

Submitter : Mr. Robin Stemple

Date: 05/26/2006

Organization : Somerset County Blind Center

Category : Consumer Group

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

I fail to see how CMS distinguishes between someone who needs a prosthetic leg to walk and someone who need a cctv or other low vision device to see. The logic of the arguement that eyeglasses are eyeglasses, no matter how powerful just doesn't hold water. This would tantamount to calling an artificial leg a shoe; therefore not eligible under Medicare/Medicaid. I can't tell the government what to do. However, I can ask that your regulations follow a clear logical pattern that treats everyone fairly. Wither buy low vision aids, or stop providing prosthetic devices to others, including the physically disabled, wheelchair bound, hearing impaired, etc. Be consisten and treat everyone with the same general standard. Thank you. I can be reached at 814-445-1310, Ext. 111

Robin Stemple

Submitter : Dr. Mary Lou McGregor
Organization : Children's Hospital Columbus
Category : Physician

Date: 05/26/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

We oppose the recent statement issued by the Centers for Medicare and Medicaid Services (CMS), announcing their intention to bar Medicare coverage for any low vision aid. This policy is a short-sighted attempt to extend the prohibition on ordinary eyeglasses to an entire class of devices that help rehabilitate vision.

There are 6.5 million older adults who are blind or visually impaired (Bureau of the Census, Survey of Income and Program Participation, 1994-95). Visual impairment is a leading cause of the loss of independence in older adults. The impact of low vision aids on the ability of people with visual handicaps to remain independent is well known. Low vision aids, such as closed-circuit television systems (CCTVs), magnifiers, telescopes and binoculars allow people with vision loss, particularly those with low vision, to make use of remaining vision.

This policy is an unacceptable rollback of benefits denying vital coverage to people with vision loss, especially millions of America's senior Medicare beneficiaries. And although our primary concern is the health of children, we are also worried about the impact of this ruling on their future needs.

Please reconsider the economic and social value of low vision aids, and extend Medicare's coverage to these important assistive devices.

Submitter : Ms. Barbara Christ
Organization : Ms. Barbara Christ
Category : Individual

Date: 05/29/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

My 83-year-old widowed mother who suffers from advanced macular degeneration, as well as diabetes, chronic bronchitis, high blood pressure, chronic back pain, and diminished hearing currently resides in an assisted living facility in Baltimore, MD. This truly amazing woman continues to be extremely sharp mentally while she struggles to keep from falling into a depression caused by her physical world insidiously closing in and literally going dark on her. Without a doubt, her continued mental health is primarily due to her low-vision device that enables her to continue processing accounting documents for a Maryland firm, as well as look at her mail, read the newspaper, and work her beloved crossword puzzles.

As the need for these devices increases along with the expected life span of the population, it is imperative that coverage for them continues. We must do whatever we can to assist older Americans in leading productive lives and maintaining as high a quality of life as possible during their remaining years.

I urge you to consider extremely carefully the profoundly negative effect that this action would have on a substantial segment of our society; one that hopefully we and our loved ones will one day be members of.

Thank you.

Submitter : Mrs. RENEE SCHICK
Organization : RENEE'S SURVIVOR SHOP LLC
Category : Other Health Care Provider

Date: 05/30/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

TO WHOM IT MAY CONCERN,

I AM A CANCER SURVIVOR WHO FOUND OUT FIRST HAND THAT THERE WAS A NEED FOR A SHOP SUCH AS MINE. I OWN RENEE'S SURVIVOR SHOP IN TOLEDO, OHIO. IN MY SHOP I OFFER TO WOMEN WHO HAVE HAD CANCER SURGERY MANY OPTIONS. WE OFFER SILICONE BREAST FORMS AND CUSTOM BREAST FORMS. ALONG WITH THE FORMS WE ALSO OFFER AFTER SURGERY CAMISOLES AND BRAS ALL OF THIS IS IN A UPLIFTING, PRIVATE SURROUNDING . MY STAFF AN MYSELF ARE BOC CERTIFIED FITTERS AND WE ARE CURRENTLY PROCEEDING TO HAVE OUR FACILITY ACCREDITED. I HAVE CONCERNS THAT I WOULD REALLY LIKE ANSWERS ON. HOW WILL A SMALL SHOP LIKE MINE EVER BE ABLE TO COMPETE WITH LARGE DURABLE MEDICAL COMPANIES? WHEN A WOMEN HAS LOST HER BREAST SHE WANTS TO COME TO A PLACE LIKE MINE NOT A PLACE THAT OFFERS WHEEL CHAIRS AND POTTY CHAIRS. THIS IS A PLACE OF COMPASSION NOT A IN THE DOOR OUT THE DOOR DRIVE THROUGH. PLEASE PASS MY COMMENTS ON TO WHOEVER CAN HELP WITH THIS SITUATION. IS THERE ANYTHING ELSE WE CAN DO HERE AT OUR SHOP?

THANK YOU IN ADVANCE,

RENEE' SCHICK
RENEE'S SURVIVOR SHOP
5401 SECOR RD.
TOLEDO, OH 43623
419-471-0603
222.RSURVIORSHOP.COM
rsurvivorshop@buckeye-access.com

Submitter : Ms. Allison Atkins
Organization : Ms. Allison Atkins
Category : Occupational Therapist

Date: 05/30/2006

Issue Areas/Comments

GENERAL

GENERAL

I am interested in making my opinion known, as a practicing OT of 10 years, on the bidding of orthotics. This is completely insulting that a government agency would like to put professionals in healthcare in a sparring match against each other when OT as a profession has a skill level specific to the needs of the individual with the ability to fabricate splints. When a patient is referred to OT and the orthotic is beyond that OT's capability, we have the professional and ethical standards to consult another colleague or a prosthetist/orthotist. When a government agency decides they have better knowledge of what is best for that patient, I get infuriated! Where is the governments' skill in this? There is none. Leave this to the professionals. The healthcare industry is volatile enough with physician competition. Don't allow this to happen at the direct patient care level between the therapists and orthotists. Are prosthetists/orthotists skilled? Of course, however leave the splinting and equipment needs to the experts who deal with these patients on a daily or high frequency basis - we know what will work best for our patients because we KNOW them, and as their OT I get them the right equipment at the best possible price, that's my job!

Submitter : Mr. Daniel Heckman
Organization : Heckman Healthcare Services
Category : Health Care Provider/Association

Date: 05/30/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

In the proposal it is stated that CMS has the "discretion to define a CBA to be either current with an MSA, larger than an MSA, or smaller than an MSA." I am concerned that, in the later stages of implementation, it will be expedient for CMS to group smaller MSAs that are proximate to each other into CBAs. It might be cost-effective to administer the largest MSAs individually, but the bureaucratic behemoth required to administer the remainder of the 360-plus MSAs individually will prove impractical. While this, in itself, is not of concern to me, the proposal also states that a "contract provider cannot refuse to furnish items or services to a beneficiary residing in a CBA based on the beneficiary's geographic location within the CBA."

Ours is an independent, family-owned, single location company that has been providing service to Decatur, Illinois and the surrounding area for 25 years. My concern is that these provisions could force us to expand to serve areas that we have not traditionally served. Over the past years, we have made a conscious effort to consolidate our service area and focus on the areas where we could provide the best service in the most cost-effective manner. Forcing a smaller provider to expand its territory would be unfair and counterproductive. All providers should be allowed to designate their service areas (especially if able to document with historical data that the service area has not been modified because of the CBA), and should not be forced to accept patients outside of their traditional service area.

Payment Basis

Payment Basis

In the proposal, it is stated that a beneficiary would have no financial liability to a noncontract supplier unless the grandfathering exception applies. I feel that this section should also include the statement "unless the noncontract supplier has obtained an Advance Beneficiary Notice indicating that the beneficiary was informed prior to receiving service that there would be no coverage due to the supplier's noncontract status, and that the beneficiary still desired to receive the service from the noncontract provider."

After reading the proposed description of the program, it appears that CMS expects the overall quality of service to improve as it is implemented. Perhaps this will happen, but the majority of us (who have made the provision of quality home medical equipment, supplies and service our careers) do not share your optimism.

Declining margins and the ever-increasing costs of doing business (fuel, healthcare insurance and utilities, to name a few) could very well lead contract suppliers to provide a minimal level of service.

If a beneficiary was not allowed to seek service from a noncontract supplier (with a properly executed ABN and at his own expense), it would seem to be a rather egregious limitation of his rights as a consumer.

Submitter : Mr. Herb Paserman
Organization : JAMES
Category : Health Care Provider/Association

Date: 05/31/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Please see attached document

CMS-1270-P-77-Attach-1.DOC

“Competitive Bidding Areas” comments

On page 58 of the Proposed Rule there is a discussion of exempting areas in conformity with the Rural Exclusion provision. It says that Section 1847(a)(3) allows them to exempt “rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item.” It proposes to exempt areas under this rule that meet the following criteria:

- 1) Low utilization volume relative to other similar geographic areas.
- 2) Low numbers of suppliers relative to other areas
- 3) Low number of Medicare FFS (Fee For Service) beneficiaries relative to other similar areas.

Basically, this means that if you are in a low population density area, you are probably going to be excluded. However, if you live in a high population urban area that is under-served, the exclusion will not help you. Please note the language that exempts “areas with low population density within urban areas that are not competitive.” What exactly is a low population density urban area? A park? This is clearly legislative double talk that denies many under-served inner city areas any benefit of the rural exclusion.

If you flip to pages 49 and 50, we are shown a chart of the top 25 MSAs. Most revealing are the numbers given for “Suppliers per beneficiary” and “Allowed Charges.” First look at New York, Chicago and Detroit. New York has the highest allowed charges, \$312 million and one of the lowest ratios of suppliers, 34 DMEs for every 10,000 beneficiaries (convert the decimal into a fraction), Chicago has 33 and Detroit only 29 for every 10,000.

Meanwhile Virginia Beach, with 1/8th the allowed charges of NY, has 47 DMEs per 10,000 beneficiaries, 38% more dealers per unit of population. Kansas city has 55/10,000 and Charlotte 66/10,000. Yet NY, Chicago and Detroit will be hit with a 37% cut in suppliers while areas like Virginia and North Carolina may be excluded.

The original purpose of the Rural Exclusion was to exempt areas that are poorly serviced. The assumption was that a low population density meant fewer and farther dealers. This has done a great injustice to many urban areas and the minorities that live there. Clearly any protection has been denied to them. The term “low population density urban area” is a cruel joke that deliberately discriminates against the poor and minorities, heaping an intolerable cut in services upon them, while leaving many wealthier rural areas untouched.

The Americans with Disabilities Act forbids setting aside any group of disabled in any location and treating them differently in the distribution of services than any other groups receiving the same services. Here we have groups of disabled being treated differently from other groups of disabled in the delivery of government services, solely because of where they live. We also have inner city minorities suffering a disproportionate cut in services.

I believe this interpretation of the “Rural Exclusion” is highly discriminatory against the poor and disabled who live in high population density urban areas.

Herb Paserman

Submitter : Mr. Robert Petronio
Organization : Garro Drug Store of Utica, Inc.
Category : Pharmacist

Date: 06/01/2006

Issue Areas/Comments

GENERAL

GENERAL

My Drug Store is located in an inner city neighborhood with a high elderly & immigrant population.

Mandatory mail order is not a good option for this group of people for the following reasons:

1. This population has many issues with communicating their needs. They may not be comfortable with ordering via phone or computer and waiting for a mailman to bring their critical supplies. Stores like mine provide face to face service with language interpreters.
2. Many DME items require fitting, adjusting, maintenance & repair. Many independent community suppliers provide free pick up and delivery, fittings, calibrations, set up & product demonstrations. Something as simple as using diabetic strips with the wrong code programmed in your test machine can cause life threatening consequences. Patients using a quad cane, set up for the right hand, in their left hand is a safety issue. Many braces (even simple cock-up splints for the wrist) require bending to insure proper fit & function. Many patients panic when something as simple as a diabetic test machine requires new batteries. We will replace their batteries and reprogram their machine for them.
3. Finally nothing can replace face to face demonstration of the proper use of a product by a qualified health care professional. Telephone & written communications can only go so far in this area, especially for the elderly & language challenged population. Improper use of these types of supplies can create patient safety issues, as well as impede patient progress for successful treatment of their condition.

Submitter : Dr. Mary Powers
Organization : University of Toledo
Category : Pharmacist

Date: 06/01/2006

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 offer the following comments for consideration as CMS develops the final regulation with special concerns about the resulting impact on beneficiaries with diabetes. First, 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.

Second, 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.

Third, 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.

In conclusion, I urge CMS to revise the regulation to require beneficiaries to obtain replacement supplies through designated providers, especially beneficiaries who are diabetic, and preserve the ability of diabetic patients to have convenient access to needed supplies through their local pharmacies.

Thank you for considering my view.
Sincerely,

Mary F. Powers, R.Ph., Ph.D.
mary.powers@utoledo.edu

Submitter : Dr. Elise Corgiat, O.D.

Date: 06/01/2006

Organization : Dr. Elise Corgiat, O.D.

Category : Other Health Care Professional

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

There are people who are dependent on low vision devices to function in their daily lives. Without payment or partial payment for devices the insurance companies are leaving these people handicapped. Most of the people in need are elderly and on fixed income.

Submitter :

Date: 06/02/2006

Organization :

Category : Individual

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Denial of coverage for low-vision devices, like CCTVs, would mean that countless individuals dependent on these types of devices would not be able to conduct activities that are essential for everyday life!

Submitter : Ms. Maryellen Bednarski
Organization : Ms. Maryellen Bednarski
Category : Other Health Care Professional

Date: 06/02/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

I am a certified low vision therapist with 16 years working with Medicare beneficiaries with low vision. In addition, I have been the leader of a Low Vision Support Group for 16 years. I am writing to oppose the proposed ruling that would categorically deny Medicare coverage for low vision aids because they are assigned to the same category as "eyeglasses". Low vision aids are far more than simply a pair of eyeglasses or contact lenses; in fact, the magnifiers, video magnifiers (closed circuit television reading systems), and telescopic lenses that are prescribed by low vision specialists are generally used in conjunction with the patient's own eyeglasses or contact lenses. Low vision devices are not simply "another form of eyeglasses", as the proposed rule would specify. In fact, they serve as a prosthetic type device by enabling the eye to perform visual tasks that would be impossible without low vision aids. Though they are not "implanted" into the eye, they enable the eye to function to its fullest capacity. Thus, they are medically necessary for the individual with low vision. They are vital tools that enable the individual with low vision to maintain their independence and to function safely in the home, the workplace, and the community. Magnifiers and video magnifiers (closed circuit television reading systems), along with telescopic lenses that have a reading cap to adapt them for reading tasks, allow the individual to safely and independently perform the following activities: read their mail; write checks and handle their financial affairs; read directions on medication packaging and food packaging; prepare insulin syringes and read glucose meters (for diabetics); properly set their appliance dials and thermostat; and a host of other activities. Telescopic lenses that enable distance viewing allow the individual to navigate safely when travelling on foot by reading signage and viewing potential hazards such as oncoming vehicular traffic. Without these vital tools, many individuals with low vision would become dependent upon their family or upon the health system. Many Medicare recipients are on a fixed income and cannot afford to purchase these vital tools. Without these tools, they and their families may conclude that they can no longer live independently within their own homes. Then, the burden for their care is shifted to the Medicare system as these individuals are placed in assisted living or nursing home facilities- which is far more costly than providing the low vision aids that allow them to continue living safely and independently at home.

Low vision aids are just as necessary to the safe and independent functioning of an individual with low vision as a wheelchair for an individual with a mobility impairment, or an artificial leg or arm for an individual with an amputation.

Thus, I strongly oppose this proposed ruling and I urge CMS NOT to enact this unwise and hurtful proposed ruling. Thank you.

Maryellen Bednarski, M.S., M.Ed., C.L.V.T.
Certified Low Vision Therapist
Support Services Coordinator for the Philadelphia Affiliate of the Foundation Fighting Blindness

Submitter : Dr. Lorraine Marchi
Organization : National Association for Visually Handicapped-NAVH
Category : Health Care Professional or Association

Date: 06/03/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

NAVH, founded in 1954 is the only national voluntary health agency solely devoted to the "hard of seeing," the second largest group of the disabled in the nation. As Founder and CEO, I find it unconscionable that CMS has "announced their intention to bar, without exception, Medicare coverage for any device such as CCTV's, magnifiers and any other low vision aids or technologies, allowing people with vision loss, especially those with low vision, to make use of their remaining vision."

Statistics disclose that 65% of those with vision loss are 60 and older. Therefore, the numbers of people requiring these types of devices in order to retain independence is growing dramatically as the "baby boomers" enter their sixth decade.

The majority of individuals with vision loss are not classified as "legally blind," and therefore, in most states do not receive governmental assistance. Through the years, I have worked with thousands who are not classified in this category - many of whom require as much - if not more - help in coping with vision loss than those labeled "legally blind."

In addition, so many older Americans are living on limited income and cannot afford to purchase these important aids which can enable them to retain their independence and continue to live fruitful lives.

Submitter : Mr. Herb Paserman
Organization : JAMES
Category : Health Care Provider/Association

Date: 06/03/2006

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

Please see attached comments

CMS-1270-P-84-Attach-1.DOC

On page 158 in the Proposed Rule CMS predicts that, nationally, 37% of the total number of DME suppliers will be eliminated in each bidding round. A 37% decrease in the number of suppliers means an even higher increase in patient load for the remaining suppliers. For example, say the current ratio of patients to DMEs is 10,000 patients per hundred DMEs, that's **100 patients per DME**. What happens if we decrease the number of DMEs by 37%? The new ratio is 10,000 patients per 63 HMEs or **159 patients per DME**. Clearly the patient load per DME has jumped from 100 to 159, a **59% increase!** This remains true regardless of the number of patients or DMEs that are used in the calculation. In the actual CBAs the effect will be even greater, as 50% of bidding suppliers will be excluded from the program in their immediate geographic areas.

The problem with this figure is that, going back to page 87 of the Proposed Rule, we are told that CMS had asked the PAOC for advice on dealer market capacity and were told at the Feb. 28, 2005 meeting that most suppliers would be able to increase their capacity by up to **20%**, with a higher percentage for less labor intensive items like diabetic products. This was the only hard figure on potential capacity increase mentioned in the Proposed Rule. Increasing capacity for a DMEPOS is not really that easy. Because of accreditation, they must thoroughly train and test all new employees for competency (usually a year process). This is not just a simple matter of new inventory. Licensed professionals must be hired, additional facilities and vehicles purchased, new credit extended, billing issues resolved, etc. Clearly, if there are increases in patient load above 20% in life support services, there are real dangers both to the patient and accreditation standards. Yet the targeted 37% cut in available suppliers will forcibly raise the patient load for each contracted supplier by 59%. This is an intolerable workload increase for any health care company in a short span. Imagine a hospital suddenly raising its patient census by 59% before there has even been an opportunity to expand its qualified staff and facilities?

This proposed cut in participating suppliers is arbitrary and presents an unacceptable peril to the home health care system. Furthermore, it endangers accreditation standards, state licensing standards and the risk of malpractice lawsuits. Based on the initial advice of the PAOC, the patient load increase per supplier for all life support services should be no higher than 20%.

Herb Paserman

Submitter : Dr. Thomas Bass
Organization : San Joaquin Drug
Category : Pharmacist

Date: 06/05/2006

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

We are a small, independent pharmacy in a rural area. Our concern is that the competitive bidding process will lower our reimbursement beyond the point of reasonable profit. Since our volume is small and our customers poor, we must be able to pass the cost of expensive DME on to medicare or else stop carrying it.

It would be a disservice to Medicare's recipients to remove their neighborhood pharmacies from the DME market. Regulators should be very careful that any new rules not have such an effect.

Submitter : Mr. Dale Stoverud
 Organization : Clinic United Pharmacy, Inc.
 Category : Pharmacist

Date: 06/05/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I object to this whole proposal because it will deny our patients the correct products and consulting that only local pharmacy providers can give. Further, this will create a huge, inefficient mail order situation that, as history has shown in the drug distribution system, will cost more than dealing with your providers that are in place now. We see mail order firms 'automatically' sending unwanted and un-ordered products to our patients often. Local providers are more cost efficient.

Criteria for Item Selection

Criteria for Item Selection

Any competitive bidding program should not include common supplies such as those particular drugs and testing supplies that are more reasonably available at their local pharmacies. Perhaps the bidding should be restricted to specialized items that are not the high usage, common items.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

The payment rate now in place is often below retail pharmacy's acquisition cost. A median bid process will be nearly impossible to keep up to date in the economic fact that costs go up quite often. We quite simply will not be able to supply our patients many medicare "B" items due to below cost acquisition and disincentives for profit. With the onerous "ASP" method you know employ, it's obvious that CMS hasn't a clue on how pharmacy providers will be able to stay in business!

Opportunity for Networks

Opportunity for Networks

I believe that any pharmacy belonging to a network such as a co-op or chain should be considered grandfathered under that network, since said networks already have strong criteria for belonging. For example, my pharmacies belong to a co-op, United Drug, which has a strong credentialing program. I would think it would make sense to accept that credentialing as one covering the entities belonging. I urge CMS to take these steps to preserve beneficiaries access to their local providers and to maintain established patient/provider relationships.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Small providers such as pharmacies should be exempt from the bidding process, especially if they are already a provider. Also, if we were to accept CMS' single payment amount, we should be allowed to join the bidding program without having to submit a formal bid process.

Submitter :

Date: 06/05/2006

Organization :

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 : Ms. Linda Alley

Date: 06/06/2006

Organization : Southside Community Hospital

Category : Nurse

Issue Areas/Comments

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

Submission of Bids Under the Competitive Bidding Program

Competitive bidding would restrict the patient's right to choose by limiting the available agencies for medical equipment. Also small independent providers, invaluable in local communities, would be forced out of the market. These small companies are usually the ones most willing to assist when patients have limited or no resources to pay for equipment. Competitive bidding is just a very bad idea for everyone but the large companies who just want to make more money and don't really care about the individuals they serve. Please cancel this proposal.

Submitter : Brad Phelps
Organization : The Medicine Shoppe
Category : Pharmacist

Date: 06/06/2006

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 item 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.

I urge CMS to take steps to insure that small suppliers - which include the majority of pharmacy-based suppliers - can participate in the competitive bidding program. It would be extremely difficult for small suppliers to compete in large metropolitan areas. After CMS establishes the fair 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.
Thank-you for considering my comments.

Brad Phelps
The Medicine Shoppe
Greeneville TN

Submitter : Dr. ORIN SMITH
Organization : MY PHARMACY
Category : Pharmacist

Date: 06/06/2006

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

CMS must!!!, do much more than they are now doing to ensure that pharmacy based suppliers, which tend to be smaller than the big national suppliers, can participate in the competitive bidding program. Even in the large market of South Florida we are well received by Physicians and Rehab Centers in our area. The reason for this is that we care. We go above and beyond.

CMS should have any willing provider language in their final rule. That would entitle anyone that can provide that service for that amount to still take care of their patients. That should be our choice. Like I said before, our services are as good if not better than most suppliers.

We have a problem with the single payment amount provision. Using the median bid will set an artificially low payment rate that. That rate may keep small suppliers out of the market. CMS must review the rate and make sure that is reasonable and fair and will cover the costs to acquire and provide the products and services provided. They must periodically review these rates to make sure that they remain viable.

Submitter : Mrs. Karen Bright
Organization : Apple Discount Drugs
Category : Pharmacist

Date: 06/06/2006

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers
May 6, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

Thank you for allowing me to comment on the proposed regulation to implement a competitive bidding program for DMEPOS. Please consider my comments.

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. We are in a small community with an elderly population and it is hard for older individuals to drive. They detest mail order and many are unable to do required paperwork for mail order. This proposal would severely restrict beneficiaries access to needed items and supplies and would compromise patient health outcomes.

Please consider including small suppliers-which include the majority of pharmacy-based suppliers-can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to competitive in large metropolitan areas. After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier. CMS must take these steps to preserve beneficiaries convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

I currently provide diabetic testing supplies, diabetic shoes, inhalation therapy, wheelchairs, and walkers. Without these revisions to the final regulation, I will be unable to continue providing these valuable services-to my patients. Please have consideration for the older population as well as small independent pharmacies like ours.

Thank you for considering my comments.

Sincerely,

Karen Bright, D.Ph.

Apple Discount Drugs
512 Clinch Ave.
Clinton, TN 37716

Ph. 865-457-0300
Fax 865-457-1383

Submitter :

Date: 06/06/2006

Organization :

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

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

Submitter : Dr. David Freedman
Organization : Dr. David Freedman
Category : Physician

Date: 06/06/2006

Issue Areas/Comments

GENERAL

GENERAL

June 6, 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 the highest quality medically necessary care to my patients. I urge the Centers for Medicare & Medicaid Services (CMS) to exempt all physicians, including podiatric physicians, from the competitive acquisition program and to instead allow us 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 like myself. If physicians can no longer supply DMEPOS items, patients will suffer.

Consider a patient who presents complaining of foot pain following an injury. I diagnose the patient with a foot fracture and determine that a walking boot L4360 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 that 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 additional injuries.

As another example, consider a patient who sustains an acute ankle injury. As the treating physician, I determine that an ankle brace L4350 and crutches E0114 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 us to supply DMEPOS items used in the treatment of Medicare beneficiaries.

Sincerely,

David J. Freedman, DPM., FACFAS

Submitter : Dr. Michael Tritto
Organization : Dr. Michael Tritto
Category : Physician

Date: 06/06/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-94-Attach-1.DOC



*** DR. MICHAEL TRITTO, PA**
PODIATRIC MEDICINE AND SURGERY

* DIPLOMATE, AMERICAN BOARD
OF PODIATRIC SURGERY
* FELLOW, AMERICAN COLLEGE
OF FOOT AND ANKLE SURGEONS

June 6, 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. My ability to diagnose and treat a Medicare beneficiary than dispense the appropriate DMEPOS device ensures that the patient gets the proper device required to treat the problem immediately.

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, getting the appropriate care at one point of service is a benefit that will be taken away from Medicare beneficiaries with the proposal as it stands.

I do not believe that the Centers for Medicare & Medicaid Services (CMS) considers it to be in the best interest of patient care to impede a physician's ability to provide medically necessary and quality care to Medicare beneficiaries.

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

Sincerely,

Michael Tritto, DPM

THE FORUM
11801 ROCKVILLE PIKE
ROCKVILLE, MARYLAND 20852

TELEPHONE: (301) 881-6222
FAX: (301) 881-1639

Submitter : Dr. Edward Orman
Organization : Dr. Edward Orman
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-95-Attach-1.DOC

Edward S. Orman, DPM, PA
Diplomate, American Board of Podiatric Medicine
Fellow, American College of Foot and Ankle Surgeons

5629 Harford Rd.
Baltimore, MD 21214
410-426-6123

2303 Belair Rd.
Fallston, MD 21047
410-877-3369

June 6, 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 in practice for 26 years, I supply DMEPOS items to Medicare beneficiaries. I believe 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 Centers for Medicare and 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 sustains an injury to the foot or ankle. I diagnose a fracture and determine that a walking boot and crutches are necessary. If I no longer function as a supplier in the new competitive acquisition program and those items are subject to bidding, the patient will be forced to travel to another location to obtain the necessary items. The patient risks converting the existing injury to one that is more severe, with greater recovery time and increased risk for complications.

There are many other examples that could 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 in the treatment of Medicare beneficiaries.

Sincerely,

Edward S. Orman, DPM

Submitter : Mr. Jon Marcaccini

Date: 06/07/2006

Organization : Jon's Drug

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

small pharmacy must have the ability to serve our customers with a wide range of dme. We are the front lines of patient care. Do not make this overly complicated. Why not just let us sell what we buy for a fair markup. This isn't rocket science. Let small Drug stores play in the game. We can't lobby or tell you how much better we are but we are. We do not have a huge middle man. But you must keep it simple for us. We are to busy taking care of old needy people to work with a complicated twisted program. thank you

Submitter : Dr. Joseph Borreggine
Organization : The Family Foot Care Center
Category : Physician

Date: 06/07/2006

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,

Joseph S. Borreggine, DPM

Submitter : Dr. Stanley Beekman
Organization : Dr. Stanley Beekman
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

June 7, 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 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,

Stanley Beckman DPM

Submitter : Dr. Michael Stegman
Organization : American Foot & Ankle Specialists
Category : Physician

Date: 06/07/2006

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, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. This rule would include physicians in a competitive acquisition program for certain DMEPOS items. I urge Centers for Medicare & Medicaid Services (CMS) 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. Certain DMEPOS items are provided to my patients as part of the normal course of quality care. My patient's will suffer if I am no longer able to supply those items.

I want to ensure that my patients receive appropriate care for their particular problem(s). Being able to dispense a medically necessary DMEPOS items 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 at the time of their visit. They should not have to go to another provider to get their brace, walker boot, supports, etc. I need to be able to control the quality and type of device. With this proposal I will lose that ability to control that part of their care and it could put me at a liability risk as well as put the patient at risk from an unscrupulous supplier. Patients should be able to get the full range of care they require for a particular problem from me, with this proposal that may no longer be possible.

Sincerely,

Michael B. Stegman, DPM

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

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

June 7, 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 20 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. A number of these patients are referred to me by other physicians with the understanding that their condition requires dispensing of an appropriate DME at the time of treatment. 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. In a number of cases, the inability to dispense the appropriate item at the time of treatment puts the patient at further risk with potential complications. These considerations were factored in to my decision to become a DMEPOS supplier. I would have a difficult time telling a patient that they need to travel across town to obtain an item that is both medically necessary and appropriate.

I respectfully request that you 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,

Mark S Block DPM
Insurance Chairman FPMA/CAC Representative
First Vice-President FPMA (Florida Podiatric Medical Association)

Submitter : Miss. Juancarlos Barra
Organization : Miss. Juancarlos Barra
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-101-Attach-1.DOC

June 5, 2006

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

Dear Dr. McClellan:

I am 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,

Juancarlos Barra, DPM
3133 New Germany Road
Suite 62
Ebensburg, PA, 15931

Submitter : Dr. David Armstrong
Organization : Rosalind Franklin University / CLEAR
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

As a clinician and researcher dedicated to amputation prevention in persons with diabetes, I am somewhat concerned by my interpretation of this issue (CMS 1270-P). My interpretation-- specifically for wound care and "advanced modalities"-- is that it might have the unanticipated consequence of LIMITING choice for evidence-based therapy. I speak specifically of Negative Pressure Wound Therapy (NPWT). CMS, to my knowledge, includes two offerings here: 1) VAC therapy (KCI) and 2) Versatile1 Therapy (BlueSky).

I would wager that any clinician with even a modest amount of experience in wound healing that has used or even evaluated either device could see glaring differences between them. They simply don't work the same way. One offers the ability for patients to transfer home rapidly and remain mobile (#1), while the other (#2), which doesn't have a safety filter or alarm, could cause spills, backwash, and is impossible to walk around with. One device uses a highly-specialized foam interface (which, through cellular microdeformation is likely a prime source of its clinical success), while the other uses gauze, which actually damages a wound when removed during changes. One device has robust evidence to support it (300+ manuscripts), whilst the other astonishingly has no bona-fide peer-reviewed series or RCTs despite its being available since the beginning of the decade.

As a full-time clinician and full-time researcher, there is no one I know that would urge more competition in this space. I believe that competition fosters innovation and innovation helps our patients. However, there is no competition here. The two devices are completely different and, I fear, that one is throwing out the therapeutic baby with the bathwater. I urge you to please consider this when you make your consideration.

As a matter of disclosure, I have received research support from the federal government (VA/NIH) as well as many wound healing and pharmaceutical companies, including KCI, the manufacturer of the VAC device.

Yours very truly,

David G. Armstrong, DPM, PhD
Professor of Surgery
Chair of Research and Assistant Dean
Dr. William M. Scholl College of Podiatric Medicine at
Rosalind Franklin University of Medicine and Science
3333 Green Bay Road
North Chicago, IL 60064
520-360-0044
847-557-1457 (FAX)
www.rosalindfranklin.edu/scpm/CLEAR

Director,
Center for Lower Extremity Ambulatory Research (CLEAR) at
Rosalind Franklin University of Medicine and Science
www.diabetic-foot.net

CMS-1270-P-102-Attach-1.DOC

CMS-1270-P-102-Attach-2.DOC

RE: CMS 1270-P

As a clinician and researcher dedicated to amputation prevention in persons with diabetes, I am somewhat concerned by my interpretation of this issue (CMS 1270-P). My interpretation-- specifically for wound care and "advanced modalities"-- is that it might have the unanticipated consequence of LIMITING choice for evidence-based therapy. I speak specifically of Negative Pressure Wound Therapy (NPWT). CMS, to my knowledge, includes two offerings here: 1) VAC therapy (KCI) and 2) Versatile1 Therapy (BlueSky).

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Yours very truly,

David G. Armstrong, DPM, PhD
Professor of Surgery
Chair of Research and Assistant Dean
Dr. William M. Scholl College of Podiatric Medicine at
Rosalind Franklin University of Medicine and Science
3333 Green Bay Road
North Chicago, IL 60064
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Director,
Center for Lower Extremity Ambulatory Research (CLEAR) at
Rosalind Franklin University of Medicine and Science
www.diabetic-foot.net

RE: CMS 1270-P

As a clinician and researcher dedicated to amputation prevention in persons with diabetes, I am somewhat concerned by my interpretation of this issue (CMS 1270-P). My interpretation-- specifically for wound care and "advanced modalities"-- is that it might have the unanticipated consequence of LIMITING choice for evidence-based therapy. I speak specifically of Negative Pressure Wound Therapy (NPWT). CMS, to my knowledge, includes two offerings here: 1) VAC therapy (KCI) and 2) Versatile1 Therapy (BlueSky).

I would wager that any clinician with even a modest amount of experience in wound healing that has used or even evaluated either device could see glaring differences between them. They simply don't work the same way. One offers the ability for patients to transfer home rapidly and remain mobile (#1), while the other (#2), which doesn't have a safety filter or alarm, could cause spills, backwash, and is impossible to walk around with. One device uses a highly-specialized foam interface (which, through cellular microdeformation is likely a prime source of its clinical success), while the other uses gauze, which actually damages a wound when removed during changes. One device has robust evidence to support it (300+ manuscripts), whilst the other astonishingly has no bona-fide peer-reviewed series or RCTs despite its being available since the beginning of the decade.

As a full-time clinician and full-time researcher, there is no one I know that would urge more competition in this space. I believe that competition fosters innovation and innovation helps our patients. However, there is no competition here. The two devices are completely different and, I fear, that one is throwing out the therapeutic baby with the bathwater. I urge you to please consider this when you make your consideration.

As a matter of disclosure, I have received research support from the federal government (VA/NIH) as well as many wound healing and pharmaceutical companies, including KCI, the manufacturer of the VAC device.

Yours very truly,

David G. Armstrong, DPM, PhD
Professor of Surgery
Chair of Research and Assistant Dean
Dr. William M. Scholl College of Podiatric Medicine at
Rosalind Franklin University of Medicine and Science
3333 Green Bay Road
North Chicago, IL 60064
520-360-0044
847-557-1457 (FAX)
www.rosalindfranklin.edu/scpm/CLEAR

Director,
Center for Lower Extremity Ambulatory Research (CLEAR) at
Rosalind Franklin University of Medicine and Science
www.diabetic-foot.net

Submitter : Dr. Phillip Ward
Organization : American Podiatric Medical Association
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

June 7, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and 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.

As a podiatric physician who has been in practice for more than 16 years, 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, my patients will suffer due to complications related to this mandated delay of appropriate 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.

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 and in the long run more cost effective. 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 will no longer occur.

I respectfully 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, would interfere with my ability to provide medically necessary and quality care to Medicare beneficiaries and could actually harm my patients.

Sincerely;

Phillip E. Ward, DPM, FACFAS, FACFAOM
Trustee, American Podiatric Medical Association
Past-President, North Carolina Foot and Ankle Society

Mail address:
Foot and Ankle Center of NC, PA
3 Regional Circle, Suite B
Pinehurst, NC 28374
910-295-9262

E-mail address:
Peward@apma.org

Submitter : Thomas Colonel
Organization : Tar Heel Drugs
Category : Pharmacist

Date: 06/07/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Not enough information has been given about the bidding process. Is a range of bids going to be accepted or will all of the business go to the lowest bidder? If all of the business goes to the lowest bidder, it will limit availability to purchase products for the beneficiaries in need of the DME(durable medical equipment) and more importantly, the employees of small businesses that provide these services will be penalized. Small business is the backbone of America and accepting only the lowest bids, will threaten the livelihood of millions of American citizens, unnecessarily. With a basically unlimited budget, the Armed Forces are protecting American's freedom worldwide. Use this instance to protect Americans freedom from limitations within America.

I am available to discuss this issue or come to Washington to help inform the legislature about this issue. My phone number is (336) 584-3558 in the heartland of America, Burlington, NC.
Thank you.

Submitter : Mr. Greg Hines
Organization : Hines Pharmacy
Category : Pharmacist

Date: 06/07/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

If CMS creates a national mail service program, beneficiaries must have the option to continue to obtain their DME supplies from their provider of choice and not be forced to use one provider over another. Also I strongly object to CMS' alternative proposal that would limit patients choice of providers. If CMS limits patients choice to mail order, then both access and convenience will greatly suffer and more importantly, the patients health which will lead to hospitalizations and doctor visits. CMS must also prohibit suppliers from automatically refilling and sending supplies which have not been requested.

Criteria for Item Selection

Criteria for Item Selection

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

**Determining Single Payment
Amounts for Individual Items**

Determining Single Payment Amounts for Individual Items

While I understand CMS is required to set a single payment amount for each item, I am concerned that using the median bid price will set an artificially low payment rate that many small supplies wil 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 suppliers cost to acquire and provide the product. Also, I appreciate CMS' intention to update the single payment rate based on the consumer product index during the second and third years of the suppliers contract, however, this proposal does not address situations in which the manufacturer or distributor raises the acquisition cost of the product. CMS mus make provisions to increase 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 established 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 and patient relationships.

Submitter : Dr. Julie Fike, PharmD

Date: 06/07/2006

Organization : Snyder Drug

Category : Pharmacist

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 provider-- this restricts beneficiaries' choice. This proposal would severely restrict my patients' access to needed items, such as diabetic testing supplies and machines, and may compromise patient health outcomes.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should NOT include common DMEPOS supplies as diabetic testing supplies. Please limit the competitive bidding program to unique products that could be provided by a central supplier. My patients need the ability to receive their diabetic testing supplies from the person who teaches them how to use their glucose meter and fills their monthly prescriptions, their community pharmacist.

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 a 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- such as my community pharmacy dealing with diabetic testing supplies, but not canes, wheelchairs, and other home health items. 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.

Please preserve the ability I have as a community pharmacist, by allowing me to dispense diabetic testing supplies. I am a pharmacist who has special certification in diabetic education and teach a large number of patients how to use their glucometer. It is imperative that they be able to get the glucometer, strips and lancets from me. Without these revisions to the final regulation, I will be unable to continue to provide these valuable services to my patients, as testing their blood glucose is at the heart of treating the diabetic patient.

Submitter : Mr. Robert Bertelli
Organization : Bertelli's Drugs
Category : Pharmacist

Date: 06/07/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

1. 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.
2. 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.
3. 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

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

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

1. 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.
2. 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.

GENERAL

GENERAL

I currently provide the following types of DMEPOS in my practice at the 3 pharmacies I operate, Bertelli's Sonora Drugs, Bertelli's King City Pharmacy and Bertelli's Drugs, and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients. I know the value of the service I provide my Medicare patients with diabetes. I help regularly help them learn to manage their disease and information from their blood glucose testing is a valuable part of what I help them with. If we as providers can no longer supply them with testing supplies, they will lose a valuable source of help and training that can keep them healthier and keep overall medical costs down. Thank you for your consideration in this matter.

Sincerely,
 Robert Bertelli

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

1. CMS must do more to ensure that small suppliers which include the majority of pharmacy-based suppliers can participate in the competitive bidding program.
2. 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.
3. 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.
4. I urge CMS to take these steps to preserve beneficiaries convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Submitter : Dr. Grace Torres-Hodges
Organization : Dr. Grace Torres-Hodges
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

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,
Grace Torres-Hodges, DPM

Submitter : Dr. Samir Vakil
Organization : Dr. Samir Vakil
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

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, my patients will suffer.

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. Physicians cannot compete with large corporations on price, but win everytime in regards to looking out for the patients first. I am glad to say every patient we have placed in diabetic shoes and accomodative insoles have been prevented from developing ulcers and none have required amputations. The cost of hospitalizing a diabetic foot infection is in the range of 25--30,000 dollars. Please do not be "pound foolish and penny-wise".

- 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. Having my fracture and sprain patients leave my office without the appropriate properly fitted brace or boot walker not only leaves us open to liability, but falls far short of providing good standard of care.

- 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.

Fraternally yours,

Samir S. Vakil, DPM
941-639-0025

Submitter : Dr. Jerry Katz
Organization : Dr. Jerry Katz
Category : Physician

Date: 06/07/2006

Issue Areas/Comments

GENERAL

GENERAL

June 7, 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 with over 15 years experience, I supply DMEPOS items to Medicare beneficiaries. 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 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. Physicians supply only 3% of the current DMEPOS items.

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.

As an example, consider a patient who presents with the chief complaint of a foot fracture. I diagnose the patient with the fracture and determine that a walking boot is necessary to treat it. 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,

Jerry Katz, D.P.M.

Submitter : Dr. Luis Eiber
Organization : Hialeah Foot Center
Category : Physician

Date: 06/08/2006

Issue Areas/Comments

GENERAL

GENERAL

Dr. Luis B. Eiber
Hialeah Foot Center
7150 West 20th Avenue, Suite 110
Hialeah, Florida 33016

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

June 07, 2006

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,

Luis B. Eiber, D.P.M.

Submitter : Dr. DAVID URSTEIN
Organization : GAGE PHARMACY
Category : Pharmacist

Date: 06/08/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Small community pharmacies that serve Medicare Part B beneficiaries with their diabetic test strips and lancets and inhalation solutions must be exempted from this proposal. We serve a specific population with these few products in a neighborhood setting with great efficiency. Test strips, lancets and inhalation solutions should be exempted from these proposed regulations

Submitter : Dr. Makabis Yousefpour
Organization : Dr. Makabis Yousefpour
Category : Physician

Date: 06/08/2006

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClella,

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 finished my residency program in 2005. My training was focused extensively on foot and ankle reconstructive surgery. I could not wait to get out and do 1000 cases per month. However, it was not until I joined my group practice, to realize that surgery is the last thing a patient wants. I had a diabetic male, 67 y.o. with a Wagner's grade 2 ulcer x 2 yrs. The bone was exposed, and no matter how much I debrided, and medicated it the ulcer would not heal. I recommended surgery, a partial amputation of the 5th digit, along with the resection of the 5th metatarsal head. Pt, on the other hand, was very adamant about not wanting surgery. So, I, the foot and ankle surgeon, resorted to using a cam walker to off load the forefoot area. Several weeks after dispensing the walker, and multiple in office debridement of the ulcer, there was evidence of angiogenesis, and in about 2 months, the wound closed. Then I provided the patient with DM shoes and inserts, and until this day, the ulcer is closed.

I am sure that you have heard these stories over and over again, but these are not just stories. These are real people, they are not fictitious characters. By providing my patient with the necessary durable medical equipments, not only the patient was cured, but it also prevented me from taking him to the OR and actually saved Medicare a lot of money.

So please exclude us, the physicians, from this rule and allow us to serve our patients with best care. At the end that is all that matters.

Sincerely,

Makabis Yousefpour DPM "Board qualified foot surgeon"
7306 Berry Hill Dr
RPV, CA 90275
818-554-4687

Submitter : Dr. Hans Blaakman
Organization : Dr. Hans Blaakman
Category : Physician

Date: 06/08/2006

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:

As a podiatric physician who has been in practice for more than 14 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.

This would be especially difficult for some of my patients as I live in a small town and in order to receive some DMEPOS items this would require them to travel 20 plus miles to the nearest supplier. The pains of current gas prices, acquiring a ride and then potentially acquiring the inappropriate DMEPOS item, patients will further lose their own patience with healthcare system and now supplies. Often adjustments may be needed for the DMEPOS item, which again would require travel. Frustrated patients would risk further injury; days lost from work and prolonged pain and suffering. Often the supplied item is either 'all they have' or 'close enough', this is NOT acceptable with my working class patients who need to get back to work as soon as possible.

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,

Hans E. Blaakman
1604 North Limestone St
Gaffney, SC 29340

Submitter : Dr. Marc Katz
Organization : Dr. Marc Katz
Category : Physician

Date: 06/08/2006

Issue Areas/Comments

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

Submission of Bids Under the Competitive Bidding Program

June 8, 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 15 years, I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I support excluding all physicians, including podiatric physicians, from the new program.

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

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

Sincerely,

Marc A. Katz, DPM
Tampa, Florida

Submitter : Dr. Vincent Hartzell
Organization : Dr. Vincent Hartzell
Category : Pharmacist

Date: 06/08/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I strongly object to CMS' alternative proposal that would require beneficiaries to obtain replacement supplies for certain items through designated providers, thus eliminating the beneficiary's choice. If a provider is willing to contract with CMS, why should the beneficiary be forced to obtain replacement supplies from another source? This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies, such as diabetic testing supplies. This could significantly effect patient access to supplies and eliminate patient choice. Many customers of mine get both their diabetic testing supplies and medications through my store. This arrangement is convenient for the patient and allows them access to ask pharmacists questions concerning their supplies and how to appropriately use them. 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.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I would urge CMS to take steps that would ensure that smaller suppliers (many of which are pharmacy-based) 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, almost impossible, for a small supplier to be competitive in a large market. Small DMEPOS suppliers that are willing to accept the bid contracted payment amount should be allowed to become contracted suppliers once CMS establishes the single payment amount for each item of DMEPOS. In my opinion, if these steps are not taken by CMS, beneficiaries' convenient access to DMEPOS supplies will be jeopardized. I know of many pharmacies that will not be able to continue to provide these services to their patients if these changes are not made, including my own. My practice currently offers a wide variety of DMEPOS, including but not limited to diabetic supplies, ostomy supplies, walkers, wheelchairs, hospital beds, oxygen, etc. Please consider the negative impact these regulations would have on patients and the pharmacies that currently service them.

Submitter : Dr. David Gurvis
Organization : David E. Gurvis, DPM Inc PC
Category : Physician

Date: 06/08/2006

Issue Areas/Comments

GENERAL

GENERAL

Plcase see attachment

CMS-1270-P-117-Attach-1.DOC

David E. Gurvis, DPM
8244 E. US Hwy 36, Ste. 120
Avon, Indiana 46123
(317) 272-0556

June 8, 2006

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

Dear Dr. McCellan:

I am writing to you about my concerns with the proposed rule establishing a competitive acquisition program for durable medical goods, orthotics and supplies (DMEPOS).

I am a podiatrist who has now been in practice in Avon, Indiana for nearly 30 years. I take pride in being able to care for my patients by doing what I do, including the Medicare and Medicaid population. I provide quality, professional and – to the best of my abilities – cost effective care for all my patients, including durable medical equipment and supplies. I have always believed, in this manner, my patients are well taken care of, and they obtain exactly what I want, not what some other supplier may dispense.

If your competitive bid program is implemented, I fear this may end this kind of care for my patients, and for those of other patients: unless physicians, including podiatric physicians, are excluded from this bid program.

Picture the scenario where I examine a Medicare patient, and diagnose a fracture and feel a Walking boot is the best treatment. If I am no longer a supplier, the patient, on a fractured foot, may be required to travel to another location to obtain that boot. If the patient is unable to bear full weight on the extremity due to pain, then he/she is at risk for falling, or further injury, while traveling to that supplier. This can be complicated by the fact that I keep what I feel are the appropriate items in stock for my patients, and he/she will get exactly what I ordered, not what another supplier has in stock.

I can give further examples, but they all follow the same lines: my fear that my patients may not get exactly what equipment they require for proper care, and it is they who will suffer.

David E. Gurvis, DPM
8244 E. US Hwy 36, Ste. 120
Avon, Indiana 46123
(317) 272-0556

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 the appropriate equipment and items directly to my Medicare beneficiaries.

Sincerely,

David E. Gurvis, DPM

Submitter : Dr. Bret Ribotsky
Organization : Dr. Bret Ribotsky
Category : Physician

Date: 06/08/2006

Issue Areas/Comments

GENERAL

GENERAL

June 8, 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:

If no change is made, PATIENTS will SUFFER, thus, 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 18 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, wound care supplies. My patients in south Florida are old and the need to make many trips is often impossible. 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,

Bret Ribotsky, DPM, FACFAS, FACFAOM
ribotsky@yahoo.com

Submitter : Dr. David Mader
Organization : Family Footcare PC
Category : Physician

Date: 06/08/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-119-Attach-1.TXT

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,

Dr. David W. Mader

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Submitter : Dr. JOHN CHAFIN
Organization : CHRISTIANS PHARMACIES
Category : Pharmacist

Date: 06/08/2006

Issue Areas/Comments

GENERAL

GENERAL

Christian's Pharmacy has been in business since 1947 and is the second oldest business in Clayton County. I have always heard government refer to "a level playing field". I always felt that government should provide an environment which is fair to everyone and prohibit the policy of exclusion.

I am a hard working community pharmacist who has served my community for over 32 years. I have served in the General Assembly of Georgia, as a City Councilman, the Hospital Board, Chairman of the Boy Scouts, and The Water Authority of Clayton County.

I would like this to be fair and equitable for the "little guy". We have evolved in the pharmacy world to treat patients as numbers. Let's start over and give patients the quality of care they deserve.

Sincerely,
John Chafin Pharm.D.

Submitter : Dr. George Fulk
Organization : Northeastern State Univ College of Optometry
Category : Other Practitioner

Date: 06/09/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

I oppose the re-classification of low vision aids and grouping them under "eyeglasses". Such a re-classification will deny medicare coverage of low vision aids and make those aids unavailable to many people. Low vision aids often make a person with impaired sight productive in our society. Without them many people will need further services thus increasing the cost of providing health care and degrading the quality of life of these citizens. Just one example of how denying access to low vision aids can increase health care costs is the fact that persons with low vision cannot read prescription labels without such aids. That could lead to patients taking their medications in inappropriate ways. Without low vision aids many people will not be able to live independently and will require institutionalization, which will put additional demands on resources. From a purely economic point of view, never mind the obvious humanitarian issues, low vision aid exclusion will do more harm than good.

Submitter : Mr. Charles Moore
Organization : Charlie's U-Save Pharmacy
Category : Pharmacist

Date: 06/09/2006

Issue Areas/Comments

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

Submission of Bids Under the Competitive Bidding Program

Our Pharmacy is a one store organization, and does only a small amount of business that is DME, and we still submit our billing on paper forms. We however are in rural area, and there are no other suppliers within 40 miles of us who would be doing competitive bidding for the DME. If we have to bid to remain a supplier, we will seriously consider discontinuing the DME part of our business as far as Medicare B is concerned, and our patients will have to go 40 miles or more to obtain the service!

Submitter : Mr. Eric Smith
Organization : Young's Drug Store, LLC
Category : Pharmacist

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-1270-P-123-Attach-1.DOC

Young's Drug Store, LLC

PO Box 67
Lineville, AL 36266
256-396-5632

June 12, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

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

Competitive Bidding Areas

I fervently object to CMS' proposal that would require beneficiaries to obtain replacement supplies of certain items through designated providers. This proposal will restrict the beneficiaries' choice. Additionally, it will create a hardship in some cases to obtain the needed items and supplies due to inability to get transportation to the new designated providers which **WILL** compromise patient health. As a small supplier in a rural setting, I may not have high volume of DMEPOS; however, I do make deliveries when a patient is not able to get their supplies. CMS must take steps to protect beneficiaries' convenient access to DMEPOS supplies and to preserve established provider/patient relationships.

Criteria for Item Selection

The competitive bidding program should absolutely **NOT** include common DMEPOS supplies such as diabetic testing supplies.

Opportunity for Participation by Small Suppliers

I urge CMS to take steps to ensure that I and other small suppliers—which include the majority of pharmacy-based suppliers—can participate in the competitive bidding program. Small suppliers such as me 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 with large metropolitan suppliers.

In conclusion, I would like to thank CMS for considering my comments on CMS-1270-P. I hope you will make the right choice for the sake of the beneficiaries.

Sincerely,
Eric S. Smith, Jr., RPh

Submitter : lee newton
Organization : lee newton
Category : Individual

Date: 06/09/2006

Issue Areas/Comments

GENERAL

GENERAL

If I am reading this right, looks like your are trying to eliminate a lot of businesses from doing business with Medicare. This is the most outrageous and Un-American thing I have ever heard of. You guys should be looking to reduce costs but running small companies out of business is just wrong.

Why don't you reduce your allowed charges and let everybody continue working with Medicare? What about the small companies? Is there a plan to allow them to continue to bill Medicare even though they didn t win the bid?

I hope you will reconsider this program and find a more equitable way of reducing our Medicare cost.

Submitter : Dr. Scott O'Connor

Date: 06/09/2006

Organization : Dr. Scott O'Connor

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 9, 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 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,

Scott O Connor, DPM, FACFAS

Submitter : Dr. Chester [Chet] Yee
Organization : Menlo Park Pharmacy
Category : Pharmacist

Date: 06/10/2006

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 beneficiaries' choice. This proposal would severely restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

I urge CMS to take steps to ensure small suppliers, which include the majority of pharmacy-based suppliers, can participate in the competitive bidding program. Small providers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small providers to be competitive in large metropolitan areas.

Submitter : Dr. Robert Katz
Organization : Cortez Foot and Ankle Specialists
Category : Physician

Date: 06/10/2006

Issue Areas/Comments

GENERAL

GENERAL

June 10, 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 in the state of Florida, 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 ligamentous tear and determine that a walking boot is necessary to treat the injury. 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,

Rob Katz, DPM, MBA
Cortez Foot and Ankle Specialists
Past President, Florida Podiatric Medical Association
1800 Cortez Road West
Bradenton, FL 34207
941-758-8818

Submitter : Mr. DAVID MCCALL
Organization : A DME SERVICES, PC
Category : Other Practitioner

Date: 06/10/2006

Issue Areas/Comments

Opportunity for Networks

Opportunity for Networks

As we began to evaluate the possible benefits of forming a network for the purpose of participating in the competitive bidding program several challenges presented themselves. The first challenge is the legal form of such a network. We believe that the entity responsible for forming, controlling, billing for and administering the network must not be in direct competition with the members of the network. It is not reasonable for anyone to expect the members of a network to turn over patient information to another entity with whom they are in direct competition. Therefore, the entity responsible for oversight of the network and submitting claims to Medicare must not be a supplier. This should effectively eliminate the inherent mistrust that would arise if suppliers were required to provide information to another supplier with whom they are in direct competition. This conflict of interest is very likely to have been the reason why there was a complete absence of bids from networks during the demonstrations. The entity in charge of the network should have extensive experience in the Medicare program and the day to day operations of a supplier including compliance with all local, state and national regulations and legal requirements as well as proper billing and documentation procedures/requirements. In addition to these advantages having the entity in control of a network who is not a supplier will afford Medicare the opportunity to set rules for the network administrator which are specific to the administrator and separate from the rules of the suppliers/members of the network.

The second challenge that presented itself is the ability to continue participation in the program by the network should one or more of the members of the network become ineligible for any reason. We suggest that if a member of the network becomes ineligible for any reason that the network should be allowed to replace said member with another suitable member within a reasonable time so as not to disrupt the other members ability to participate in the program. This would alleviate the burden of the members who are in compliance from suffering the negative impact created by any single member through no fault of their own. This would also eliminate the need for Medicare to choose a new winning contract bidder and should result in a smooth and continuous flow of services to Medicare beneficiaries.

The third challenge that presented itself is the proposed limitation of no more than 20% of the market share for any one network in any one competitively bid area. This is by far the most difficult obstacle to overcome simply because it is not within the control of the network itself. Given the fact that there was a complete absence of bidding by networks during the demonstrations the likelihood that there will be at least five networks submitting bids in the upcoming bidding process is extremely low. Furthermore, placing a limit on networks and not other large suppliers is in and of itself anticompetitive. We feel very strongly that this limitation be entirely eliminated.

Submitter :

Date: 06/11/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 11, 2006

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

Dear Dr. McClellan:

I am writing in opposition to the proposed rule, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. 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,

Stuart Codron, DPM

Submitter : Mr. joe grasel

Date: 06/11/2006

Organization : medical center pharmacies

Category : Pharmacist

Issue Areas/Comments

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

Submission of Bids Under the Competitive Bidding Program

we are against competitive bidding for DME. DME suppling is very complicated and limited access as it is . if it goes out to bidders the patient will not have access to DME in their area. right now there are so much complications billing for DME that its getting harder and harder to get paid. there are a lot of items that are never paid by the secondary insurance, because they simply refuse to pay. now cutting the fees even for will drive most out of the DME buisness.

Submitter : Dr. Elly du Pri
Organization : Lighthouse of Broward
Category : Other Health Care Provider

Date: 06/11/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

I strongly oppose the proposal that low vision aids be barred from Medicare coverage--aids such as closed-circuit television systems (CCTVs), magnifiers, and any other low vision aids or technologies, allowing people with vision loss, particularly those with low vision, to make use of remaining vision. Does Medicare want to save money? Providing access to low vision aids is a low cost way to do so. FIRST OF ALL, visually impaired people can take their medications correctly and avoid unnecessary care due to misusing drugs if they have low vision devices that assist reading prescriptions, dosage, refill information, etc. One hospitalization avoided will save more than any low vision device costs. SECOND, low vision aids make it easier to access alerts, warnings, new treatment information and make it easier to implement healthy lifestyles using information gathered. THIRD, drug store errors will be caught by the user of a low vision aid who can see the color, shape, lettering on the pill and avoid mis-medicating. FOURTH, low vision aids significantly improve the quality of life of their users, thereby enlisting the optimistic approach to life that is known to improve health in the panoply of Medicare cost-saving strategies. The health care crisis will not be solved by employing cost-cutting methodologies that fail to understand what actually helps patients succeed in furthering their own health. A lack of imagination clearly drives the proposal to ban low vision aids from Medicare coverage. I urge the complete abandonment of this approach.

Submitter : Dr. Katherine Schneider
Organization : Dr. Katherine Schneider
Category : Individual

Date: 06/12/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

These devices keep seniors independent, able to pay their own bills, etc. so they don't land in nursing homes which are way more costly; don't exclude them!

Submitter : Mr. JIMMY CATER
Organization : HOSPITAL DISCOUNT DRUGS
Category : Pharmacist

Date: 06/12/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

BENEFICIARIES SHOULD ALWAYS HAVE THE CHOICE OF WHERE THEY WOULD LIKE TO DO BUSINESS. REQUIRING THAT THEY OBTAIN THEIR INITIAL SUPPLIES FROM ONE SUPPLIER AND THEN REPLACEMENTS FROM ANOTHER WOULD HAVE THE INITIAL SUPPLIER DOING ALL OF THE WORK OF TRAINING THEN THE DESIGNATED SUPPLIER COULD REAP THE BENEFITS THEREAFTER.

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

SMALL SUPPLIERS LIKE INDEPENDENT PHARMACIES SHOULD BE ASSURED OF A CHANCE TO PROVIDE NEEDED SUPPLIES TO THEIR LOCAL CUSTOMER BASE. IT WOULD BE ALMOST IMPOSSIBLE FOR THESE TO BE COMPETITIVE WITH LARGE METROPOLITAN BUSINESSES. MANY LOCAL CUSTOMERS PREFER TO DEAL WITH LOCAL WELL-KNOWN PEOPLE WHO THEY CAN SEE AND TRUST.

Submitter : Mr. Leonard Givens
Organization : Givens Pharmacy
Category : Other Health Care Professional

Date: 06/12/2006

Issue Areas/Comments

**Opportunity for Participation by
Small Suppliers**

Opportunity for Participation by Small Suppliers

I would like for you to know that with what you are proposing to do with the small independant pharmacies is not right. We were the ones who were around long before your big chains of any kind. Your idea of competitive bidding leaves the small guys out who started all of this. We do not have the power that all of the Lincars or Aprias have of this world but we can still provide the same service as the rest of the suppliers. Please reconsider your idea for competitive bidding. thank you small guys

Submitter : Ashley Bailey
Organization : Cooley Medical Equipment
Category : Other Health Care Provider

Date: 06/12/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

June 12, 2006

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

Re: CMS-1270-P

Dear Sir or Madam:

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

I urge CMS to keep in mind that some of the contracting provisions in the MMA have the effect of restricting competition, reducing access to homecare, and hurting small homecare providers. The regulations should be written so as to protect patient access to homecare and allow qualified small providers to participate in the bidding program. CMS should:

" Require that competitive bidding not be implemented until quality standards are in place. Only accredited providers should be eligible to submit bids. CMS needs to identify the criteria it will use to evaluate the accrediting bodies now, and grandfather all providers accredited by organizations that meet the criteria CMS identifies;

" Exempt smaller, rural (populations under 500,000) Metropolitan Statistical Areas (MSAs);

" Allow all qualified providers that are small businesses and that submitted a bid below the current allowable to participate at the selected award price. Specifically, after a single payment amount for each item of DMEPOS is established, any supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier;

" Not disqualify bids above the current fee schedule amount for an item. This artificially limits bidding and does not reflect pricing that is rational and sustainable in a truly competitive market;

" Exempt items and services unless savings of at least 10 percent can be demonstrated, compared to the fee schedule in effect January 1, 2006;

" Protect beneficiary access to care by conducting a comparability analysis for areas that are not competitively bid to ensure the rate is appropriate to costs and does not reduce access to care.

Cooley Medical is a provider of DMEPOS in mostly rural areas of Appalachia. We have built a reputation of going above and beyond to service the needs of our patients in isolated and impoverished areas. Exclusion of local companies such as ours will restrict the market to national chain suppliers better capable of controlling costs, but only at the expense of quality service to our patients.

In conclusion, I urge CMS to preserve beneficiaries' convenient access to DMEPOS and their freedom of choice of a healthcare provider. Without these assurances within the final regulations, we will be unable to continue providing these valuable services to our patients.

Thank you for considering my view.

Sincerely,

Hon. Ashley Bailey
Director of Legal Affairs
Cooley Medical Equipment

Submitter : Angela Kendrick

Date: 06/12/2006

Organization : Angela Kendrick

Category : Individual

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

In order to maintain good glucose control, insulin dependent diabetics are encouraged to test their glucose up to 10 times a day-more if they are experiencing highs or lows. This is a difficult enough task as it is. If they are not allowed to use the meter and strips that work best for them, they will not be able to follow this strict regimen. Please do not limit the options that diabetics have for keeping good control. The monetary and health costs would not be worth it.

Submitter : Ms. Nadine Uplinger
Organization : Albert Einstein Healthcare Network
Category : Dietitian/Nutritionist

Date: 06/12/2006

Issue Areas/Comments

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

Quality Standards and Accreditation for Supplies of DMEPOS

I am concerned about the regulation for competitive bidding for blood glucose meters for individuals with diabetes. As a practicing certified diabetes educator for the last 17 years, I have seen many of the advancements made with blood glucose monitoring. By monitoring their blood glucose, the patient can determine if their treatment regimen is working or not. It also provides crucial information necessary to determine insulin doseages. However, this is one area many people with diabetes show resistance. We need to make every effort to make testing easier, not harder, for patients. Not every meter is equal in terms of quality, the amount of blood required or accuracy. Often, the least expensive meter is also the one which requires the largest drop of blood and takes the longest time to provide a result. Unless the individual's technique is correct, a false result may also be provided. Blood glucose monitoring is not an area where cost cutting measures should be employed, especially with some of our most vulnerable older individuals living with diabetes. I implore you to please not enact competitive bidding for blood glucose monitoring.

Thank you.

Nadine Uplinger, MS, MHA, RD, CDE, LDN

Submitter : Ms. Margaret Schwafel

Date: 06/12/2006

Organization : Self

Category : Individual

Issue Areas/Comments

Issue

Issue

Do not pass this CMS-1270-P. Diabetics like me want choices of quality diabetic testing equipment, including meters and test strips. The cheapest is not the way to go!

Issue

This would impact the individual citizens, taxpaying citizens who vote, and are diabetics. Cheap products are not good products! Quality products need to be used to accurately monitor and control blood glucose levels. We are enabled patients who want choices of quality equipment.