suppliers from automativally refilling and sending replacement supplies without recieving refill requests from patients as certain circumstances may result in the overdispensing of supplies to patients. This practice could lead to increased risk of fraud and abuse and may unnessecarily increase costs to the Medicare program and beneficiaries.

We, as a pharmacy and a DME supplier that accepts medicare assignment work for the benefit of Medicare and beneficiaries and want to have eqaul oppurunity to continuc to maintian our standard of excellent customer service and commitment to Medicare. We should not be left out of any area that we wish to participatc in or limited by a mail order mandate that will lead to reduced care of patients.

Submitter : Dr. Scott Aronson
Organization : Scott M Aronson, DPM, PC
Category : Physician

Date: 06/20/2006

Issue Areas/Comments

GENERAL

GENERAL

June 20, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthoses, and supplies (DMEPOS).

As a practicing podiatric physician for the past 8 years, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide medically necessary care of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exclude all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, patients will suffer. Patients often express their appreciation of the convenience of having the items dispensed in my office without the waiting and hassle of going across town.

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.

As another example, consider a patient who has a diabetic ulceration. As the treating physician, I determine that certain wound care products are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, the patient will need to go elsewhere to obtain the medically necessary items. The patient may not receive the items in a timely manner (or at all) with greater recovery time and increased risks for complications.

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,

Scott M. Aronson, DPM, FACFAS

CMS-1270-P-262-Attach-1.DOC

June 20, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthoses, and supplies (DMEPOS).

As a practicing podiatric physician for the past 8 years, I supply DMEPOS items to Medicare beneficiaries. I believe that the proposed rule, if implemented, would significantly impact my ability to continue to provide **medically necessary care** of the highest quality to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to **exclude all physicians, including podiatric physicians, from the competitive acquisition program** and to instead allow physicians to continue to supply DMEPOS items as part of the normal course of providing patient care.

A competitive acquisition program that requires physicians to bid to supply items to patients will result in the elimination of some physician suppliers from the program. If physicians can no longer supply DMEPOS items, **patients will suffer**. Patients often express

their appreciation of the convenience of having the items dispensed in my office without the waiting and hassle of going "across town".

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.

As another example, consider a patient who has a diabetic ulceration. As the treating physician, I determine that certain wound care products are appropriate in treating the patient. If I am not a DMEPOS supplier in the new competitive acquisition program and those items are among those subject to bidding, the patient will need to go elsewhere to obtain the medically necessary items. The patient may not receive the items in a timely manner (or at all) with greater recovery time and increased risks for complications.

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,

Scott M. Aronson, DPM, FACFAS

Submitter : Dr. Lisa Selby-Silverstein
Organization : ASPEN Physical Therapy
Category : Physical Therapist

Date: 06/21/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-263-Attach-1.DOC

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

Dear Dr. McClellan,

6-20-06

The following letter concerns:

The Centers for Medicare and Medicaid Services (CMS) issue of a proposed rule, May 1, to implement a competitive bidding (also known as "competitive acquisition") program for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) in the Medicare program.

My name is Lisa Selby-Silverstein. I am a physical therapist working in an outpatient rehabilitation center that provides Medicare services to a number of senior citizens from a wide geographic circle. These citizens are people struggling to maintain their independent home living status, often without local family members to take care of them or with family members that work. As physical therapists, we try our best to assist them in this goal. This task often involves helping our patients to access equipment they need them to support their mobility, assist them in doing home exercise, or support an injured limb (enabling it to bear weight, relieve pain or prevent further injury). These products are recommended to patients, when they are necessary, in support of reaching the patient's mobility goals. Generally we know and will recommend providers or specific brands of items because they provide the *specific item* with the specific characteristics the patient needs in a way that patient can access. Ultimately, based on their abilities resources and needs, the patient chooses where to go for their walker, cane, wheelchair or over the counter splint or orthosis, or exercise equipment. However, searching for equipment that best addresses particular needs is already a cumbersome process.

At times, many of these specialized equipment items are not needed by large numbers of people and therefore are not widely available, or

may not be made by anyone other than those with particular brand names. Often it takes groups of professionals to make recommendations for the proper wheelchair, insert, wheelchair attachments, orthosis or exercise device, etc. Often we are lucky to find any item that meets the patient's specialized needs, let alone find multiple providers, or manufacturers, that could participate in a competitive bid process. Also, when a DME provider knows that they will get business from a professional site, they are willing to provide critical loans of equipment so that patients can try the equipment for a period of time and determine if the equipment meets their needs. This critical process will be squelched by a competitive bid process

If these items need to go out for competitive bid, senior citizens and disabled individuals on Medicare or Medicaid will have a great deal of time added to the process of procuring equipment before they are provided with the equipment they need. Many of these people with disabilities also may be unable to withstand, follow through with, or wait for a convoluted and discouraging competitive bid process.

In addition, ***this will not save money***. The detailed descriptions of equipment, including specific descriptions, that will be necessary to assure that individual clients have their needs met, will be extremely time consuming and costly; requiring professional physical therapists time and perhaps engineering input (not to mention support staff time and cost). These personnel expenses would be entirely new costs adding to the cost of caring for these individuals. In addition, Medicare reimburses according to a fee schedule regardless of what the vendor lists as their price for DMEs. It is confusing why a competitive bid process would be helpful.

Consider one of my recent patients who upon evaluation was determined to need a specific type of rolling walker with particular specifications to avoid falling in her home. She lives alone. Every day she functions without this device, either her mobility is halted making her dependent, or she functions at high risk of falling and fracturing a hip, with the common sequelae of this being devastating and costly. If I made a particular specification for this walker, I would need to learn what level of cost cutting would impair the function of the device to the level that it would still be of use to this client. Otherwise the specification would not be detailed enough and an enterprising business could provide a cheaper device that would not

meet the client's needs. This would be beyond my current knowledge and job scope and would likely require a design engineer's input to develop an adequate "specification document" for competitive bid.

If individual patients are deprived of getting their needed equipment, either because of the added time requirements, lack of tenacity, or lack of resources to even participate in this process, their rehabilitation process will be negatively influenced, making them much more dependent people than they need to be.

Finally, there is another aspect of this bill that would significantly add costs to care. This bill excludes orthoses or prostheses that would need significant adjustment from a certified orthotist. It must be understood that certified orthotists are not the only professionals that make significant adjustments to DMEs, including molding shaping, bending of materials to fabricate orthoses, splints or positioning devices etc. Physical and occupational therapists and podiatrists regularly do this also within the regular course of a patient's plan of care. These skills are part of our training, our practice acts and listed in the Guide to Physical Therapists Practice, published by the American Physical Therapy Association. However, if only devices molded and adjusted by certified orthotists are covered by Medicare, then people will start to use orthotists when they are not needed, because the less expensive alternative is not covered, or requires a cumbersome competitive bid process. Therefore, this bill will encourage people to seek more expensive custom options, when off-the-shelf options, or potentially lower cost clinician-made devices will serve the purpose.

In summary, this bill will delay and perhaps negate disabled people's access to necessary equipment that enables them to optimize their independence and functioning in the most cost effective method possible. In addition, it adds layers of bureaucracy and cost to an already difficult cumbersome process.

Thank you for taking the time to review my comments.

Sincerely,

Lisa Selby Silverstein, PT, PhD, NCS
License Physical Therapist
Mount Holly, NJ 08060

Submitter :

Date: 06/21/2006

Organization :

Category : Physician

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

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

Dear CMMS,

I am an Orthopaedic Surgeon. I believe the CMS-1270-P should be amended to allow me to continue to protect my patients with the supply of appropriate braces, splints, crutches and other devices to treat their orthopaedic medical problems. Often it is unsafe to send a patient out of the office to procure a DME type equipment because a fracture or other significant injury will worsen or cause a patient to fall creating further medical costs beyond those saved by instrumentation of this rule. Please allow the current situation of providing these devices to continue.

Thank you

Roy C. Terry, MD
1616 West Main Street
Lebanon, TN 37087

Submitter : Dr. Peter Paicos Jr.
Organization : Massachusetts Podiatric Medical Society
Category : Physician

Date: 06/21/2006

Issue Areas/Comments

GENERAL

GENERAL

June 21, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) 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 current proposal, if finalized in its suggested format, will 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 and surgeon who has been in practice for seventeen 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 those medically necessary items to properly treat and prevent further injury to my patients. Items such as walking boots used for fractures or other structural instabilities, crutches to offload an at risk neuropathic diabetic Charcot foot, necessary wound dressings that could help heal a difficult lower extremity situation. 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 at the time that a patient is seen and managed. It makes no sense to send a patient, your mother perhaps, across town to a vendor who may be totally unfamiliar with the actual medical condition and more importantly perhaps dispensing the most cost-effective products rather than the most medically appropriate.

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.

Professionally Yours,

Peter C. Paicos Jr., DPM, FACFAS
Immediate Past President, Massachusetts Podiatric Medical Society

Submitter : Dr. Richard Peffley, D.P.M.

Date: 06/21/2006

Organization : Salem Foot Clinic

Category : Physician

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 : Mr. Tim Good
Organization : GoodCare by CPCI
Category : Other Health Care Professional

Date: 06/21/2006

Issue Areas/Comments

Issue

Issue

I think an indication of the importance of the whole DME industry in the eyes of CMS is in the fact that even to make comments to CMS regarding the competitive bidding program, DME Provider is not even listed in the list of categories in this Docket Management Comment Form. We have to register as 'other'.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I feel that these comments are probably futile, particularly in view of comments by CMS officials in the section "Effect on Suppliers", that there will be 50% fewer DME providers in the Medicare program when all its rules are fully implemented.

As a small supplier, accredited by JCAHO, and in business for over 28 years, we will probably be unable to bid due to our size and limited market area. This is extremely unfortunate for us and the many other small dealers of quality who are important employers in their community. The opportunity for Medicare beneficiaries to use local providers will be eliminated in most small towns across America. In spite of CMS's protestations to the contrary, the final effect of the competitive bidding "scheme" will be moving the majority of the provision of DME to large national companies. Small business is the "goat" of this change.

Payment Basis

Payment Basis

The whole issue of REBATES is just begging for abuse. This issue will be driven by large national companies and will complicate significantly the ability of small providers to participate in this program.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

CMS has arbitrarily rejected many of the recommendations of the Program Advisory and Oversight Committee that was established by Congress to advise CMS on its implementation of the bidding program. As I have written in other forums, Medicare seems to have 'cognitive dissonance' regarding this issue; requiring accreditation of any provider who wishes to continue billing the Medicare program, yet minimizing quality patient care issues as CMS rushes headlong towards implementation of the competitive bidding. CMS's process in analyzing bidders under this program seems to be focused on the financial issues, and quality and patient care issues will have to 'catch up'. This is probably to be expected in that the whole rationale of competitive bids is to address cost - perceived cost in this instance - and patient care is only minimally on their radar screen.

Submitter : Mr. Jeffery Patterson
Organization : Patterson Drugs inc d/b/a City pharmacy
Category : Pharmacist

Date: 06/21/2006

Issue Areas/Comments

GENERAL

GENERAL

i would like to see a simple fee/cost/reimbursement system with medicare. the present system is very confusing. All blood glucose test strips and monitors should not be reimbursed at the same price. Medicare should continue to allow access to all providers, without limits or restrictions.

Submitter : Mrs. Kim Herron

Date: 06/21/2006

Organization : Ethica Health

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

We have found that in order for a supply program to be successful and fully support the needs of patients in Long Term Care Centers it is imperative that the nursing center along with the attending physician build a clinical relationship with the individual supplier. Enteral, ostomy, urological and wound care supplies provided to long term care patients are specialized areas and requires a willingness on the supplier's part to work at the required acuity level and within the clinical protocols of the nursing center.

With all due respect, we can see that this may of benefit for the general population regarding certain supplies but not to the long term care population. It is also my understanding that in previous competitive bidding trials it was concluded that enteral nutrition and services to nursing home patients 'is not as well suited for competitive bidding as other products tested'.

We would urge CMS to exclude long term care residents from competitive bidding. The disruption to care plans, disease specific enteral nutrients, clinical protocols and standards of care could cause serious complications for long term care residents and result in an increase cost of care.

Submitter : Mrs. Tammy Zelenko
Organization : Advacare Home Services
Category : Other Health Care Professional

Date: 06/21/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The competitive bidding areas should be announced at least 6 months prior to the bidding requirement date. This will allow the home care provider the opportunity to work through the bidding process, and determine if they should be part of a network or a sub-contractor. These different business models require the time to make good business decisions. This will also allow the smaller providers to work through these issues.

Conditions for Awarding Contracts

Conditions for Awarding Contracts

Any provider that has not been awarded the bid should have a legal right to correct any information that was submitted in error, or request a review of the decision.

**Determining Single Payment
Amounts for Individual Items**

Determining Single Payment Amounts for Individual Items

There must be an opportunity to provide pricing for items that are currently provided at no charge to the patients, and do not have a HCPC code. This will allow for a single payment for that specific product.

Issue

Issue

The rebate program that was written into the NPRM falls under the anti-kickback Statute and the Beneficiary Inducement Statute. What happens when the patient has a secondary insurance? Are we to give them a rebate.

Opportunity for Networks

Opportunity for Networks

If a home care company submits a bid, and is not a winning bidder, can they become a sub-contractor for a winning bidder? How will networks affect the capacity requirements if they can only represent 20%?

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

There needs to be a provision in place to protect the small home care provider, by allowing them to be part of the network, if they have submitted a reasonable bid, and are willing to accept the new allowable.

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

Quality Standards and Accreditation for Supplies of DMEPOS

The home care industry strongly agrees for the need of quality standards for the industry, however they must be available to all providers prior to submitting their bid. This information is critical to the bidding process. Competitive bidding should be delay until the quality standards have been provided.

Submitter : Mr. Bo Callaway

Date: 06/21/2006

Organization : Fuller Rehabilitation Independent Living Aids

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Fuller Rehabilitation Independent Living Aids is a Durable Medical Equipment supplier with locations throughout the United States. We have been in business for sixteen years, providing our patients with the best in mobility equipment and service. We have worked with the Centers for Medicare and Medicaid Services to develop our clinical process which we use, along with physicians and treating practitioners, to determine beneficiary needs.

Our Company is fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

I.E. "See Attachment" for comments

CMS-1270-P-271-Attach-1.DOC

Comments for CMS proposed rule.

Fuller Rehabilitation Independent Living Aids is a Durable Medical Equipment supplier with locations found in the southeastern United States. We have been in business for sixteen years, providing our patients with the best in mobility equipment and service. We have worked with the Centers for Medicare and Medicaid Services to develop our clinical process which we use, along with physicians and treating practitioners, to determine beneficiary needs.

Our company is fully accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

To follow are the comments we have in reference to the Department of Health and Human Services Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues proposed rule.

General Comments:

It is our belief that power wheelchairs should be excluded from competitive bidding because they are uniquely fitted, computer programmed devices individually prescribed to meet each patient's needs and thus should not be treated as commodity items.

Wheelchairs/POV's are listed as number two on expenditures. The Wheelchairs/POV category includes manual wheelchairs, transport wheelchairs, power wheelchair and scooters. We believe the ranking for this category is flawed. It is based on 2003 figures which included the Houston, Texas fraud cases. In 2005, the power wheelchair code K0011 was responsible for only 0.15% of CMS expenditures.

CMS has reflected in the proposed rule that the first round of competitive bidding will occur in 2006 with prices taking effect in October 2007.

Comment:

It is the view of our company that this time frame is unrealistic. Our industry is currently waiting for the Local Coverage Determination (LCD) and new allowables for power mobility products. From the end of the

comment period (June 30) and subsequent replies to the comments there will not be sufficient time for the supplier to submit a well thought out bid.

CMS proposes Beneficiary Rebates.

Comment:

Fuller Rehabilitation Independent Living Aids is opposed to beneficiary rebates.

Competitive Bidding Demonstration Areas – Polk County Florida had five categories in the first round of competitive bidding demonstration, and the same categories in the second round minus enteral nutrition. Neither round included wheelchairs and accessories. San Antonio showed five DMEPOS categories which included wheelchairs and accessories.

Comment:

Upon investigation wheelchairs and accessories in the San Antonio demonstration did not include power wheelchairs. This data should be considered inaccurate. Showing power wheelchairs as a product used in the demonstration is false. There is no supporting data to show power wheelchairs can be competitively bid, or savings can be gained by inclusion in competitive bidding.

Establishing fee schedule amounts – CMS is proposing a modified version of the existing gap-filling process to be used in establishing fee schedule amounts for DMEPOS items to which are assigned new HCPCS level II codes.

Comment:

We are opposed to using a gap filling method to establish the new fee schedule. Gap filling takes existing information and creates the fee schedule using past data. The DME industry, specifically power mobility, will have no past data to reference in establishing new allowables.

We support realistic allowables for durable medical equipment. We ask that CMS consider that companies such as ours are taking very costly actions, CMS recommended, to improve the durable medical equipment industry's adherence to high quality standards.

A business plan that includes achieving accreditation, providing thorough patient assessment, application of the Clinical Process, and follow-up

service for life, requires a comprehensive trained professional staff. Our concern is that if allowables are cut too deeply, we and other suppliers cannot afford to provide the quality care needed and required by CMS.

Authority to Adjust Payments in Other Areas – CMS wants to use the payment information determined under the competitive bidding program to adjust the payment amounts otherwise recognized in areas not included in a competitive bidding program.

Comment:

We are opposed to giving CMS the authority to adjust payments in areas outside the ten MSA's. It is too early to make this judgment.

Quality Standards and Accreditation – A grace period may be granted for suppliers that have not had sufficient time to obtain accreditation before submitting a bid.

Comment:

It is our strong belief that bids should be accepted only from accredited suppliers. Bids from unaccredited suppliers are likely to be unrealistically low, adversely affecting the outcome of the bidding process. Suppliers that have gone through the accreditation process will have a better understanding of the cost and the quality standards required for accreditation on an ongoing basis. Furthermore, suppliers who have already undergone the process and the ongoing expense of accreditation must not be put at a competitive disadvantage by lower-bidding non-accredited companies. Suppliers who have not completed the accreditation process will have no idea how costly the process is. That cost should be a fundamental component of any bidder's ultimate bid price.

Financial Standards – The RFBs will identify the specific information required to evaluate suppliers, which may include: a supplier's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency.

Comment:

We agree that it is essential that all bidding suppliers are financially solvent and capable of handling the level of business required. A high standard of financial performance should be expected and verified by such methods as: supplier's bank reference and general financial condition,

- **credit history, insurance documentation, business capacity and lines of credit.**

Assurance of Savings – CMS will not be awarding to any entity unless the amounts to be paid to contract suppliers in a competitive bidding area are expected to be less for items than would have otherwise been paid.

Comment:

The DME industry, specifically power mobility, is waiting on new allowables. There will be no past data or fee schedules to reference to show savings.

Repairs and Replacement of Patient Owned Items Subject to Competitive Bidding – The contract supplier cannot refuse to repair or replace patient-owned items subject to competitive bidding.

Comment:

It is the practice of this company to repair any product we have supplied to our beneficiaries. We believe it is inappropriate to require suppliers to repair equipment they did not deliver because: acquiring replacement parts, technical specifications, and customer information may be unavailable from original manufacturer or supplier due to unfair pricing, discontinuation of item, or other unpredictable circumstances. This policy, if adopted, would allow manufacturers to inflate parts pricing to suppliers who do not handle their product, but would be required by this regulation to repair it.