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

Organization : BritKare Home Medical

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-901-Attach-1.TXT

TO: DEAPRTMENT OF HEALTH AND HUMAN SERVICES

FROM: SUSAN RILEY, BUSINESS MANAGER

DATE: JUNE 29, 2006

RE: COMMENTS ON COMPETITIVE BIDDING FOR DME SUPPLIES

SUPPLIER STANDARDS AND ACCREDITATION should be finalized in a timely manner before proceeding with competitive bidding process. A timeline of this process would benefit the CMS as well as the providers who truly desire to participate and comply. CMS further need to identify the accrediting bodies so that providers who are not currently accredited can begin the process and the ones that are already accredited can begin to update their policies to be compliant. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

MAKE COMPETITIVE BIDDING COMPETITIVE - require manufacturers to disclose quality of products and lowest cost or allow them to bid for government contracts to provide to reduced cost to Medicare providers. Don't artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices.

IMPLEMENTATION should be done on a progressive basis. Possibly staggering the bidding in 2007 to allow for an orderly roll out of the program. This will also allow CMS an orderly way to identify problems that might occur and correct before they become widespread and ultimately cause a negative effect on the beneficiaries. Disclosure of the MSAs and products selected should be identified in the final rule.

CONSIDER THE IMPACT ON THE PATIENT. CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substituted for appropriate medical policy.

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

Organization : Mr. Ray McClure

Category : Individual

Issue Areas/Comments

Administrative or Judicial Review

Administrative or Judicial Review

The movement of the Judicial Review to a part of the Medicare Contractors ection away from the non-related Social Security System may cause the fairness of a third party review. This is the only place a provider can go if they do not agree that the regulations were interpreted correctly. Needs to be moved back to Social Security Review.

Competitive Bidding Areas

Competitive Bidding Areas

The exclution of the largest MSA's from competitive bidding is not fair to the areas that competitive bidding will replace for the 8th, 9th and 10th spots. The simple reason that the Competative bidding committee says it will be to hard and inflict the lost of 50% or more of the DME businesses in the last 3 regions is very unfair to these cities.

Opportunity for Networks

Opportunity for Networks

As I understand this section to justify meeting the Laws requirement for participation by small business, you suggest small suppliers group together. This is not rational. Small suppliers have all different types of business, different ways of doing business, and different financial liabilities to deal with. This is not what the spirit of the law wanted for the participaiton of small suppliers to be.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

Same comments as for networks.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

People that are already been through accreditation should be grandfathered until their next renewal.

Submitter : Dr. KIRK BROCK **Date:** 06/29/2006

Organization : MIDSTATE PODIATRY ASSOCIATES LTD

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Attn: Mark McClellan, M.D. PhD I am a podiatrist in Bloomington, Illinois. I am requesting that CMS modify the "physician" definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I do prescribe and supply durable equipment and supply items to my patients only. If I am required to bid to supply an entire MSA, my patients may no longer be able to acquire medically appropriate DME items from me which are integral to the care I am providing.

Additionally, I need to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

I am required to maintain a vlid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same State requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to the other suppliers, which should include the ability to bid to supply select DME items to my patients only, and the right to execute a physician authorization.

If a patient I am treating for an ankle injury needs an ankle brace for stabilization, if I am not a DMEPOS supplier under the new competitive acquisition program because I was unsuccessful in my bid to supply the entire MSA, rather than just my patients, that particular patient would need to go elsewhere to obtain the necessary equipment. Thus, the patient would risk converting the exisitng injury into one more severe, requiring longer recovery time and increased risk of complication.

I am sure you can understand why is is so important the "physician" definition be changed from 1861(r)(1) to 1861(r), so that all podiatric physicians will be eligible to bid to supply items to their own patients and execute physician authorizations. This is absolutely necessary in order to provide appropriate care to our patients.

Sincerely,

Marc Leonard, D.P.M.

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

Organization : Midwest Medical Services, Inc

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1270-P-904-Attach-1.DOC

Midwest Medical Services, Inc
615 6th St SE
Watertown, SD 57201

June 29, 2006

Department of Health and Human Services
Attention: CMS-1270-P

I am part of a small DME under 2 million dollars. I have studied and review the document relating to Competitive Bidding and it concerns me that there has not been a lot of sensible thought put into compiling this rule.

Access by Medicare beneficiaries is my main concern as South Dakota is a very rural area. Only today we had several examples of how beneficiaries are not always able to come and pick up supplies and/or equipment.

The following statement summarizes my concerns. Please exercise caution before instituting such an enormous project that has not been very well thought out

CMS file code CMS–1270–P

Rebates (§414.416(c))

This is a notion that took everyone by surprise and with good reason. It appears contrary to decades of healthcare law and rules that prohibit Medicare providers from offering beneficiaries rebates on healthcare items and services (remember the beneficiary inducement statute?). The rebate concept is structured to encourage providers to submit the lowest bid possible--so they can increase their chances of winning the bid and gain an advantage over other winning providers. The greater the difference between the provider's low bid and the winning bid amount, the greater the cash rebate the beneficiary will be able to pocket if he chooses you. For the consumer, that's a pretty attractive proposition. Think about it: When the rebate amount is greater than the beneficiary's co-payment amount, you could be paying patients to use your services! In an attempt to address the obvious legal issues, CMS proposes that providers not be able to advertise rebates. Presumably, the government will advertise the respective rebates of various winning providers. Interesting. This section is extremely flawed and should be reconsidered.

Grandfathering (§414.422 or 414.408k?)

If a provider loses the bid and no longer wishes to serve his existing Medicare beneficiaries, winning HMEs must take over that business. That means winners will have to provide ongoing rentals for beneficiaries with medical needs for cap rental items or oxygen. For example, a winning provider may be required to take on 100 hospital bed rentals that have been occurring for 11 months or oxygen rentals that have been occurring for 30 months. As CMS states in the proposed rule, providers should be accounting for these additional costs when determining the bid to submit for particular items. While CMS will have estimated projected utilization for each HCPCS code it intends to bid, CMS will not be able to provide information regarding how many beneficiaries have been renting a hospital bed or have been on home oxygen therapy by the time the contract will begin. How then can any provider begin to intelligently calculate these additional costs into their bids?

Quality Standards (§414.414)

One of the largest and yet to be resolved issues is the Quality Standards. While the proposed rule was officially published May 1, and CMS scheduled a meeting of the Program Advisory and Oversight Committee (PAOC) in late May, the final Quality Standards were not scheduled to be issued until sometime in June. Quality Standards are so integral to the implementation of competitive bidding that it is difficult to provide meaningful comments to the proposed rule while we are unaware of the content and requirements of the Quality Standards. Perhaps the one positive statement in the entire competitive bidding proposed rule is CMS's apparent attempt to make sure that Quality Standards are implemented at the same time as competitive bidding, and that providers in the initial bid geographic areas will be required to be accredited by an organization whose standards are determined by CMS to meet the CMS Quality Standards. But at another point in the proposed rule, CMS states that the accreditation organizations will be able to grant providers in a bid area a grace period to become accredited within some unstated period of time. Now that's clarity.

Getting It Right Is More Important than Rushing Implementation

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

Have Accreditation and Standards in Place before Starting

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

Make Competitive Bidding Competitive, and Sustainable

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either. This portion of the rule is predicated on the illusion that some how the current fee schedules are adequate to sustain providers. In fact there are provisions in the rule that essentially require the provider to provide equipment to a patient that is brand specific if the physician so orders. If the CB providers bid was based on a relationship they have with a manufacturer for a specific brand then there will be a substantial burden on the provider to bear the cost of a specific brand. This will adversely impact the provider.

Don't Make it Harder for Providers to Sell their Businesses

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Consider the Impact on the Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Impact Analysis

In this section, a number of statements appear to directly contradict other statements in this section and throughout the rule, particularly regarding the ability of smaller providers to successfully bid in the programs. While CMS continually alludes to the demonstration programs in Polk County and San Antonio, stating that small providers were able to successfully participate in those bids, CMS's impact statement says that this rule "will have a significant impact on a substantial number of small providers." Two pages later, CMS continues: "We anticipate that the bidding process will be designed to neither reward nor penalize small providers." In a similar vein, CMS states that "since providers can choose whether to submit a bid for the competitive bid program, the regulation imposes no direct cost." Sure, if you don't submit a bid you don't incur the costs of submitting a bid; but if you don't submit a bid you have eliminated all chances for becoming a winning provider. Furthermore CMS proposes to put into place a whole new bureaucracy in order to formulate, analyze and evaluate all the bids. What additional cost will this mean. Will there be any savings after that bill is paid?

Bullet Point Comments Regarding MSA Selection Criteria

Background Information

Section 1847(a)(3) of the Act allows CMS to exempt from the Medicare DMEPOS Competitive Bidding Program 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. CMS proposes to use this authority to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on a combination of the following indicators:

- Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas.
- Low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas; and/or
- Low number of Medicare FFS beneficiaries in the area relative to other similar geographic areas.

CMS proposes to make decisions regarding what constitutes low (non-competitive) levels of utilization, suppliers, and beneficiaries on the basis of our analysis of the data for allowed charges, allowed services for items that may be subject to competitive bidding, and the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, CMS proposes to use the definitions currently in §412.64(b)(1)(ii) of the regulations. CMS invites comments on the methodologies proposed for determining whether an area within an urban area that has a low population density is not competitive. CMS will be reviewing the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding. In addition, CMS also invites comments on standards for exempting particular rural areas from competitive bidding.

Comments:

1. Rural areas tend to be underserved under the present system. Providers routinely travel hundreds of miles to provide services in various areas of the country.

2. In certain areas of the country complex Rehab Technology services are available from only one or two providers for several hundred miles in any direction. Access is already compromised in many areas as a result.

3. CMS has no published criteria outlining the optimal number of providers serving a geographic area. Furthermore there is nothing to indicate once the winners are picked what time frame would be used to establish whether or not there are adequate providers to serve the CB area. The greatest fallacy in this is that once some of these suppliers are not the successful bidder it won't be long and they will be out of business. Then who would be called on to fill the void. There are no network adequacies standards what-so-ever for CMS to follow.

4. The proposed criteria to use a review of the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding is subjective at best.

5. The analysis of the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas may not reflect reality. This is due to the great distance that patients must travel to receive services in rural areas of the country. In addition discrimination is a problematic area, especially in remote areas with significant lower income populations where beneficiaries already have limited access to services due to significant transportation issues. Rural areas tend to have a greater percentage of elderly population compared to urban areas, and these areas already suffer from a primary care physician shortage.

Thank you for allowing time for this comment period.

Respectfully submitted,

Kay Johnson

Submitter :

Date: 06/29/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-905-Attach-1.PDF

The American College of
FOOT & ANKLE ORTHOPEDICS & MEDICINE

5272 River Road
Suite 630
Bethesda, MD 20816

1.800.265.8263
301.718.6505
Fax: 301.656.0989
Web site: www.acfaom.org
E-mail: info@acfaom.org

June 29, 2006

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

Dear Dr McClellan,

I am writing to you on behalf of the American College of Foot & Ankle Orthopedics & Medicine (ACFAOM) to let you know of our firm opposition to the inclusion of physicians in the proposed competitive acquisition program for certain DMEPOS items. We believe this will have a negative impact on the quality of patient care

Perhaps CMS feels that this type of competitive program will save money. However, as you well know, delaying appropriate medical care because a physician may be required to send a patient elsewhere for needed DEMEPOS items, especially in the Medicare population, risks further degeneration of the medical condition which will lead to much more costly care and unnecessary suffering on the part of the patient. We cannot believe that this is what CMS intends. However, if podiatric physicians can no longer supply the necessary item(s) based on their diagnosis of the medical condition and must send the patient elsewhere and then hope they get the correct product, this is very likely what will happen.

Our College represents over 900 doctors who are board certified or qualified in podiatric orthopedics and medicine. They are well qualified to diagnose and treat many different lower extremity pathologies. They want, as their patients do, to ensure that appropriate timely care is provided. Being able to dispense appropriate medically necessary DEMEPOS items at the time of treatment, and to be able to ensure proper fit and function, just makes sense and is better and more efficient medicine. Patients should be able to expect and receive from their doctor the full range of care they require. Unfortunately, Dr. McClellan, with this proposed change that may no longer be the case.

Thus, the American College of Foot & Ankle Orthopedics & Medicine, urges you to do the right thing and exclude not only podiatric physicians but also all physicians from the requirement to competitively bid, so that our ability to provide complete and quality care to our Medicare patients is not hindered.

Sincerely,

Craig Garfolo, DPM, FACFAOM
President

Submitter : **Dr. David Mader** **Date: 06/29/2006**

Organization : **podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-906-Attach-1.PDF

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

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

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

Submitter : **Ms. Rose Schafhauser** **Date: 06/29/2006**

Organization : **Midwest Association for Medical Equipment Services**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-907-Attach-1.DOC

MAMES
10480 PERKINS AVENUE NORTH
STILLWATER, MN 55082
PHONE: 651-351-5395 FAX: 651-351-0391
EMAIL: INFO@MAMES.COM WEB SITE: WWW.MAMES.COM

SINCE 1982

The Midwest Association for Medical Equipment Services (MAMES)
Comments on Medicare Competitive Bidding draft proposal
CMS file code CMS–1270–P

Rebates (§414.416(c))

This is a notion that took everyone by surprise and with good reason. It appears contrary to decades of healthcare law and rules that prohibit Medicare providers from offering beneficiaries rebates on healthcare items and services (remember the beneficiary inducement statute?). The rebate concept is structured to encourage providers to submit the lowest bid possible--so they can increase their chances of winning the bid and gain an advantage over other winning providers. The greater the difference between the provider's low bid and the winning bid amount, the greater the cash rebate the beneficiary will be able to pocket if he chooses you. For the consumer, that's a pretty attractive proposition. Think about it: When the rebate amount is greater than the beneficiary's co-payment amount, you could be paying patients to use your services! In an attempt to address the obvious legal issues, CMS proposes that providers not be able to advertise rebates. Presumably, the government will advertise the respective rebates of various winning providers. Interesting. This section is extremely flawed and should be reconsidered.

Grandfathering (§414.408)

If a provider loses the bid and no longer wishes to serve his existing Medicare beneficiaries, winning HMEs must take over that business. That means winners will have to provide ongoing rentals for beneficiaries with medical needs for cap rental items or oxygen. For example, a winning provider may be required to take on 100 hospital bed rentals that have been occurring for 11 months or oxygen rentals that have been occurring for 30 months. As CMS states in the proposed rule, providers should be accounting for these additional costs when determining the bid to submit for particular items. While CMS will have estimated projected utilization for each HCPCS code it intends to bid, CMS will not be able to provide information regarding how many beneficiaries have been renting a hospital bed or have been on home oxygen therapy by the time the contract will begin. How then can any provider begin to intelligently calculate these additional costs into their bids? This becomes a huge liability to the providers where as in many cases by inheriting the Medicare beneficiary at a debt and the provider suffers significant losses in this types of scenario.

Quality Standards (§414.414)

One of the largest and yet to be resolved issues is the Quality Standards. While the proposed rule was officially published May 1, and CMS scheduled a meeting of the Program Advisory and Oversight Committee (PAOC) in late May, the final Quality Standards were not scheduled to be issued until sometime in June. Quality Standards are so integral to the implementation of competitive bidding that it is difficult to provide meaningful comments to the proposed rule while we are unaware of the content and requirements of the Quality Standards. Perhaps the one positive statement in the entire competitive bidding proposed rule is CMS's apparent attempt to make sure that Quality Standards are implemented at the same time as competitive bidding, and that providers in the initial bid geographic areas will be required to be accredited by an organization whose standards are determined by CMS to meet the CMS Quality Standards. But at another point in the proposed rule, CMS states that the

accreditation organizations will be able to grant providers in a bid area a grace period to become accredited within some unstated period of time. Now that's clarity.

Getting It Right Is More Important than Rushing Implementation

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

Have Accreditation and Standards in Place before Starting

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

Make Competitive Bidding Competitive, and Sustainable

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either. This portion of the rule is predicated on the illusion that some how the current fee schedules are adequate to sustain providers. In fact there are provisions in the rule that essentially require the provider to provide equipment to a patient that is brand specific if the physician so orders. If the CB providers bid was based on a relationship they have with a manufacturer for a specific brand then there will be a substantial burden on the provider to bear the cost of a specific brand. This will adversely impact the provider.

What is CMS proposing if a doctor writes a prescription for a brand name product that a provider is contractually unable to provide:

Examples:

A. A physician writes a prescription for a Hoverround power wheelchair. Hoverround is a manufacturer that follows a direct to consumer business model. The winning provider will not be able to supply a Hoverround product because Hoverround will not sell the product to the winning provider. What will be CMS's solution to this problem?

B. A physician writes a prescription for a portable concentrator. The manufacturer of the portable concentrator has a distribution contract with a non winning provider. In this case the winning provider will not be able to provide that equipment due to the contract. What will be CMS's solution to this problem?

If the physician writes a prescription for a product that the acquisition cost for the product is below the reimbursement for the product - what options does the provider have to substitute for the brand name?

Don't Make it Harder for Providers to Sell their Businesses

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS

should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Consider the Impact on the Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Impact Analysis

In this section, a number of statements appear to directly contradict other statements in this section and throughout the rule, particularly regarding the ability of smaller providers to successfully bid in the programs. While CMS continually alludes to the demonstration programs in Polk County and San Antonio, stating that small providers were able to successfully participate in those bids, CMS's impact statement says that this rule "will have a significant impact on a substantial number of small providers." Two pages later, CMS continues: "We anticipate that the bidding process will be designed to neither reward nor penalize small providers." In a similar vein, CMS states that "since providers can choose whether to submit a bid for the competitive bid program, the regulation imposes no direct cost." Sure, if you don't submit a bid you don't incur the costs of submitting a bid; but if you don't submit a bid you have eliminated all chances for becoming a winning provider. Furthermore CMS proposes to put into place a whole new bureaucracy in order to formulate, analyze and evaluate all the bids. What additional cost will this mean. Will there be any savings after that bill is paid?

CMS has published that they are expecting competitive bidding to provide a 20% cost savings based on the demonstration projects and that CMS feels that 20% cost savings is achievable. In this projection CMS has failed to consider the following:

A. Increase operational costs that have occurred since 2002:
   1. Gas
   2. Insurance- Liability, Auto, workers compensation, and Health insurance
   3. Personnel costs- Raises
   4. 2003 and 2004 CPI freezes
   5. The FEBHP allowable cuts that occurred Jan 1, 2005
   6. The general and administrative costs to administer the program

With the above mentioned increases and cuts, how is CMS calculating a 20% cost savings? We would like to see the projected cost savings example to verify the accuracy of CMS's prediction. CMS should be more concerned about providing an accurate savings prediction rather than a politically sensitive savings prediction.

Bullet Point Comments Regarding MSA Selection Criteria

Background Information

Section 1847(a)(3) of the Act allows CMS to exempt from the Medicare DMEPOS Competitive Bidding Program 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. CMS proposes to use this authority to exempt areas from competitive bidding if data for the areas indicate that they are not competitive based on a combination of the following indicators:

- Low utilization of items in terms of number of items and/or allowed charges for DMEPOS in the area relative to other similar geographic areas.
- Low number of suppliers of DMEPOS items subject to competitive bidding serving the area relative to other similar geographic areas; and/or

- Low number of Medicare FFS beneficiaries in the area relative to other similar geographic areas.

CMS proposes to make decisions regarding what constitutes low (non-competitive) levels of utilization, suppliers, and beneficiaries on the basis of our analysis of the data for allowed charges, allowed services for items that may be subject to competitive bidding, and the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas. In defining urban and rural areas, CMS proposes to use the definitions currently in §412.64(b)(1)(ii) of the regulations. CMS invites comments on the methodologies proposed for determining whether an area within an urban area that has a low population density is not competitive. CMS will be reviewing the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding. In addition, CMS also invites comments on standards for exempting particular rural areas from competitive bidding.

Comments:

1. Rural areas tend to be underserved under the present system. Providers routinely travel hundreds of miles to provide services in various areas of the country. Travel costs have never been covered by Medicare.

2. In certain areas of the country complex Rehab Technology services are available from only one or two providers for several hundred miles in any direction. Access is already compromised in many areas as a result.

3. CMS has no published criteria outlining the optimal number of providers serving a geographic area. Furthermore there is nothing to indicate once the winners are picked what time frame would be used to establish whether or not there are adequate providers to serve the CB area. The greatest fallacy in this is that once some of these suppliers are not the successful bidder it won't be long and they will be out of business. Then who would be called on to fill the void. There are no network adequacies standards what-so-ever for CMS to follow.

4. The proposed criteria to use a review of the total allowed charges, number of beneficiaries, and number of suppliers to determine whether a rural area should be exempted from competitive bidding is subjective at best.

5. The analysis of the number of Medicare FFS beneficiaries and DMEPOS suppliers in specific geographic areas may not reflect reality. This is due to the great distance that patients must travel to receive services in rural areas of the country. In addition discrimination is a problematic area, especially in remote areas with significant lower income populations where beneficiaries already have limited access to services due to significant transportation issues. Rural areas tend to have a greater percentage of elderly population compared to urban areas, and these areas already suffer from a primary care physician shortage.

Submitter : **Ms. Claudia O'Neill** **Date: 06/29/2006**

Organization : **Home Medix, Inc**

Category : **Health Care Industry**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I have found that the most troubling aspect of the NPRM is its persistent direct contradiction of CMS's stated goals. You must realize that tens of million of Medicare beneficiarites are going to be placed at risk and many will incure direct and specific injury or loss due to implementation of policy that is in direct contradiction of CMS's stated goals. Enclosed you will find my attachment addressing all matters of concern:
Sincerely
Claudia K O'Neill, Operations Manager
Home Medix, Inc.

CMS-1270-P-908-Attach-1.DOC

CMS-1270-P-908-Attach-2.TXT

Supplier Standards and DRA Implementation
Prior to implementing competitive bidding, CMS should:

1. Issue an interim final rule to allow additional stakeholder comments.
2. Because the NPRM raises more questions than it answers, does not identify the markets, the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Opportunity to Comment on the Supplier Standards
CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized.

1. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards.
2. Since the final standards will likely differ significantly from the draft under principles of administrative law, CMS must give stakeholders another comment period.
3. Additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.
4. CMS should schedule a PAOC meeting after it publishes the standards.
5. AAHomecare strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited.
6. It is also critical that final supplier standards apply to any supplier desiring to submit a bid.
7. By allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental.
8. CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Timeline
CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. CMS needs to adopt a realistic timeline and not rush through the process. The remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSA
- Payment Basis

Inflation Update
CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Problem area with this are listed below

1. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year.
2. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U.
3. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage
The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare.

1. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier.
2. What rules will apply to this patient population under competitive bidding?
3. Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program?
4. I recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers
The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to

furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. **CMS states that suppliers must factor these additional costs into their bids**.

1. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment.
2. CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item.
3. This artificial ceiling on the bids further complicates bidding under this scenario.
4. I appreciate CMS' desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program.
5. I recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients
Will the "grandfathered" relationship terminate at the conclusion of 36 months? The implementation of the DRA forced ownership provisions on oxygen and capped rental equipment have important ramifications for competitive bidding. How can we provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. CMS needs to publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas
CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

Limitation on Beneficiary Liability
We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation
CMS should phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

Nationwide or Regional Mail Order Competitive Bidding Program
Why has CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. What are the definition for a "mail order" supplier under Medicare program rules. Many suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. Due to this reason who would qualify to participate in a national competition for mail order supplies.

Establishing the Competitive Bidding Area
CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established in an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Criteria for Item Selection

Items Included in Competitive Bidding
CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" as defined under §1834a(13) for which payment would otherwise be made under §1834(a) and "supplies used in conjunction with durable medical equipment;" enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings
CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- Annual Medicare DMEPOS allowed charges: Is there a threshold expenditure level that will trigger CA for a product category?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- Number of suppliers: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- Savings in DMEPOS demonstrations: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- Reports & studies: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Additional Criteria for Item Selection
Under the current proposal item selection is driven by costs and utilization only. What about the risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. Has CMS consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

Brand-Specific Requirements

This is not necessary for CMS include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising. Physicians often are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. CMS should not include this provision in the final rule.

Coding Issues and Item Selection
The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS.

Product Categories for Bidding Purposes

General Issues
Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids

Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category
Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic.

Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Quality Standards and Accreditation
The overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, only accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

Evaluation of the supplier's financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount.

CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during the PAOC meeting so that CMS

Market and Supplier Capacity
CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

Assurance of Savings
CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA. The payment amount should be at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category.

Rebate Program
CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

Bulletin at 1.

The supplier could not pick and choose which beneficiaries would get a rebate as a way of enticing desirable patient populations. For example, the supplier could not offer the rebate only to patients with a specific chronic diagnosis requiring long-

Bulletin at 5 (Emphasis supplied).

This type of activity distorts patient decision making and undermines true competition among health care providers. Importantly, the rebate program would promote exactly what Congress chose to prohibit when it enacted prohibitions on beneficiary inducements under §1128A(a)(5) - competing for business by offering Medicare beneficiaries remuneration. Consequently CMS should withdraw the proposal.

Terms of Contract

Repair or Replacement of Equipment
CMS should allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB.

Termination of Contract
CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

Judicial and Administrative Remedies
CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership
It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owners on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and confirm to other requirements of competitive bidding.

Participation of Small Suppliers
CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

Getting It Right Is More Important than Rushing Implementation

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

Have Accreditation and Standards in Place before Starting

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

Make Competitive Bidding Competitive, and Sustainable

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

Don't Make it Harder for Providers to Sell their Businesses

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Consider the Impact on the Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

"Composite Score" Methodology

CMS should make clear that it will provide suppliers with the weighting factors that CMS will use to evaluate the bids in each MSA so that suppliers are able to determine how best to bid each HCPCS within a category using the same criteria as CMS.

Rebates

There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute.

Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay.

The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

CMS said the rebates would allow providers to be "more competitive", but PAOC member Dave Kazynski, president of VGM's Homelink, noted that beneficiaries are mainly concerned about quality, not a small rebate.

Product Selection

CMS does not specify what products will be put up for bid, but it does say that selection will be based on potential savings. The agency will begin with items that have the highest volume and highest cost. The rule also proposes grouping similar items into product categories, such as hospital beds and accessories, so that beneficiaries would be able to get all related items in that category from one supplier. Suppliers will then be required to submit a bid for all items included in any product category.

A competitive bidding product group may include products (and more specifically HCPCS codes) from multiple medical policies. The intent of the law is to exclude products where bidding would affect access or quality, but this protection is lost if medical policies are combined. In order to ensure quality of care, CMS should ensure that providers that specialize in specific conditions are able to bid.

If medical policies are combined, then the only providers eligible to bid would be those that carry the broadest product offering, regardless of their expertise.

The Bid Process

Suppliers cannot bid higher than the current fee schedule amount, even if they incur additional administrative or operational costs serve the competitive acquisition area, The proposal's use of "capacity" is non-specific & variable. Utilization can change, e.g., patients moving in & out of HMOs. While the demonstrations used the median of all bids to determine the single price, the proposed rule uses only the capacity concept.

Determination of Number of Suppliers

CMS' process to determine the number of suppliers to meet projected demand in a MSA and its methodology to estimate supplier capacity are stacked in favor of large, high volume regional suppliers despite CMS' assertion that the NPRM provides opportunity for small suppliers to participate. Moreover, there are no guarantees that any of the winning bidders is a small business or a network of small businesses.

CMS needs to consider the negative impact the NPRM will have on small DME businesses and on the competitiveness of the second and third rounds of competitive bidding.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses.

Clarification of "Competitive" and Potential Savings

CMS should explain and clarify what methodology will be used to determine whether a MSA is "competitive" during the 2008 - 2009 expansion.

CMS should explain and clarify what specific measures will be used to decide whether an item's potential savings as a result of competitive bidding?

- Annual Medicare DMEPOS allowed charges: Is there a threshold expenditure level that will trigger CA for a product category?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- Number of suppliers: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?

- Savings in DMEPOS demonstrations: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- Reports & studies: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Gap Filling

The issues of Gap Filling should be addressed in a separate NPRM and/or special competitive acquisition process.

The three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. In addition, none of the methodologies appear to involve the manufacturer and his/her health economic or other support data. Rather, functional and medical benefit assessments would be conducted by CMS contractors who may or may not have expertise in the technology/therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer in the process.

Networks & Sub-contractors

If the network utilizes an "administrative entity" to be responsible for billing Medicare, receiving payment on behalf of the network suppliers, and for appropriately distributing reimbursements to the other network members, is this entity required to be accredited? What if this legal entity ensures its provider network members are appropriately accredited? What is the accreditation process?

Can a sub-contractor / provider submit a bid and be a sub-contractor in another product category?
Can a provider whom submits a bid and loses then become a sub-contractor?

Comments on "Regulatory Impact Analysis"

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 these figures 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?

On this point, we ask that CMS concur in the general understanding that any potential product cost savings gained through National Competitive Bidding for DMEPOS---including oxygen, wheelchairs, beds, respiratory equipment, wound care, diabetic supplies etc.---will ultimately be offset by increased costs in both the tertiary inpatient and outpatient care settings.

As the experience of DMEPOS providers demonstrates, these costs are recognized through increased administrative, oversight and program management expense, and often prevent patients from getting the most efficient and optimal health care available.

RECOMMENDATIONS: CMS should stagger the bidding in MSAs in 2007 to allow for an orderly rollout of the program. This will actually allow CMS to identify problems that occur in the competitive bid areas and to work with providers and patients alike to help correct them before the problems become even more widespread.

The initial MSA's and products selected should be clearly and distinctly identified in the final rule. Unfortunately however, under the current proposed CMS timeline, it appears that small DMEPOS providers will not have enough time to create legitimate and functional networks, which will ultimately eliminate "small" DMEPOS providers that want to participate, regardless of their industry knowledge, experience, and/or specialized expertise

We would urge that CMS consider the significant and potential negative impact that the NPRM may/will ultimately have on small DME businesses and upon the actual, "true" competitiveness of the second and third rounds of the competitive bidding process.

CMS should consult with the Small Business Administration to better assess the impact the NPRM will have on small businesses as both tax-paying members and constituents of the communities that they serve.

CMS should further explain and clarify the specific methodology that will be used to determine whether an MSA is "competitive" during the 2008 - 2009 bid expansion process.

CMS Bid scoring still needs to be better, and more clearly defined. Suppliers need to know exactly what factors are/will be utilized and what weights will be given to these factors, especially if/when providers are attempting to bid subsets of a major product category.

CMS should explain and clarify what specific measures will be used to decide and how much an item's potential savings could be as a result of competitive bidding.

QUESTIONS:

1. Annual Medicare DMEPOS allowed charges - Is there a specific volume/quantity, or simply a dollar threshold expenditure level that will trigger "competitive acquisition" for a particular product and/or product category? Alternatively, is there a specific threshold growth percentage in a product category that will determine whether it will be subject to competitive acquisition and/or will it vary by the overall dollar expenditures within the product category?
2. How will CMS determine the appropriate number of suppliers for a product category in each MSA? What specific supplier capacity thresholds will be used to determine this and how will those "capacity" thresholds be specifically determined?
3. How will potential "cost savings" through Competitive Acquisition be statistically determined and/or validated by actual data for the vast majority of products and categories that were not included in the two initial Demonstration Projects in FL and TX? What reports and/or types of data will be reviewed and considered when evaluating potential cost-savings? Who (either within or outside of CMS) will review the studies and determine their actual statistical validity and applicability for modeling potential future Medicare program savings?

Lack of Established Quality Standards and/or qualified "Accrediting Bodies"

Providers must meet "quality standards," yet the proposed "final" version of the DMEPOS provider quality standards have not yet been released. It is, therefore, difficult at best, if not impossible, to fully articulate and provide clear comments on these proposed rules for competitive biding when these rules refer to quality standards that have not been fully defined and released.

CMS should not proceed with competitive bidding until it is certain that this is possible. CMS needs to clearly identify and establish both the objective and subjective criteria that it will use to identify and deem the accrediting bodies now, before proceeding with trying to implement the actual competitive acquisition processes.

Accreditation is and should be required for any provider to service patients under the proposed rules, but again, no final, specific accreditation standards and criteria and/or approved accrediting bodies have yet been clearly identified. The proposed rule appears to still allow non-accredited organizations to bid and be awarded a bid prior to being accredited.

It remains unknown if any of the accreditation bodies will even be interested and/or have the functional accrediting capacity to undertake the standards and criteria which are yet to be specifically defined and established by this proposed rule. Therefore, accreditation organizations, as well as the associated standards, should be in place prior to any further movement towards any competitive bid. Only providers that have attained accreditation should be allowed to bid or be awarded any bid. Patient safety and care dictates that providers should not be awarded a bid and be able to provide equipment and supplies without first demonstrating competency and proficiency in this area.

CMS should however, grandfather any/all providers that are already accredited by organizations that meet the new criteria that CMS identifies. However, CMS should then allow additional time for providers to analyze the quality standards in conjunction with the overall NPRM rule.

FUNDAMENTAL ISSUES: The potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs"

out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum.

REBATE COMMENTS/ISSUES:

We believe that the potential use of "rebates" to beneficiaries in health care delivery is ultimately an unwise, and potentially fraud-encouraging concept that is without clear or reasonable legal precedent. The provision of rebates to beneficiaries is actually contradictory to other laws and regulations applicable to the Medicare program, including the Anti-Kickback Statute and the beneficiary inducement statute.

We therefore strongly encourage the elimination of this proposed "rebate" provision. It is fairly certain that Congress did not intend competitive biding to include cash rebates to consumers with the potential of increasing unnecessary product utilization. We question as to whether this feature is consistent with the law.

RECOMMENDATION: The actual items that will be put up for bid should be identified now to solicit and allow further provider-based discussions and comments. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities, could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home is not only dangerous from a patient safety perspective, but extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care.

The bid process needs to allow for economically realistic and sustainable bids, rather than simply encouraging "lower priced" bids.

A statistically valid and accurate screening mechanism needs to be developed to completely remove and eliminate unreasonably low and ultimately unsustainable bids. The proposed rule appears to have a loophole where bidders can "low ball" their bid to grantee inclusion, yet not have to honor that "low ball" bid as their actual price paid. The use of statistical models to prevent this situation should be clearly established, defined and implemented prior to the actual biding process.

The determination of supplier's potential service capacity also needs to be better defined. It is still somewhat unclear exactly how CMS will determine a supplier's potential capacity. The proposed rule appears to discriminate and favor the large, regional providers, while the small and medium providers will effectively be shut out of the bidding process as it is currently proposed.

What economic provider relief is being considered for other areas of the healthcare continuum that will ultimately be exposed to increased costs and administrative burdens posed by NCB? Since none of these impacts were apparently evaluated or studied during the demonstration projects, there is certainly additional potential negative care and cost implications that will likely be the result of the implementation of widespread NCB.

To rapidly facilitate acute-care inpatient and/or outpatient facility discharges, the implementation of an NCB mandate has the potential to disadvantage patients within physicians networks, hospitals, integrated healthcare delivery systems, home health, hospice, outpatient and long term care settings who will simply have to employ detrimental cost-shifting.

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

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

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

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

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

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

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

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

Not enforcing this policy will produce bidders who do not understand the cost of such quality standards and are therefore incapable of accurately factoring them into a bid price.

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

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

CMS's stated goal is to deal with financially stable companies but this policy will result in the opposite effect, namely:
a) Creating financially unstable companies and
b) Make it impossible for firms to produce a bid that covers the cost of transitioning patients since the winning bidders have no control over how the loosing bidders choose to conduct, or not conduct, their business.

6. Price Fixing = Non-competitive Bidding:
If CMS wants market dynamics to set prices then why does it mandate price caps? This CMS policy is diametrically opposed to its stated goal of achieving market dynamics.

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

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

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

Submitter : **Dr. Marc Leonard** **Date: 06/29/2006**

Organization : **Midstate Podiatry Associates Ltd**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Attention: Mark McClellan, MD, PhD Re: CMS1270-P
I request the Center for Medicare and Medicaid Studies modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment and supply items to my patients only. If I am instead required to bid to supply an entire Metropolitan Statistical Area, my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

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

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

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

Sincerely,
Marc Leonard, D.P.M.

Submitter : Dr. George Andros

Date: 06/29/2006

Organization : Los Angeles Vascular Specialists

Category : Physician

Issue Areas/Comments

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

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

Via email: http://www.cms.hhs.gov/eRulemaking

To Whom It May Concern:

It has come to my attention that CMS is planning to establish a policy of competitive bidding for Negative Pressure Wound Therapy (NPWT) Devices. I wish to comment on the criteria that must be met to qualify as a successful bidder.

I am a vascular surgeon working in a large vascular referral center in Los Angeles, CA. In our practice we care for large numbers of patients with venous ulceration and gangrenous extremities that require vascular intervention on the arterial and venous systems. Once the circulation has been restored, we are also responsible for the care of complex wounds involving the foot, ankle and leg.

Having done this sort of work for nearly four decades, several lessons have emerged. First, care for these complex patients is a team effort requiring the assistance of vascular surgeons, plastic surgeons, podiatrists, infectious disease specialists and others. Multiple modalities of treatment are often needed on a single patient. Education of the team and the patients enables wounds to heal more quickly and stay healed.

Of the major advances in wound care in the last ten years, nothing compares, in my opinion, with Negative Pressure Wound Therapy as provided by the VAC therapy device (KCI, San Antonio, TX) . At any given time in our institution we have between five and fifteen patients with complex wounds receiving VAC therapy. This device improves the quality of nursing care, shortens the time to healing, relieves pain, and has high acceptance by patients and treating doctors. Countless lives and limbs around the country have been saved by the development of the VAC system.

Our large diabetic population here in Southern California inevitably results in the occurrence of ten to fifteen new diabetic foot ulcer patients every month. Fortunately, not all of them have large, complex wounds, but those who do invariably have their healing time shortened and their results improved by VAC therapy. Just last week and elderly woman with a 6 x 6 x 1.5 inch ulcer over her right knee received outpatient VAC therapy for six weeks. Her only hospitalizations were for two debridements and a skin graft. The excellent final result that she achieved would have taken considerably longer, and possibly never occurred, had she not been able to have VAC therapy. Indispensable to her care was the teaching and support provided by the VAC therapy clinical consultants from KCI. Like the medical wound care team, VAC therapy is backed up by a team as well.

I do not believe that competitive bidding will achieve all of the objectives of CMS. Certainly, you may find a less expensive product than VAC therapy, but there is nothing comparable to it for the care of wounds. You must be cautious in allowing bidders to describe themselves as "just like the VAC" when there are no clinical data, no research data, and no well established systems for providing VAC therapy inclusive of education , and inpatient and outpatient support systems. The only data with clinical validity for Negative Pressure Wound Therapy are with the VAC system from KCI . Until a reliable body of data is available regarding comparable outcomes, length of stays, cost, as well as fundamental research on mechanism of action, complications, and clearly delineated indications, competitive bidding will not be possible.

It would be regrettable that this great advance in wound care would become unavailable to needy patients in the name of "competitive bidding" when there are no truly competitive products available.

Sincerely,

George Andros, M.D.
Contact information

Submitter : **Mr. Thomas Cronin** **Date: 06/29/2006**

Organization : **Neighborhood Diabetes**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-911-Attach-1.DOC

NEIGHBORHOOD Diabetes
Helping to Make a Difference™

Submitter: Thomas Cronin
Title: Chief Executive Officer
Organization: Neighborhood Diabetes
Category: Durable Medical Equipment Supplier
Reference CMS 1270-P
Issue/Areas for Comment: General

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

To whom it may concern:

Neighborhood Diabetes is a small business with about 50 employees that provides supplies for Self Monitoring of Blood Glucose (SMBG) to approximately 20,000 clients in the Boston area.

The large majority of our clients are covered by Medicare. Unlike other Medicare DME diabetes suppliers whose business model depends on consumer advertising to attract new clients, Neighborhood Diabetes receives its referrals from clinicians, over 1,500 of whom provided us with a referral over the last twelve months. These clinicians vary from nurse practitioners at overwhelmed urban health clinics to endocrinologists at Boston teaching hospitals such as Massachusetts General Hospital.

Our clinicians provide us with referrals because we offer services that help make their patients healthier. These services include: Home visits to new clients to ensure that they are properly trained on their glucose testing equipment in a comfortable environment, home delivery of testing supplies and prescription medications, live people answering the phone, creation of support literature to ensure that common barriers to glucose testing are overcome, and targeted follow-up calls geared toward ensuring not only that clients test their blood sugar, but that they obtain ADA recommended laboratory tests and physician visits as well. We perform these services in the client's native language. Our staff includes native speakers of English, Spanish, Portuguese, Haitian Creole, Khmer and Vietnamese.

Diabetes is different from other conditions because of the chronic nature of the disease, the number of people affected, and the important role that self-care plays in limiting downstream complications. Data clearly shows that better

adherence to self-monitoring of blood glucose levels significantly improves quality of life and decreases the cases of complications related to diabetes. In addition to providing our clients with their testing supplies, Neighborhood Diabetes has taken on the responsibility of educating and supporting them in order to achieve better adherence to their testing regimens. Taking this extra step is expensive for us, but it has proven to be a successful educational supplement to what our clients are learning from their clinician. Compared to significant studies, our clients' adherence levels are far better than the average US diabetic population. (For instance, we did a study which found that 74% of our non-insulin dependent Type II diabetics regularly check their blood sugar, as opposed to 39% that were identified in a study[1] of insureds at Kaiser-Permanente of Northern California) .

My concerns with the proposed new rules can be summarized as follows:

Competitive Bidding on diabetes supplies will not save money in the long run:
Implementing a competitive bidding program for diabetes supplies will lead to a 'penny wise and pound foolish' situation. The ripple of short term cost savings from the program will be dwarfed by the tidal wave of costs that will come from diabetic complications suffered by Medicare participants who are not trained sufficiently or face language issues that leave them unable to adhere to their recommended treatment regimen. These complications include very expensive conditions such as heart disease, hypertension, neuropathy, retinopathy, and other conditions. A recent study[2] showed the following:

Average annual healthcare cost for a non-diabetic insured: $2,560

Average annual healthcare cost for a diabetic insured: $14,233

Average annual healthcare cost for a diabetic insured with heart disease and an HbA1c > 10.0 : $46,879

Annual cost blood glucose testing supplies cost (est.) [3] ~$500

Using this data, if the changes caused by Competitive Bidding lead to even a 1% increase in the development of complications such as heart disease among insureds, the cost increase would be $326 per insured (($46,879-$14,233)*.01). This amounts to over sixty percent of the amount paid per year for supplies. Is it possible that being served by the lowest bidder (or a low bidder) as opposed to a company like Neighborhood Diabetes could lead to 1% of the insured population 'veering off track' from their glucose testing regimen and suffering these complications? Based upon our experience we would say "Absolutely". Is there any way that the competitive bidding program will save sixty percent of

annual blood glucose testing supply costs? We would say "Absolutely not". Will this program be cash positive for the Medicare program? Again, we would say "Absolutely not".

Competitive Bidding is inequitable to Small Businesses

Clients and health care providers alike agree that Neighborhood Diabetes provides extraordinary service to diabetes patients. With this service level and our additional educational and support efforts, we have consistently helped to make our clients healthier. Our hard work over the years has built a strong business with 20,000 clients. The efforts we have made to build a company based on 'making a difference' to patients should be rewarded, not potentially cast aside by a new set of rules from Washington.

If competitive bidding in diabetes were to take place in our market, we would essentially lose our entire client base. This is patently unfair to small, regional, single product line companies like ours. Unlike the 'national' companies in our business, we can not bid for contracts in several markets, offering a variety of prices in the hopes of winning some or all of them. To make small firms like ours essentially 'bet the company' on a single bid for our local area puts us at a significant disadvantage to larger concerns. Again, this is just not fair to small businesses.

Competitive Bidding will be bad for Patient Health

As I mentioned in my first point, having potentially low-cost providers offering generic glucose testing equipment and little training or support to patients would actually lead to higher long-term costs for the Medicare Program. This wouldn't just be bad for the program, it would be very bad for the patients covered by Medicare.

In the current reimbursement environment, Medicare suppliers of diabetes testing equipment such as Neighborhood Diabetes compete for clients based on the level of service they provide, rather than price (since the price is set by Medicare). Overall, this leads to better-educated patients, who receive information and training from their suppliers that supplements information received from sometimes overwhelmed clinicians, who face continuously declining reimbursable time with their patients.

To self monitor their blood glucose, seniors who often have difficulty seeing, hearing, or understanding English are being asked to use complex technological devices that are foreign to them. A company that has had to submit a competitive bid will have an incentive to provide the lowest cost product in the most efficient possible manner. We believe this will 'leave behind' Medicare participants who need the type of support or special products we routinely provide. For instance, one of the elements of service that

our company takes great pride in is offering a client the glucose monitoring system that best fits the client's needs. We have products that are best for clients with dexterity issues, vision problems, and those for whom 'coding' a glucometer is difficult. In a 'provide a meter at the lowest possible cost' environment, with a limited number of suppliers to turn to, these Medicare patients will have more difficulty getting the meter and training they need to adhere to their treatment regimen, and could develop the terrible complications that diabetes routinely causes, such as heart disease, blindness, foot amputations and the like. The New York Times and other publications have described diabetes as an "epidemic" in the United States today. For CMS to consider instituting a competitive bidding program that could lead to more suffering for the victims of this epidemic, is, I believe, reprehensible.

Footnotes:

1) Karter, AJ et al, *American Journal of Medicine*, Volume 111, July 2001
2) Gilmer, TP et al, *Diabetes Care*, Jan 2005, 28(1): 59-64
3) Neighborhood Diabetes estimate

NEIGHBORHOOD Diabetes
Helping to Make a Difference™

Following are a few of the testimonials that Neighborhood Diabetes has received concerning its services:

"My staff and I at the Massachusetts General Hospital Healthcare Center in Revere have utilized the programs and services offered by Neighborhood Diabetes. The feedback received from our patients has been extraordinary. My staff has been able to take advantage of a service that is an intangible asset, the home delivery and in-service training. Their unique services allow my staff to spend more quality time with our patients. The courtesy, professionalism, and knowledge of glucose monitors offered by ND gives our staff the utmost confidence in referring our patients to them for diabetic testing supplies. The customer service exhibited by ND is proof positive that they are truly caring and cognizant of their client's needs. The attention to detail, prompt, accurate, and precise customer service makes ND the most competent diabetes equipment provider. Neither my staff nor I would even think of referring our current or newly diagnosed diabetics to any other company than ND. Another wonderful feature that my patients have commented on is their ongoing telephone follow-up. This feature allows my patients to troubleshoot their monitor questions and avoid running out of testing supplies. The bottom line is that my patients do not feel 'lost' using ND. There are no voice-recorded messages when calling the office, you get answers immediately and my patients have developed a trust with ND."

Pat Roberge, LPN, *Massachusetts General Hospital - Revere*, Revere, MA

"They (ND) have been exemplary in their care of diabetic patients including in-home training and routine follow up and this has been unmatched by any of our other suppliers. The personal attention that they give patients helps to improve their heath and makes it more efficacious for us to treat patients in an excellent manner."

Dr. Eric Schreiber, Endocrinologist, *Riverside Healthcare Associates*, Medford, MA

"I just wanted to thank you for being so reliable, honest and consistent. I have never gotten one negative report from any of the clients I have referred to your agency. Only the following actual comments from my clients, heard on several occasions:

You get to talk to a real person.
Those boys were so patient with me.
I call them all the time because I forget how to use my machine but they keep helping.
I never run out of test things any more because they call me.

Thank you for making a difference in the lives of elders, and continuing to find new ways to accommodate and serve them as well as you do. Even after your expansion, you managed to offer the same quality customer service and you

are setting a fine example for other growing small businesses to live up to. IMPRESSIVE!"

Melissa Manderson, Diabetic Care Case Manager, *SeniorCare, Inc.*, Gloucester, MA

"They (ND) will not only deliver diabetes product supplies in a timely manner but will educate clients on the use of the diabetes related equipment. They will actually visit the home of a client to demonstrate on the use of a meter. . . . It is most refreshing to have a local company, which offers personal care with unprecedented service."

Andrea Penney, RN/CDE, *Joslin Diabetes Center - Anna Jaques Hospital*, Newburyport, MA

"I am writing to sing the praises of Neighborhood Diabetes. They have been wonderful to work with. They are a class act that follows up on their word, a rarity in this present age. Our patients are very grateful for the personal care that they receive from ND, who go to the patient's home and give follow up calls. When we refer to ND I know that the patient will receive excellent care and quality products."

Nancy Perrault, RN,CCM, *South Shore Medical Center*, Norwell, MA

"In my thirty years as a healthcare provider, I can't top the service that this provider has supplied to us and our patients."

Margaret Davis, MS, RD, LDN, FADA, CDE, *Live Nutrition*, Brewster, MA

"I often recommend my clients contact Neighborhood for their diabetes supplies. I have used their services for about two years now and I have no complaints whatsoever about their service. They are responsible, courteous, and best of all, they are the only company I know that sends someone to the client's home to teach them how to use a meter. You can't imagine how valuable a service that is. Not only do they help the client, but they also help the nurses and the diabetes educator in the meter teaching process. As you may know, we have a shortage of time to spend with our clients, and sometimes do a quick review on how to use a meter, or sometimes don't even have time for a review. A quick phone call to Neighborhood enrolling the client with their services and making sure they review the meter usage with the client is a lifesaver."

Virginia Hernandez, RN, BSN, CDE, *Diabetes Management Center*, Dartmouth, MA

Submitter : **Mrs. Stacey Doyon** **Date: 06/29/2006**

Organization : **Mrs. Stacey Doyon**

Category : **Occupational Therapist**

Issue Areas/Comments

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

To: Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P
Date: 6-28-06

I am writing this letter in regards to the Medicare proposed rule on competitive bidding systems. As an occupational therapist and certified hand therapist I have the knowledge and expertise in providing the right type of splint for the injury and how to fit them properly. The basic level of knowledge for an Occupational Therapist is at least 4 years of college with education in regards to disease process, ergonomics, body mechanics, anatomy, physiology, neurology, kinesiology, etc. It is imperative that we have an education in these areas in order to supply the proper splint and then to fit it properly. When fitting a splint one needs to be concerned with the type of splint that is most appropriate for the injury. For a hand splint this would include whether they are hand based, crossing the wrist, or if the thumb need to be included. Fitting them properly may include making sure there is plenty of room for fingers to move (distal palmar crease is free) and that if the wrist is included that it is two thirds the length of the forearm so the weight of the hand doesn t make the splint push on the forearm.

Many independent DME providers are not educated in these areas and do not have knowledge of how to properly fit the splint, how often the patient should wear it and what type of splint would be best. Often I have seen even simple wrist cock up splints be to short for my patients which ultimately causes forearm pain or they needed to have the thumb included and it was not provided. The other thing I have seen is not properly fitting a splint to someone that has a very skinny wrist but larger forearm. They often fit the forearm portion and then the wrist is too big and does not get properly supported.

So, with your program in effect the care the patient receives may be both inefficient and ineffective. A possible scenario would be that the patient will see the therapist to determine what type of splint is appropriate, then go purchase a splint, return to the therapist a second time to make sure it is the correct splint and that it fits properly and to be provided with the appropriate wearing schedule. If it is the wrong splint then the process starts all over again, however another splint now has to be purchased. So besides the extra cost of the new splint, the patient has now waited several weeks to get the appropriate splint. Although waiting would not be a problem for someone with a chronic condition, it would be intolerable to someone with an acute flare of tenosynovitis, a wrist sprain or other acute condition. This obviously interferes with the patient s continuity of care.

I am hoping you will reconsider your position on this competitive bidding process and see that Occupational and Physical therapists should be exempt from this ruling.

Thank you for your time and consideration in this matter.

Sincerely,

Stacey L. Doyon, OTR/L, CHT
207-828-2121
sdoyon@orthoassociates.com

Submitter : Ms. Virginia Willette-Green **Date:** 06/29/2006

Organization : Traverse Bay Hand Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

I am against the use of a competitive bidding system for prefabricated orthoses. I have been an Occupational Therapist for over 28 years, specializing in Hand Therapy all of that time. I have seen many prefabricated and custom splints. Fitting a splint and choosing a design, whether it is prefabricated or custom made, is an important part of using splints for patient care. An ill-fitting splint, or a splint immobilizing, or allowing mobility of the wrong joints is poor care at best and a cause for a lower functional outcome at worst. Having splints competitively bid encourages use of the least expensive product with the least overhead towards service(fitting). We have all seen a cheaper version of nearly every product. That is not the product I would necessarily want to provide good care for my patient in that less has gone into the design and the materials. If a single product wins a bidding, chances are high that it will be of inferior quality and there will not be the opportunity to fit an individual with the design that best fits her. The smallest size in some designs will fit a petite person, others will not. Not all prefab wrist splints are equal. Not all of any kind of splint are equal.

Submitter : Dr. K. D. Brock **Date:** 06/29/2006

Organization : Midstate Podiatry Associats, Ltd.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

To: Dr. Mark McClellan: Concerning CMS-1270-P, I request that the Center for Medicare & Medicaid Studies modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment and supplies to my patients only. If I am instead required to bid to supply an entire Metropolitan Statistical Area, my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide. This would result in inconvenience to my patients, with additional time and travel involved to obtain the necesssary items. This would prevent me from providing my patients with medically necessary treatment in a timely fashion.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

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

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

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

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

Sincerely,

K. D. Brock, D.P.M., MIDSTATE PODIATRY ASSOCIATES, LTD.

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

Organization : **Arizona Medical Equipment Suppliers Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-915-Attach-1.DOC

Comments from The Arizona Medical Equipment Suppliers Association (AZMESA) on Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition CMS file code CMS-1270-P

Competitive Bidding Implementation Timeline

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to not rush to meet deadlines that are realistic. The remaining steps include: Publication of the supplier standards; Selection of who will be the accrediting bodies; Publication of interim final and final regulations; Publication of the initial 10 MSAs and product categories; Publication of the RFB; Evaluation of bids and selection of contract suppliers; Education of beneficiaries and referral sources; Implementation within each MSA.

Supplier Standards are Not Finalized

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. Due to all the comments CMS received on the draft supplier standards, most likely the final standards will differ significantly from the draft. If so, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

AZMESA has always supported a requirement that all suppliers billing the Medicare program for DMEPOS must meet standards to protect the beneficiary. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. CMS should not rush to implement the quality standards or any other aspect of competitive bidding.

Quality Standards and Accreditation

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

Implementation of Competitive Bidding

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

AZMESA
10480 Perkins Avenue North, Stillwater, MN 55082
Ph: 651-439-2944 **Fax:** 651-351-0391
Email: ArizonaMESA@aol.com

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule.

Grandfathering

The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

In addition, it is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months?

Adjusting Payment

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived form competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under §1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

Inflation

CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Limitation on Beneficiary Liability

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding

program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a "mail order" supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are unsure who would qualify to participate in a national competition for mail order supplies.

There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

CMS should publish an interim final rule to solicit additional public comment before implementing a national or regional competitive bidding program.

Items Included in Competitive Bidding

CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" *as defined under §1834a(13)* for which payment would otherwise be made under §1834(a) *and "supplies used in conjunction with durable medical equipment;"* enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Item Selection

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

Brand-Name Items

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

We believe it is unnecessary for CMS include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Further the proposal is contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. Inasmuch as CMS' authority to implement this requirement is discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

Coding Issues and Item Selection

The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed.

Product Categories

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries.

Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space.

In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.

- Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.
- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Number of Suppliers

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

Rebate Program

The NPRM describes a rebate program that allows contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

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

Repair or Replacement of Equipment

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the competitive bidding program. We recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation

for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract supplier's bid, depending on the payment methodology CMS adopts in the final rule.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

Submitter : Ms. Mimi Rowlette **Date:** 06/29/2006

Organization : Turnare, Ltd.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

We would like to express a number of concerns related to the NPRM on Competitive Acquistition involving the overall time line, grandfathering the Medicare Advantage, staggered implementation of the 10 MSAs, inclusion of mailorder suppliers, and many additional complicated factors. The number of suppliers slated for competition within a specific category of service, and several additional areas for consideration in determining the awarding for competitive contracts. Please read the attached document for our full comment declaration. Thank you.

CMS-1270-P-916-Attach-1.PDF

CMS-1270-P-916-Attach-2.PDF

Comments on the Notice of Proposed Rulemaking (NPRM) on Competitive Acquisition

Timing Concerns

Supplier Standards and Deficit Reduction Act Implementation
Because of the impact that the implementation of the Deficit Reduction Act of 2005 will have on competitive bidding, the information in the NPRM is inadequate to serve as a basis for public comments. Before implementing competitive bidding, we recommend that CMS issue an interim final rule to allow additional stakeholder comments.

Because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, we advise that CMS also allow adequate time to schedule a meeting of the Program Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will allow CMS to have industry input one more time before publishing a final rule and implementing the program.

Opportunity to Comment on the Supplier Standards
All interested parties must have an opportunity to comment on the quality standards before they are finalized. Our understanding is that CMS received comments from more than 5600 organizations and individuals on the draft supplier standards, and it is anticipated that the final standards will differ significantly from the draft. If so, under principles of administrative law, CMS has an obligation to give stakeholders another comment period.

Moreover, an additional comment period is essential because CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rule-making process applicable to the quality standards.

It is extremely important that final supplier standards apply to every supplier desiring to submit a bid. Allowing an additional comment period is unlikely to have a substantial impact on the overall implementation time-line. Competitive bidding is a radical departure from traditional Medicare and this program is still largely experimental; consequently, we think that CMS should consent to reasonable delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Time-line
It is crucial that CMS establish an implementation time-line that identifies all steps leading up to competitive bidding. Given the number of steps that must be commenced and completed, however, we ask that CMS adopt a realistic time-line and not rush through the process. Some of the remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSAs

Payment Basis

Inflation Update
CMS says that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U, but providers have no promise that Congress will not override the update through subsequent legislation in any given year. CMS must make certain that the inflation update to the competitive bid prices will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this guarantee, then the only appropriate course of action is to instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage
The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to re-enter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they re-enter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing providers under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers

The NPRM says that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program; we do, however, strongly recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of DRA to Oxygen Patients

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

Authority to Adjust Payment in Other Areas

In implementing its authority under 1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived from competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under 1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rule-making to solicit comments on a specific proposal before implementing this authority in a final rule.

Limitation on Beneficiary Liability

Our understanding is that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS must clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs; we also *strongly recommend* that select only one MSA per state when implementing the first 10. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread; selecting only one MSA per state will also minimize negative impacts on beneficiaries in each state – especially those states with higher beneficiary populations – until problems can be solved.

Nationwide or Regional Mail Order Competitive Bidding Program

We are uncertain as to why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009; a separate program for them in 2010 is completely unnecessary. In addition, there is no definition for a mail order supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes.

There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed might change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

Though mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Finally, we note that this proposal represents another example of CMS' lack of success in providing the necessary level of detail for notice and comment rule-making. We recommend that CMS publish an interim final rule to solicit additional public comment before implementing any type of competitive bidding program.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of 1847(a)(2): Covered items *as defined under 1834a(13)* for which payment would otherwise be made under 1834(a) *and supplies used in conjunction with durable medical equipment*; enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under 1834(a)(13), a covered item means durable medical equipment as defined under 1861(n). Ostomy products and supplies are not durable medical equipment and consequently do not meet the definition of covered items as defined under 1834(a)(13). CMS must confirm that ostomy products and supplies are not included in competitive bidding under 1847(a)(2).

Potential for Savings

CMS has an obligation to explain and clarify what specific measures will be used to decide an items potential savings as a result of competitive bidding. CMS must address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger CA for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Additional Criteria for Item Selection

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS must also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

We strongly recommend that CMS publish the items it intends to include in the initial competitive bidding program in an interim final rule to solicit additional public comment after it announces the product selections.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier

does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

We believe it is unnecessary for CMS include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. It is important to note that this requirement will promote a demand for premium- or brand-name items based on direct-to-consumer advertising, even though the brand-name product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patients' needs to the supplies. The proposal is also quite contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. Inasmuch as CMS authority to implement this requirement is discretionary under the MMA, we strongly recommend that CMS *not* include this provision in the final rule.

Coding Issues and Item Selection

The tactics that CMS proposes to use for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed.

Product Categories for Bidding Purposes

General Issues

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their usual quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. We advise that CMS define products categories narrowly to ensure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs is likely to be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Because of its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for Wheelchairs could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM says that CMS will allow a grace period during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that all suppliers who may want to submit bids have had a fair and reasonable opportunity to get accredited.

In addition, the evaluation of the suppliers' financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. CMS should consider the following evidence of suppliers' financial stability:

- D & B report
- Insurance Certificates
- Trade References
- Income / Balance Sheets
- Letters of Credit

Finally, it is essential that CMS identify the criteria it will use to select accrediting bodies *now*. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers currently accredited and/or who are currently undergoing accreditation. We recommend that CMS fast-track accreditation in the manner that was suggested during the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published.

Market and Supplier Capacity

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. CMS needs to take exceptional care in evaluating capacity issues to guarantee adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or pivotal bid. This method does not include any mechanism to rationalize the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their best bid, in fact there will be suppliers with small individual capacity who will submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

It is necessary that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. We very strongly urge that CMS eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS will designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is extremely unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS must consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the

demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the winning suppliers. This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. We believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance that the submitted bids are rational and not unreasonably low, is to pay contract suppliers an amount equal to their individual bids. Although we understand that the MMA requires CMS to pay a single payment amount and that CMS intends to comply with this requirement, the statutory payment basis is the fee schedule amount or the actual charge, whichever is less. Consistent with the requirement, CMS could calculate a single payment amount equal to the pivotal bid and require winning bidders to submit claims in the amount of their bid the actual charge not the single payment amount. This approach also achieves price transparency for CMS and beneficiaries.

Rebate Program

The NPRM describes a rebate program that allows contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under 1128A(a)(5) of the Act.

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

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

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

Bulletin at 1.

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

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

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

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

CMS will compel contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also demand that contract suppliers repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we propose that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract suppliers bid, depending on the payment methodology CMS adopts in the final rule.

Termination of Contract

CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

Judicial and Administrative Remedies

CMS must include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards and whether a buyer has, in the past before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning-supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet all applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

Submitter : **Mr. Stephen Carr** **Date: 06/29/2006**

Organization : **Otto Bock Healthcare**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-917-Attach-1.DOC

Otto Bock®

QUALITY FOR LIFE

June 27, 2006

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

RE: **CMS-1270-P:** Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

As a *manufacturer* of orthotics and prosthetic components and rehabilitative products and as a *service provider* of post-surgical rehabilitation therapies to patients recovering from orthopedic surgery, Otto Bock is in a unique position to expertly comment on the competitive bidding process. The following provides a brief overview of our position and specific remarks in response to the questions posed in the current proposal.

Our Position

Otto Bock is opposed to competitive bidding in the Off-the-shelf (OTS) product category. We feel that the San Antonio demonstration project did not effectively demonstrate cost savings in the "General Orthotics Category" to CMS over the two year life of the project. As the rule states, the Secretary has the authority to grant exceptions to product categories that did not show significant cost savings and we feel the Secretary should exercise this option in the OTS Product Category. We recommend CMS to pursue accreditation and quality standards as proposed in the rule to ensure quality standards are established and followed.

1) The scope of competitive bidding should be limited to ensure that providers are not forced to overextend their skills to obtain a contract. By limiting the breadth of products in any given bid, providers are better able to provide high standards of care.

2) We understand that the law does not include custom, made-to-individual patient products but we would like to reiterate that the competitive bidding categories should not include custom Orthotics or Prosthetics now or in the future for consideration. In terms of the Off-the-shelf Orthotics devices should be limited to only those devices that do not

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require any clinical knowledge to provide to the patient and can be applied by a beneficiary or a caregiver to the beneficiary without risking harm to the beneficiary.

Response to Specific Sections of the Proposed Rule for Competitive Bidding

"Authority to Adjust Payments in Other Areas"

We are opposed to the authority to adjust payments in other areas as we feel economic geographic regions and rural areas should not be affected by competitive bidding.

The result will be poor patient care and ultimately higher costs to Medicare. Poor care results in additional surgical interventions, problems with limb health, reduced function for the patient, unnecessary treatments, and conceivably the death of the patient.

"Financial Standards"

We recommend that entities that are not considered Small Businesses, as described in the document, be only required to submit banking information, certificate of insurance, credit rating, and/or Dunn & Bradstreet reports.

"Rebates"

We suggest completely removing this section from the proposed rule for two reasons.

1) We believe it would create an unfair advantage to larger suppliers that bid less than the set fee schedule as compared to small businesses that do not have the buying power to sustain lower costs for the competitive bidding products.

2) The labor intensive process of tracking rebates by product for each individual contradicts the efficiency goals of electronic remittance advice by requiring manual review of each Medicare Remittance. It would increase the complexities of the current billing system. In a competitive bidding area it is likely that a patient could shop for suppliers that are paying rebates. This would add an additional competitive burden on the industry and does not provide a cost savings to CMS which is the intent of the rule in the first place.

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"Opportunity for Networks"

We propose that it should be acceptable to contract in multiple networks or be given the opportunity to apply as a network and as an individual supplier for different product categories. It would greatly impact the industry in the division of product categories if a small business owner is limited to one network to fulfill the product category complement and unable to apply as an individual in another product category. More importantly, you may be precluding certain small businesses from participating in a network as they may not be attractive as a potential network participant.

We would be happy to provide further comment if that would be helpful, and appreciate the opportunity to make suggestions to the current proposal.

Sincerely,

Stephen Carr
General Counsel
Otto Bock HealthCare

Submitter : **Dr. Mark Schilansky** **Date: 06/29/2006**

Organization : **Dr. Mark Schilansky**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

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

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

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

Sincerely,

Submitter : **Dr. H. R. Hadden** **Date: 06/29/2006**

Organization : **Midstate Podiatry Associates, Ltd.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS 1270-P

Attention: Mark McClellan, MD, PhD In the proposed rule that would establish a competitive acquisiton program for certain durable medical equipment, prosthetics, orthotics, and supplies, the Center for Medicare & Medicaid Services used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition form 1861(r)(1) to 1861(r).

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients, and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other state and federal regulatory requirement that apply to MD and DO suppliers.

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

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

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

Sincerely,

H. R. Hadden, D.P.M.

Submitter : **Mr. charles argo** **Date: 06/29/2006**

Organization : **apollo services**

Category : **Other Practitioner**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Dear sir or maam,

I am an independent medical equipment provider in the midwest and rural community. I would like to express my feelings on the competitive bidding issue. Being an independent provider, I feel the service I am able to give to my patients far exceed any service a corp. company can provide, even though I deal with the daily struggles of competing with corporate medical providers I am able to treat and take care of my patients fairly. My patients have voiced their concerns of not being able to use my company if Im not chosen as a provider, and are really concerned of the cap being discussed on their oxygen and supplies. I play by the rules and seem to lose ground because I dont have the deep pockets of corporate medical providers with their solicitation and payoff techniques, only to face fines, when they made ten times that from it. I dont understand how either of these could happen, the cap on oxygen after 36 months and competitive bidding . The large companys will get the bids because how could a small company that wins a bid supply what corporate companys do. Personally , I dont think it would work as good as everyone thinks. Why not ask for bids, select a fair price and then suggest to all providers if you want to participate in the medicare program this is what you will need to do (get accredited) and this by a census of bids is what you will get reimbursed. This is giving the provider a choice whether to participate or not, if they choose not to they will still get reimbursed for existing patients at NEW RATE , and those who choose to will know their expectations. The medicare recipients deserve a choice, as well as providers to participate. Thank you for your time and allowing me voice my concerns for my patients.

Submitter : **Mrs. Fran Pesek** **Date: 06/29/2006**

Organization : **AllMed Sales & Rentals Inc**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Are you trying to put small businesses out of business? Where will the rural areas, like ours, fit into the total scheme of things? Will we be able to service our customers adequately or will we be squeezed out? We have worked hard to build a client list and to take good care of them. We would like to stay in business! Please look at the overall plan! Will it take care of the American people in the future?

Submitter : **Mr. Doug Hoey** **Date: 06/29/2006**

Organization : **National Community Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment -

This is part 1 of a 7-part attachment (addendum) to NCPA's comments

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

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

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

Submitter : Ms. Linda Aukett **Date:** 06/29/2006

Organization : United Ostomy Associations of America, Inc.

Category : Consumer Group

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

2c. Nationwide or Regional Mail Order Competitive Bidding Program.
It is stated that beginning in 2010, mail order suppliers would be eligible to submit bids in one or more CBAs to furnish items that are not included in a nationwide or regional CB program. It is not clear why mail order suppliers could not submit bids in CBAs prior to 2010 if they currently service those areas. If they are eligible to submit bids in these areas, it is not clear why a separate provision for mail order suppliers is in the NPRM. Additionally, the criteria for choosing items to be bid on a national or regional basis are not included in the NPRM.
We recommend that the selection criteria for such programs take into account the important role of local suppliers in providing medical supplies such as those for an ostomy that require an element of personal service. For example, a patient who has just undergone ostomy surgery is often discharged after three or four days. Their stoma changes in size and shape for several weeks post discharge, requiring them to seek assistance in selecting different ostomy products over that period to ensure a good fit and adequate skin protection. Local suppliers are often the main source of this type of personal training and in helping the patient to determine what products are most suitable for their long-term use. This is often an iterative process because of differences in body contours and skin type and condition.
In keeping with the above rationale, we further recommend that, if CMS does decide to allow mail order suppliers to bid in the DMEPOS competitive bidding prior to 2010, those mail order suppliers should not count towards the two-supplier minimum that CMS is establishing in each CBA.

Criteria for Item Selection

Criteria for Item Selection

The proposed rule concentrates almost exclusively on item selection based on the potential for savings. Ostomy supplies were not included in the Demonstration Projects and thus no potential savings were demonstrated.
We believe that quality of service to beneficiaries should also be a significant factor in item selection. In particular, product groups such as ostomy supplies that require a significant degree of personal service are inappropriate for inclusion in CB. Moreover, past surveys conducted by the UOAA have shown that, due to low fee levels, only around 16% of Participating Providers choose to supply ostomy products. We believe that the requirement in the proposed rule that bids must be below existing fee levels will reduce participation even more and lead suppliers to engage in product switching; thus reducing beneficiary access to the most medically appropriate products.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

1. Setting Single Payment Amounts for Individual Items
CMS preferred methodology of basing the payment amounts on the median of the selected supplier s bids has the disadvantage that some supplies would inevitably have to accept a fee for some products that was below what they bid. They would likely also have overall payment amounts below what they bid. This introduces an element of risk to the bidding process that would be especially difficult for small suppliers to accept. The Demonstration Projects employed an adjustment factor would greatly reduce this risk for small suppliers. As CMS are using the results from the Demonstration Projects as the basis for the introduction of CB, we would suggest that a similar methodology be employed for determining the contract payment levels.

2. Rebate Program
The proposal to introduce a rebate program is ill advised and likely to give rise to legal issues. The savings for beneficiaries are likely to be very small and any benefits would be far outweighed by beneficiary confusion and the costs of monitoring its implementation. We therefore strongly recommend that this proposal be dropped.

Opportunity for Networks

Opportunity for Networks

We do not think that allowing suppliers to form networks is likely to be of great benefit to small suppliers. It is a challenging proposition for them to work with their competitors and might well lead to additional legal considerations and costs.
We would recommend the introduction of a grandfathering provision allowing small suppliers who are not winning bidders to continue to supply an agreed amount of product to their existing customers at the contract payment levels. This, we feel, would retain a far greater number of small suppliers which is a critical element in allowing newly-operated patients to find a satisfactory product.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

The preservation of small suppliers is crucial to beneficiaries with an ostomy. The proposed rules are not conducive to the continued viability of small community-based suppliers of ostomy products, which are frequently a major source of education to the new ostomate as they learn which pouching system will provide the best outcome. We believe there are many elements in the proposed rule that are inimical to the long-term survival of a large portion of the community-based provider

industry.
-- -- Please see the attachment -- --

Payment Basis

Payment Basis

5. Authority to Adjust Payments in Other Areas
From 2009, CMS has the authority to adjust payments in non-CB areas in the light of a CB program elsewhere. If this authority is exercised, it could have devastating effects on small suppliers serving areas in which the economics of serving beneficiaries is greatly different from the Competitive Bidding Area (CBA). The proposed rule gives no indication of what methodology would be used to adjust payments, and we request that CMS publish an Interim Final Rule which includes a substantive proposal with the opportunity to comment.

6. Requirements to Obtain Competitively Bid Items from a Contract Supplier
Many seniors in general, including people with an ostomy, spend significant periods of the year away from their permanent residence. When someone resides in a CBA but visits a location that is not, it is unreasonable to expect a supplier in the non-CB area to supply at the contract price ruling in the beneficiary s usual area of residence. It is even more unreasonable to expect someone traveling into a CBA to know where it is possible to obtain needed supplies that will fulfill all the medical requirements.
This provision, if implemented, would certainly lead to confusion, administrative waste, and most importantly, to considerable anxiety on the part of the beneficiaries who cannot get their supplies. It should therefore be amended to allow a supplier in a non-CB area to be reimbursed in accordance with the appropriate fee schedule, when supplying items and services to a resident visiting or traveling outside of a CB area.

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

This section contains a provision for the prescribing of a specific brand. However we are concerned that winning bidders are likely to provide only a limited range of products and may offer only the low cost, low quality alternatives within a HCPCS code. This could effectively be an informal formulary that encourages brand substitution. The proposed rule states that if a physician/treating practitioner specifies a brand that the supplier does not carry, the supplier can request the physician/practitioner to allow substitution or help the beneficiary to find a contract supplier who will supply the specific product. We do not believe that the latter is likely and the outcome will often be that the beneficiary will not get the specific medically appropriate product they need.
This is particularly a problem with products such as ostomy that are self-administered and often selected by the beneficiary him/herself as the one that is especially suitable for their specific skin type/skin condition, body contours and other factors. This is a strong argument for products such as ostomy supplies not to be included in CB, and if they were, we feel that the supplier should be required to provide the exact product that the beneficiary needs unless the beneficiary agrees to try something else.

Regulatory Impact Analysis

Regulatory Impact Analysis

E. Effect on Beneficiaries
We foresee two major problems for beneficiaries residing in a CBA:
1. That people with an ostomy may often have trouble finding a contract supplier that will supply the exact product they have used for what may often have been a period of years. There is a real risk of their being forced to use low cost, low quality alternatives.
2. That a large proportion of beneficiaries will be forced to change suppliers because their local supplier is not a winning bidder. This would result in the loss of an important relationship and source of support. Being forced to use an unfamiliar supplier would often lead to a reduction in quality of care with significant negative implications.
F. Effect on Suppliers
1. Small Suppliers: Small suppliers are needed. Many people with an ostomy use small local suppliers who are able to provide a more personal service. Such suppliers have a higher than average proportion of customers who need support, tend to be more specialized and are more able to work with the patient through the iterative process of determining the optimal product. In the long run, if CB leads to business becoming too concentrated among a few suppliers, we believe it will ultimately become less and less competitive.

Small suppliers are more vulnerable and will not fare well with Competitive Bidding Programs. Many suppliers specialize in only one or two product categories such as ostomy supplies. As a result of this specialization, the loss of one category of business through a failed bid is much more likely to precipitate the closure of a small supplier, especially as contract periods will be for three years. Also, small suppliers are less likely to be designated suppliers for other insurers, thus the proportion of their business with Medicare is much higher than the 50% predicted by CMS. UOAA surveys of ostomy suppliers have shown that 70% of their business is with Medicare. Moreover, the yet-to-be-finalized accreditation and quality standards will clearly be more burdensome for small suppliers with their more limited resources. The burden of accreditation as a percentage of revenue will be higher for small than for larger suppliers. CMS estimates that 50% of bidders will be winners, but that was based on the comparatively small scope of the Demonstration Projects, which utilized a different methodology for determining the contract prices.

Small suppliers are likely to have a much lower success rate for a number of reasons:
1. They are generally at a disadvantage as they have higher acquisition costs.
2. The methodology of arriving at a pivotal bid by accumulating capacities in ascending order of bid level will inevitably lead to fewer and larger winners.
3. They are less able to take the risk that the contract price for some HCPCS will end up being below what they bid.
4. The provision in the Proposed Rule allowing for suppliers to form networks is not likely to be of great benefit as it is difficult for a small business to reach out to its competitors, and there would likely be associated legal considerations and costs.

Regulatory Impact Analysis

see next entry

Use of terms

Use of terms

Ostomy supplies are covered by Medicare under the Prosthetic Device benefit. Although they are reimbursed under the same methodology as DME in accordance with section 1834a(2)(B) & (C), they are not a covered item as the term is defined under 1834a(13). Section 1834a(13) defines a covered item as durable medical equipment. Under Section 1847a, the items included in competitive bidding are DME and supplies used in conjunction with DME, enteral nutrients and off-the-shelf orthotics. Ostomy products and supplies are part of the prosthetic device benefit and are not listed under Section 1847 (a) as subject to Competitive Bidding (CB). It has therefore been our understanding, especially as it was supported by information presented at the December 2004 PAOC meeting, that supplies unrelated to DME (such as ostomy, tracheostomy and urological supplies) were not within the scope of CB. Additionally, the Proposed Rule states that surgical dressings are ineligible for inclusion.

CMS has been unable to provide an unequivocal response regarding the possibility of inclusion of ostomy supplies in CB. We request that the Final Rule include a definitive list of those product categories that are eligible for inclusion.

CMS-1270-P-923-Attach-1.DOC

Submitter : Ms. Angelene Adler

Date: 06/29/2006

Organization : Care Medical Equipment, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-924-Attach-1.PDF

1877 NE 7th Avenue
Portland, Oregon 97212
Phone: (503) 288-8174
FAX: (503) 288-8817

June 29, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1270-P
Mail Stop C4-26-06
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program (NPRM); Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues

Care Medical Equipment, Inc. is pleased to submit comments on CMS' Notice of Proposed Rulemaking for Competitive Acquisition for Certain DMEPOS and Other Issues. Established in 1970, Care Medical Equipment, Inc. an independent, family-owned company. has grown to include nine branch locations throughout Oregon and Washington states. Care Medical specializes in home medical equipment services, rehabilitation equipment services including custom seating and positioning, bariatric equipment and respiratory equipment services including home medical oxygen, ventilators, and sleep apnea product and has been serving the needs of the Pacific Northwest for over 35 years.

Care Medical Equipment submits the following comments on CMS' Notice of Proposed Rulemaking published May 1, 2006 in the *Federal Register* (71 *Federal Register* 25654),

Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplier (DMEPOS) and Other Issues. As CMS requested, our comments are divided into sections with "headers" that correspond to the particular subject in the proposed rule.

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Due to the accelerated changes CMS is presently undertaking with the development of new HCPC coding for wheelchairs, parts, cushions, adaptive seating, etc, the Interm Final Rule (IFR), National Coverage Determination (NCD), FEHBP reductions and the fee schedule relating to the new codes, CMS and suppliers must establish data to determine what products could potentially be part of the bidding process. CMS needs to factor what savings, if any, could actually be achieved. By waiting until the final rule is published, CMS is making it extremely difficult for providers to begin gathering the necessary data to submit realistic bids. This is the third time within the past two years that mobility codes have been re-worked by CMS. CMS is currently 18 months behind its original timeline. To implement competitive bidding in a rational and logical way that minimizes the inconvenience to the Medicare beneficiary is to implement competitive bidding in a reasonable timeframe.

Rushing implementation also negatively affects manufacturers by requiring that independent labs perform testing of manufacturer's equipment after the manufacturer has already invested in extensively testing the apparatus. Continuing to conduct internal testing for non-Medicare purposes will only add unnecessary costs to the manufacturer and the supplier. CMS states that manufacturers will have at least one year to re-test devices in an independent testing facility using the SADMERC's new testing criteria. This requirement is unrealistic and the cost would

be exorbitant for manufacturers, and in turn suppliers, which will result in higher bid amounts. If CMS continues to require that independent labs are used, manufacturers need time to add these additional costs into the products they are selling suppliers. How can a supplier know what to bid for a product or if they can afford to buy a product for bidding purposes if the product cost increases from the manufacturer after the bidding process has begun?

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS has already received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

CMS needs to realize that competitive bidding eliminates incentives for suppliers whether the supplier "wins" the bid or not for any product category. Presently, beneficiaries' have numerous choices regarding equipment selection because of our free-market enterprise system that allows patients to choose their provider and type of equipment. Competitive bidding will force suppliers into providing lesser quality products and supplies in order to maintain sound business practices. Suppliers will be unable to provide equipment in as efficient a manner under competitive bidding regulations. Services to patients that include delivery, setup, maintenance, education, quality control, product availability, and patient access will decline as a direct result of this incentive elimination.

"General"-Grandfathering Medicare Advantage. The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM. As CMS chooses the implementation

structure and timelines for competitive bidding, it needs to realize that confusion already exists for suppliers and beneficiaries. Multiple significant changes have already occurred recently, including Part D and the resulting increase of beneficiaries transferring to Medicare Advantage plans.

"General" – Medicare As Secondary Insurance. CMS should exclude those Medicare beneficiaries where Medicare is a secondary payor from the competitive bidding process. These beneficiaries' claims should be paid under the standard fee schedule rate.

"General"- Getting It Right Is More Important Than Rushing Implementation. CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. In addition, CMS should stagger the bidding in MSAs over a twelve-month period to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Under the timeline CMS is proposing, providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

"General"-CMS Must Publish An Updated Implementation Timeline. CMS must publish an implementation timeline that at a minimum identifies the following steps and expected completion dates: a.) Publication of Supplier Standards; b.) Approval of accrediting organizations; c.) Issuance of final regulation; d.) Publication of final 10 MSAs and product categories; e.) Commencement of bid solicitations; f.) Conclusion of bid solicitations; g.) Announcement of winning bidders; h.) Education of beneficiaries and medical community; and i.) Implementation within each MSA. These projected completion dates should be realistic and not overlap one another. It is expected that the publication of such a timeline will highlight the significant problems that lie ahead based on an overly aggressive implementation plan.

"General"- The Program Advisory And Oversight Committee (PAOC) Must Be Included By CMS In The Review Of Public Comments And The Development Of The Final Rule. CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of establishing the PAOC.

"General Comments" – Complex Rehab. Care Medical acknowledges that CMS and its contractors have given extensive consideration to the many proposals within this NPRM. However, Care Medical remains concerned that the only reason identified for products to be excluded from the competitive bidding program are purely based on potential savings. Care Medical believes that Congress intended for consideration to be given to clinical outcome for Medicare beneficiaries. Care Medical recommends that CMS accept the recommendations of PAOC committee members and presenters during the February 2006 PAOC meeting to exempt complex rehab and assistive technology devices from competitive bidding. We do not believe that products which are evaluated, fitted, configured, adjusted or programmed to meet the specific and unique needs of an individual with a primary diagnosis resulting from injury or trauma or which is neuromuscular in nature are appropriate for competitive bidding. While Care Medical will provide comments to many components in the NPRM for competitive bidding, our strongest recommendation is to exempt rehab and assistive technology devices and we want to be very clear that any recommendations regarding the NPRM are not in the least intended to offer alternatives to an exemption.

"Payment Basis"- Special Rules For Certain Rented Items Of DME & Oxygen. (proposed §414.408(k)) It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? If Congress mandates a decrease in the number of months of capped rental, will the supplier still be required to convert ownership of the equipment? A supplier cannot predict this type of financial change when formulating a bid, so how can the supplier be expected to do so? The implementation of the DRA forced ownership provisions on oxygen and capped rental equipment has important ramifications for competitive bidding. Stakeholders cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

"Payment Basis"-Authority To Adjust Payment In Other Areas. The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for

those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived from competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under §1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

"Use of Terms" – Purposes & Definitions. (proposed §414.400) CMS needs to provide additional explanation of what the definition of "cumulative capacity" is and how cumulative capacity is calculated into the bidding program.

"Implementation Contractor" - The proposed rule states that CMS will contract with a new entity, the Competitive Bidding Implementation Contractor (CBIC), whose primary functions will be to provide oversight and decision making, operation design functions, bidding and evaluation, access and quality monitoring. There is no further information regarding how CMS

plans to choose the CBIC; but Care Medical recommends that CMS ensure that any CBIC entity avoids any potential conflict of interest. For example, a conflict of interest would exist if a CBIC were also a private payor that negotiates directly with DME/HME providers in a managed care context.

"Payment Basis" Requirement To Obtain Competitively Bid Items From A Contract Supplier. Under the CMS proposal, in a state with 12 MSAs there could be 13 rates for the same item – one in each MSA and a non-contracted rate. CMS proposes that the supplier would be paid based upon a single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. For suppliers billing Medicare pricing confusion would be unfathomable. The time and expenses in billing will increase the cost of the product substantially. Requiring suppliers to accept payment based on another MSA bid amount where the beneficiary maintains permanent residency is unreasonable.

"Payment Basis" Inflation Update. (proposed §414.408(b)) CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. The durable medical equipment industry already has a history of being hit with CPI-U freezes. In 1990, 1998, 2000, 2002, and 2004, a freeze was placed on all equipment. In 2001, 2003, 2004, and 2005, a freeze was placed on a portion of products. In other words, the DMEPOS industry has not received the CPI-U increase referenced in nearly a decade. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids. Care Medical supports CMS' proposal to apply an annual inflation update to the single payment amounts established for a competitive bidding program, and recommends that CMS do this even if Congress were to not allow a CPI increase (or a portion thereof) for items not subject to competitive bidding.

"Payment Basis"- Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowables. (proposed §414.408(f)) The NPRM states that if a beneficiary is visiting a non-competitive bidding area and requires service, the supplier would be paid at the single payment amount for the item in the competitive bidding area where the

beneficiary maintains a permanent residence. This proposed plan will make it difficult for beneficiaries to obtain products and services in some areas. Although it is current Medicare policy, the maximum payment difference from one State to another is currently only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that. If a beneficiary receives service in a non-bid area, CMS should pay the traditional Medicare allowable amount that corresponds with the beneficiary's permanent residence for up to five months.

"Payment Basis" – Authority To Adjust Payments In Other Areas. (proposed §414.408(e)) Effective for items furnished on or after January 1, 2009, CMS has the authority to use payment information from the competitive bidding program to adjust payment amounts to items in an area not in a CBA. CMS is proposing to use this authority, but has not proposed any specific methodology for doing so. Instead, CMS invites comments and recommendations regarding a methodology CMS should use to implement this authority. Care Medical recommends that CMS issue a separate NPRM addressing this issue to allow for substantive comments on specific proposals.

"Payment Basis" – Rehab & Assistive Technology (proposed § 414.408) (a) In this section, CMS proposes that a beneficiary could chose, at any time, to transition to a contract supplier and the contract supplier would be required to accept the beneficiary as a customer. Care Medical finds this requirement to be especially problematic. At this point in time, rehab and assistive technologies are primarily classified as inexpensive or routinely purchased and in the case of power wheelchairs, have a day-one purchase option. However, there was consideration given by Congress as recent as last year to remove the day-one purchase option for power wheelchairs. Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental would be unrealistic. Care Medical believes that the costs associated with the initial set-up of highly configured and individually prescribed products are too high for a supplier to accept any amount below a full (13 months) rental period. In addition, the supplier would incur significant costs in acquiring medical necessity documentation to facilitate billing of power wheelchairs. Care Medical recommends that CMS must start the rental period over if beneficiaries are transferring to a contract supplier and payment is under capped rental. Care Medical believes it would be impossible for suppliers to accurately estimate their financial loss in these situations. Therefore, suppliers cannot accurately account for this loss in a bid amount.

"Payment Basis" Limitation on Beneficiary Liability. We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier. CMS should allow a comment period and PAOC review of this clarification.

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

"Competitive Bidding Areas" – Establishing Competitive Bidding Areas. Care Medical recommends that CMS identify the initial ten MSAs in an interim regulation implementing competitive bidding. The geographic location of the initial ten MSAs is the most critical information that must be made public as soon as possible, to allow suppliers as much time as possible to become accredited and be able to prepare to submit bids.

"Competitive Bidding Areas" – Rates/Areas. CMS should first undergo an analysis of whether a bid rate is actually appropriate to apply in a non-bid geographic area. Factors such as distance needed to travel to beneficiaries being far greater will significantly impact suppliers' "total delivered costs" in, for example, a rural area, making application of bid amount from a densely populated metropolitan area wholly unreasonable in a rural area. CMS identified this criterion in its final rule in inherent reasonableness, acknowledging that amounts for a category of items or services in a particular locality may be higher or lower than payment amounts in other localities due to the relative costs of furnishing the category of items or services in the different localities.

Second, CMS should undertake an impact analysis before applying bid rates from a competitive bid area to items in a non-competitive bid area. That analysis should focus on the ability of suppliers to provide the item at that bid rate and the impact on beneficiaries and their ability to access quality items at that bid rate.

CMS should stagger the implementation of competitive bidding in the initial ten MSAs to allow for a more orderly roll out of the program. This would also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread or occur in all ten initial MSAs at once.

"Competitive Bidding Areas" - Do Not Extend Competitive Bidding Beyond Defined MSA Boundaries. (proposed §414.410(b)): CMS is proposing to establish competitive bidding areas (CBAs) in ten of the largest MSAs in 2007, and 80 MSAs in 2009. However, CMS does not believe it is confined to areas within an MSA, and proposes specific criteria for when to include areas outside an MSA. The statute appears crystal clear that CMS does not in fact have the authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***"in"*** an MSA. Therefore, we strongly oppose any criteria CMS proposes to use to annex areas next to an MSA, and we urge CMS to reject its proposal to have the discretion to define a CBA to be larger than an MSA. The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done. Dependent upon location, this could encompass rural areas where the cost of providing services are obviously higher. CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established in an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

Nationwide or Regional Mail Order (proposed §414.410(d)(2)) CMS is proposing to establish a nationwide or regional competitive bidding program, effective January 1, 2010, for the purposes of awarding contracts to suppliers to furnish these items across the nation or a region to beneficiaries who elect to obtain them through the mail order outlet. It is unclear why CMS anticipates having a separate CB program for mail order suppliers in 2010. Since mail order

suppliers are not excluded from participating in CB in MSAs during 2007 and 2009, a separate program for them in 2010 would be unnecessary. In addition, many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. A cleaner definition of "mail order supplies" needs to be established.

There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

These mail order situations should also be addressed in the supplier standards and the accreditation process. Glucose test strips are one thing, but drop shipping items which require adjustment, fitting or education should be excluded. An adjustable cushion for example, if not properly inflated or utilized could create a costly pressure sore and injury to the patient.

Finally, we note that this proposal represents another example of CMS' failure to provide the level of detail necessary for notice and comment rulemaking. CMS should publish an interim final rule to solicit additional public comment before implementing a national or regional competitive bidding program.

"Criteria for Item Selection"- Product Selection Must Be Conducted With Beneficiary Welfare In Mind. (proposed §414.412) (Criteria for Item Selection) How will "savings" be calculated;

exempt items and services unless savings of at least 10 percent can be demonstrated as compared to the fee schedule in effect January 1, 2006; recognize problems with beneficiaries having to deal with multiple suppliers; recognition of items that are custom and service oriented that should not be competitively bid.

"Criteria for Item Selection"- Items Included In Competitive Bidding. CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" as defined under §1834a(13) for which payment would otherwise be made under §1834(a) and "supplies used in conjunction with durable medical equipment;" enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Regarding CMS' proposed criteria for selecting items to including in competitive bidding, Care Medical recommends that CMS add a critical step as it determines which products will be included in competitive bidding. Specifically, CMS should first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the administrative costs related to implementing competitive bidding for that product category. We find it difficult to fathom that the costs associated with implementing the program would, in many product category cases, make the approach cost effective. Specifically, CMS estimates that its aggregate savings in 2008 will be $110 million. Using CMS' tables for the top ten eligible DME policy group allowed charges, with the allowed charges of $7.4 billion, savings of $110 million indicates a savings of 1.4% in 2008. That seems to be a waste of time and resources, including the creation of a new bureaucracy with new Medicare contractors, and other obvious related financial costs. We understand CMS is under a Congressional mandate, however, it would be far more logical for CMS to focus on product categories that will ensure savings that more than balance the associated administrative costs. Therefore, Care Medical recommends that CMS first identify the savings it believes may be attained by including the particular product category, and should compare those costs with the total administrative costs related to implementing competitive bidding for that product category.

Care Medical recommends that CMS exclude power mobility device and accessory codes from the 2007 round of competitive bidding. This is because all of these products are subject to a new coding system (64 codes replacing the four prior codes), new coverage, and most importantly, new fee schedules. Both CMS and the industry need time to implement and adjust to the new PMD coding and payment system; CMS needs to gain accurate utilization data under the new codes and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. While we recognize that power wheelchairs are high in utilization and cost, CMS will already have realized significant savings as a result of the vast changes in coding, coverage and payment that has occurred in this product category over the last year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding. Again, once the new fee schedules for the new 64 codes are implemented, scheduled for October 1, 2006, we anticipate there will be no opportunity for any real savings associated with these new power wheelchair codes.

"Criteria for Item Selection"- Potential for Savings. CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- Annual Medicare DMEPOS allowed charges: Is there a threshold expenditure level that will trigger CB for a product category?
- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- Number of suppliers: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how will those thresholds be determined?
- Savings in DMEPOS demonstrations: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- Reports & studies: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

"Criteria for Item Selection"- Additional Criteria for Item Selection. Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding. CMS should publish the items it will include in the initial competitive bidding program in an interim final rule. CMS should also schedule a meeting of the PAOC to solicit additional public comment after it announces the product selections.

"Criteria for Item Selection"- Consider The Impact On The Patient. CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

"Criteria For Item Selection" - Coding Issues and Item Selection. The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed.

"Criteria For Item Selection" - Submission of Bids Under the Competitive Bidding Program (proposed §414.412) Under the proposed rule, each product category would also include all of

the ancillary related supplies. Suppliers would be required to submit bids to reflect all items within the product category. We support this approach as it should allow Medicare beneficiaries a "one stop shopping" opportunity to receive the needed products and accessories in a product category from one contract supplier. Likewise, we support the proposal that would permit a supplier to bid for only the products and accessories they are seeking to furnish under competitive bidding as it permits suppliers to specialize if they so choose.

CMS needs to be more specific about the information it will give bidders so that they can determine an appropriate bid in light of the requirement that they must accept any beneficiary in the MSA regardless of the number of rental months remaining on capped rental or oxygen equipment.

CMS must supply data suppliers will need to determine "worst case" scenario – how many beneficiaries using oxygen and capped rental items – that winners may be forced to take on.

"Criteria For Item Selection" – Rehab & Assistive Technology (proposed §414.412) Care Medical believes that CMS should establish a savings threshold including on-going administrative costs to assess the appropriateness of competitive bidding for each product category. Care Medical further recommends that CMS use a consistent threshold of 10% net savings after adjusting to include administrative costs associated with the on-going support of the competitive bidding program to determine whether a product group should be competitively bid.

In addition to believing that there are no cost savings available for complex rehab and assistive technology items, Care Medical believes that to attempt to competitively bid these devices would result in a negative impact on the clinical outcome for the beneficiary. CMS, then HCFA, included K0004 high strength lightweight manual wheelchairs in the competitive bidding demonstration in San Antonio, TX. CMS had proposed including K0005 Ultra-lightweight Manual Wheelchairs also, but after receiving comments from the industry, CMS decided to exclude this category of products. Therefore, K0004 coded products are the closest CMS has come to demonstrating the impact of competitively bidding items that are uniquely prescribed for an individual. While K0004 coded products are not all equally configurable, we did glean some important information about the clinical impact for beneficiaries based on the San Antonio demonstration project.

In the November 2003 Final Evaluation Report, Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, page 181, section 4.5 Wheelchairs and Accessories evaluates the impact of competitively bidding this class of wheelchairs. The report states that "referral agents raised a number of issues about wheelchairs". Further, the reports states," Referral agents also found that the prescriptions needed to be very detailed to ensure that beneficiaries got the required product" and "prior to the demonstration, referral agents used suppliers who would provide wheelchairs with removable arms and adjustable leg rests as standard equipment. After the demonstration, they found that some suppliers stopped providing this equipment in every case, opting to do so only if these features were specifically ordered". The report also indicated a change in the service/delivery model for these wheelchairs. Some referrals noted that, prior to the demonstration, suppliers usually either had a physical therapist on staff or the wheelchair would be delivered by someone who was familiar with the product and how to measure its fit. When the wheelchair was delivered, the supplier delivering the chair would have the beneficiary sit in the chair and check the fit. However, during the demonstration, referrals reported examples of wheelchairs being delivered and left folded with no attempt to check fit, delivery staff being unknowledgeable about the products being provided or how to adjust or check for proper fit, and even that one supplier's policy was to deliver a 18" wheelchair to all patients and then replace it if a different size was required. Care Medical does not believe that the same degree of measuring, fitting and adjustments are needed for all manual wheelchairs. In fact, standard products are only available in limited sizes and with little to no adjustability. However, as one considers the products moving up the spectrum of manual wheelchairs, those that are available in more sizes, configurations and are adjustable to meet the functional needs of the patient require a more labor intensive evaluation on the part of the supplier and in collaboration with a clinician/physician to ensure that product solutions meet the current and anticipated medical needs of the beneficiary. The rehab company must employ trained and knowledgeable staff to perform the technology evaluations, fittings, adjustments as well as technicians to repair and service complex technologies. We recognize that many of the issues identified could be mollified by developing specific supplier standards for complex rehab and assistive technology. We believe CMS needs to create specific standards for complex rehab and assistive technology, this will ensure that all Medicare beneficiaries will be better served. Actually, CMS may find that the Medicare program will experience savings by using only suppliers that are qualified to provide this level of technology. This savings would result from the beneficiary receiving a

comprehensive evaluation of their technology needs which would facilitate appropriate product selection up front as opposed to beneficiaries finding that the products they have been provided do not meet their functional needs or the progressive nature of their disease was not taken into consideration in the initial evaluation.

In addition to exempting rehab and assistive technology devices from competitive bidding, Care Medical recommends that CMS exclude all manual and power wheelchair and accessory codes from the 2007 round of competitive bidding. This would allow time for CMS to implement new HCPCS codes for power and manual wheelchairs, gain accurate utilization data and assess how the coding changes impact cost before attempting to determine which if any of these products would produce adequate savings while ensuring Medicare beneficiaries achieve their desired clinical outcome. Care Medical recognizes that power wheelchairs are high in utilization and cost. However, we also believe that significant savings will result from the vast changes in coverage and conditions for payment that has occurred in this product category over the last year and the additional coding, coverage and payment changes that are imminent. There must be ample time to analyze the true impact of the changes before determining if any of these products are appropriate for competitive bidding.

Care Medical also recommends that CMS exclude wheelchair cushions, adaptive seating and positioning products and speech generating devices. Clients in need of complex rehab or assistive technology typically require a complete system to meet their functional and medical needs. A complete system means various pieces of equipment, each meeting a specific medical or functional need, have been determined to be compatible technologies.

"Submission of Bids Under the Competitive Bidding Program"- Only Companies Currently Delivering Service To Medicare Beneficiaries In An MSA Should Be Allowed To Submit A Bid For That MSA. Any company that submits a bid should have a track record of serving the targeted geography to validate its capabilities and service record.

"Submission of Bids Under The Competitive Bidding Program" – Inexpensive & Routinely Purchased DME Items. (proposed §414.412) Requiring a supplier to offer the option of renting routinely purchased DME items that are of minimal cost would create a financial hardship on the supplier and CMS and is unrealistic. An example would be a single-point cane at $2.00 per

month based on a purchase allowable of $21.00 or a walker at $12.00 per month based upon a $128.00 purchase allowable. Imagine CMS processing multiple rental claims for these amounts. The time and costs involved in processing these claims is significant for CMS and the supplier.

"Submission of Bids Under The Competitive Bidding Program" – Product Categories For Bidding Purposes. (proposed §414.412) Beneficiaries having to potentially deal with four companies for the same treatment: If a beneficiary needs a hospital bed, wheelchair, cushion and a concentrator, they would have to deal with four different suppliers to orchestrate their care. If a patient needs items for discharge from a hospital and the multiple suppliers cannot meet the needed delivery time for discharge, the patient will remain in the hospital potentially costing Medicare thousands of dollars. We have great concern that products will be grouped-based on product categories. This approach doesn't address the individual medical policy groupings that do not always follow product groupings. Even in the best grouping situations, patients and providers, along with inpatient and outpatient referring entities, could feasibly be placed at a significant disadvantage, since they would have to deal with multiple providers of different products for the same patient. Multiple providers of DMEPOS in a home is not only dangerous from a patient safety perspective, but extremely inefficient for the provider and physician who are supervising and coordinating the patient's overall care. Using product categories for determining the bidding process is confusing and cumbersome for a beneficiary who is experiencing physical and possibly mental difficulties as well as the referral sources coordinating their care. This could also lead to lost equipment for suppliers when another supplier inadvertently picks up another supplier's items when equipment need ends.

"Product Categories for Bidding Purposes" - General Issues. Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

"Product Categories for Bidding Purposes" - Requirements to Bid on all Products in a Category. Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.

Manual wheelchairs HCPCS codes will be subjected to a similar re-coding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.

Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.

Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

"Product Categories" – Submission Of Bids Under The Competitive Bidding Program" (proposed §414.412) Care Medical strongly believes that complex rehab products should not be competitively bid. The accessory codes are the same for accessories whether they are provided on a standard wheelchair or a complex mobility system. While Care Medical believes this is an inadequacy in the HCPCS code set, there is not time to address this issue. Care Medical believes any contract supplier for competitive bidding would be able to provide accessories even if they were not competitively bid. If necessary, CMS could require suppliers that provide the base wheelchair to also provide all needed accessories. This would meet the stated goal of minimizing disruption for the beneficiary while allowing non-contract suppliers to bill for the accessories needed for non-bid items.

"Bidding Requirements" – Capped Rental Items. (proposed §414.408) CMS proposes that the lump sum purchase option in §441.229(d) for power wheelchairs be retained under the Medicare DMEPOS Competitive Bidding Program. Care Medical agrees with this proposal, but again recommends that power wheelchairs not be included in the 2007 round of bidding and that utilization and price data be analyzed to determine which if any should be included in 2009. Complex rehab and assistive technology should be exempt.

"Conditions for Awarding Contracts" - Quality Standards and Accreditation (proposed §414.414) CMS is proposing to phase-in the accreditation requirement. Care Medical strongly recommends that CMS explicitly require all suppliers submitting bids to demonstrate, as part of the bid submission, that they have already received accreditation status through an accreditation organization that has received "deemed status" from CMS. A "phase-in" approach is inappropriate because it leaves open the possibility that bids from suppliers who may not be successful in receiving accreditation status will be included in the single payment amount calculation, and would therefore taint the bid calculation and contract supplier selection processes.

Therefore, Care Medical disagrees with CMS's proposal in the NPRM where CMS states that it will allow a "grace period" during which unaccredited providers can participate in the bidding process. Care Medical strongly recommends that CMS not allow unaccredited providers to complete accreditation during any grace period. If CMS allows unaccredited suppliers to submit bids, then bid information from bidders who do not become accredited during the grace period will be woven into the various calculations – including supplier capacity, pivotal bids and single payment amount calculations, fundamentally tainting the validity of those calculations. CMS cannot eliminate this deficiency by simply later eliminating those bidders who do not become accredited. Instead of going through the administratively burdensome process of recalculating supplier capacity, pivotal bids, and single payment amounts, it will be far more efficient to allow a defined time period (consult accreditation organizations for what would be the appropriate period of time) to allow suppliers interested in submitting bids to go through the accreditation process.

CMS should not include any price in calculating the single price unless they are currently accredited. Suppliers that have actually been through the accreditation process will inherently have a better understanding of the costs associated with accreditation. It is critical that the final single bid amount be reflective of precise and informed bids.
Finally, CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies.

"Conditions for Awarding Contracts" - Eligibility (proposed §414.414) Care Medical recommends that the proposed eligibility rules be expanded to require that each bidder must provide documentation in its bid submission that it has been accredited by an organization that has received "deemed status" with CMS.

"Conditions for Awarding Contracts"- Provisions Must Be Developed To Guard Against Unrealistic Bid Amounts. (proposed §414.414(e)) Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy, it could profoundly affect the single bid price.

"Conditions for Awarding Contracts"- Financial Standards Must Be Clearly Defined And Evaluated Prior To Consideration Of Any Bid. (proposed §414.414(d)) Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required. The length of time a supplier has been supplying a specific product category should also be considered in determining a supplier's capacity to provide equipment to a beneficiary.

"Conditions for Awarding Contracts"- A Bidding Company Should Be Required To Submit Specific Financial Information To Verify Financial Capability Review. This information should consist of: (a.) Two-year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "review" from an independent Certified Public Accountant. Audited financial statements should not be required as they place an undue expense on the bidding supplier. An audited financial statement for our organization would cost anywhere between $35,000 - $40,000. CMS did not specify "audited" financial reports as a requirement to bid in the CM-1270-P proposal; however, according to the draft form CMS-10169A (Medicare DMEPOS Competitive Bidding Program) application, the financial information required to bid lists "Audited Financial Reports". Audited financial reports are unnecessary when reviewed financial reports, credit rating and score reports, bank statements, insurance documentation, adequate business capacity, and a line of credit are already required, creating sufficient considerations for evaluating financial stability. Audited financial statements review a companies' accounting system practices whereas a reviewed financial statement, which would cost our organization approximately $14,000, analyzes the relationship of procedures and analytical approaches to accounting practices in an organization. Care Medical has been in business for over 36 years and has never been required to have an audited financial statement performed. Generally, audited financial statements are only required for publicly held companies. CMS states that according to 2003 Bureau of Labor Statistics (BLS) data, the average hourly rate for an accountant and auditor was $24.35. This is not a realistic amount for the hiring of an outside (non-employee) accountant. In Oregon, the hourly rate for an accountant is between $150.00 and $350.00 per hour. We strongly oppose the requirement of having an audited financial statement regardless of the size of the organization submitting the bid. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship. (d.)

Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from recognized credit rating organization. Once received, CMS should (a.) review all submitted documentation for completeness and appropriateness; and (b.) calculate basic business ratios to verify company's financial stability to consist of "Debt to Equity Ratio" and "Current Assets to Current Liabilities".

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

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

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

"Conditions for Awarding Contracts"- Do Not Restrict Submitted Bid Amounts. (proposed §414.414(f)) CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. It is acknowledged that CMS cannot contract for an amount higher than the fee schedule. However, requiring that the bid be equal to or less than the fee schedule as a requirement artificially restricts bidding. CMS should allow suppliers to bid based on the true costs associated with each bid item; otherwise, the competition is not truly competitive based on

market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. Concerns stated in the NPRM about a shift in utilization to higher priced items could be eliminated through appropriate coverage policies. This strategy makes competitive bidding competitive and sustainable and better ensures that Medicare beneficiaries have access to the most appropriate device to meet their medical needs.

"Conditions For Awarding Contracts" – (proposed § 414.414). CMS intending to include information from unqualified bidders in calculating a payment amount means that a supplier who is incapable of meeting the financial and qualifying standards to be a provider under the competitive acquisition program can submit a "low ball bid" that will fundamentally taint the calculation of the final amount. CMS should require all suppliers who submit a bid be accredited before they are allowed to submit their bid. CMS needs to recognize the cost to become accredited is only part of the financial impact on an organization that becomes accredited. Maintaining quality standards adds significant costs to DMEPOS. Additional staff, supplies and equipment are necessary to meet accreditation standards. CMS stated that it would phase in mandatory accreditation and ask approved accreditors to give preference to providers in those areas. These accrediting bodies are businesses and CMS cannot tell them who they must accredit first.

"Conditions For Awarding Contracts" – Market Demand & Supplier Capacity. (proposed § 414.414). CMS states that to calculate demand for an item in a competitive bidding area CMS proposes to examine claims data to determine the number of units of each item supplied to Medicare beneficiaries during the past 2 years and then determine the number of new beneficiaries that have entered the market during the last 2 years. Two years worth of data is sufficient to identify trend analysis and utilization measurements; however, with the changes in cushion, wheelchair, and respiratory coding, allowables and supplier documentation requirements, there is not currently two years of applicable data to determine beneficiary demand for all product codes.

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must

carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time. The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

"Conditions For Awarding Contracts" – Composite Bidding. (proposed § 414.414). Determining the bid amount for any product or product category under the CMS proposal of "item weight" or "weighed bid" is confusing and cumbersome. A bid process for determining bid rates should not need an outside agency to help formulate a bid. A straight forward bidding process is needed for suppliers. The proposal to composite bid using item weight and weighed bid would require outside assistance in many cases in order to make an educated bid.

"Conditions For Awarding Contracts" - Assurance of Savings (proposed §414.414(f)) CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Care Medical strongly opposes the proposal that suppliers cannot submit a bid that is above the current allowable. Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding areas are expected to be less than the total amounts that would otherwise be paid. To meet this requirement, CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. Care Medical strongly disagrees with this proposal because it places artificial constraints on a process that is trying to be designed to harness market forces. If CMS is truly using competitive bidding as a way to understand the price the market will bear, then CMS must allow suppliers to submit their lowest possible bid. Given the many new requirements associated with providing the items and related services under the bid program, bids may rationally and realistically be greater than the current fee schedule amount for the particular item. Given the fact that the majority of suppliers will be incurring new costs of accreditation (compliance with quality standards), and the fact that in the last few years reimbursement has been cut for many of the major product categories (*e.g.*, FEHBP-based reductions), and some products have increased suppliers' documentation costs (e.g., power mobility device documentation requirements), it is highly likely that bids for certain product categories may realistically be at a rate that is higher than the current allowable.

CMS can still meet the "assurance of savings" requirement through alternative means. If bids received are higher than the current allowable, CMS should choose not to include that particular item or product category in the competitive bid program, because that is a strong indicator that savings are unlikely. Requiring that the bid be equal to or less than the fee schedule as a requirement of the RFB artificially restricts bidding. Instead, CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. The "assurance of savings" requirement would be met when CMS only included items for which the winning bid amount were less than the current allowable.

"Conditions For Awarding Contracts" – Selection Of New Suppliers After Bidding. (proposed § 414.422) CMS needs to establish how a supplier will be chosen if there is not a supplier located in a MSA or none willing to supply products and services under competitive bidding. CMS should not assume that unwilling or unavailable providers will not be an issue.

"Conditions for Awarding Contracts" - Evaluation of Bids (proposed §414.414(e)): Overall, the bid evaluation and the selection of winning bidders processes should be designed to result in pricing that is rationale and sustainable. CMS has not identified any process in its proposed evaluation of bids procedures that will enable CMS to determine that the submitted bids are rational. Once it receives bids, after CMS arrays suppliers' composite bids from low to high, CMS must conduct an analysis of the composite bids and discard any that are unreasonably low.

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

"Conditions for Awarding Contracts"- Competitive Bidding Must Be Competitive And Sustainable. CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Bid evaluation and the selection of winning bidders should be designed to result in pricing that is rational and sustainable. CMS has not identified any process through which it will seek to determine that the bids are either. Beneficiaries are already receiving limited access to some DMEPOS items based on current allowables. The proposed cap on bid amounts could potentially eliminate CMS even receiving bids on some items.

"Conditions for Awarding Contracts"- Do Not Make It Harder For Providers To Sell Their Businesses. (proposed §414.414(e)) The proposal to restrict the acquisition of a winning

provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA. If the sale of a contracted supplier does not weaken the company's ability to deliver service per their competitive bidding agreement and post-sale that company continues to meet the contract requirement, that contracted supplier and its new ownership should retain its contract.

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

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers" that are at or below the pivotal bid for each individual item within each product category. This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA. Care Medical believes that no supplier should be paid less than their bid amount. It is also important that CMS analyze deviations in bid amounts to determine whether these deviations may indicate extremely high or extremely low bid prices. It is critical to ensure that the price ultimately established in a CBA for each item is adequate to ensure that beneficiaries receive quality products and services and to provide market stability in that CBA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance that the submitted bids are

"rational" and not unreasonably low, is to pay contract suppliers an amount equal to their individual bids. Although we understand that the MMA requires CMS to pay a "single payment amount" and that CMS intends to comply with this requirement, the statutory payment basis is the fee schedule amount or the actual charge, whichever is less. Consistent with the requirement, CMS could calculate a single payment amount equal to the pivotal bid and require winning bidders to submit claims in the amount of their bid - the actual charge - not the single payment amount. This approach also achieves price "transparency" for CMS and beneficiaries.

"Determining Single Payment Amounts for Individual Items"- Setting Single Payment Amounts For Individual Amounts. (proposed §414.416(b)) CMS has requested comments on setting methodologies for single payment amounts. The current fee schedule determines what kinds of products are available as much as the available products determine the fee schedule. The current system is not very flexible. As technology changes, fee schedules have been extremely slow to adapt adding a complex bid structure won't improve that situation and could well create a feedback loop that leads to technological stagnation in the provision of DME permitting neither cost savings not advancement in care. This locks suppliers and manufacturers into only considering the lowest priced item. Innovation in product will be non-existent; therefore, quality patient care will suffer.

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

The NPRM describes a rebate program that allows contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive

bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

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

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

Offering gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider raises quality and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers

with greater financial resources for such activities, disadvantaging smaller providers and businesses.

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

Once an inducement is in the public domain, its harmful effects cannot be contained, even with the safeguards CMS intends to implement. The fact that a provider does not "actively" promote an inducement does not change the illegal nature of the activity or the disruptive repercussions it has on competition and quality of care. The OIG would be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate: The "inducement" element of the offense is met by any offer of valuable . . . goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as "word of mouth" promotion by practitioners or patient support groups.

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

Currently, the standard cost to a supplier to refund a Medicare claim is approximately $30.00. The amount of paperwork and labor time required to process a rebate would burden the supplier.

Beyond the financial burden to the supplier, a rebate program has the potential to harm the providers' business and would ultimately confuse the beneficiary. For example, suppose two companies in the same MSA that are geographically located close to one another and service the same neighborhoods win a bid. Dealer One bids $100, which is the payment established by CMS, and Dealer Two bids $90.00 and then offers a rebate. Then a patient serviced by Dealer One and a patient serviced by Dealer Two go to a senior activity center and talk about their equipment. The patient serviced by Dealer Two talks about the $10.00 he/she got back. Dealer One's patient wonders where their $10.00 is, and when they call, are told they don't get it. Both dealers have complied with the law, but now patients are complaining about how they were ripped off by Dealer One. Also, the administrative costs associated with managing this rebate program will far exceed the savings CMS will achieve. The possibility of a "rebate" only serves to complicate an already challenging bidding process and implementation plan. Finally, allowing an illegal practice in the context of the competitive bidding program will only perpetuate the industry's cloud of fraud and abuse; CMS should not be fostering that perception through inappropriate means.

"Terms of Contract"- Modify Requirement That Only Winning Suppliers May Repair Patient-Owned Equipment. (proposed §414.422(c)) Any willing Medicare provider should be allowed to repair or do modifications and supply warranty services to all Medicare beneficiaries; however, we do agree it is appropriate for winning suppliers to be required to service any equipment they provide. However, this requirement should not be placed on equipment that is supplied by others. The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these unknown costs into their bids.

"Terms of Contract" – Length of Contracts (proposed §414.422) CMS states that the length of the contracts may be different for different product categories. Care Medical strongly urges CMS to have the same length contract for all products in a particular competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bid; the boundaries of the competitive bid, etc.), it will simply add significantly more confusion if there are different lengths of contracts for different product categories in the same geographic area.

"Terms of Contract"- Repairs & Replacements Of Patient-Owned Items Subject To Competitive Bidding. (proposed §414.422) CMS does not realize that repair centers for DMEPOS are not profit centers for a supplier. DMEPOS that currently provide repair services to beneficiaries do so to enhance the supplier's scope of services for the patient. Repair centers are an invaluable resource for beneficiaries of POV/PMDs. There are a limited number of providers who have repair facilities or vehicles for outside repair of equipment. Patients should not be required to receive repair services from only winning suppliers. This limitation restricts patient access and will harm the beneficiary whose wheelchair is their sole means of mobility. Limiting suppliers in this fashion is another means of monopolization. If there are only two DMEPOS that can repair equipment in an MSA, then a beneficiary may have to wait an extended period of time before their wheelchair can be repaired. This "waiting time" can cause serious injury and harm to the patient. When competition is limited in an area, there is no incentive to provide good after market service to a beneficiary. If a supplier does not have a repair facility, the supplier should not be able to bid on an item that requires routine maintenance, repairs or replacement. Manufacturers should also be required to certify DMEPOS repair facilities. In addition, contract suppliers may not have access to the parts necessary to repair equipment sold by another supplier. Suppliers do not all carry the same brand of equipment. Also, some manufacturers desire to limit access to their products to those suppliers with sufficient knowledge to properly service, repair and otherwise support their products. To require that contract suppliers be able to service all patient owned equipment would require manufacturers to open accounts with suppliers that they may feel do not meet their requirements.

"Terms of Contract"- Termination of Contract. CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

"Terms of Contract"- Judicial and Administrative Remedies. CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

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

"Terms Of Contract" – Furnishing Items To Beneficiaries Whose Permanent Residence Is Outside A CBA. The NPRM states that if the area that the beneficiary is visiting is not a competitive bidding area, or if the area is a competitive bidding area but the item needed by the beneficiary is not included in the competitive bidding program for that area, the supplier would be paid at the rate of the single payment amount for the item in the competitive bidding area where the beneficiary maintains a permanent residence. This proposal will make it difficult for traveling beneficiaries to obtain products and services in some areas. While we recognize that this is the current Medicare policy, the maximum payment difference from one state to another is only 15%, while the difference between a single payment price under competitive bidding and the fee schedule amount in a non-bid area could be substantially more than that.

There are a significant number of beneficiaries who are "snowbirds," who spend a good portion of the year in a more southern area of the country. This proposed requirement will have a significant and undue impact on suppliers providing items and services to snowbird beneficiaries. It is simply not equitable to impose a bid rate on an item on a supplier in a different area of the country, without any analysis regarding the appropriateness of that new lower price. This proposal will have an undue negative impact on suppliers serving "snowbird" beneficiaries, and CMS should reject this proposal in the final rule. We recommend that CMS modify its claims jurisdiction policy for these beneficiaries because these beneficiaries will likely find it difficult to obtain quality items and services when they are not at their permanent residence. This proposal needs to be changed to ensure that beneficiaries maintain appropriate access to medically necessary items.

Further, CMS states that it will monitor the programs to ensure that this type of "abuse or circumvention of the competitive bidding process and requirements to obtain items from a contract supplier does not occur." If this "avoidance of competitive bidding contract suppliers" activity does occur, CMS should understand that it is likely a strong indication that the competitive bid program is not meeting physician and beneficiary needs in that area. Beneficiaries would only seek out non-contract suppliers if they, and their referring physicians, are dissatisfied with the quality of items and services available from contract suppliers. This activity should therefore be monitored as a measure of whether contract suppliers are providing beneficiaries with a suitable level of quality and access; there would be nothing nefarious about this activity.

"Terms of Contract"- Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier. (proposed §414.422(c))
CMS proposes that a contract supplier must agree to accept as a customer a beneficiary who began renting the item from a different supplier regardless of how many months the item has already been rented. The supplier is supposed to factor the cost of furnishing items to beneficiaries' whose supplier chooses not to continue to furnish the item in accordance with the grandfathering provisions. Suppliers are suppose to factor the cost of furnishing items into their bid submissions. How can a supplier possibly figure a bid amount with the amount of unknown variables such as:

- The number of beneficiaries in the MSA who are currently renting equipment
- The number of suppliers who chose not to participate in the "grandfathering" program and who do not win the bid for that item.
- The number of months left on a capped-rental for a particular item, for the number of beneficiaries who receive that item.

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

Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

"Opportunity for Networks"- Clarify Network Regulations. (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?

"Opportunity for Networks" (proposed §414.418) CMS states that a provider cannot submit an independent bid and also bid as part of a network. Suppliers should be allowed to bid independently and as part of a network so every opportunity is afforded to the supplier to help ensure a successful bid.

"Opportunity for Networks"- Do Not Place Unreasonable Limitations On Formation Of Networks. (proposed §414.418) The 20% market share limitation should be removed. This is unnecessarily restrictive and does not apply to single entities that bid separately. Network members should be able to also bid through other means.

"Education & Outreach" – Beneficiary Education. The competitive bidding education must be provided by CMS to the supplier's referral sources, such as home health agencies, health insurance companies, HMOs (Health Managed Organizations), hospitals, physical and occupational therapists, and others. These agencies and the individuals they employ are an integral part of helping coordinate care of beneficiaries. CMS has a responsibility to provide education to them on the competitive bidding program and mandates under the program. Care Medical believes that CMS must hold educational sessions for suppliers to ensure that there is some level of consistency in the way beneficiaries are educated and the information they are provided. In addition, Care Medical recommends CMS provide materials that can be used by suppliers to effectively educate beneficiaries regarding the Competitive Bidding Program. In addition, CMS should not depend solely on suppliers or the CMS website to educate Medicare beneficiaries. Care Medical recommends that CMS hold multiple town hall meetings in each CBA to ensure that beneficiaries and referral sources are knowledgeable about the competitive bidding program. Including the formal complaint system and how to lodge a complaint and what resources CMS is providing to remedy issues and problems.

"Monitoring & Complaint Services For the Competitive Bidding Program" CMS is proposing to establish a formal complaint monitoring system to address complaints in each competitive bidding area. CMS needs to establish protocols for addressing these complaints in a timely and effective manner. The proposal by CMS states an ombudsman will be established for each region. An independent evaluation committee made up of consumers, suppliers, manufacturers, industry leaders, and PAOC must be part of helping solve problems and resolve issues brought forth by industry stake holders. The formal complaint monitoring system needs to continually inform beneficiaries of the process for lodging a complaint with CMS. While creating these policies and regulations, it needs to be examined how a resolution can be determined. This complaint resolution is extremely subjective. Some consideration must also be given to the concept that on occasion a beneficiary may be at fault, not the supplier. Will there be exceptions to the requirement of servicing beneficiaries in extreme circumstances (i.e. on occasion suppliers have "discharged patients from service")?

"Physicians Authorization/Treating Practitioner" – Physician Authorization/Treating Practitioner & Consideration Of Clinical Efficiency & Value Of Items In Determining Categories For Bids. The supplier must have the ability to determine what brands to offer based upon an allowable. This decision will be based on medical necessity not solely at the discretion of the physician due to the cost of the item. The request must be based on need not want. If a supplier carries an item that meets medical need and is a product category that has been bid, is the supplier required to provide any item the manufacturer sells in that product category? For the physician to prescribe a particular brand or mode of delivery of an item within a particular HCPC code is not compatible with competitive bidding by product category. How can a supplier determine a bid price if an outside entity has the ability to determine what brand of product is provided or the mode of delivery which the beneficiary will receive the item? If a supplier chooses one or two brands in a product category they have established that can make a reasonable or sustainable profit, an outside source cannot dictate an item of higher cost to the supplier. The cost of the item is an integral part in supplier's computing a sustainable bid.

We believe it is unnecessary for CMS to include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand

name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Further the proposal is contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. Inasmuch as CMS' authority to implement this requirement is discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

"Quality Standards and Accreditation for Suppliers of DMEPOS"- Only Companies That Are Accredited Should Be Eligible To Bid. Only accredited providers should be eligible to submit bids. CMS should not proceed with competitive bidding until it is sure that this is possible. CMS needs to identify the criteria it will use to identify the accrediting bodies now. CMS should grandfather all providers accredited by organizations that meet the criteria CMS identifies. CMS should also allow additional time for providers to analyze the quality standards in conjunction with the NPRM rule. The quality standards will affect the cost of servicing beneficiaries and are an integral part of the bid process.

Finally, CMS needs to identify the criteria it will use to select accrediting bodies now. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited before the bid solicitations are published.

At the very least, CMS should schedule a PAOC meeting after it publishes the quality standards. Care Medical Equipment strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional

comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

It is important to note that the IR methodology established by Congress requires CMS to make a determination that using the "standard rules for calculating payment" results in a payment amount that is inherently reasonable. Congress directed the Secretary to identify the factors that it would use to determine that a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. In determining whether a payment amount is inherently reasonable, and in establishing a new payment amount, CMS or its contractors must use "valid and reliable data" that meets specific criteria applicable to the data collection and analysis. 42 C. F. R. §405.502 (g). Importantly, the IR methodology contains specific procedural safeguards that apply to any determination to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, on factor CMS must consider is the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates." §1842b (8) (C).

Care Medical recommends that CMS identify the factors it would consider in deciding to initiate a technology assessment. Care Medical further recommends that CMS allow participation in the technology assessment by interested stakeholders. Additionally, Care Medical recommends that CMS develop an appeals process in situations where the manufacturer disagrees with the recommendation of a contractor and has data to support their opinion.

This proposal has broad sweeping impact on the Medicare program, not only the competitive bidding program. The competitive bidding program proposals and the proposal regarding establishing payment for DME both inside and outside of the competitive bidding program should be two separate Rules. Sixty days does not provide enough time to develop substantive comments for both of these significant issues. As such, Care Medical recommends that CMS initiate a separate rulemaking proceeding to solely address changes to the pricing methodology for DME.

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

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

CMS proposes not to require suppliers to provide every brand of products included in a HCPCS code. However, regardless of what brands the contract supplier furnishes, the single payment amount for the HCPCS code would apply. The current code set is inadequate and therefore only requiring suppliers to supply an item that meets the descriptor of the code will not adequately meet the needs of Medicare beneficiaries.

The current coding system, especially for complex rehab and assistive technology, groups items into very general codes. In many cases the items are designed for a similar use, but because of the anatomical anomalies, asymmetries, tone, functional limitations etc., beneficiaries must have access to a specific device within a code. Unfortunately due to differences in design, product cost and other factors, the costs associated with the devices are fundamentally different.

A basic example of problems within the current HCPCS code set is the current code for head rests- E0955. This code currently is used for all levels of headrests. However, an extremely broad range of technology falls within this code. The most basic item; a flat single pad with no adjustability and fixed, non-adjustable hardware would be the item most suppliers would base their bid on. However, this same code represents products with multiple pads, independently adjustable and contoured to allow intimate interface with the beneficiary's head, hardware that is adjustable in multiple directions that will also swing out of the way for transfers. The price differential between a basic headrest that merely supports the head when the beneficiary is tilted or reclined is significantly less than the headrest that controls the head, keeps it in proper alignment to prevent tonal reflexes and allows the beneficiary to drive a power wheelchair using an alternative input device controlled with precise head movements.

While focused and aggressive efforts are occurring that will hopefully develop an appropriate code set for rehab and assistive technology devices, the current HCPCS code set is grossly inadequate to support competitive bidding.

This proposal has broad sweeping impact on the Medicare program, not only the competitive bidding program. The competitive bidding program proposals and the proposal regarding establishing payment for DME both inside and outside of the competitive bidding program should be two separate Rules. Sixty days does not provide enough time to develop substantive comments for both of these significant issues. As such, Care Medical recommends that CMS initiate a separate rulemaking proceeding to solely address changes to the pricing methodology for DME.

"Gap Filling" - Adjustments To Competitively Bid Payment Amounts To Reflect Changes In The HCPCS Codes. (proposed §414.426) CMS proposes that when revisions to HCPCS codes for items under a competitive bidding program occurs in the middle of a bidding cycle and a single HCPCS code for two or more similar items is divided into two or more separate codes, the payment amount applied to these codes will continue to be the same payment amount applied to the single code until the next competitive bidding cycle. Care Medical strongly opposes this proposal. Allow manufacturers access to the contractor to be able to provide cost information related to engineering, product development and customer support, as well as costs associated with product support, service and delivery of the products in the field. In cases when a single

HCPCS code for two or more similar items is divided into two or more separate codes, the single payment amount applied to these codes is the same single payment amount to the single codes, and contract suppliers must furnish the items in accordance with the new codes.

Care Medical disagrees with this proposal. The reasons that CMS would determine that new HCPCS are need is when there are differences in technology, clinical application and pricing. In these situations, it is inappropriate to expect suppliers to provide these products at the price of the single payment amount of the single code. Care Medical recommends, that in the event a single HCPCS code is divided into two or more separate codes during a bidding cycle, CMS should re-bid the codes in the new code set which are appropriate for competitive bidding.

"Regulatory Impact Analysis" - 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 CMS' figures 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 yearly 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%.

It is our view that the term "Competitive Bidding" is a misnomer for a flawed system which might more aptly be described as "Selective Acquisition." It is also our belief that the two pilot projects have demonstrated significant negative consequences for beneficiaries by effectively eliminating the normal, healthy competition that currently exists between the DMEPOS provider community to provide beneficiaries with fast, efficient, and effective products and services.

Reasonable and significant cost-savings from providers can and should ultimately be achieved without eliminating normal competition in the marketplace and without eliminating virtually the entire, existing DMEPOS provider panel. We believe that creation of a "limited provider panel" through the proposed national competitive bidding (NCB) program is bad policy for beneficiaries and providers alike. While this NCB option may, in some instances, result in product price reduction, it will at the same time severely reduce overall patient access, choice and service, ultimately shifting increased care costs to other areas of the hospital system and health care continuum; e.g., increased length of stay in inpatient/acute settings and/or increased patient re-admission frequency or disease severity, etc. from moving to a "low price" model being encouraged by NCB.

The proposed rule appears to primarily utilize cost and volume for product selection. Unfortunately, the potential negative impacts in terms of overall patient access and inclusion and continuity with established care plans and protocols does not appear to be addressed. Consideration to overall medical appropriateness needs to be considered, as well as overall patient access to care and services.

Potential cost considerations that will affect many other areas of the overall health care continuum do not appear to be adequately considered or addressed. There appears to have been no examination of negative cost implications for physicians, home health nursing care providers, hospice, inpatient and outpatient hospitals, integrated healthcare delivery systems and owned-providers, as well as multiple and various other healthcare providers. It is obviously critical that protections and minimization of overall cost impacts throughout the health care service and cost continuum are clearly identified, discussed, and fairly addressed in the final rules. Pushing "costs" out of products alone will most certainly result in detrimental cost-shifting and even cost-increases in other areas of the continuum. Medicare will ultimately have to absorb these costs regardless of what "bucket" the money comes from.

"Summary" - Care Medical Equipment, Inc. has several strong concerns and objections regarding competitive bidding and the proposed rule. "Competitive Bidding" appears to be a poor choice of words for a horribly flawed system. While our responses to the individual items in the proposed rule have been outlined, we would like to emphasize the following points:

- We truly do not expect that Medicare will see any significant cost savings from this program. In the "Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics and Supplies", it is suggested that an additional 669 full time equivalent personnel at an approximate expenditure of $68.9 million will be required to manage competitive bidding. The proposed rule mentions a small staff at CMS being needed and perhaps an ombudsman in each region. These numbers grossly conflict with one another. There is also discussion within the NPRM of the need for an "implementation contractor". The projected costs associated with yet another entire contractor are not even mentioned. While we understand that perhaps some of these monies are pulled from different "buckets", we are not convinced that the administrative costs in managing competitive bidding truly will allow for the projected savings.

- The Medicare program as it stands has the lowest administrative cost of any other healthcare program in the country. Private insurance companies are competitive and we have to bid to be on the panel for every private payor we contract with and yet they all have higher administrative costs than Medicare, typically a five-fold higher administrative cost. Why

would Medicare want to take a plan that is working to change it to emulate private plans whose administrative costs far exceed their own.

- The concept that the federal government is intentionally implementing policies, which will reduce the number of DMEPOS providers by over a third, is tantamount to the federal government intentionally creating monopolies. This system is only going to enhance the strength of national DMEPOS providers. These national providers are already decreasing the volume of staff involved in customer service and education. We firmly believe that decreasing the number of DMEPOS suppliers in this manner will not allow for increased competition. We believe this system will encourage lower quality product and less customer service being supplied to beneficiaries. We also find it abhorrent that apparently no thought or consideration has been given to the emotional or economic impacts of the resulting displaced workers. This is a bigger picture issue than realized at first glance. These employees and their families are dependent upon their jobs for basic food, shelter and healthcare. The economic impact of 37% of the DME industry going on unemployment is unfathomable.

- As appears to be increasingly common with governmental regulations, we firmly believe the "cart has been put before the horse". This is made evident by several conflicting pieces of information. We agree that accreditation is appropriate for suppliers, so how then is it appropriate for non-accredited entities to submit a bid, "win" a bid and supply equipment to a beneficiary when CMS itself is stating that accreditation should be mandatory?

- We also firmly believe that product selection should be done extremely carefully. Rehab and custom equipment should be excluded including powerchairs and scooters. It has been demonstrated time and again that inappropriate equipment can cost significantly more in the long run. Creation of pressure sores, respiratory complications, contractures, etc. from inappropriate equipment only increase costs in other areas of healthcare, not to mention the pain and suffering of the beneficiary and family members, nor the economic impacts to all of us.

- Care Medical applauds CMS for its apparent intent to ensure that all suppliers providing items and services under the competitive acquisition programs meet defined Quality

Standards. At the time of this writing, however, CMS has not issued the final DMEPOS Supplier Quality Standards. We believe that these Quality Standards must be analyzed in the context of this proposed regulation, and therefore ***recommend that CMS either extend the comment deadline for the NPRM to 60 days after CMS issues the final Quality Standards, or allow for a formal comment period on the Quality Standards, for a period of at least 60 days after CMS issues the final Quality Standards.*** In addition, ***CMS should respond to public comments on the Quality Standards as part of its response to comments it receives on this NPRM.***

- Suppliers are being asked to make a bid that encompasses analyzing so many variables that are out of their control. Suppliers cannot control shipping costs; gas costs and manufacturer price increases, as well as increases in employee benefits such as health insurance. We propose that all suppliers be allowed to bid, regardless of the size of the organization. If suppliers agree to quality and financial standards set by CMS and they accept established payment amounts, suppliers should be allowed to service all Medicare beneficiaries in the areas they serve.

- CMS states that ""During the demonstration, evaluating quality and financial standards was time-consuming for the bid evaluation panel....". This statement implies that CMS may not plan to evaluate the quality and financial standards of all suppliers that submit bids at the outset of the bid evaluation process especially considering the implementation timeline CMS is holding supplier to. We are very disturbed by this implication. *(And CMS should not short-cut the procedures simply because it may be more administratively burdensome – such is the nature of this bidding process.)* Further, it is entirely unclear in the proposed regulation at what point CMS plans to evaluate whether bidders do in fact meet all the requirements, including quality standards (accreditation), financial standards, Medicare supplier standards, etc. It is imperative that CMS conduct this evaluation process at the outset before the bid evaluation process begins to ensure that bid information from a bidder that does not meet one or more of the requirements is not included in any part of the evaluation process. Otherwise, the entire bid calculation (including pivotal and single payment amount calculations) and contract supplier selection process will be fundamentally tainted with information from non-qualifying bidders.

Care Medical appreciates the time you have taken to read our comments on CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program (NPRM); Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues. If you have any questions or need further clarification regarding our comments, please do not hesitate to contact me.

Sincerely,

Angelene Adler, Vice President of Operations
Care Medical Equipment, Inc.
Phone: (800) 952-9566 ext. 155
Email: angelene@caremedical.com

Submitter : **Dr. Morgan Lorio** **Date: 06/29/2006**

Organization : **NeuroSpine Solutions**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

My name is Morgan Lorio, M.D. and I am an orthopaedic hand/micro surgeon who frequently treats Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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

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

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. Am I expected to inadequately fit and/or unprotect my patients?

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

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

Sincerely,

Morgan P. Lorio, M.D., F.A.C.S

CMS-1270-P-925-Attach-1.DOC

Submitter : Dr. Gary Cortese **Date:** 06/29/2006

Organization : Dr. Gary Cortese

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 27, 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 have been a podiatric physician for 25 years in the city of Pottsville, Schuylkill County, Pennsylvania. I have a well diversified practice with at least 1,000 diabetic patients under present medical guidelines. I have been participating in the diabetic therapeutic shoe program since it s inception. I have seen it work beyond expectations in it s present form. Diabetic shoes are an integral part of my comprehensive foot care treatment plan for these patients. These shoes require constant adjustments and tweaking through their life span. I routinely perform these services, usually at no cost to you or my patients during their regularly scheduled foot care treatment in my office. This continuity of care is paramount to effective prevention of serious complications. If you break this cycle, the system will fail. I have seen this with private insurance carriers for this service, in this area.

In this geographic area, transportation for my elderly, compromised diabetic patients usually must be scheduled in advance due to the lack of public transportation. To give such a patient the additional responsibility, cost, and stress in the presence of an emergent complication to arrange additional transportation is simply unacceptable, in my opinion.

Comprehensive foot care is what I practice all day, every day. As stated above, I prescribe, dispense, monitor, and adjust select DMEPOS items to my patients. I do not supply items to individuals who are not my patients, and I feel that requiring me to do so would harm and interfere with my present patients care. I am a current supplier with a valid supplier number who adheres to existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to M.D. and D.O. suppliers. As a physician in the Medicare system, I should have the same rights as they and CMS should use the 1861(r) definition of a physician in finalizing its regulations in this instance.

I strongly urge CMS to consider its interpretation of a physician to apply to a broader definition that would include podiatric physicians. I thank you for your time and attention.

Sincerely,

Gary A. Cortese, D.P.M.

Submitter : Dr. Thomas Pusterla

Date: 06/29/2006

Organization : Dr. Thomas Pusterla

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-927-Attach-1.DOC

June 29, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Thomas E. Pusterla, DPM, C. Ped.

Submitter : **Dr. George Yarnell** **Date: 06/29/2006**

Organization : **Dr. George Yarnell**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

GEORGE L. YARNELL, D.P.M.
Diplomate, American Board of Podiatric Orthopedics
23 N. Lansdowne Ave.
Lansdowne, PA 19050
610-626-3338
GeorgeY120@aol.com
June 28, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

If I see a patient who I diagnose with a fracture of the mid-foot, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. There is a delay in providing the necessary supplies, if I am not a supplier in the new program. My patients will suffer and have additional transportation expense, especially since many of my patients have to take public transportation.

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

Sincerely,

George L. Yarnell, D.P.M.

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

Organization : EDGE MEDICAL SUPPLY

Category : Other Health Care Provider

Issue Areas/Comments

Issue

Issue

COMPETITIVE BIDDING IS GOING TO DESTROY SERVICE FOR THE MEDICARE BENEFICIARY. THERE WILL BE NO INCENTIVE FOR AN AWARDED SUPPLIER TO PROVIDE QUICK SERVICE TO THE PATIENT BECAUSE AN AWARDED SUPPLIER HAS THE BID AND THE PATIENT WILL JUST HAVE TO WAIT UNTIL THE SUPPLIER GETS AROUND TO PROVIDING THE EQUIPMENT TO THE PATIENT. COMPETITIVE BIDDING WAS TRIED IN FLORIDA AND IN SAN ANTONIO, TEXAS AND WAS NOT SUCCESSFUL. PATIENT CARE SUFFERED. THE DMEPOS INDUSTRY ESPECIALLY THE HOME MEDICAL EQUIPMENT PROVIDERS HAVE BEEN CONTINUALLY THE RECIPIENT OF ONE REIMBURSEMENT CUT AFTER ANOTHER AND OTHER VERSIONS OF THIS HAVE BEEN TRIED IN THE PRIVATE INSURANCE SECTOR WHERE A FEW COMPANIES SUBMITTED BIDS BELOW WHAT THE COULD OPERATE AND AFTER GETTING INTO IT WENT OUT OF BUSINESS AND LEFT PATIENTS WITHOUT SERVICE. ALL IN THE SPIRIT OF TRYING TO GET THE BID AND UNDERCUT THE COMPETITION. THIS INDUSTRY IS THE CHEAPEST COST PER MEDICARE DOLLAR AND YET WE KEEP FACING ONE REIMBURSEMENT CUT AFTER ANOTHER WHEN THE HOME HEALTH AND OTHER SECTORS GET RAISES. THE COST TO PROVIDE SERVICE CONTINUALLY IS GOING UP WITH FUEL COSTS, SUPPLY COSTS POST HURRICANE IN THE SOUTH, AND RISING INSURANCE AND LIABILITY COSTS AND AGAIN REIMBURSEMENTS CONTINUE TO DECLINE AND/OR STAY FLAT. RURAL AREA PROVIDERS THOUGH MAY NOT BE HIT WITH THE INITIAL WAVE IF COMPETITIVE BIDDING GOES THROUGH BUT WILL BE HIT POSSIBLY WITH THE SECOND WAVE HAVE HIGHER COSTS TO PROVIDE SERVICE BECAUSE OF HIGHER DISTANCES TO DRIVE TO SERVICE THE PATIENT. THIS SIDE OF HEALTHCARE IS TRYING TO SAVE MEDICARE BY ALLOWING THE PATIENTS TO BE TREATED AT HOME, TO FUNCTION AT HOME WHICH KEEPS THEM OUT OF THE HOSPITAL. COMPETITION ALREADY EXITS WITH THE EXISTING SYSTEM. WE ALL HAVE TO ABIDE BY THE SAME FEE SCHEDULE. IF YOU WANT MORE BUSINESS, THEN YOU PROVIDE BETTER SERVICE AND THE BUSINESS WILL COME TO YOU. IF YOU CANNOT PROVIDE GOOD SERVICE TO THE PATIENTS, THEN THE PATIENTS, THE DOCTORS, THE NURSES, THE HOSPITALS, THE SOCIAL WORKERS AND CASE MANAGERS ARE NOT GOING TO CALL AND/OR RECOMMEND YOUR COMPANY. SO WE AS DMEPOS SUPPLIERS HAVE TO PROVIDE GOOD CARE TO OUR PATIENTS IF WE WANT TO CONTINUE TO HAVE BUSINESS. SO THE GOOD SERVICE PROVIDERS WILL WEED OUT THE BAD SERVICE PROVIDERS ON OUR OWN. WHAT IS MORE OF A STRUGGLE IS SUPPLIERS OUT THERE NOT FOLLOWING THE RULES AND CONTINUALLY DOING THE WRONG THINGS. MEDICARE NEEDS TO SPEND ITS EFFORTS IN LEVELING THE PLAYING FIELD AND COMING DOWN HARD ON THOSE NOT FOLLOWING THE RULES ESPECIALLY WITH THE NATIONAL COMPANIES THAT ARE ALWAYS IN THE NEWS FOR DOING ONE THING AFTER ANOTHER. STOP SPENDING MILLIONS OF DOLLARS ON PLANS THAT HAVE ALREADY BEEN SHOWN TO NOT WORK AND PUT THAT MONEY TO BETTER SERVICES FOR THE BENEFICIARIES AND REIMBURSEMENT RAISES TO COVER COST OF LIVING INCREASES AND THE ASTRONOMICALLY INCREASED FUEL COSTS THAT WE ARE HAVING TO BEAR TO PROVIDE GOOD SERVICE TO THE MEDICARE BENEFICIARY

Submitter : Ms. CAROL LAUMER LPN **Date:** 06/29/2006

Organization : RICE HOME MEDICAL

Category : Other Health Care Professional

Issue Areas/Comments

Issue

Issue

QUALITY STANDARDS (414.414)
Quality standards for the HME industry are needed, but the issue is not having them in place and accredititing bodies chosen prior to the bid process starting. Also the initial standard were not reflective of the industry of businesses of small to large companies.

Grandfathering (414.408):
This proposal is completely unrealistic under the current methods of rental and forced ownership. A HME company that gets the bid can not take over rental during the rental period. There isn't a method of calculating this in the bid and it would be a hardship on the medicare bene to have to switch out in the last few months of rental and then get "worn-out,used up,bid price" eqiupment that would quit operating one month after the ownership was transferred to the bene. This is a way of "putting it" to the old folks that use medicare!

REBATES (414.416):
This is way off the mark for legal, ethical businesses. Who would pay it,why would they pay it, and this is an example of rulemakers not knowing this business of HME and the legal obligations everyone operates under.

COMPETITIVE BIDDING;
We compete everyday in our business by the service we provide because we all get paid the same in our areas. Competitive bidding is a farce, it is selective contracting. Minnesota has bidding for the oxygen under medical assistance....the bidder bids low knowing that over 90% of the patients will be put into a PMAP program and the payment is then at or above medicare allowables. It is another way for a gopvernment agency to move the figures around for paper savings and all it does is reduce service and confuse providers and their customers.

IMPACT ANALYSIS:
The paper savings are recognized but they do not include the administrative costs for the NCB project to save medicare dollars.
It is reported by CMS National Health Expenditure Data 2006 that home care expenses are flat, where is the real saving? I can even answer that THERE ISN'T, IT IS ONLY SHIFTING!

STOP THIS MADDNESS UNTIL A HONEST,REALISTIC,WELL PLANNED PROCESS FOR THIS COMPETITIVE BIDDING IS PUT INTO PLACE.

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

Organization : **Medicap Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

My name is Robert Miller and as a person suffering from diabetes and as a community independent pharmacy owner, I respectfully request that diabetes testing supplies be deemed exempt from the Competitive DME Bidding process. It is imperative that all patients, just not my own, retain their current level of health care recieved at the retail pharmacy level. If competitive bidding becomes a reality for diabetes testing supplies at the retail pharmacy level, it will detrimentally impact the patient's health and well-being. As a diabetic and a Diabetic educator, the education of Diabetes is crucial to health and well-being of our patients:
1. Retail pharmacists offer critical clinical services to patients offering education on daily diabetes care,
2.Retail pharmacists have the ability to impact adherence in all aspects of diabes care and provide a local presence for assistance with complications of therapy,
3.Retail pharmacists work in conjunction with the patient's physicians in an effort to facilitate the best possible diabetes care. If you have any questions or comments to my response please call me at 618-997-2030 or e-mail at medicapmarion@midwestmail.com.

Tom Miller RPh

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

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

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

Sincerely,

Heather A. Holdermann, DPM, AACFAS

Submitter : Mrs. Christina Payne **Date:** 06/29/2006

Organization : Mrs. Christina Payne

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-933-Attach-1.DOC

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

Position: **Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.**

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. **You would be loosing an important component in the treatment of the upper extremity beneficiary**; the therapist input and expertise in the supply of an OTS orthosis.

In conclusion, **I request that Medicare revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding process**. Thank you again for the opportunity to comment on this proposed regulation.

Sincerely,

Christina K. Payne, OTR, CHT

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

Organization :

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

James S. Holdermann, DPM, FACFAOM, AACFAS

Submitter : Mrs. Monica Seiberling **Date:** 06/29/2006

Organization : Cornerstone Physical Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS
CMS-1270-P
Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.
Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries.
My name is Monica Seiberling OTR, CHT, and I am an occupational therapist specializing in the treatment of upper extremity disorders. My husband, Steve Seiberling PT, is a physical therapist treating hand and upper extremity patients. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in Chippewa Falls, Wisconsin, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.
Therapists are unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.
Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk.
In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.
A patient s needs are thoroughly evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, a specific brand may be the only one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on all brands of a certain orthosis. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that I know the beneficiary and the referring physician will require.
Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses.
In conclusion, I request that Medicare revise the proposed regulation.
Respectfully, Monica Seiberling OTR, CHT

Submitter : **Dr. Florence Gabrielle Summers** **Date: 06/29/2006**

Organization : **Dr. Florence Gabrielle Summers**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-936-Attach-1.DOC

June 26, 2006

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

Dear Dr. McClellan:

I am writing to request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supply (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patient may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

I routinely see Medicare beneficiaries and, as a current DMEPOS supplier, I am able to provide my patients with the wide range of care they require. If I see a patient who I diagnose with Posterior Tendon Dysfunction, I may decide that it is medically necessary and appropriate to use a Colorado Brace to treat my patient. I want to ensure that I have this easily brace available and that it is fitting properly for that patient.

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

Sincerely,

Florence Gabrelle Summers, D.P.M.

Submitter : Dr. Courtney Lyder **Date:** 06/29/2006

Organization : University of Virginia

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-937-Attach-1.DOC

CMS-1270-P-937-Attach-2.DOC

UNIVERSITY of VIRGINIA
SCHOOL of NURSING

June 28, 2006

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

To Whom It May Concern,

I would like to support the general rule of implementing a competitive bidding program for certain items of durable medical equipment, prosthetics, orthotics, and supplies throughout the United States in accordance with sections 1847(a) and (b) of the Social Security Act.

As a practicing gerontological nurse practitioner, educator, clinical researcher, former President of the National Pressure Ulcer Advisory Panel, and consultant to CMS for over ten years, I believe where equipment/products have been demonstrated to be of equal quality and produce similar/equivalent outcomes, the process of identifying the optimal equipment/product makes economical sense for both payers and patients.

My major concern lies in placing Negative Pressure Wound Therapy in the first round of piloting. It is clear that many home care patients have chronic wounds. In fact, some studies indicate that 1 and 4 home care patients have a chronic ulcer (e.g. pressure ulcer, venous stasis ulcer). These ulcers can limit mobility, decrease quality of life and increase mortality if not treated appropriately. Since the development of Negative Pressure Wound Therapy many patients have found hope in a therapy that has healed their chronic ulcer allowing them to resume a normal life. The great problem I anticipate in the new competitive acquisition is that only two products are currently approved by CMS for Negative Pressure Wound Therapy. These two products include the Vacuum Assisted Closure ((Kinetic Concepts Inc.) and the Wound Vacuum System (Blue Sky Medical Group, Inc.). To my knowledge the only product with any substantive objective data supporting its clinical outcomes is the Vacuum Assisted Closure (Kinetic Concepts Inc.). Thus, the clinical efficacy of the Blue Sky product is highly questionable and may compromise wound healing outcomes.

Overall, I commend the architects of the competitive bidding programs. I believe the methodologies to determine the pilot areas and optimal bid is logical. However, I would suggest that given the paucity of data on the Blue Sky Wound Vacuum System that before negative pressure wound therapy is placed in the competitive bid model additional studies are conducted to its clinical efficacy. Thus, I strongly encourage you to reconsider placing negative pressure wound therapy for competitive bidding at this time period.

If you have any questions, please feel free to contact me at Lyder@Virginia.Edu or 434-982-3298.

Respectfully,

Courtney H. Lyder, N.D., G.N.P., F.A.A.N.
University of Virginia Medical Center Professor
Professor of Internal Medicine and Geriatrics
Chairman, Department of Acute and Specialty Care

202 15th Street, SW, P. O. Box 800782, Charlottesville, VA 22908-0782
Phone: 434/924-0063/Fax: 434-243-2721
www.nursing.virginia.edu

Submitter : Mrs. Karen Thomas **Date:** 06/29/2006

Organization : Contact Physical Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-938-Attach-1.RTF

CONTACT
PHYSICAL THERAPY

10304 N. Hayden Rd, Suite 8
Scottsdale, AZ 85258
Phone: 480-429-5266
Fax: 480-429-5297

June 29, 2006

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Karen A. Thomas, OTR/L, CHT

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

Organization :

Category : **Occupational Therapist**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

Therapists are unique from other suppliers of DMEPOS. While orthoses are a critical component in the treatment of my patients, they are just one part of their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat and custom tailor treatment .

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Tina M. Steen OTR/L, CHT

Submitter : Dr. Leonard Gerber **Date:** 06/29/2006

Organization : Dr. Leonard Gerber

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-940-Attach-1.DOC

June 26, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of my patient care. I do not supply items to individuals who are not my patients. I hold a valid supplier number and adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

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

Sincerely,

Leonard Gerber, D.P.M.

Submitter : Dr. Carla Porter

Date: 06/29/2006

Organization : Dr. Carla Porter

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-941-Attach-1.DOC

June 26, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician, I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. My patients look to me to use my best medical judgment and clinical skill in their treatment.

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

If I see a patient who I diagnose with a fracture of the 5th metarsal, I may decide that it is medically necessary and appropriate to use a walking boot to treat my patient. I want to make sure the patient is not putting weight on the injured extremity and I need to make sure the walking boot fits properly for that patient. If I am not a supplier in the new program, I will not be able to do that and my patients will suffer.

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

Sincerely,

Carla Porter, D.P.M.

Submitter : Dr. Audra Siegel **Date:** 06/29/2006

Organization : Dr. Audra Siegel

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-942-Attach-1.DOC

June 26, 2006

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

Dear Dr. McClellan:

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

In my practice, I use a variety of DMEPOS items. For example, when a patient who is Diabetic presents to my office with concern of ulceration to his foot, part of my treatment plan may include off-loading the area of ulceration using a modified walking boot. This off-loading is necessary to aide in the healing of the ulcer as well as increase the speed of healing, thus decreasing this patient's chance of developing a limb-threatening infection. If I am not a DMEPOS supplier, the patient will need to go elsewhere to obtain this medically necessary item, increasing the healing time and increasing this patient's risk of infection. In addition, I would also like be able to ensure that the modification to this boot is done to properly fit this patient's needs.

Additionally, I would like to be able to execute a physician authorization when I determine that a brand of item is necessary for my patient.

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

Sincerely,

Audra R. Siegel, D.P.M.

Submitter : Dr. Christopher Bromley **Date:** 06/29/2006

Organization : Dr. Christopher Bromley

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-943-Attach-1.DOC

June 26, 2006

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

Dear Dr. McClellan:

I am writing to request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

Consider a patient who presents with a concern of foot pain following an injury. I may diagnose the patient with a foot fracture and determine that a non-weight bearing cast and crutches is necessary to treat the fracture. If I am no longer a supplier, my patient will be force to go elsewhere to obtain medically necessary items, placing the patient at risk of further injuring the foot. I want to verify that the patient is not putting weight on the foot, is using the crutches properly, that the item fits properly and functions as it should. If I am not a supplier in the new program, I will not be able to do that and 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 is part of the just makes sense and is better medicine.

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

Sincerely,

Christopher Bromley, D.P.M.

Submitter : **Mrs. Elizabeth de Herder** **Date: 06/29/2006**

Organization : **ASHT**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-944-Attach-1.DOC

June 29, 2006

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

My name is Elizabeth de Herder, and I am an occupational specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I have specialized in the treatment of hands and upper extremities for 23 years as an OTR. I am currently working in a private practice the services a large part of the hand therapy market in our local area as well as seeing people from a larger region who have limited availability to quality healthcare. I frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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

Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly interfere with my ability to react to these changes, putting repairs and patients at risk. As patient enter our practice, we evaluate their rehabilitation and orthotic needs strictly addressing the most cost effective way to provide the needed service. Often a combination of orthoses (prefabricated and custom) can increase our reliance on a home program substantially reducing the number of visits and healthcare dollars needed for additional therapy. For this system to work, especially for the clients who live very far away and have limited access to ongoing rehabilitation, they need to become independent in their

home program in a single visit. Often prefabricated orthoses with or without modifications can help simplify a patient's program and increase compliance thus goal achievement.

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations. It is essential that the skilled therapists have the opportunity to provide the patients with the correct DME. Cheaper products offered with inadequate skill for fitting and complete education result in higher costs to the healthcare system in the long run.

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Elizabeth de Herder, OTR/L,CHT

Submitter :

Date: 06/29/2006

Organization :

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

As a practicing podiatric physician, who prescribes and supplies DMEPOS items, I am greatly concerned about the negative impact the competitive bidding program will have on my patients. Presently, I provide my patients with wound care supplies, fracture boots, and ankle splints among other items. My patients are able to leave the office with appropriate care, and with detailed instructions on use of the the dispensed DMEPOS items.
Previously, I would have outside companies ship wound care supplies for patients, which would delay treatment, and then have the patient come in, not understanding how to use the wound care supplies they were sent.
I also would not want to put an elderly patient in a fiberglass cast, when a pneumatic walker would allow them to heal in a more timely fashion, as well as reduce the chance of a fall from being placed in a cast. Sending a patient across town for a similar DMEPOS item also would delay care. Many times, patient are brought in by transport companies, who will only allow a stop at the office and then home.
I strongly urge CMS to change the physician definitition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my pateints only and execute physican authorizations.

Submitter : Mrs. Diana Guth **Date:** 06/29/2006

Organization : Home Respiratory Care

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Charles Renner **Date:** 06/29/2006

Organization : Advantage Hand Therapy & Orthopedic Rehabilitation

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1270-P-947-Attach-1.DOC

CMS-1270-P-947-Attach-2.DOC

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

Proposed Rule for Competitive Acquisition of Certain DMEPOS,
1270-P

My name is Chuck Renner, OTR, and CHT. I am a Certified Hand Therapist and work closely with Board Certified Hand Surgeons. As part of my practice I routinely fabricate custom splints and issue pre-fabricated hand splints to patients. I also am the patients treating clinician. In many cases I see the patient as soon as their post operative dressing is removed. At that time I often make a protective splint as ordered by the physician. As I am leading the patient through their rehabilitation process I have the opportunity to make adjustments to the splint as their wounds heal, swelling resolves or their muscle function improves. I also am able to asses the patient's ongoing need for joint protection devices or functional splints that they may need after their course of rehabilitation is over.

I have a great concern over the proposed rule 1270-P. This rule, if imposed, would add expense and inconvenience to the patients covered my Medicare. At our clinic the doctor often sends a patient to me immediately after cast removal. With this rule the patient would have to travel to another location, possibly not in my town, get a splint made, and then return to my office to start the therapy. The splint may not be what I need to rehabilitate the patient properly and all adjustments would have to be performed off site, when the patient is already coming here for rehabilitation.

Lastly, there are many hand injuries that can occur. With different problems and hand sizes and surgeries one particular brand cannot possibly meet the needs of all patients. I am concerned that if you limit vendors by bidding you will deny the patient a chance to receive the most appropriate splint for his or her problem. This could decrease their overall outcome and function. Plus this segment of supplies must be proportionally a very small percentage and the cost savings to Medicare negligible.

I strongly oppose the adoption of CMS-1270.

Thank you for your consideration.

Chuck Renner, OTR, CHT

Submitter : **Dr. Robert Warkala** **Date: 06/29/2006**

Organization : **Dr. Robert Warkala**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Physician Authorization/Treating Practitioner

Physician Authorization/Treating Practitioner

Current proposal for DME excluding podiatrists being defined as physicians will negatively impact patient care. I feel it is important to maintain the ability to dispense medically necessary DME products that without having to compete with large DME providers who are not integrally involved with the care of the patient.

Submitter : **Dr. Brian Gale** **Date: 06/30/2006**

Organization : **Dr. Brian Gale**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Brian Gale, DPM, FACFAS
107 West Main Avenue
Bismarck, ND 50501
7012553338

Submitter : Mrs. Tammy Carlin **Date:** 06/30/2006

Organization : Kentfield Rehablitation Specialty Hospital

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

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

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

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

Submitter : **Ms. Darlene Mosley** **Date: 06/30/2006**

Organization : **Oak Knoll Health and Rehabilitation**

Category : **Long-term Care**

Issue Areas/Comments

GENERAL

GENERAL

Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

To Whom It May Concern:
I am writing today to voice my concerns regarding the Centers for Medicare and Medicaid Services' competitive bid proposal for certain durable medical equipment, prosthetics, orthotics and other suplies("DMEPOS")
I am the Administrator at Oak Koll Health & Rehabilitation, located at 824 6th Ave. West Birmingham, Al. Our facility has 100 beds and employs 135 employees. We offer long term care and short term rehabilitation services.
The proposed rule is a significant change to the current "any willing provider" environment. As a long term care professional, and a caregiver, requiring skilled nursing facilities to competitively bid in order to continue to receive Medicare Part B reimbursment for certain DMEPOS items could directly impact our ability to provide the best possible care to our resident/patients.
Medicare part b residents are often among the most frail and critically ill in a skilled nursing facility. I am concerned that by mandating a competitive bid process for DMEPOS and other specialty items, existing care plans could be interrupted, thereby affecting our ability to provide the care seniors need and deserve.
At Oak Knoll Health and Rehabilitation we have residents whose care could be interrupted as a result of this implementation, which would jeopardize their health and safety. The proposed rule has the postential to compromise a resident's access to specific services and products, resulting in long-term increased costs of care.

I feel it is critical that skilled nursing homes be excluded from the implementation of this rule. The level of care required by nursing home prtients should not be threatened or compromised by a mandate who impact, although well-intended, is not conducive to the long term care environment or continuum.

I appreciate your attention to the matter.

Sincerely,
Darlene Mosley
Administrator

Submitter : Dr. Tremaine Oatman

Date: 06/30/2006

Organization : Dr. Tremaine Oatman

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

CMS will allow MD and DO suppliers to competitively bid to supply DMEPOS only to their patients and will permit them to execute a physician authorization. As a physician in the Medicare program, I should have those same rights.

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

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

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

Sincerely,

Tremaine B. Oatman, D.P.M.

Submitter : Dr. Ira Kraus **Date:** 06/30/2006

Organization : Advanced FootCare

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-953-Attach-1.DOC

CMS-1270-P-953-Attach-2.DOC

Advanced Foot Care, LLP

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

June 22, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician, who has been in practice for 17 years I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

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

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

Sincerely,

Ira Kraus, DPM FACFAS

2368 Battlefield Pkwy	4308 Brainerd Rd	5741 Highway 153	8142B E Brainerd Rd	12978-B North Main St
Ft Oglethorpe, GA 30742	Chattanooga, TN 37411	Hixson, TN 37343	Chattanooga, TN 37412	Trenton, GA 30752
(706) 861-6200	(423) 698-1966	(423) 875-9211	(423) 553-8556	(706) 657-2467

Submitter : Dr. Thuy-Trang Lam **Date:** 06/30/2006

Organization : Clackamas Foot & Ankle Clinic, Inc.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Thuy-Trang Lam, DPM

Submitter : **Dr. James Korponay** **Date: 06/30/2006**

Organization : **Dr. James Korponay**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r)(3).

Not until recently have I supplied DMEPOS items to my patients. Not wanting to stock and dispense such items, I always wrote prescriptions for them and left it up to the patient to obtain them, but there were always problems:
1) Patient non cmpliance - the patient either never gets the item or doesn't get it soon enough.
2) The patient gets the item but is dispensed by someone unfamiliar with the patients problem and / or the patient does not receive proper instruction on applying the item or on its use.
3) The patient obtains an item of inferior quality that is inadequate in treating the problem.
4) The patient receives the wrong item or has to wait weeks for it to be ordered becsuse it is not in stock.
5) The patient hobbles around on the injured part in search of the item making the problem worse.

I then learned that by directly supplying the DME items to the patient at the time the diagnosis is made, these problems were not only solved, but the treatment outcomes were markedly enhanced.

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,

James Korponay, DPM

Submitter : Mrs. Lori Garber **Date:** 06/30/2006

Organization : Criticare Home Health Services, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

attachment

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

attachment

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

attachment

CMS-1270-P-956-Attach-1.DOC

CMS-1270-P-956-Attach-2.DOC

CMS-1270-P-956-Attach-3.DOC

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

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

Re: Written Comments file code CMS-1270-P

I am the owner of Criticare Home Health Services, Inc. We are a DME with an emphasis in oxygen and have been providing services for almost 20 years in Douglas County, Kansas and surrounding rural communities. We are located outside of the greater Kansas City area of about 45 miles to the west. Our county is about 100,000 residences. We employ 9 full time employees. We are a viable business who takes our patient's health care needs seriously. We do not mail equipment with instructions. We make every possible attempt to service our patients under the technical compliance rules of Medicare. I object to the introduction to the final rule which sets forth conclusions without support for the success of the Polk County project. There is plenty of data as to the failure of those projects. Also, I object to our industry being continually punished for those bad actors, who did commit fraud, and who should be punished. There does not need to be another layer of administration created as in this final rule when the NSC already had been charged with approval of enrollment. If the NSC needs to be funded then fund it.

I object to a lack of addressing an exemption to competitive bidding for small businesses, as defined gross revenues less than 5 million. Most rules exempt small businesses as it is the bread and butter of the American economy and that should be addressed in this proposed rule. That should be addressed forthwith.

The grandfather clauses should be expanded to allow businesses such as Criticare to continue to take on new patients until such time as accreditation is possible in a reasonable manner.

The proposed rules as stated are adding extra layers of administration costs and are just cost shifting from Medicare Part B to Part A and ultimately to the beneficiaries.

My remaining comments are as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the beneficiary an informed ABN regarding services and qualification of beneficiaries for patient owned concentrators will be unavailable for after hour's services.

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

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

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

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

Identification of beneficiary eligibility for DMEPOS either capped or purchased will prove time consuming and for after hours services, impossible. Based upon the 2003 figures for oxygen equipment provided, there are an estimated eleven million oxygen patients currently served by the fee for service system. Putting so large a population of frail, elderly, infirm patients who are dependent upon oxygen services at risk is an example of government "unconcern" on an unprecedented scale. When disaster strikes, contracting suppliers will not know if a beneficiary "qualifies" for equipment, indeed, the supplier will not even know who the beneficiaries are who own equipment. Serious consideration must be given to providing contract suppliers with qualifying information, patient information and patient addresses for beneficiary owned equipment in order to mitigate emergency services when needed. Remember, this is a vulnerable patient population whose medical necessity for oxygen has been established. The delay between finding a supplier and receiving services will likely cause increased emergency room visits and subsequent hospitalization. Where will the "savings" be with that?

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

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

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

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

- Transtracheal Oxygen patients – these patients require specialized instruction, care and supplies. A contract supplier must be able to provide such services or should not be allowed to accept such patients.

A Respiratory Therapist is usually specially trained to address specific patient issues such as catheter care, cleaning and instruction.

- Tracheostomy patients – again, such patients require specialized instruction, care instruction and supplies, usually by a Respiratory Therapist.
- High Oxygen Liter Flow patients – such patients require special attention to their oxygen needs – a "standardized" approach to their care will prove both dangerous and inadequate.
- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
- Patients without caregivers/family helpers – DMEPOS providers often assist patients in the home without reimbursement simply because the service interval has been increased for at risk patients. The low bid scenario will eliminate such assistance and these patients will utilize the ambulance, emergency room and hospital services at a much higher cost to the Medicare Trust Fund.
- Deaf patients – special patient populations require added time and instruction, even specialized equipment services. These un-reimbursed "services" will not be available under the competitive bidding model.
- Disabled patients (wheelchair bound) – these patients are often unable to perform routine daily maintenance of equipment due to their disability. Such services are un-recognized by the competitive bidding model and will be unavailable or at an increased cost to the beneficiary.
- Ventilator patients – this high risk patient population must not be forgotten. Numerous factors regarding mobility, emergency services and patient/caregiver instruction will be unavailable in the competitively bid "product". A lack of professional services will place this patient at great risk of injury or death.
- Medicated patients – many patients suffer from confusion and/or medication effect(s), causing them to be unable to perform simple tasks such as filter and humidifier changes, etc. Who will provide these services using the competitive bidding model? These patients are often confused and unable to understand instructions, much less perform complex maintenance on medical equipment.
- Hospice transfers to Medicare – patients who revoke hospice services to enter the Medicare program will not have access to services and/or will be required to change suppliers. Such continuity changes are distressing and often dangerous to this special population of patients. A contract supplier will be required to provide equipment, but will they be able to provide the "service" that these critically ill patients require?
- No transportation patients (no drivers license or vehicle) – public transportation is not everywhere, these patients will likely over-utilize emergency services when their equipment fails as they are likely unable to afford the service charges that will be required of a contract supplier.
- No telephone patients – this patient population will not even be able to "call" a contract supplier for emergency and/or after hour services, even if they are able to identify such a supplier. Who will care for them when a disaster strikes? Who will know that they even need assistance?

SUMMARY:

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

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

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

Access to new technology will be stifled – travel will be limited to what the beneficiary can afford to pay for privately – and no out of MSA competitive bidding area provider will be willing or able to provide services for the new reimbursement amount, whatever it may be. The intake process alone, considering paperwork burden, compliance with standards of care, etc. will cost the provider more than reimbursement (which, by the way, is the current situation as well, except they can attempt to at least break even if they provide a concentrator at the current low level of reimbursement).

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

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

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

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

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

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

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

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

While, I believe that competitive bidding is a misnomer and not the appropriate form of distribution of medical equipment to beneficiaries, if competitive bidding were to continue on its current coarse, the proposed competitive bidding timeframe is unrealistic and impossible to implement in a reasonable manner.

First the accrediting bodies have not been chosen. In fact, the standards for the accrediting bodies have not been determined, therefore, how can companies be expected to become accredited when there is no approved competitive body nor are there standards. There are no standard approved for the industry except for the existing supplier standards.

Next how can the time frame for competitive bidding be met. There is not enough time to implement in an orderly fashion that an industry deserves.

Action should be: Delay competitive bidding until reasonable standards for accrediting bodies are determined. Second: Come up with the standards for DME companies allow for a reasonable time frame for DME companies to become accredited. Third, implement competitive bidding in the LARGEST MSA, such as Miami and New York, because if you cannot make it work there, it is inherently unfair to implement in a small market and drive out hard-working businesses when there is no workable plan for the rest of the nation. Frankly, greater dollars are spent in the largest MSA's than the smaller ones. If competitive bidding is implemented, which I sincerely hope not in its current state, then continue to implement it over the years and not just fix a price reduction and make it a sham.

Lori L. Garber
Owner and President of Criticare Home Health Services, Inc.
Lawrence, Kansas 66044
785.749.4878

Submitter : Mr. Brad Bryan **Date:** 06/30/2006

Organization : West End Orthopaedic Clinic

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

The persons who are supposed to be helped by the competitive bidding process are the ones who will be hurt the most. Whatever cost savings may come about for the DME consumer will be more than offset by the inconvenience, the deleterious effect of delays in implementation, and the prospect of being provided with a poorly-fitting or even harmful orthosis by an untrained person who is not familiar with the disease process. This program, if implemented, will cause great harm in order to achieve a benefit that is miniscule.

Submitter : Mrs. Leslie Gibola **Date:** 06/30/2006

Organization : Adapt 2 It, Inc

Category : Occupational Therapist

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I am an Occupational Therapistwho owns a small DME in So. Cal.I have serious concerns fro the health of my business if competitive bidding goes through . I have noted that it has been said that the bids from national suppliers will hold more weight than those of smaller suppliers like myself. I need to understand how the standards are being set, and exactly the process by which to submit bids, and the items in a particular category. how are we(the smaller provider supposed to handle stocking every type of mannual wheelchair . what about custom manual chairs that are personalized from the ground up and that there are no standards for. will the customer have to settle only for off the shelf items which may in turn cause pain, increased postural deficits, decreased fuctioning, comprimised respiratory systems, decreased interpersonal relationships etc??? how are the smaller businesses able to stock every power chair in the category, and how is this going to be determined/enforced.

Submitter : Ms. Toni-Ann Esposito, RN BSN **Date:** 06/30/2006

Organization : Toni

Category : Health Care Professional or Association

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Please include a grandfather clause for those Accreditation compaines
that have already been identified by CMS
Please include THE COMPLIANCE TEAM as one of the 4 that have been stated by CMS! I would also suggest to be fair and to allow a fair foundation for providers and CMS to have this until deem status has
been granted. I would then allow the current accreditiation
to continue until Feb of 2009
Thank you very much
Toni Esposito, RN, BSN

Submitter : Dr. Jeffrey DeSAntis **Date:** 06/30/2006

Organization : APMA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 22, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

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

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

Sincerely,
Jeffrey R. DeSantis, DPM

Submitter : Ms. JULIA KLEINMAN **Date:** 06/30/2006

Organization : SOUTH FLORIDA ORTHOPAEDICS, P.A.

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

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

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

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

Submitter : Dr. WARREN MANGEL **Date:** 06/30/2006

Organization : Dr. WARREN MANGEL

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

I have been practicing in Camden, NJ for over 22 years. This city is one of the poorest in the nation with a very high percentage of elderly and disabled people, most on Medicaid and/or Medicare. Accessibility and language are two of the many barriers these people have preventing them from receiving necessary medical care. In this city of over 70,000 people, I am the ONLY full time Podiatric Physician caring for the needs of these people. I have for years been supplying my patients with medically necessary braces, orthoses, therapeutic shoes and wound care items, that otherwise would have been extremely difficult if not impossible for them to obtain on their own, especially in a timely fashion. Not being able to readily supply these DMEPOS items when they are needed, will not only cause a delay in treatment, but in most cases result in unnecessary pain and suffering and possible exacerbation of the problem increasing the cost of care. If I have to prescribe a DMEPOS item I can currently provide during the patient s visit to my office, it will require not only additional office visits, but additional medical transportation costs as well, in order to obtain the items.

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). As a podiatric physician, I currently prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), I know my patients will no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide. To me this is unthinkable. I have already dealt in the past during the 1990 s, with the last round of Medicare HMO s and their preferred suppliers. The DMEPOS items supplied were often worthless to the patients requiring mine and my staff s time and energy trying to correct, when they could have received the proper items from the beginning.

I am sure that there are large DMEPOS suppliers lining up their personnel in order to get ready for the expected windfall. Items will be supplied by these companies that will barely meet the minimum standards, purchased by these companies at a fraction of the cost of the better quality items myself and other Podiatric physicians provide, leaving us to deal with these companies on the patient s behalf, leaving the large supplier as the only beneficiary.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

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

Please change the physician definition from 1861(r)(1) to 1861(r) so that I am eligible to bid to supply items to my patients only and execute physician authorizations. Without this rule change, I will not only be unable to continue to provide all the medically necessary and appropriate care to the patients I serve, but I strongly believe CMS costs will see an increase due to the issues I described above.

Dr. Warren B Mangel, DPM

Submitter : Eric Spreeman **Date:** 06/30/2006

Organization : BenchMark PhysicalTherapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

See Attachmet

CMS-1270-P-963-Attach-1.DOC

Dear sir or madam and members of committee,

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

Thank you for the opportunity to comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries who seek out my services in a relatively rural setting.

My name is Eric Spreeman, and I am an occupational therapist who specializes in the treatment of the upper quartile. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I am currently working in Dayton, Dunlap and Jasper, TN, and frequently treat Medicare and Medicaid beneficiaries that require custom as well as off the shelf orthoses.

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

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

In addition, I feel that this system has a high degree of probability in placing me in a very precarious legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis and assume some aspect of liability for a device that I did not

supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Eric Spreeman, MHSA, OTR, CHT

Submitter : Mr. Larry Ambroson **Date:** 06/30/2006

Organization : The Medicine Shoppe

Category : Pharmacist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

As an independent community pharmacist, I respectfully request that diabetes testing supplies be deemed exempt from the Competitive DME Bidding process. If competitive bidding becomes a reality for diabetes testing supplies at the retail pharmacy level, it will detrimentally impact the patient's health and well-being.

Submitter : Dr. Steven Ginex **Date:** 06/30/2006

Organization : Palm Desert Podiatry Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-965-Attach-1.DOC

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Steven L. Ginex, DPM
Palm Desert Podiatry Center

Submitter : **Dr. Jay Tischler** **Date: 06/30/2006**

Organization : **Tidewater Podiatry Group**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

Mark B. McCellan, MD, PhD

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan

I am writing to urge the centers for Medicare & Meidcaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitve acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861 (r)(1) to 1861(r)(3).

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

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

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolotian Statistical Area (MSA) my patients will be negatively impacted.

Sincerely,
Jay I Tischler, DPM

Submitter : Ms. Beverly Myers **Date:** 06/30/2006

Organization : Rush University Medical Center

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

As an occupational therapist and a certified hand therapist I have been working with patients who have hand injuries for over 15 years. I would like to strongly urge you to drop the competitive bidding program for upper extremity orthoses for the following reasons.

First, most of the orthoses require ongoing evaluation and possible adjustment due to the acute nature of the patient's condition which frequently changes. Inflammation, pain, instability and weakness may fluctuate during the course of treatment. The type of the splint, fit of the splint and wearing time may need to be adjusted at various times. Who will best be able to do this for the patient?

Second, changes in orthotic support may be required as the patient returns to work or engages in different activities. Who will be best trained to evaluate the patient's performance in the activity and make appropriate orthotic selection and adjustments?

Lastly, continuity of care may be as important to the patient as the saving of a few dollars from off the shelf splints. Having the patient travel back and forth between orthotic supplier and therapist may create some legal and ethical problems not to mention inconvenience for the patient. Who will adjust the possible inappropriate splint issued by the winner of the competitive bid?

In summary, I would strongly recommend that upper extremity orthoses be omitted from the competitive bidding process. The orthoses are integrated into the therapy program with frequent reevaluation and upgrading as the patient's physical needs and functional demands change. Sending a patient across town to obtain splints and receive the ongoing adjustments may delay the supply of the orthosis and certainly interfere with efficient and most likely quality of care.

Submitter : **Ms. Charlene Gates** **Date: 06/30/2006**

Organization : **Dartmouth Hitchcock Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist who works primarily with individuals who have complications of cancer treatment. This issue is important to me because in the course of treatment for problems with swelling (lymphedema, venous stasis), I measure for over the counter compression garments (sleeves, gloves and stockings). Physicians here at DHMC refer patients to me because they trust my judgment in recommending specific garments and devices. I also may recommend donning aids or ambulation aids.

The billing for these items is done by a medical supply company. However, I am the professional who has the direct contact with the patient and the best overall assessment of their function and needs. Some brands work better than others for specific purposes, for example, one brand of compression sleeve tends tends to hold up better and have more sizes available for women who have larger upper arms.

Thanks you for your consideration of these comments.

Sincerely,
Charlene Gates PT
Dartmouth-Hitchcock Medical Center
603 650-5978

Submitter : Ms. Coral Andrews **Date:** 06/30/2006

Organization : Healthcare Association of Hawaii

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

The Healthcare Association of Hawaii is a non-profit trade association representing the full spectrum of health care, including acute and long term care facilities, and home care and hospice providers throughout the State. I am commenting in opposition to competitive bidding as the process stands to negatively impact the urban and rural markets within our Islands. The neighbor islands rely heavily on small business owners who provide home medical equipment supplies and individualized service to remote areas. Enabling the retention of the small business market of home medical equipment suppliers on each Island is essential to sustaining a tiered health care delivery system in our State. Competitive bidding will benefit larger, wholesale suppliers and drive the smaller companies out of business. In addition, developing a competitive bidding process that focuses on cost, not quality, has the potential for lowering the quality and variety of DME provider inventories.
Should you have questions regarding my comments, please do not hesitate to contact me at 808-521-8961 or candrews@hah.org. Thank you for this opportunity to comment.

Submitter : Mrs. Deanne Blanco **Date:** 06/30/2006

Organization : Mrs. Deanne Blanco

Category : Occupational Therapist

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Therapists are trained to evaluate a patient's current abilities and fabricate a splint that is appropriate for that person. Some diagnosis require spints to be adjusted as that paient progresses through the healing phase of an injury such as various tendon repairs in the upper extremity. An orthosist is not trained to evaluate and make clinical descions on what is appropriate for the patient's functional needs. Making patients go between a therapist for treatment and an orthotist for splinting is not cost effective for medicare and makes follow throughfor patients more difficult. Making patients go to an orthotist for splints wll delay treatment for patients. Making rehab more costly as an end result.

Submitter : **Dr. Edward Orman** **Date: 06/30/2006**

Organization : **Dr. Edward Orman**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

I am a podiatric physician practicing in the Baltimore Metropolitan area for 26 years. In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPS), the Centers for Medicare and Medicaid Services (CMS) used the definition of physician that excludes podiatric physicians. I urge CMS to change the definition from 1861(r)(1) to 1861(r).

I prescribe and supply select DMEPOS items as part of patient care. These items include CAM walkers, plantar fascia night splints and AFOs. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

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

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

Sincerely,

Edward S. Orman, DPM

Submitter : **Dr. Edwin Harris** **Date: 06/30/2006**

Organization : **Dr. Edwin Harris**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Edwin J. Harris, DPM, FACFAS
10540 W. Cermak Road
Westchester, IL 60154

Submitter : **Dr. Lori Weisenfeld** **Date: 06/30/2006**

Organization : **Dr. Lori Weisenfeld**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McCellan:

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

I am a podiatric physician who has practiced in New York City for seventeen years. I often see patients who require DMEPOS. It is unrealistic to expect a patient to travel to another location to obtain items that are integral to their treatment while suffering with a foot injury. If DPM s are not given the same considerations as our MD and DO colleagues are, we will not be able to render comprehensive treatment to our patients.

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

Sincerely,
Lori S. Weisenfeld, DPM

Submitter : **Ms. Sheila Soderberg** **Date: 06/30/2006**

Organization : **Jorgenson Drug Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

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

As the owner of a small business in rural Montana, I urge CMS to take steps to ensure that small suppliers, such as myself and 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 impossible for small suppliers to be competitive in large metropolitan areas.

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

I currently serve a rather large rural area, with the closest pharmacy being 50 miles south and the closest DME provider being 65 miles south. For our rather large elderly population, and with a large precentage of these people having diabetes, emphasemia, COPD, being able to provide DMEPOS supplies is more of a service than a financial money maker in my area. Without these revisions to the final regulation, I will be unable to continue providing these valuable services for my patients.

In conclusion, I urge CMS to revise the regulation to allow provisions so that the small suppliers can still continue to provided much needed services to our patients. Without these changes, many people will go without necessary supplies and in the long run more hospitalizations will occure as a result of this. Where is money being saved there?

Please be logical and wise in your decision making, because it effects not only me and my business, but is greatly affects a large rural population in our country.

Thank you for considering my request.

Sincerely,

Sheila Soderberg, R.Ph.

Submitter : **Date: 06/30/2006**

Organization :

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a certified hand therapist working in an outpatient private clinic. I am very concerned about the impact this will have on patients across the board. I am especially concerned with the post-op patients we receive as walk-in clients. They require immediate splinting in custom orthotics specific to custom protocols our physicians have requested. For example, a flexor tendon repair calls for a type of dynamic orthotic you cannot purchase off a shelf and cannot wait for the time required by orthotists. We are able to fabricate the orthotic within hours of the patient arrival, in addition the material used allows for constant adjustments and changes as required by protocol- so one splint can be adapted rather than having to make several. We are experts in the treatment and care of upper extremity injuries, having both the education and certifications to make custom orthotics. If this passes, it will be an injustice to the public and will create chaos for all involved.

Submitter : Mrs. Jeannette Muller **Date:** 06/30/2006

Organization : Wellington Orthopaedics and Sports Medicine

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

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

Please do not change the rule and sinificantly limit my ability to help my patients in the area of appropriate orthoses.

Submitter :

Date: 06/30/2006

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

You have a 52 page document CMS-1270-P - I don't understand at all. Who writes these things.

Submitter : Mrs. Margarita Vileno-Sosa **Date:** 06/30/2006

Organization : Mrs. Margarita Vileno-Sosa

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

This bidding will be a detriment to provide quality care. What happens if the patient receives the wrong brace or a poor fitting brace or splint at a different facility? If timing is essential for patient recovery and the patient must go to another provider his or her recovery may encounter complications that will result in a more expensive rehabilitation.

Submitter : Mrs. charlene McNeill **Date:** 06/30/2006

Organization : Orthopaedic Specialist of Alabama

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-979-Attach-1.DOC

June 29, 2006

Orthopaedic Specialists of Alabama
1020 Tower, Suite 220
Alabaster, AL 35007

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Charlene McNeill, OTR/L, CHT

Submitter : **Dr. Gerald Calia** **Date: 06/30/2006**

Organization : **Advanced family footcare**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,
Dr. Gerald B. Calia (DPM, MS(Pharm.)

Submitter : **Dr. John Parrinello** **Date: 06/30/2006**

Organization : **Doctor of Podiatric Medicine**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

JOHN F. PARRINELLO. D.P.M.
9441 Wilderness Trail,
Brooksville, Florida 34613 Tel: (352) 592-4711
Fax: (352) 592-4788

June 29, 2006

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

Dear Dr. McClellan:

In the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, like prosthetics, orthotics, diabetic shoes and other (DMEPOS) supplies, the Centers for Medicare and Medicaid Services (CMS) used the definition of a physician that excludes Podiatric Physicians.

I urge CMS to change the definition from 1861r(1) to 1861r.
CMS will allow MD and DO suppliers to competitively bid to supply DMEOPS only to their patients and to execute a physician authorization. I am a physician in the Medicare program and should also maintain those same rights. The broader definition includes podiatric physicians. I urge CMS to reconsider its definition.

Sincerely,

John F. Parrinello, D.P.M.

Submitter : **Dr. Jane Graebner** **Date: 06/30/2006**

Organization : **Dr. Jane Graebner**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only.

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

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

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

Sincerely,

Jane Graebner DPM
29 Grandview Avenue
Delaware, OH 43015

graebner@midohio.net

Submitter : Mr. Greg Pitts **Date:** 06/30/2006

Organization : Ky. Hand and Physical Therapy

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-983-Attach-1.TXT

Sample Letter

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Greg Pitts MS, OTR/L CHT

Submitter : **Dr. Matthew Wilkin** **Date: 06/30/2006**

Organization : **Dr. Matthew Wilkin**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

Mark B. McClellan, MD, PhD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1270-P

Electronic Comments

Dear Dr. McClellan:

I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician definition used in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) from 1861(r)(1) to 1861(r)(3).

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

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

I urge CMS to modify the physician definition from 1861(r)(1) to 1861(r)(3) before finalizing the regulations for the competitive

acquisition program. I want to be able to continue to supply DMEPOS items for my patients only and believe that if I am required to instead bid to supply the entire Metropolitan Statistical Area (MSA) my patients
will be negatively impacted.

Sincerely,

Dr. Matthew M. Wilkin

Submitter : **Mrs. Elizabeth Dillard** **Date: 06/30/2006**

Organization : **Mrs. Elizabeth Dillard**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I would like to submit the attached letter for your review.

Thank You,
Elizabeth Dillard, MSOTR/L, CHT

CMS-1270-P-985-Attach-1.DOC

Sample Letter

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be losing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Elizabeth A. Dillard, MSOTR/L, CHT

Submitter : Mr. Jeffrey McPherson **Date:** 06/30/2006

Organization : Tennessee Orthopaedic Clinics, P.C.

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-986-Attach-1.DOC

June 28, 2006

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

Dear Dr. McClellan:

We are writing to urge the Centers for Medicare & Medicaid Services (CMS) to revise the physician participation in the proposed rule that would establish a competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

It is our request that CMS exempt physicians from the competitive acquisition program for certain DMEPOS, and allow physicians to continue supplying DMEPOS to the patients that are deemed medically appropriate and necessary. If we are instead required to bid to supply an entire Metropolitan Statistical Area (MSA), our patients may no longer be able to get medically appropriate and necessary DMEPOS items from us even though they are integral to the care we provide.

In our practice, we use a variety of orthopaedic DMEPOS items and supply these items to Medicare beneficiaries as an integral part of patient care. For an example, if a patient presents complaining of foot pain and swelling following an injury, we may diagnose the patient with multiple fractures of the metatarsals, and determine that a walking boot is necessary for immobilization of the injured foot. Another example, a patient my present with extreme shoulder pain following an injury, and may be diagnosed with a possible rotator cuff injury and we determine that a shoulder sling with wedge be appropriate to immobilize the patient until a confirmed diagnosis can be obtained with further testing. If we are no longer able to function as a supplier because we were not accepted in the competitive acquisition program for certain DMEPOS, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to their current condition. For example, if the patient with the foot pain is unable to bear full weight on the injured extremity, a fall might occur, which could result in additional injuries.

We urge CMS to ensure that the physicians with a valid supplier number will be exempt from the competitive acquisition program for DMEPOS, and allow them to continue supplying these items based on medical necessity and appropriateness.

Sincerely,

Tennessee Orthopaedic Clinic Physicians

Submitter : Mrs. Kathleen Katai **Date:** 06/30/2006

Organization : STAR Therapy

Category : Occupational Therapist

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

Occupational and Physical Therapists who are trained in the specialty area of upper extremity rehab. are extremely qualified to fit and dispense splints/orthotics to patients. I am a Certified Hand Therapist, with 18 years experience, who treats patients with orthopedic injuries, arthritis, and cumulative trauma conditions. I have significant skill in the proper fit and fabrication of custom splints, and pre-fabricated splints. You must include OT/PT in the providers able to dispense splints without having to competively bid for the right to do so. You will take away the therapist's ability to properly fit the patient efficiently, at the least cost to the pt. and the insurance company, if you only allow a few clinicians in an area to dispense them. It makes no sense for one therapist to have to send their patient elsewhere for a splint, while they complete the remainder of the treatment.

The patients will have less quality care, additional cost, and less than optimal outcome for their conditions, if the current system of allowing OT's and PT's to splint is taken away. I can't tell you how many times I have been able to fit a patient with a good-fitting splint, when they come in with one that is either too small, too big, or not supporting the injured or arthritic limb appropriately. Therapists have the skill to determine what the patient needs, and provide the appropriate splint(s) for the conditon. We have an excellent background in anatomy, injuries and preventitive measures for a wide variety of conditions. There are many highly skilled clinicians who will not be allowed to provide pts. a valuable and needed service if you limit it to a select number of providers.

Thank you for your time. Please don't take away my option to provide my patients with splints.

Kathleen Katai, OTR/L, CHT
Occupational Therapist, Certified Hand Therapist

Submitter : **Dr. Kendale Ritchey** **Date: 06/30/2006**

Organization : **Tennessee Orthopaedic Clinics, P.C.**

Category : **Physician**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

See Attachment

CMS-1270-P-988-Attach-1.DOC

June 28, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of orthopaedic DMEPOS items and supply these items to Medicare beneficiaries as an integral part of patient care. For an example, if a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals, and determine that a walking boot is necessary for immobilization of the injured foot. If I am no longer able to function as a supplier because I was not accepted in the competitive acquisition program for certain DMEPOS, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to his/her current condition. For example, if the patient with the foot pain is unable to bear full weight on the injured extremity, a fall might occur, which could result in additional injuries.

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

Sincerely,

Kendale L. Ritchey DPM
Tennessee Orthopaedic Clinics, P.C.

Submitter : Dr. James Engblom **Date:** 06/30/2006

Organization : Tennessee Orthopaedic Clinics, P.C.

Category : Physician

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

See Attachment

CMS-1270-P-989-Attach-1.DOC

June 28, 2006

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

Dear Dr. McClellan:

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

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

In my practice, I use a variety of orthopaedic DMEPOS items and supply these items to Medicare beneficiaries as an integral part of patient care. For an example, if a patient presents complaining of foot pain and swelling following an injury, I may diagnose the patient with multiple fractures of the metatarsals, and determine that a walking boot is necessary for immobilization of the injured foot. If I am no longer able to function as a supplier because I was not accepted in the competitive acquisition program for certain DMEPOS, the patient will be forced to travel to another location to obtain the necessary item and will risk further injury to his/her current condition. For example, if the patient with the foot pain is unable to bear full weight on the injured extremity, a fall might occur, which could result in additional injuries.

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

Sincerely,

James A. Engblom, DPM
Tennessee Orthopaedic Clinics, P.C.

Submitter : **Ms. Barbara Fong** **Date: 06/30/2006**

Organization : **Tri Valley Orthopedic Specialists, Inc**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-990-Attach-1.TXT

CMS-1270-P-990-Attach-2.TXT

Dear Sir or Madam:

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

My name is Barbara Fong, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the exam. I have specialized in the treatment of hand and upper extremity for 18 years. I am currently working in a private orthopedic office that is owned by a group of 8 orthopedic surgeons, two of whom are hand surgeons. We are in the process of getting Medicare certification for Occupational and Physical Therapy. As a hand therapist I would frequently treat Medicare patients that require custom and/or off the shelf orthoses.

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

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

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an

inappropriate orthoses, supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Barbara Fong, OTR/L, CHT
Tri Valley Orthopedic Specialists, Inc.
5565 West Las Positas
Pleasanton, CA

Submitter : **Dr. Bruce Lawrence** **Date: 06/30/2006**

Organization : **Dr. Bruce Lawrence**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

I am a podiatric physician who has been in practice for 38 years. I am a DMEPOS supplier, and treat Medicare patients on a daily basis. I am currently able to provide my patients with the wide range of care they require. I request that CMS exclude all physicians, including podiatric physicians, from the new competetive acquisition program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). I believe that the proposal could interfere with my ability to provide quality care that is medically necessary.

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

Sincerely

Bruce R. Lawrence, D.P.M.

Submitter : **Dr. Warren Levy** **Date: 06/30/2006**

Organization : **Dr. Warren Levy**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

As a podiatric physician practicing for the past 25 years in Chicago, IL , I prescribe and supply DMEPOS items to Medicare beneficiaries as an integral part of patient care. These individuals are my patients and they rely on me to use my best medical judgment and clinical skills in treating them. I am required to maintain a valid DMEPOS supplier number, adhere to the current supplier standards and am subject to the same Stark requirements that apply to MD and DO physician suppliers. Podiatric physicians should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to my patients only and the right to execute a physician authorization.

In my practice, I use a DMEPOS items, especially diabetic shoes and inserts. My practice consists largely of elderly homebound patients, many of which are diabetics with need of diabetic shoes. My patients benefit greatly by my ability to provide the proper guidance for diabetic shoes, including the right style and size for each individual patient. Often the patient lacks the ability or assistance to obtain the shoes elsewhere. If I no longer function as a trusted supplier, or be able to provide the diabetic shoes, it will seriously affect the care provided and increase medical risks to the patient. I have often observed when patients need to purchase shoes elsewhere they lose largely the ability to make sure the shoe fit properly and the recourse if they don t. When patient are forced to travel to another location to obtain the necessary item, they would often do without and will have greater risks of injury or ulcerations to the foot.

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

Sincerely,
Warren Levy, D.P.M.

Submitter : **Dr. Douglas Richie** **Date: 06/30/2006**

Organization : **American Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Podiatrists should be included with Physicians and DO suppliers as those professionals who can competitively bid to supply DMEPOS only to their patients. I dispense approximately 20 DMEPOS products to patients per month who require immediate intervention with these devices to treat acute injuries of the foot and ankle.

Sincerely,

Douglas H. Richie Jr. D.P.M.
Adjunct Associate Clinical Professor, California School of Podiatric Medicine at Samuel Merritt College

Submitter : **Ms. lori stotko** **Date: 06/30/2006**

Organization : **MidPeninsula Hand Rehabilitation/Cresswell PT**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Lori Stotko. I have been an occupational therapist and hand therapist for 18 years. I have been a certified hand therapist for 12 years. I feel this regulation will put our patients who have acute splinting needs (or need for an orthosis) at risk, and will make us less efficient and effective as hand therapy practitioners. The profit margin for all hand splints is very low and they are often provided at cost to Medical patients, so it is hard for me to believe that the savings for Medicare will justify the inconvenience placed on elderly patients who are receiving care in one facility, but are forced to travel to another to get their orthosis. Also, if a wrong or ill-fitting orthosis is provided by an outside facility, and the patient suffers further injury because of it, or because it is inappropriate who is to blame? I have made thousands of splints in my career and consider myself an expert judge of what will be effective and medically appropriate, along with the guidance of my referring surgeons and other physicians.
Please consider revising or revisisting this legislation to continue to allow us experienced hand therapists to perform our jobs and provide the best possible care to our Medicare and Medical patients.
Respectfully submitted,
Lori Stotko OTR CHT MidPeninsula Hand Rehabilition, Menlo Park Ca.

CMS-1270-P-994-Attach-1.DOC

Submitter : Mrs. Mojca Herman **Date:** 06/30/2006

Organization : Advanced Therapy Center

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

CMS-1270-P-995-Attach-1.TXT

CMS-1270-P-995-Attach-2.DOC

Sample Letter

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Mojca Herman, MA, OTR/L, CHT

Submitter : **Mrs. Lauren Gordon** **Date: 06/30/2006**

Organization : **American Society of Hand Therapists**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-996-Attach-1.TXT

CMS-1270-P-996-Attach-2.DOC

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

My name is Lauren Gordon, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years experience in the treatment of these patients prior to sitting for the examination. I have over thirty years of experience working in the area of hand and upper extremity rehabilitation. Currently I am working in an outpatient hand therapy clinic in Gurnee, Illinois, and frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses.

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

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

In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis,

assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with inevitable possibility of delay, knowing that they are potentially fitted inadequately and/or leaving a critical post surgical procedure unprotected? This very possible scenario has both legal and ethical considerations.

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Lauren A. Gordon OTR/L CHT

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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In addition, I feel that this system has the potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses, supplied by another entity, am I to adjust this orthosis,

assuming some of the liability for a device that I did not supply or charge for? Or should I let them leave my office and drive to another facility, with inevitable possibility of delay, knowing that they are potentially fitted inadequately and/or leaving a critical post surgical procedure unprotected? This very possible scenario has both legal and ethical considerations.

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

Sincerely,

Lauren A. Gordon OTR/L CHT

Submitter : S Louie **Date:** 06/30/2006

Organization : Northwest Hand Therapy LLC

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

We are all concerned that medicare dollars be utilized wisely for our futures sake. As a hand therapist who provides service to many elderly patients in an outlying rural area, the necessity of providing appropriate functional splints as part of treatment is most economically and efficiently provided by the treating therapist. A good example is over the counter splints for carpal tunnel syndrome...how many times do we see patients who exacerbate their symptoms with ill-fitting, tight, and motion restricting elastic splints? Sadly, these patients don't even understand the purpose of the splint. Could therapists be saving the patient's time and medicare's money by providing for their individual needs at the initial time of service? The treating therapists' knowledge of the patient's lifestyle, medical needs, and physical barriers combined with the therapists' expertise leads to the success of the right splint for the right hands. The hands of elderly patients frequently means deformities from arthritis, poor skin integrity, sensory losses, painful joints, and other challenges that are best provided for by their treating therapist. I would also be conerned as their treating therapist that splints provided by another facility would not meet the needs of the therapeutic intervention a physician intents. It is true that as a therapist we can be creative with what we have, but are we truly serving the needs of the elderly patient who is challenged with physical mobility, weakening memory skills, limited transportation, and limited dollars to find another facility to partially meet their many needs?

Submitter : **Dr. Joseph Borreggine** **Date: 06/30/2006**

Organization : **Dr. Joseph Borreggine**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

Joseph Borreggine,DPM

Submitter : **Mr. Banji Adereti** **Date: 06/30/2006**

Organization : **Elim Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

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 to ensure that the payment rate is adequate to cover a supplier's costs to acquire and provide the product.CMS proposal does not address situations where the 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 thier acquisition cost which will make it difficult to continue to provide DME supplies. CMS must 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 biddin program.
Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS.
Any small supplier willing to accept CMS' single payment amount should be allowed to join the competitive bidding program as a contracted supplier.
If CMS allows competitive bidding from large supplies to the detriment of smaller suppliers, that will be contrary to the American way of business that promote competition even at small levels.
Small businesses are a vital part of the American economy and should not be eliminated.
Todays big corporations and suppliers all started as 'a small business' and got their chance to grow.
I urge CMS to take these steps to prevent beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.

Submitter : **Dr. Stuart Courtney** **Date: 06/30/2006**

Organization : **Dr. Stuart Courtney**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 29, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

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

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

Sincerely,

Stuart A. Courtney, DPM
1250 E. Hallandale Beach Blvd., Suite 1005A
Hallandale Beach, FL 33009
Tel: 954-458-2228
Fax: 954-458-2530
E-mail: courttoe@aol.com
Years in practice: 28
Patient population: geriatric

Submitter : Mr. Joseph Rolley **Date:** 06/30/2006

Organization : ConvaTec, a Bristol-Myers Squibb Company

Category : Device Industry

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

It is unclear why CMS anticipates having a separate CB program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in CA in MSAs during 2007 and 2009, a separate program for them in 2010 would seem unnecessary. In addition, many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. A cleaner definition of mail order supplis needs to be established.

The Medicare program must allow multiple distribution channels to meet beneficiary needs. While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies, it may not meet the needs of all beneficiaries who require such supplies. Whether or not a beneficiary receiving such supplies lives in a contracted MSA, they should have the option of being able to obtain these supplies locally. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Also, there are many complicating factors such as changes in a beneficiary s level of supply needs that may inhibit the supplier s ability to get reorder supplies to a beneficiary within the required time frame. The type/brand of supplies that a beneficiary is initially prescribed may change later on based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary with an ostomy may require different size products or skin protection as he/she ages or as his/her medical condition changes post-discharge from the hospital.

Criteria for Item Selection

Criteria for Item Selection

We commend CMS for determining that surgical dressings are ineligible for competitive bidding due to the lack of cost savings in the two rounds of Competitive Bidding in the Demonstration Project in Polk County. (Section V, Regulatory Impact Analysis , Part D, Program Savings on page 151 of the NPRM). We recommend that ostomy supplies also be excluded from CA because the category already has a competitive fee schedule with one of the lowest billing assignment rates of all DMEPOS, the category was not included in the Demonstration Projects so projected savings have not been determined, and the prosthetic, personal nature of the devices does not fit well in competitive bidding models.

Ostomy supplies are covered by Medicare under the Prosthetic Device benefit. Although they are reimbursed under the same methodology as DME in accordance with section 1834a (2) (B) & (C), they are not a covered item as the term is defined under 1834a (13). Section 1834a (13) defines a covered item as durable medical equipment. Under Section 1847a, the items included in competitive bidding are DME and supplies used in conjunction with DME, enteral nutrients and off-the-shelf orthotics. Ostomy products and supplies are part of the prosthetic device benefit and are not listed under Section 1847 (a) as subject to CA. It has therefore been our understanding that supplies unrelated to DME (such as ostomy, tracheostomy and urological supplies) were not within the scope of CA.

Also, CMS should specify a de-minimus threshold for certain items that constitute such a small portion of the DME budget as to not practically be included in CA. For example, ostomy supplies constitute less than 0.1% of total Part B expenditures in 2003.

We request CMS to clearly articulate in the Final Rule which product categories are exempt from CA and which are eligible for inclusion. CMS should also identify which medical supplies categories it envisions including in CA in the rollout to mail order suppliers in 2010.

Finally, with regard to deciding an item's potential savings as a result of CB, we request CMS to explain and clarify the specific measures that will be used:
-- Annual Medicare DMEPOS allowed charges: Is there a threshold expenditure level that will trigger CA for a product category?
-- Annual growth in expenditures: Is there a threshold growth percentage and does it vary by the dollar size of the category?
-- Number of suppliers: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined? (We recommend that mail order suppliers not count towards the two supplier minimim per MSA.)
-- Savings in DMEPOS demonstrations: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
-- Reports & studies: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

The NPRM describes a rebate program that allows contracted suppliers to rebate the difference between their bid and the established payment amount to the beneficiary. We are opposed to such a rebate program for the following reasons:
-- There is no legal basis under the law for permitting rebates
-- Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute.
-- Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay
-- The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

We recommend CMS reconsider introducing such a program in the Final Rule.

Gap-filling

Gap-filling

We agree with CMS that Gap Fill as a mechanism for setting fees for new technologoies is inadequate. However, we further believe that proposal to replace it requires detailed proposals in a separate NPRM for public comment. The provision for replacing the Gap Filling methodology as a part of competitive bidding is inappropriate.

Also, the three methodologies proposed to replace Gap Filling are not objective and not directly related to price/value assessment. Moreover, none of the methodologies appear to involve the manufacturer/innovator and his/her health economic or other support data. Rather, functional and medical benefit assessments would be conducted by CMS contractors who may or may not have expertise in the technology/ therapeutic area. The proposal to use these methods to adjust prices that were established using Gap Filling at any time after January 1, 2007 makes it all the more important to include the manufacturer in the process.

Opportunity for Networks

Opportunity for Networks

Formation of supplier networks (Proposed section 414.418) is an unrealistic option for many small suppliers as this would require a high degree of collaboration with competitors under stressful and unique circumstances, and without knowing the quality standards that they would be required to meet. Small suppliers also may not possess the business resources or experience necessary to form these networks, and will be hard pressed to do so under such short notice. In addition, formation of a network arrangement will likely require costly and lengthy legal arrangements beyond the financial reach of many small suppliers.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

ConvaTec believes CA will have a larger negative impact on small suppliers and result in more business consolidation than is currently anticipated by CMS. There are huge variations in DMEPOS suppliers. We request that CMS take into account these differences in its definition of small suppliers. Revenue and payer mix are valid measures of supplier size . However, the types of DMEPOS sold should also be taken into account and separate provisions should be allowed for small suppliers of technologies that require a degree of personal and on-going customer service, such as ostomy supplies. We believe CA may result in negative impacts on beneficiaries that rely on small suppliers. There are several reasons why we believe this may occur.

CMS estimates that 50 percent of bidders will be winners based on the experience with the Demonstration Projects. We believe a much smaller proportion of small suppliers will be successful under the process outlined in the Proposed Rule:

-- The methodology used to arrive at a pivotal bid using accumulating capacities in ascending order of bid level is different from what was used in the demonstrations and will likely lead to fewer and larger winners.

-- Higher acquisition costs due to new supplier standards and accreditation requirements and the need to bid on every HCPCS within a product category will inevitably put small suppliers at a disadvantage.

-- The contract price will be below the bid price for some successful bidders which introduces a significant financial risk that will be more difficult for smaller suppliers to tolerate.

Lastly, allowing suppliers to bid on only one or a few categories is not a significant benefit to small suppliers because in many cases, they are already specialized and able to bid only a few categories.

To mitigate the impact that CA will have on small suppliers, ConvaTec recommends that for small suppliers, CMS relax the rule requiring winning suppliers to cover an entire MSA. While this will obviously impact CMS' determination of supplier capacity and number of winning bids per MSA, it would allow winning small suppliers to service their existing geographic area without the burden of expanding capacity or forming networks. In addition, ConvaTec recommends that the grandfathering provisions in the NPRM be expanded to include all bid DMEPOS product categories and not be limited to rental DME and oxygen supplies. This would allow small suppliers that are willing to accept the contract prices for their MSA and meet the accreditation and quality standards, the opportunity to continue servicing their existing Medicare customers and potentially stay in business until the next bid period.

If CMS decides to allow mail order suppliers to bid in the DMEPOS competitive bidding prior to 2010, we further recommend that those mail order suppliers not count towards the two-supplier minimum that CMS is establishing in each CBA.

Lastly, we recommend that CMS consider adopting geographic coverage guidelines similar to those already required of Medicare Part D drug plan for retail pharmacy networks. For example:

' Urban areas -- At least 80% of the Medicare Part B beneficiaries must, on average, live within 2 miles of a contracted supplier;

' Suburban areas -- At least 80% of the Medicare Part B beneficiaries must, on average, live within 15 miles of a contracted supplier; and

' Rural areas -- At least 80% of the Medicare Part B beneficiaries must, on average, live within 25 miles of a contracted supplier.

We believe geographic guidelines similar to these will help protect small suppliers and ensure beneficiaries access to the medical supplies they need without the hardship of traveling great distances to obtain them or to receive product assistance.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

We believe that in the rush to implement CA, important considerations in timing and resources related to the implementation of quality standards will be overlooked. CMS currently anticipates that there will be 8,000 contracted suppliers when CB is rolled out. Because 90% of DME suppliers are small businesses, it is likely that the vast majority of those suppliers will not be accredited at the time they are awarded contracts. We question whether the accrediting bodies have the capacity to accredit all of these suppliers during the grace period following contract award. We recommend CMS base its decision on how long the grace period should be by developing a realistic estimate of the number of contracted suppliers requiring accreditation for the first time vs. the capacity of existing accrediting bodies to do the work.

In addition, the Competitive Acquisition NPRM was released for public comment prior to the release of the new Supplier Quality Standards. The new supplier standards are referenced throughout the NPRM, yet without knowing what those standards will be, it is difficult to provide an accurate assessment of the impact these two important and complementary programs will have on beneficiaries. We encourage CMS to issue an Interim Final Rule for CA and include a second round of public comments after the Supplier Standards are issued

Submitter : **Dr. Animesh Bhatia** **Date: 06/30/2006**

Organization : **Dr. Animesh Bhatia**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

June 30, 2006

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

Dear Dr. McClellan:

This letter is regarding the proposed rule that would establish a competitive acquisition program for certain durable medical equipment DMEPOS, in which the CMS used an improper definition of physician that excludes podiatric physicians. I am writing to request that CMS change the definition from 1861(r) (1) to 1861(r). The current definition in the proposed rule will hurt Medicare patients in need that are served by podiatrists.

As podiatrists, we supply DME items as part of a comprehensive plan of care. It leads to increased compliance, a great convenience for the patient, and eventually leads to better outcomes. In addition to that, there is appropriate follow-up and monitoring of the correct use and effectiveness of the items.

Since podiatrists maintain a valid DMEPOS supplier number, adhere to the 21 supplier standards and are subject to the same Stark requirements that apply to MD and DO physician suppliers, they should be given the same considerations given to MD and DO suppliers, including the ability to bid to supply select DMEPOS items to their patients only and the right to execute a physician authorization. If CMS plans on making specific allowances for physician suppliers, podiatric physicians must be included. My use of DME items as an integral part of patient care is no different than that of my MD and DO colleagues.

To name just a few examples, DME items are dispensed in situations such as fractures and other trauma, wound care and for correction of various debilitating deformities. These items are most effective when dispensed and instructed on use by the podiatrist. If the patient leaves the office to obtain them elsewhere, apart from thr risk of immediate injury, there is no assurance of immediate compliance, therefore risking adverse results and medico-legal issues, and importantly, further complicates the process for the overburdened and anxious patient.

With these issues in mind, I urge CMS to apply the broader definition that includes podiatric physicians.

Sincerely,

Animesh Bhatia D.P.M
Certified Wound Specialist

Submitter : Dr. Joel Schancupp

Organization : Dr. Joel Schancupp

Category : Physician

Date: 06/30/2006

Issue Areas/Comments

GENERAL

GENERAL

I am writing to ask you to revise the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r).
I am a Board Certified podiatrist practicing in Roswell, Georgia for 24 years. I, like MD and DO suppliers, am required to obtain a valid supplier number and must adhere to all of the current supplier standards. I am subject to the Stark laws and other Federal and State regulatory requirements.
I use DMEPOS items for my patients on a daily basis as do my MD and DO colleagues.
Podiatric physicians should be given the same considerations as MD and DO suppliers, including the ability to supply select DMEPOS items to my patients only and the right to execute a physician authorization.
My patients would be significantly and adversely affected if you do not change your definiton. Patients present to my office with acutely painful injuries and require immediate DMEPOS items to relieve their painful conditions. If the definiton is not changed, my patients will be significantly inconvenienced to have to go to another location to obtain the necessary item and risk further injury to their condition.
Please change the physician definiton from 1861(R)(1) to 1861(R) before finalizing the regulations for the competitive acquisition program.
Thank you.
Joel Schancupp, DPM

Submitter : **Ms. Carol Napierski** **Date: 06/30/2006**

Organization : **New York Medical Equipment Providers Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1004-Attach-1.PDF

#1004

NYMEP
NEW YORK MEDICAL EQUIPMENT PROVIDERS ASSOCIATION
Protecting the Home Medical Equipment Industry and those we serve.

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Albany, NY 12207

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June 29, 2006

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

Dear Dr. McClellan,

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

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

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

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

Getting It Right Is More Important than Rushing Implementation
CMS should stagger the bidding in MSAs in 2007 to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. Also, the initial

MSAs and products selected should be identified in the final rule. And under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate.

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

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

All the Supplier Product Specific Services Requirements refer to products or equipment provided in the home setting. There were no standards for supplying products to patients in a Skilled Nursing Facility (SNF). If there are no standards to apply to a company that only services the SNF community how they can be included in the accreditation process. CMS has to either issue standards or exclude SNF residents from consolidated billing.

Conditions for Awarding Contracts

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

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

Do Not Make It Harder For Providers To Sell Their Businesses. (Proposed §414.414(e)) The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's

requirement that contracted supplier and its new ownership should retain its contract.

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

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

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

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

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

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

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

Terms of Contracts

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

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

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

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

Opportunity to Participate by Small Supplies Opportunity for Networks

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

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

Payment Basis

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

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

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

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

bid and the established payment amount to the beneficiary. There is no legal basis under the law for permitting rebates. Providing rebates is contrary to other laws applicable to the Medicare program, namely the Anti-Kickback Statute and the Beneficiary Inducement Statute. Providing rebates also is contrary to the statutory requirement that beneficiaries incur a 20% co-pay. The OIG has stated in several Fraud Alerts and Advisory Opinions that any waiver of co-pays likely violates both the Anti-Kickback Statute and the Beneficiary Inducement Statute.

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

NYMEP appreciated the opportunity to submit these comments and remain available to discus with you in greater detail.

For further information contact:
Carol Napierski
New York Medical Equipment Providers Association
27 Elk Street
Albany, New York 12207
Telephone: 518-436-9637
E-Mail: NYMEP@NYMEP.org

Respectfully Submitted

Carol Napierski
Executive Director

Submitter : Ms. Virginia Clark

Organization : Ms. Virginia Clark

Category : Occupational Therapist

Date: 06/30/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1005-Attach-1.DOC

#1005

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

As a therapist who is both a provider and a supplier of DMEPOS, I feel that these two "hats" are inseparable. There is never a time when I fit a beneficiary with a custom or prefabricated orthosis that I do not function as a therapist. This means while I instruct in proper fit, donning, and maintenance, I also look at the disease process, functional and ADL needs, ergonomics, precautions, future orthotic needs, etc. I more often than not adjust these prefabricated orthoses to obtain the maximum benefit for the patient. I question whether or not any of the prefabricated orthoses that I supply would be considered "OTS" for this reason. The provision of an orthosis is usually performed as part of a complete treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat these patients.

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

I have grave concerns re: my patient's ability to get the correct orthosis and instruction through this system. I have been known to supply a prefabricated orthosis that actually costs me more than the current Medicare reimbursement rate. I do this because I feel that it is the most appropriate devise for that patient, and am able to do this because prefabricated orthosis are a very minimal part of my bottom line. I do not believe that a supplier, whose very existence is dependent on the money they make from DME,

would be willing to supply a device that will cost them money. The beneficiary, therefore, would not necessarily receive the best device, but one that fits the description and offers the supplier the greatest profit.

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Virginia Clark, OTR, CHT

Submitter : **Date: 06/30/2006**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1270-P-1006-Attach-1.DOC

#1006

Comments on CMS-1270-P

CMS-1270-P: Payment Basis

The grandfathering procedures described in the NPRM are based on flawed assumptions of supplier behavior, particularly in the case of providers who lose a subsequent bid. These suppliers will probably be unhappy and/or financially stressed (they bid too high and lost) and will likely not elect to continue as a grandfathered supplier if a reasonable alternative exists. Their patients may be difficult to place with other suppliers due to lack of capacity.

Asking suppliers to "include in their bid costs" the costs of accepting grandfathered patients is unreasonable since it is impossible to estimate what those costs might be. Whether patients decide to change suppliers, how many may make this decision, and at what month in their rental contract they may currently be in would be impossible to estimate.

Concerning traveling patients, requiring a non-contract supplier to accept the CB fee schedule for a patient who is traveling is grossly unfair. These suppliers will not have participated in CB and should not be subjected to an administrative process over which they had no direct input or participation.

A non- contract supplier should not be penalized for providing items to a patient who resides in a CBA. Patients have been known to misrepresent pertinent information (e.g., capped rental history). Once they discover they can get items for free outside the CBA, a whole new fraud industry could develop by patients - especially along CBA boundaries.

CMS-1270-P: Competitive Bidding Areas

The decision to exclude the top three MSA's is arbitrary and discriminatory. How did CMS arrive at three? Why not exclude the top five or top ten? If CMS is genuinely interested in assessing the CB program, it should begin in the most challenging areas. If you want a good education, you don't attend an easy school. You go where you can find academic challenges. If you want to improve your athletic performance, you want to compete against the best competition. You can only get better by taking on the challenges. CMS should have solved most problems in the program by the time the additional 70 MSA's are implemented if they begin with largest and most challenging MSA's.

CMS-1270-P: Criteria for Item Selection

The NPRM makes frequent references to "substantial savings" but the definition of "substantial" is not established. Why not establish a threshold of savings for each category prior to bidding that must be attained? If the bids do not meet or exceed the savings threshold, eliminate the category from competitive bidding.

On page 74 it states that the "use of product categories will allow Medicare beneficiaries to receive all of their related products (for example, hospital beds and accessories) from one supplier, which will minimize disruption to the beneficiary." What has not been taken into account is that many, if not most, patients receive items from several product categories. By bidding each category independently, the likelihood increases that patients may have to obtain the products they need from 2, 3 or more suppliers. This also creates a burden for the referral agent who must now contact 2, 3 or more suppliers to place orders for some patients. These patients, who are elderly and usually chronically ill, will likely have service and safety issues since they must now sort out who is the appropriate supplier for the particular item that requires service or replacement. With multiple suppliers involved, patients will receive multiple remittance notices generated by the separate billing done by these multiple suppliers. All these burdens will be imposed on patients who, in many cases, do well to remember their address and phone number.

CMS-1270-P: Conditions for Awarding Contracts

In the discussion on market demand and supplier capacity, the assumption appears to be that winning bidders will always be successful and that losing bidders will simply wait in the wings waiting for CMS to call should they be needed. In the real world, there will be attrition of winning bidders for any number of reasons including financial difficulties, owner death or health issues, fraud or other criminal behavior, disasters, fire, and floods, to mention a few. Losing bidders will very likely exit the market at some point and will not be available to help with unanticipated market demand. There is no provision for allowing new suppliers to enter the market. The assumption that the existing population of suppliers will be sufficient to service the market demand for the future is flawed.

Bid amounts should not be capped at the current payment amount. Many current payment amounts are at or below supplier cost. If CMS is interested in promoting market forces, let the market work and accept bids regardless of the amount. Suppliers currently provide some items at a loss because there are other items that can help make up the difference. With CB, every item must be profitable for a supplier to provide it. This is not competitive, and it is not true bidding if bids are artificially capped.

CMS-1270-P: Terms of Contract

In this section, it is once again reiterated that winning suppliers must agree to accept capped rental patients from other suppliers regardless of months remaining in the rental contract. See the previous comment in the first and second paragraphs under Payment Basis.

CMS-1270-P: Opportunity for Participation by Small Suppliers

The NPRM states that carve out areas for small suppliers would lead to confusion of beneficiaries. They certainly could not be any more confused than by having to obtain their equipment and supplies from multiple suppliers.

It also states that carve out areas would allow selection of more favorable market areas by small suppliers. A small supplier should be allowed to service whatever area it feels can be comfortably served given it's applicable resource constraints. Suppliers already target markets - that's a part of business management and competition. Allow suppliers to compete.

CMS-1270-P: Opportunity for Networks

The NPRM states that supplier networks should be limited to a 20% market share within a CBA so as not to "limit competition." This contradicts a basic premise of competition, that is, suppliers should be rewarded for competing effectively and providing efficient, quality services. One reward for quality and efficiency is market share. If we do a good job, we should get more business. If we do a poor job, we should get less business. The message here, in effect, is that suppliers are expected to be good, just not ***too*** good. This is nonsense.

Submitter : **Elizabeth Hogue** **Date: 06/30/2006**

Organization : **Elizabeth Hogue**

Category : **Other Health Care Provider**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Opportunities for Networks

(1) Although a network is defined in the proposed rules as two (2) suppliers who collectively submit a single bid to furnish the items included in a product category, it remains unclear what constiutes a network. If, for example, at least two (2) suppliers form a new corporation with equal ownership interests in order to participate in competitive bidding, is the new corporation a network? This issue should be clarified in the final rule.

(2) It is also unclear what documentation of arrangements between suppliers must be submitted to CMS. The proposed rule says that any "agreement" between suppliers must be submitted. Does this language refer to contractual arrangements only? If not, will suppliers who form corporations, partnerships or limited liability companies be required to submit documents related to formation to CMS? This issue should also be clarified in the final rule.

(3) The proposed rule says that each network member must meet all accrediation and quality standards that are required. It is unclear whether this requirement will apply to all shareholders of corporations, partners in partnerships and members of limited liability companies. If this reqirement does apply to all shareholders, partners and members, the same requirement should apply to all parent, affiliated and subsidiary coporations of large national companies that participate in competitive bidding.

(4) The requirement that networks' share of the market cannot exceed 20% is unjustified. Our review of the antitrust issues indicates that there is no difference in the analysis of potential antitrust violations when large market share is controlled by natioinal companies who win competitive bids and networks that may control more than 20% of the market if they win competitive bids. There should be no distinction between market share for individual bidders and networks. The antitrust issues are the same and should not be applied only to networks.

(5) In addition, the proposed rule is unclear with regard to how the "Medicare market" is defined. Is it 20% of the number of beneficiaries in the area? Is it 20% of the numbers of certain products provided to beneficiaries in a geographic area? Or is it 20% of the expenditues on a particular product in the area? This issue also needs clarification.

(6) It is also unclear how and when the 20% will be measured. In order to be sure that a network does not exceed 20% of whatever the market is, the network would have to calculate market share on a rolling basis. It is unclear how networks would obtain data in order to perform such calculations on a rolling basis or any other basis. It is also unclear what happens if networks determine that, at least at that moment, their market share exceeds 20%. Does it, for example, mean that the network cannot serve any additional beneficiaries until its market share is reduced to less then 20%?

(7) Also, with regard to the 20% limit on market share by networks, it is unclear how beneficiaires will be served in the area if the market share of a network exeeds 20%. This issue should also be addressed in the final rule.

(8) In additioni, if networks are limited to 20% of market share in the final rule, they may be precluded from participation in competitive bidding as a practical matter because the economic advantages of a significant volume of items will be lost.

Submitter : Mrs. Robin Kuhls **Date:** 06/30/2006

Organization : Raleigh Orthopaedic Rehabilitation Specialists

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

As a Certified Hand Therapist I have treated multiple patients that have been fit inappropiately by a 'DME' provider that lacks the expertise to properly fit a patient. Often there are very specific needs and concerns that should be addressed. What may look like an 'adaquate' splint may in fact be determental to the functional use of affected extremity. An example is a patient that I recently treated that was issued an over the counter wrist support - this may have fit appropriately at the time but the patients condition changed and she develped significant increase in edema. The splint became too tight and she began to develop significant loss of digital range of motion. If I had not been allowed to fabricate a custom splint her condition may have had an outcome resulting in loss of function of her dominant hand. Also, Delays in the supply of an orthosis will interfere with clinical reasoning and patient treatment. There are many times when a therapist must respond immediately to changing conditions in a patient's medical condition and/or recovery from that condition. We frequently see an immediate need to alter the orthosis (possibly due to inflammation, instability, pain etc), and it is critical that we are able to respond to that need immediately. Our patients often are suffering from acute trauma which may lead to frequent changes in their orthoses to adapt to their rapidly changing condition.
I am deeply concerned that by the possiblity of having to send my patient to a different provider while under my treatment will pose legal and ethical dilemas for dedicated professionals in the fields of hand therapy/occupational therapy and physical therapy.
Thank you for your consideration in this matter
Robin Kuhls OTR/L, CHT
103 Kalmia Lane
Cary, NC 27511

Submitter : Dr. Robert Harshbarger

Organization : Dianas Pharmacy Inc.

Category : Pharmacist

Date: 06/30/2006

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.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies and respiratory medications. 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 be a central supplier.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

" While I understand that CMS is required to set a single payment amount for each item, I am concerned that using the median bid will set an artificially low payment rate that many small suppliers will not be able to accept. CMS must review the process to determine the single payment amount and ensure that the payment rate is adequate to cover a supplier s costs to acquire and provide the product. The Agency must periodically examine the payment rate as it compares to supplier acquisition costs.
" I appreciate CMS intention to update the single payment rate based on the consumer product index during the second and third years of the supplier contract; however, this proposal does not address situations in which the manufacturer or distributor raises the acquisition cost of the product. Suppliers would be required to continue providing the product at the single payment rate even if the reimbursement amount is significantly less than their acquisition cost.
Suppliers will not be able to continue providing DMEPOS supplies in this situation. CMS must make provisions to increase the payment amount during the year if acquisition costs change.
Rebate Program: CMS intends to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid and the single payment amount. For example, if a single payment amount for an item is $100, Medicare pays 80% or $80 for the item and the beneficiary is responsible for 20% or $20. However, if a contracted supplier bid $90 for the item and chose to offer a rebate, the rebate amount would be equal to the difference between the single payment amount ($100) and the contract supplier s bid ($90), or $10. The contract supplier would be responsible for providing the beneficiary with a $10 rebate. Rebates would be voluntary.
Suppliers would be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribers. However, CMS may provide beneficiaries comparative information about contract suppliers that offer rebates.

GENERAL

GENERAL

June 30, 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 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.

" Criteria for Item Selection

" The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies and respiratory medications. 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 be a central supplier.

" Opportunity for Participation by Small Suppliers

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

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

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

" I currently provide diabetic testing supplies and respiratory medications in my practice and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

As a community independent pharmacy I respectfully request that,

" diabetes testing supplies and respiratory medications be deemed exempt from the Competitive DME Bidding process.

" It is imperative that patients retain their current level of care received at the retail pharmacy level.

" If competitive bidding becomes a reality for diabetes testing supplies and respiratory medications at the retail pharmacy level, it will detrimentally impact the patient's health and well-being.

" Diabetes and respiratory education is crucial to the health and well-being of our patients:

" Retail pharmacists offer critical clinical services to patients by offering education on daily diabetes care, respiratory medications/side effects/possible drug interactions, and training on blood glucose meters and testing procedures.

" Retail pharmacists have the ability to impact patient adherence in all aspects of diabetes, respiratory care and provide a local presence for assistance with complications of therapy.

" Retail pharmacists work in conjunction with the patients' physicians in an effort to facilitate the best possible respiratory and diabetes care.

" Thank you for considering my view.

Sincerely,
Bob Harshbarger Phram.D.
Dianas Pharmacy Inc.
1567 N Eastman Rd Ste 1
Kingsport, TN 37664
(423) 245-1022
themedicineshoppe@chartertn.net

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

" Opportunity for Participation by Small Suppliers

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Submitter : **Mr. James Walsh** **Date: 06/30/2006**

Organization : **Mr. James Walsh**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I have reviewed and compiled the issues most important to me on the attached list. Thank you.

CMS-1270-P-1010-Attach-1.DOC

► Supplier standards have not been defined by CMS. Based upon the more than 5,600 comments sent to CMS on the draft supplier standards CMS has an obligation to publish the final draft standards for public comment before moving forward with any competitive acquisition program. CMS has created an informational "black hole" by not being responsive to the industry, Medicare beneficiaries and Congress in openly and accurately communicating the exact standard applying to the competitive acquisition program. Anything short of a full disclosure and appropriate period for public comment before the standards are adopted smacks in the face of every PAOC member and what is ultimately the right thing to do.

Additionally, CMS has not accepted any information other than anecdotal comments at the PAOC meetings as to the capacity of the industry's current accrediting bodies to be able to accomplish CMS's requirement of accreditation during the unknown length of the CMS defined "grace" period before a winning bidder will be allowed to participate. Has the potential impact on access in the MSA's under competitive bid even been considered should the winners not be able to achieve accreditation within this "grace" period? This is another example of a complete absence of planning on CMS's part.

► How can CMS expect to receive truly competitive bids when bidders are not allowed to submit bids at a higher rate than CMS currently pays? It was clearly demonstrated in the Polk County, Florida and San Antonio, Texas projects that CMS was paying below the market rate for certain items. Thus when the winning bid was calculated the reimbursement rate went up. If that was the market rate for a product in that specific market how can CMS create a system where beneficiaries will be denied access to products at truly competitive and fair rates?

► The issue of the methodology of the bid rate being set by the "pivotal" bid creates more problems than it solves. The "pivotal bid" will not be the rate products are reimbursed at. The reimbursement rate will be set by taking the median of the lowest submitted bid and the "pivotal bid" amount. This concept requires the intelligent bidder to careful think about the rate he will bid. By definition he must consider there is a significant chance that after the bids are evaluated he may be required to lower his bid even further to be allowed to participate should his bid be above the median bid.

The logic of this methodology is unclear. The affect it will have on bidders is for them to hedge their bids realizing they may have to participate at a lower rate. The very concept of a truly competitive bid is for the bidder to offer his absolutely lowest price as his bid. The pivotal bid methodology smacks in the face of the intent of a truly competitive bid model. It simply will not work as a bid methodology and produce the desired results.

► The proposed requirement for winning bidders to be forced to supply upgraded equipment at the bid price is ludicrous. On one hand CMS states they want the lowest price possible and then includes a stipulation which makes it **impossible** for anyone to calculate the impact to their bid. If the physician can order an upgraded product and CMS takes the position the upgraded item is included in the bid it will have a devastating impact on the marketplace. An analogous example would be for the DOD to publish a

RFB for the rental of vehicles for TDY personnel at bases throughout the continental United States. The example here would be that the rental car agencies would have to submit a per diem rate as their bid, but the base commander could require them to supply anything from a Ford Taurus to an Infinity Q45 sedan. With the inventory to be supplied out of the bidder's control, how can anyone submit an intelligent bid? What CMS needs to do is supply the manufacturer, make and model which will be required to meet the bid for each and every HCPC code contained in the RFB. Anything short of detailing exactly what is included will drastically affect the outcome of the CMS bid process. As noted above, the industry is currently absorbing the higher cost of new technology for which appropriate HCPC billing codes do not exist. Competitive acquisition will destroy the provider/patient relationship by requiring the use of ABN's for newer technologies not covered by the bid. The point here is, "saying it isn't so" doesn't make it true. CMS has a long way to go before it has any clear understanding of how **competitive** the current marketplace really is.

Supplier Standards and DRA Implementation

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Opportunity to Comment on the Supplier Standards

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

Application of DRA to Oxygen Patients

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

will administer the DRA requirements. Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a "mail order" supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are unsure who would qualify to participate in a national competition for mail order supplies.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

We believe it is unnecessary for CMS include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often

are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Further the proposal is contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. Inasmuch as CMS' authority to implement this requirement is discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

Quality Standards and Accreditation

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owners on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

Don't Make it Harder for Providers to Sell their Businesses

The proposal to restrict the acquisition of a winning provider unless CMS needs to replace the supplier's capacity within the MSA places an inappropriate restriction on the provider's property rights. While it is appropriate for CMS to consider the buyer's quality and financial stability, CMS should not make approval of the acquisition contingent on the need to preserve capacity within the MSA.

Networks & Sub-contractors

If the network utilizes an "administrative entity" to be responsible for billing Medicare, receiving payment on behalf of the network suppliers, and for appropriately distributing reimbursements to the other network members, is this entity required to be accredited? What if this legal entity ensures its provider network members are appropriately accredited? What is the accreditation process?

Can a sub-contractor / provider submit a bid and be a sub-contractor in another product category? Can a provider whom submits a bid and loses then become a sub-contractor?

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

2.) "Opportunity for Networks"- Clarify Network Regulations. (proposed §414.418) What are structural requirements? Who can do billing and collection? Other operational issues?

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

Submitter : Mario LaCute **Date:** 06/30/2006

Organization : Seeley Medical

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1011-Attach-1.DOC

#1011

Via Electronic Transmission

June 30, 2006

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

SEELEY MEDICAL

RE: CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Dear Dr. McClellan:

104 Parker Drive
P.O. Box 699
Andover, Ohio 44003
440.293.6600
1.800.473.3539
Fax 440.293.7394

On behalf of Seeley Medical, I am pleased to submit comments on CMS' Notice of Proposed Rulemaking (NPRM) for Competitive Acquisition for Certain DMEPOS. I have been a DMEPOS provider for more than 28 years and believe that our services are cost effective, medically efficacious and most importantly consumer preferred.

The following pages summarize the key issues as they affect Medicare beneficiaries and our ability to provide services related to CMS' Notice of Proposed Rulemaking published May 1, 2006 in the Federal Register.

Seeley Medical's Background

Seeley Medical is a regional respiratory and home medical equipment company founded in 1960. Currently, Seeley Medical has locations, Patient Management Centers ("PMCs"), in Andover, Cleveland, Akron, Sandusky and Poland. Each PMC serves several surrounding counties, including some counties in Western Pennsylvania.

Management

Seeley Enterprises, and its subsidiaries, (Seeley Medical, Andover, Seeley Medical, Mansfield and Seeley Medical, Cleveland) was purchased by Mario and Ann LaCute in 1989. Both had been involved in the company since 1977. Mario LaCute, BA in Business from Hiram College, Hiram, Ohio and a MBA from The Ohio State University, Columbus, Ohio. Ann LaCute, BS in Business Administration from Thiel College, Greenville, PA. Other key members on the management team include: Joe Petrolla, President, BA, Youngstown State University; Ron Adamov, Contoller, CPA, MBA, University of Akron, Linda Fee, Finance Operations Manager, BS in Business Administration, University of Toledo, Toledo, Ohio; Lisa Fleming, PMC Operations Manager; and Todd Arganti, RRT, Sales Manager, BS, Malone College, Canton, Ohio, Mike Sass, SPHR, Manager, Human Resources and Organizational Effectiveness, B.S. Kent State, and Jim Moyer, Compliance

JCAHO Accredited

Member of:
American Association for Homecare (AAH)

Ohio Association of Medical Equipment Services (OAMES)

Operations Manager. This group has over 125 years collectively in home medical services.

Operations

The company utilizes a combined centralized and decentralized approach. Our Administration, Patient Accounting Center, Management of Information Systems and the Medical Products Division are centralized in the Andover Corporate Office to take advantage of economics of scale. Seeley Medical's order intake through billing process is seamless and is facilitated through its own Management Information System. Seeley Medical has over 11,000 active patient accounts. All locations are completely networked to the system, with a combined staff of 104 employees.

Each PMC is staffed with a Center Manager, Respiratory Therapists, Customer Service Representatives, Sales Representatives, Service Technicians (all of which are Emergency Medical Technicians), Document Control Data Entry Specialist ("DCDES"). This team is closest to the patient and is responsible for implementing programs and services. All decisions relating to patient service and care are made at the PMC.

Services

Seeley Medical is a full-service home medical equipment company that focuses its efforts on the following primary areas of expertise:

Respiratory services which include:

- Long-term oxygen therapy equipment (concentrators, liquid, light weight portable cylinders, oxygen conserving devices)
- Compressor driven nebulizers ("CDNs") for aerosolized therapy. A closed door pharmacy that provides mainly respiratory medications like Albuterol, Ipratropium Bromide, etc.)
- CPAP and BiPAP therapy for obstructive sleep apnea.
- Ventilators for stable adult and pediatric patients.

Home medical equipment and supplies include:

- Disposable supplies (incontinent undergarments, dressings, enteral nutrition, etc.)
- Medical equipment (hospital beds, wheelchairs, commodes, etc.)

Commitment to Excellence

Seeley Medical places a strong emphasis on service, including professional education, quality assurance and technical maintenance. We recently completed our CHAP Accreditation, after many years being JCAHO Accredited. Another part of this commitment is reflected by its membership in the American Association for Homecare (Mario LaCute is a former Chair and is currently an Executive Board Member), the Ohio Association of Medical Equipment Services, (Mario LaCute is former President and current ex officio Board Member) and its Accreditation.

Additionally, members of our staff serve on various Boards of major service organizations such as the American Cancer Society, Health Planning Committees and Community Health Agencies. Members of our professional staff such as our Registered Respiratory Therapists, Licensed Practical Nurses and Emergency Medical Technicians are active in their respective professional organizations to maintain current standards of practice.

A. Timing Concerns

Supplier Standards and DRA Implementation:

The information in the NPRM is inadequate to serve as a basis for public comments, especially with respect to the impact that the implementation of the Deficit Reduction Act of 2005 (DRA) will have on competitive bidding. Prior to implementing competitive bidding, CMS should issue an interim final rule to allow additional stakeholder comments. Further, because the NPRM raises more questions than it answers, does not identify the markets, or the products, and the final quality standards have not been published, CMS should also allow adequate time to schedule a meeting of the Professional Advisory Oversight Committee (PAOC) after it publishes an interim final rule. This will permit CMS to obtain industry input one more time before publishing a final rule and initiating program implementation.

Opportunity to Comment on the Supplier Standards:

CMS must allow stakeholders an opportunity to comment on the quality standards before they are finalized. We understand that CMS received comments from 5600 organizations and individuals on the draft supplier standards, and the final standards will likely differ significantly from the draft. If so, under principles of administrative law, CMS must give stakeholders another comment period. Furthermore, an additional comment period is appropriate inasmuch as CMS has chosen to by-pass the procedural protections of the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget that would otherwise be part of the rulemaking process applicable to the quality standards.

At the very least, CMS should schedule a PAOC meeting after it publishes the standards. AAHomecare strongly supports a requirement that all suppliers billing the Medicare program for DMEPOS must meet quality standards and be accredited. It is also critical that final supplier standards apply to any supplier desiring to submit a bid. Allowing an additional comment period is unlikely to significantly impact the overall implementation timeline. Even so, competitive bidding is a radical departure from traditional Medicare and this program is still mostly experimental; consequently, CMS should tolerate delays and not rush to implement the quality standards or any other aspect of competitive bidding.

Overall Implementation Timeline

CMS needs to establish an implementation timeline that identifies the critical steps leading-up to competitive bidding. However, given the number of steps that must be commenced and completed, we urge CMS to adopt a realistic timeline and not rush through the process. The remaining steps include:

- Publication of the supplier standards
- Selection of the accrediting bodies
- Publication of interim final and final regulations
- Publication of the initial 10 MSAs and product categories
- Publication of the RFB
- Evaluation of bids and selection of contract suppliers
- Education of beneficiaries and referral sources
- Implementation within each MSA

B. Payment Basis

Inflation Update :

CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage :

The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? We recommend that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers:

The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs into their bids because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS also states that suppliers may not submit bids higher than the current

fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. We appreciate CMS' desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

Application of Deficit Reduction Act to Oxygen Patients:

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

Authority to Adjust Payment in Other Areas:

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics."

CMS should note that the authority under §1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends. As we explain more fully below, Congress excluded prosthetic devices from the list of DMEPOS items subject to competitive bidding. Consequently, the authority to use information derived from a competitive bidding program to adjust payment in other areas does not apply to prosthetic devices or to supplies reimbursed under the prosthetic device benefit.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived form competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has not advanced a proposal that we can consider. CMS asks only for suggestions on how to implement its authority under §1834a(1)(F)(ii). We recommend that CMS initiate a separate notice and comment rulemaking to solicit comments on a

specific proposal before implementing this authority in a final rule.

Limitation on Beneficiary Liability:

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

C. Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a "mail order" supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are unsure who would qualify to participate in a national competition for mail order supplies.
There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to get reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips requiring that they be switched to a different brand in order to comply with the prescribed testing.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, they should

have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Finally, we note that this proposal represents another example of CMS' failure to provide the level of detail necessary for notice and comment rulemaking. CMS should publish an interim final rule to solicit additional public comment before implementing a national or regional competitive bidding program.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established *"in"* an MSA. CMS must identify the MSAs in which it will commence competitive bidding in 2007 in an interim final rule. CMS should also schedule a meeting of the PAOC after it identifies the MSAs.

D. Criteria for Item Selection

Items Included in Competitive Bidding:

CMS identifies three categories of items that are subjective to competitive bidding consistent with the requirements of §1847(a)(2): "Covered items" *as defined under §1834a(13)* for which payment would otherwise be made under §1834(a) *and "supplies used in conjunction with durable medical equipment;"* enteral nutrition, equipment, and supplies, and off-the-shelf orthotics (OTS). Prosthetics and prosthetic devices and supplies were not included in competitive bidding by Congress. Under §1834(a)(13), a "covered item" means "durable medical equipment" as defined under §1861(n). Ostomy products and supplies are not "durable medical equipment" and consequently do not meet the definition of "covered items" as defined under §1834(a)(13). CMS should confirm that ostomy products and supplies are not included in competitive bidding under §1847(a)(2).

Potential for Savings:

CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of CB. Specifically, CMS should address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger CA for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?

- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?

Additional Criteria for Item Selection:

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilators patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

CMS should publish the items it will include in the initial competitive bidding program in an interim final rule. CMS should also schedule a meeting of the PAOC to solicit additional public comment after it announces the product selections.

E. Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

We believe it is unnecessary for CMS to include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. Further the proposal is contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Having to carry all possible items and equipment is extremely costly and burdensome and will increase suppliers' costs, reducing potential savings from competitive bidding. Inasmuch as CMS' authority to implement this requirement is

discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

Coding Issues and Item Selection:

The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. We recommend that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed.

F. Product Categories for Bidding Purposes

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately as the cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors resulting in service issues for beneficiaries.

Requirements to Bid on all Products in a Category:

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define products categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category

combined with the complexity of needs for the high-end rehab patient. Complex Rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex Rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex Rehab and Assistive Technology.

- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex Rehab Technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.
- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

G. Conditions for Awarding Contracts

Quality Standards and Accreditation:

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during the unspecified grace period. Winning bidders who do not become accredited during the grace period will loose the contract supplier status. Because the overwhelming majority of DME suppliers are small businesses, it is likely that many suppliers will not be accredited at the time they are awarded contracts. As a result, bids from providers who are ultimately disqualified will be considered in the determination of the pivotal bid and single payment amount. By definition, *only* accredited suppliers should be eligible to bid. CMS should not proceed with competitive bidding until it is sure that that all suppliers who may want to submit bids have had an opportunity to get accredited.

Further, the evaluation of the supplier's financial stability must take place before the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount.

Finally, CMS needs to identify the criteria it will use to select accrediting bodies *now*. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published.

Market and Supplier Capacity:

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

We recommend that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. We suggest one option below under the discussion on the single payment amount. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and

proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers.

Assurance of Savings:

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount:

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers". This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA.

CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. An alternative, which would also provide an assurance that the submitted bids are "rational" and not unreasonably low, is to pay contract suppliers an amount equal to their individual bids. Although we understand that the MMA requires CMS to pay a "single payment amount" and that CMS intends to comply with this requirement, the statutory payment basis is the fee schedule amount or the actual charge, whichever is less. Consistent with the requirement, CMS could calculate a single payment amount equal to the pivotal bid and require winning bidders to submit claims in the amount of their bid – the actual charge – not the single payment amount. This approach also achieves price "transparency" for CMS and beneficiaries.

Rebate Program:

The NPRM describes a rebate program that allows contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

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

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

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

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

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

be unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

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

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

H. Terms of Contract

Repair or Replacement of Equipment:

CMS will require contract suppliers to accept all beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount for the items or the contract supplier's bid, depending on the payment methodology CMS adopts in the final rule.

Termination of Contract:

CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated.

Judicial and Administrative Remedies:

CMS should include a procedure for debriefing suppliers who did not win a bid and an opportunity for a review to determine at a minimum whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership:

It is reasonable for CMS to review a change of ownership to determine whether the buyer meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny winning supplier status to a new owner on the basis that its capacity is not necessary within the competitive bidding area. CMS should approve a change of ownership if the new entity will meet applicable quality standards and confirm to other requirements of competitive bidding. CMS approval should not be withheld based on a determination that the supplier's capacity was not necessary.

Participation of Small Suppliers:

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating new entity. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs.

In conclusion, on behalf of Seeley Medical and our 104 employees, I appreciate the opportunity to submit these comments. Please feel free to contact me for any further clarifications, 440-812-0004 or mlacute@seeleymedical.com.

Sincerely,

Mario LaCute
CEO

Submitter : Mrs. Leslie Holcombe
Organization : Mrs. Leslie Holcombe
Category : Occupational Therapist
Date: 06/30/2006

Issue Areas/Comments

GENERAL

GENERAL

See attachements.

CMS-1270-P-1012-Attach-1.DOC

#1012

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Leslie Holcombe, MS, OTR, CHT

Submitter : **Ms. Brittany Richards** **Date: 06/30/2006**

Organization : **Physical Therapy Plus**

Category : **Physical Therapist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

06-19-06

Mark B. McClellen, MD, PhD
Administrator
Center of Medicare and Medicaid Services
Department of Health and Human Services

Attn: CMS-1270-P

Dear Dr. McClellan,

My name is Brittany Richards and I am a physical therapist writing you regarding the Proposed Rule for Competitive Acquisition of Certain DMEPOS . I am a physical therapist in an outpatient orthopedic setting. I specialize in orthopedics and sports injury rehabilitation as well. My clinic has developed close relationships with local podiatrists and we often collaborate on the decision-making process and fabrication of orthotics. I also treat a lot of running athletes and I often use orthotics as an integral part of my plan of care. I am writing to urge you to establish a process that will enable to physical therapists to continue to furnish orthotics that are critical to the care of their patients.

The proposed competitive bidding program poses a serious threat to timely patient access to medically necessary DMEPOS, proposing a system that could obstruct the way physical therapists currently furnish DMEPOS to their patients. Often in the clinical setting it is important to evaluate the need for orthotics during particular activities and to make modifications as needed while they are in the clinic.

The proposed regulations state that for orthotics to be excluded from competitive bidding, they must be items that require more than minimal self-adjustment. As stated physical therapists often need to make adjustments to the orthotic during the treatment session in order to maximize the benefits for the patient and achieve optimal outcomes. We may need to re-shape, mold the orthotic or add modifications to account for anatomical differences or areas of painful pressure. I urge CMS to revise the regulations to recognize that physical therapists perform adjustments to orthotics.

The proposed rule does not require winning suppliers to furnish all brands within a product type. However, there is a provision allowing physicians to specify certain brands if there would be an adverse medical outcome for the patient. It is important to be aware of the collaboration between the physical therapist and physician in regards to assessing the need and potential benefits of orthotic use. In the initial evaluation the physical therapist will perform a complete musculoskeletal evaluation including gait assessment and will assess and make recommendations specifying certain products that address the individual needs of their patient. Correspondence is made with the physician and the physical therapist will then carryout the casting/fabrication and fitting of the orthotics and make adjustments as needed. It is important that the therapist to make specifications in order to prevent adverse medical outcomes. For example, certain specifications often need to be accounted for with diabetic patients or patients with peripheral neuropathy, who may have compromised sensation/circulation to their feet, in order to ensure proper fit and wear. Again I urge CMS to revise the regulations to recognize the need for physical therapists to be able to specify brands to prevent adverse medical outcomes

In closing I would like to thank for the consideration of my letter. I hope that this will provide you with some useful information to guide you in your decision-making process.

Sincerely,

Brittany Richards PT, DPT KY License # 004735
Physical Therapy Plus

Submitter : Dr. Diana Harshbarger **Date:** 06/30/2006

Organization : AIMS PHARMACY INC.

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 providers --this restricts beneficiaries choice. This proposal would severely restrict beneficiaries access to needed items and supplies and may compromise patient health outcomes.

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies and respiratory medications. 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 be a central supplier.

Determining Single Payment Amounts for Individual Items

Determining Single Payment Amounts for Individual Items

" While I understand that CMS is required to set a single payment amount for each item, I am concerned that using the median bid will set an artificially low payment rate that many small suppliers will not be able to accept. CMS must review the process to determine the single payment amount and ensure that the payment rate is adequate to cover a supplier s costs to acquire and provide the product. The Agency must periodically examine the payment rate as it compares to supplier acquisition costs.
" I appreciate CMS intention to update the single payment rate based on the consumer product index during the second and third years of the supplier contract; however, this proposal does not address situations in which the manufacturer or distributor raises the acquisition cost of the product. Suppliers would be required to continue providing the product at the single payment rate even if the reimbursement amount is significantly less than their acquisition cost. Suppliers will not be able to continue providing DMEPOS supplies in this situation. CMS must make provisions to increase the payment amount during the year if acquisition costs change.
Rebate Program: CMS intends to allow contract suppliers that submitted bids for an individual item below the single payment amount to provide the beneficiary with a rebate. The rebate would be equal to the difference between their actual bid and the single payment amount. For example, if a single payment amount for an item is $100, Medicare pays 80% or $80 for the item and the beneficiary is responsible for 20% or $20. However, if a contracted supplier bid $90 for the item and chose to offer a rebate, the rebate amount would be equal to the difference between the single payment amount ($100) and the contract supplier s bid ($90), or $10. The contract supplier would be responsible for providing the beneficiary with a $10 rebate. Rebates would be voluntary.
Suppliers would be prohibited from directly or indirectly advertising these rebates to beneficiaries, referral sources, or prescribers. However, CMS may provide beneficiaries comparative information about contract suppliers that offer rebates.

GENERAL

GENERAL

As a community independent pharmacy I respectfully request that,
" diabetes testing supplies and respiratory medications be deemed exempt from the Competitive DME Bidding process.
" It is imperative that patients retain their current level of care received at the retail pharmacy level.
" If competitive bidding becomes a reality for diabetes testing supplies and respiratory medications at the retail pharmacy level, it will detrimentally impact the patient's health and well-being.
" Diabetes and respiratory education is crucial to the health and well-being of our patients:
" Retail pharmacists offer critical clinical services to patients by offering education on daily diabetes care, respiratory medications/side effects/possible drug interactions, and training on blood glucose meters and testing procedures.
" Retail pharmacists have the ability to impact patient adherence in all aspects of diabetes, respiratory care and provide a local presence for assistance with complications of therapy.
" Retail pharmacists work in conjunction with the patients' physicians in an effort to facilitate the best possible respiratory and diabetes care.

" Thank you for considering my view.

Sincerely,
Diana Harshbarger Pharm.D.
AIMS Pharmacy Inc.
1567 N Eastman Rd Ste 1
Kingsport, TN 37664
(423) 392-0226

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

' I urge CMS to take steps to ensure that small suppliers which include the majority of pharmacy-based suppliers can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas.
' After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.
' CMS must take these steps to preserve beneficiaries convenient access to DMEPOS supplies and to maintain established provider/patient relationships.
' I currently provide diabetic testing supplies and respiratory medications in my practice and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

Submitter : Ms. Tyrrell Hunter **Date:** 06/30/2006

Organization : MMS Southern Maine, Inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#1015

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

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

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

Submitter : Dr. Krisi Young **Date:** 06/30/2006

Organization : American Society of Hand Therapists

Category : Occupational Therapist

Issue Areas/Comments

GENERAL

GENERAL

Please consider the following:
As a Certified Hand Therapist treating patients in a highly specialized field, I utilize years of treatment experience and advanced education to determine the appropriate splinting device for my patient. Without this knowledge and training, inappropriate devices could be selected that would not only prevent healing, but could exacerbate the primary condition and cause a secondary or tertiary condition. With the proposed bidding rule, DME providers that do not have the advanced training of treating clinicians could inadvertantly cause the patient to require significantly more treatment through choosing an inappropriate device. These devices have an extremely small profit margin, and to risk allowing an unqualified provider to issue these devices and possibly cause further damage in order to save such a small amount seems rather foolish. Additionally, what happens in situations where damage is indeed caused by devices that are improperly fit? I have difficulty accepting responsibility for faulty devices that I did not issue to the patient.
Many times, it is very difficult for rulemakers to comprehend the magnitude of the effects of decisions they make, especially when the subject is as intricate as the treatment of the upper extremity. I understand this dilemma and plead with you to consider the downside of this very small and relatively insignificant savings plan.

Submitter : **Dr. David Schofield** **Date: 06/30/2006**

Organization : **American Podiatric Medical Association**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Comments from the American Podiatric Medical Association (APMA) have been hand deliverd to room 445-G at HHS in Washington, DC.

A copy of those comments is attached.

CMS-1270-P-1017-Attach-1.DOC

#1017

AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

June 29, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1270-P: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues, 71 Fed. Reg. 25,654, May 1, 2006

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA), the national association representing more than 11,500 of America's premier podiatric physicians and surgeons, is pleased to present comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule, *Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues*. The proposed rule would implement competitive bidding programs for certain covered items of DMEPOS. We believe that as proposed, the new program has the potential to interfere with patient care and will harm Medicare beneficiaries. We urge CMS to revise its proposals prior to implementation of a new competitive bidding program.

We would like to take this opportunity to express appreciation to your staff from the Chronic Care Policy Group and Division of Community Post Acute Care, who met with us on June 21 to discuss provisions of the proposed rule in greater detail. That meeting assisted us in clarifying specific issues of concern and we offer the following comments:

Submission of Bids under the Competitive Bidding Program

The proposed rule specifies that "physicians" that are also DMEPOS suppliers must submit bids and be awarded contracts in order to furnish items subject to competitive bidding in an area. It also notes that "physicians" that do not become contract suppliers must use a contract supplier to furnish competitively bid items to their Medicare patients. Further, the proposed rule states that "physicians" will not be required to furnish these items to beneficiaries who are not their patients if they choose not to function as commercial suppliers. In other words, such "physicians" would not be required to serve an entire competitive bidding area. Finally, the proposed rule has chosen to define the term "physician" by reference to 1861(r)(1) of the Social Security Act (which covers only doctors of medicine and doctors of osteopathy), rather than the more typical reference to 1861(r), which would also include doctors of

9312 Old Georgetown Road Bethesda, Maryland 20814-1621
(301) 571-9200 Fax (301) 530-2752 http://www.apma.org

podiatric medicine. Below we outline in considerable detail our concerns about these aspects of the proposed rule. We begin by describing how podiatric physicians use certain DMEPOS products as an integral part of the services they provide to their patients, and how the new competitive bidding program could interfere with the practice of podiatric medicine.

DMEPOS Use by Podiatric Physicians

As podiatric physicians and surgeons, our members prescribe and supply DMEPOS items as an integral part of patient care. Similar to medical doctors (MDs) and doctors of osteopathy (DOs), our members are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. Our members are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy all other Federal and State regulatory requirements.

According to CMS, there are more than 7,300 podiatric physicians who are DMEPOS suppliers. Our members provide medically necessary and appropriate DMEPOS items in treating Medicare beneficiaries. Examples of how podiatric physicians utilize DMEPOS in patient care include:

A patient presents complaining of foot pain and swelling after tripping on a sidewalk. The podiatric physician diagnoses multiple fractures of the metatarsals and determines that a Cam walker is necessary for immobilization of the injured foot. If that podiatrist no longer functions as a supplier, the patient will be forced to travel to another location to obtain the brace, treatment will be delayed or perhaps never implemented, and the patient will risk further injury to the foot.

Or, the podiatric physician may treat a patient with an acute ankle injury and determine that an ankle brace is necessary to stabilize the ankle and that crutches are necessary to limit weight-bearing on the injured extremity. If that podiatric physician is not a DMEPOS supplier in the new competitive acquisition program because he or she was unsuccessful in competing to bid to supply to the entire Metropolitan Statistical Area (MSA) rather than just to his patients, the patient will need to go elsewhere to obtain the medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

Patients with conditions requiring acute care (e.g., fractures, foot or ankle injuries), must have immediate access to appropriate treatment, including DMEPOS items such as pneumatic walkers, non-pneumatic walkers, ankle braces, crutches, canes and walkers. These items need to be sized and fitted by the doctor. The patient needs to be instructed on proper use of the item, including weight-bearing activities.

If the patient is unable to acquire the item from the treating physician and must instead obtain the item from another supplier due to the new competitive acquisition program, negative consequences could

result. A delay in care could put the patient at risk for additional injury, which could result in increased costs to the Medicare program for the care of that patient.

For instance, if the patient with the foot fracture falls because she is unable to bear full weight on the injured extremity and breaks her hip as well, additional expenses will be incurred by the Medicare program. Or, a delay in receipt of necessary DMEPOS items could result in the deterioration of the patient's medical condition. A stable fracture could become unstable, thereby increasing the severity of the existing injury. A fracture that could initially be treated with a closed reduction could require an open reduction, which would increase costs to the Medicare program. At the very least, a delay in treatment could lead to increased, prolonged disability or less than desired results that may have a permanent impact on the activities of daily living (ADLs) of the patient.

For non-acute cases, the clinical judgment and expertise of the physician remain essential. The selection of a particular item, as well as its size and fit, should be based on the physician's evaluation of the patient. Instruction on the proper application or use of the item is important. The physician dispenses the item based on the pathology of the patient and can best explain why the item is necessary and how it must be used. The physician is able to check the fit of the item and can determine if the patient will be able to use it successfully. A different item may be needed than the one originally prescribed and the physician is the best person to make this determination.

If difficulty in using an item is not immediately identified by the physician and the patient receives it from a separate supplier and the fit is incorrect, the patient may ultimately not use the item or may use it improperly, all of which could contribute to the deterioration of the patient's condition and lead to increased costs to the Medicare program. Or, some patients may return to the physician's office with questions or for assistance, which would also increase costs due to the need for additional care or instruction.

Exclude All Physicians and Qualified Healthcare Practitioners From the DMEPOS Competitive Bidding Program

The APMA believes that all physicians, including podiatric physicians, as well as other qualified healthcare practitioners who utilize DMEPOS when caring for Medicare beneficiaries, should be exempted from the requirement to competitively bid to supply DMEPOS to their own patients. According to 2004 data on DMEPOS services, practitioners were responsible for 3.1% of DMEPOS allowed charges as a percent of all allowed charges while entities categorized as "suppliers" were responsible for 96.4% of those charges. Clearly, there is a vast difference in the amount of DMEPOS supplied by physicians and other practitioners compared to that supplied by traditional suppliers.

Most of our physicians supply limited quantities of DMEPOS items to Medicare beneficiaries. They do not maintain significant inventories and sometimes may have only one or two of a particular type of item available in the office. As an item is used, it is replenished. We seriously question the ability of our members or other physician or practitioner suppliers to compete against entities with the ability to purchase vast quantities of products in bulk. If individuals believe that competing against these larger entities is hopeless, many will not even try. If CMS expects physicians and other qualified practitioners to be able to successfully bid to supply items for the future, it needs to provide more details on the selection process; otherwise, individuals will be deterred from bidding before the program even starts.

Physicians and other practitioners who operate as small businesses and whose primary mission is to provide quality patient care that is medically necessary and appropriate and who use DMEPOS solely for purposes of enhancing that care will face significant administrative and financial burdens in trying to compete in this new program. To the detriment of patient care, many will decide against submitting a bid and will be excluded as suppliers. Rather than disrupt Medicare beneficiary access to care that is in their best interest and that occurs at a single point-of-service, we urge CMS to exclude all physicians recognized by Medicare, as well as other qualified healthcare practitioners from the requirement to competitively bid.

It is clear to the APMA that any financial gains made as a result of the proposed rule would be minimal whereas the potential risks to patient health would be huge. We fail to understand the logic of this proposal that would prevent doctors of podiatric medicine (DPMs) from being defined as physicians. We also are convinced that while the competitive bidding process may save the program some money in the initial phase, it will not only cost more to care for the complications of delayed and inappropriate care but will harm the patients we are committed to serve.

Exempt Items Integral to Patient Care

If CMS is uncertain whether the current statute would permit the agency to exclude physicians from competitive bidding altogether, as we recommend, we believe there is another alternative, at least during the early rounds of competitive bidding. CMS could exempt from competitive bidding items that are used as an integral part of patient care provided by physicians and other qualified healthcare practitioners. This would not only allow physicians to continue to serve their Medicare patients without undue interference, it would also provide time for CMS to consult with relevant Congressional Committees regarding the current statutory language and the possible need for amendments or clarifications.

In broad terms, we suggest that the following product categories be excluded from competitive bidding: diabetic shoes, diabetic inlays, prosthetics for the foot, and diabetic adjustments; fractures/sprain/injury related items, such as crutches, pneumatic walkers, other fracture ankle-foot orthoses (AFOs), items for ankle injuries, including braces and splints, and plantar fascia splints; AFOs, including non-pneumatic

walkers; and select wound care products, including negative pressure wound therapy (NPWT). If CMS prefers a more detailed list of suggested products for exclusion, we will be happy to comply. We are prepared to suggest items by HCPCS code if necessary and request that CMS contact us if more specific recommendations are required.

As we understand it, CMS believes that Therapeutic Shoes for Individuals with Diabetes (TSD) items are not subject to competitive bidding, although this is not specifically mentioned in the proposed rule. APMA strongly supports such exclusion. These items are provided for patients identified as being at risk and ensuring proper fit of TSD items is essential. If items are not fitted and used properly, complications could occur that might result in loss of limb or life. Since specific existing regulations apply regarding the certification of need, prescription and dispensing of those items, we believe that including them in competitive bidding would be counter-productive to patient care.

Additionally, we note that the proposed rule mentions in passing (in the impact analysis) that surgical dressings are not eligible for competitive bidding, and we support such exclusion as well. Many of the surgical dressings are used in wound care and must be available to patients undergoing treatment for acute or chronic wounds.

Specifically in relationship to the treatment of wounds, we believe that physician choice when determining appropriate wound care products is of paramount importance. Our members treat a wide variety of wounds, including diabetic ulcers. Our members save life and limb and contribute to the improvement of the quality of life and duration of life for Medicare beneficiaries, especially those with diabetes. There are a variety of challenges in providing wound care, not the least of which is that proper care can be costly, involve pain and suffering for patients, and interfere with the patient's activities of daily living and other normal activities.

We are concerned that physician choice and access to certain wound care products could be restricted as a result of the new competitive bidding process. An item of particular concern for our members is negative pressure wound therapy. In October 2000, a new HCPCS code, E2402, was established for NPWT and since 2003 more than 3,000 physicians have ordered NPWT more than 36,000 times.

In recent months, new products have been added to the E2402 code despite the fact that these new products are clinically different from the original NPWT product. Case studies involving the original NPWT product are attached for your review. As demonstrated, these products are used for wounds that are significant. In one of the case studies, the product is used post-amputation and after eight weeks of use, wound healing is evident. If this product were no longer available because only newer items described by HCPCS code E2402 are provided by contract suppliers, it is conceivable that wound healing could be compromised.

Since the category described by E2402 includes newer items that are not yet well understood or established and physician choice in selecting an item must be respected, we suggest that it is too risky to competitively bid that category at this time. Therefore, we recommend that NPWT products are not among those subject to the initial round of competitive bidding.

Finally, we note that, as mandated by the MMA, the proposed rule calls for subjecting only off-the-shelf orthotics (and not custom-made orthotics) to competitive bidding. APMA strongly supports the Congressional decision to exclude custom-made orthotics from the list of products eligible for competitive bidding.

Allow Physicians to Continue as Suppliers at the MSA Rate

Another option CMS could consider is to allow physicians and other qualified healthcare practitioners to continue to supply DMEPOS as they currently do provided they agree to supply the item at the single payment amount, the same rate that applies to the entire MSA. Since the proposed rule suggests establishing a single rate for each product subject to bidding in each MSA, the "bid" of the physician or other qualified healthcare practitioner would simply be a statement confirming their willingness to serve as a supplier and to supply items at the rate established by CMS. For physician-suppliers, we believe that such a bid could still be viewed as satisfying the statutory requirement that a bid specify "a particular price." In addition, since all or nearly all physician-suppliers are likely to easily satisfy any definition of "small supplier," our recommended approach for handling bids from physician-suppliers would help CMS respond to the statutory requirement that the Secretary "take appropriate steps to ensure that small suppliers...have the opportunity to be considered for participation in the [DMEPOS competitive acquisition] program."

This option would ensure that Medicare beneficiaries' access to patient care and to medically necessary and appropriate items is not negatively impacted as a result of the new program. They could continue to receive items from their physician or other qualified healthcare professional while still allowing CMS to achieve cost savings since the item would be provided at the CMS rate.

Physician Definition Should be Changed to 1861(r)

Based upon our June 21 meeting with CMS representatives, we understand that it is the agency's position that the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)* requires CMS to establish a competitive bidding program for all suppliers of DMEPOS. While we continue to believe that physicians and other qualified practitioners should be exempted from the requirement to competitively bid, it appears that CMS will proceed with competitive bidding for all suppliers. There are provisions within the proposed rule that will negatively impact a podiatric physician's ability to supply

medically necessary and appropriate DMEPOS to Medicare beneficiaries as an integral part of patient care.

The proposed definition of "physician" could lead some to conclude that podiatric physicians would not be allowed to participate in the new DMEPOS competitive bidding program. However, as we understand it, that was **not** CMS' intent. As noted earlier, more than 7,300 podiatric physicians currently have DMEPOS supplier numbers, and thus it seems rather doubtful that Congress would have intended to bar these individuals from continuing to serve as suppliers. In any case, the proposed definition of "physician" would appear to have other negative consequences for podiatric physicians and their patients. Since CMS did not recognize podiatrists as physicians for purposes of the proposed rule, podiatric physicians will not be able to bid to supply DMEPOS items to their patients only. Additionally, podiatric physicians will not have the ability to execute a physician authorization when they determine that a particular brand of item is necessary for the patient. We believe this decision will have serious consequences for our members and the Medicare beneficiaries they serve.

As noted earlier, in the proposed rule, CMS defined physician using the narrow 1861(r)(1) definition, which applies to MDs and DOs only. Since the prescribing, fabricating, fitting and dispensing of DMEPOS is within our scope of practice as defined by state law, this proposed action is in direct conflict with those laws as written.

We question why CMS selected this definition when our members provide DMEPOS items the same way that they are provided by MD and DO physicians. Our members perform a thorough evaluation of the patient prior to determining a course of treatment. As stated previously, our members prescribe and supply DMEPOS items as an integral part of patient care. They are required to obtain a valid supplier number and must adhere to the existing 21 supplier standards. They are licensed in the state in which they practice, are subject to the same Stark requirements that apply to MDs and DOs and must satisfy other Federal and State regulatory requirements. If a DMEPOS item is necessary, our members prescribe the item and if they have a valid supplier number, they may dispense that item in their office. Therefore, we urge CMS to revise the physician definition to 1861(r) so that all physicians recognized by Medicare are able to bid to supply items to their patients only and are able to execute a physician authorization. Additionally, we believe that other qualified healthcare practitioners should be able to supply DMEPOS that is used as an integral part of patient care.

We see nothing in the MMA that requires the proposed, narrow definition of "physician" for purposes of the DMEPOS competitive bidding program. We recognize that a separate provision, relating to the need for a face-to-face examination of a patient for coverage of certain DMEPOS, does limit the definition of physician to 1861(r)(1), but this provision is currently being applied only to power mobility devices and does not directly relate to the competitive bidding program.

In sum, we urge CMS to modify the definition used for physicians who may bid to supply DMEPOS to their patients only and who may execute a physician authorization from 1861(r)(1) to 1861(r).

Criteria for Item Selection

We realize that CMS has yet to identify the specific products or product categories that will initially be subject to bidding. We suggest that care be exercised in establishing the product categories for the future. Scope of practice limitations exist for our members and it would not make sense to require podiatric physicians to, for example, competitively bid to supply all off-the-shelf orthotics. Our members supply lower extremity orthotics and would be unable to supply upper extremity orthotics. Other specialties could be similarly challenged. For instance, it is unlikely that orthopedic hand surgeons would supply lower extremity orthotics. When establishing product categories, we urge CMS to be realistic and avoid making the categories so broad that it actually prevents some specialties from bidding.

Quality Standards and Accreditation for Suppliers of DMEPOS

The APMA is concerned with the application of quality standards, as well as the establishment of an accreditation process, for all suppliers of DMEPOS. Specifically, if a uniform set of standards and a single accreditation process are utilized, it is conceivable that the standards and process could be so onerous or expensive that physician suppliers would be unable or unwilling to serve as DMEPOS suppliers. As a result, patient care could suffer.

While we recognize that the proposed rule was limited in its discussion of the quality standards and accreditation process, and we expect the release of the final quality standards in the near future, we believe physicians should have a unique set of quality standards and a separate accreditation process. At the very least, we object to a uniform set of standards and a single accreditation process for all suppliers of DMEPOS. We believe that the standards and accreditation process should be fair and reasonable and should be reflective of the amount of DMEPOS supplied to Medicare beneficiaries.

Podiatric and other physicians must obviously meet state licensing requirements, and subjecting them to additional or potentially duplicative requirements could be overly and unnecessarily burdensome. We believe that it is reasonable to utilize a process for physician suppliers that differs from the one used for traditional suppliers lacking professional licensure. To subject a licensed physician, who might supply $5,000 worth of DMEPOS to Medicare beneficiaries over the course of a year to the same standards and accreditation process that apply to an entity supplying $1,000,000 worth of DMEPOS seems unreasonable. We encourage CMS to be reasonable in establishing quality standards and an accreditation process for physician suppliers.

Additionally, if the costs associated with becoming accredited (including the fee paid to the accreditation organization) are excessive when compared to the amount of DMEPOS supplied, or the process is overly burdensome, physicians may decide against functioning as DMEPOS suppliers. Patient access and patient care could be compromised.

If accreditation is required for all suppliers, physicians must have equal and appropriate access to the accrediting organizations. A single accrediting body for podiatric physicians who supply DMEPOS does not exist. Since accreditation by suppliers will be required before the program starts, our members would be disadvantaged. Other physicians and qualified healthcare practitioners would likely face similar challenges. We believe that if CMS intends to require an accreditation process for physicians beyond state licensing, the agency must ensure that a reasonable and fair pathway exists for physicians and other qualified healthcare professionals who wish to become accredited. The details of the accreditation process should be immediately communicated so that physicians and other qualified healthcare practitioners who wish to serve as suppliers in the new competitive bidding program understand the process they must follow.

Conclusion

The APMA appreciates the opportunity to offer these comments. The competitive bidding program, as proposed, is of significant concern to our members and we are hopeful that CMS will revise its proposals prior to issuing final regulations. If you have questions or require additional details, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

David M. Schofield, DPM
President

9312 Old Georgetown Road Bethesda, Maryland 20814-1621
(301) 571-9200 Fax (301) 530-2752 http://www.apma.org

Submitter : Mrs. Janet Blaylock

Date: 06/30/2006

Organization : Hand Therapy of Delaware

Category : Occupational Therapist

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

See attachment

CMS-1270-P-1018-Attach-1.DOC

#1018

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

possible delay, knowing that they are inadequately fitted and/or unprotected? This very possible scenario has both legal and ethical considerations.

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Janet W. Blaylock, MOT, CHT

Submitter : Ms. Melissa Cross **Date:** 06/30/2006

Organization : O.E. Meyer Co.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1019-Attach-1.DOC

#1019

SUBMITTED ELECTRONICALLY

June 30, 2006

Mark McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
Departments of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21224

RE: **CMS-1270-P – Notice of Proposed Rulemaking, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues**

Dear Dr. McClellan:

The O.E. Meyer Co. appreciates the opportunity to submit comments on the Notice of Proposed Rulemaking (NPRM) for Competitive Acquisition for Certain DMEPOS and Other Issues. O.E. Meyer Co. is a medium size home medical equipment provider in Sandusky, Ohio. We have been employee owned since January 1989. We currently service a large number of Medicare beneficiaries.

We are a member of The Ohio Association of Medical Equipment Services (OAMES), and thus a proponent of the American Association for Homecare (AAHomecare), and a member of The MedGroup and we fully support the detailed comments and concerns of those organizations. The following pages summarize the key issues as they affect Ohio providers related to CMS' Notice of Proposed Rulemaking published May 1, 2006 in the Federal Register (71 Federal Register 25654), Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues.

Timing

CMS should push back the implementation date of October 1, 2007 to a more reasonable timeframe. In addition, CMS should stagger the bidding in MSAs over a twelve month period to allow for an orderly roll out of the program. This will also allow CMS to identify problems that occur in the competitive bid areas and correct them before the problems become widespread. And under the timeline CMS is proposing, small providers will not have time to create networks, which eliminates them as a practical option for small providers that want to participate. This is another reason for a delay in planned implementation.

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

The Program Advisory And Oversight Committee (PAOC) Must Be Included By CMS In The Review Of Public Comments And The Development Of The Final Rule

CMS must include the Program Advisory and Oversight Committee in the review of the public comments received during the 5/1/06 through 6/30/06 comment period and the development of the Final Rule. To not do so excludes the important counsel and advice of key stakeholders in a critical process and goes against the very intent of establishing the PAOC.

Quality Standards

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

Bidding Process

CMS should clearly identify a screening process that will be used to determine whether a submitted bid will be given any consideration. This process should include, at a minimum, three steps that a bid must go through before it is entered into the bidding pool. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only after the satisfactory completion of these three steps should a company's bid be processed for further review and consideration as to pricing.

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

The proposed rule refers to the possibility of extending the implementation of competitive bidding to areas adjacent to selected MSAs. This is not provided for in the legislation and should not be done.

Any company that submits a bid should have a track record of serving the targeted geography to validate its capabilities and service record.

Suppliers could bid an extremely low price and indicate extremely low capacity to ensure inclusion. If too many use this strategy it could profoundly impact the single bid price.

The draft rule requires that a bidding company service the entire MSA. This presents significant hardship to small businesses and may result in poor service in certain areas. A better solution is to allow a bidding company to indicate by zip code what areas of the MSA they will cover.

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

Provide More Details On The "Composite Bid" Calculation

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

Safeguards Must Be Put In Place To Ensure Realistic "Capacity" Amounts Are Assigned To Bidding Companies

Significant problems will result if companies are allowed to claim unrealistic capacity. A company should not be permitted to claim a capacity greater than 25% over the number of products provided to Medicare beneficiaries the previous year.

Require That A Minimum Number Of Small Suppliers Be Included In The Wining Contract Suppliers

At a minimum, small business suppliers in an amount equal to the number of winning bidders should be allowed to participate in the contract assuming they submitted a bid at or below the current allowable amount.

Clarify Network Regulations

What are structural requirements? Who can do billing and collection? Other operational issues?

Do Not Place Limitations On Formation Of Networks

Market share limitations should be removed (these do not apply to single entities that bid). Network members should be able to also bid through other means.

Do Not Make It Harder For Providers To Sell Their Businesses

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

Product Selection Must Be Conducted With Beneficiary Welfare In Mind

How will "savings" be calculated? Examples are problems with beneficiaries having to deal with multiple suppliers; recognition of items that are custom and service oriented; incorporate Hobson-Tanner provisions.

Consider The Impact On The Patient

CMS cannot rely solely on costs and volume for product selection. Consider issues such as access and medical necessity of beneficiaries who use the items. Competitive bidding should not be a substitute for appropriate medical policy.

Rebate Provisions Must Be Eliminated

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

Financial Standards

Specific steps need to be established to allow a consistent evaluation of all companies and audited financial statements should not be required.

This information should consist of: (a.) Two year comparative financial statements prepared in accordance with Generally Accepted Accounting Principles (GAAP). The financial statements must be accompanied by a "review" report from an independent Certified Public Accountant. Audited financial statements should not be required as they place an undue expense on the bidding company. (b.) Certificate of Insurance verifying a minimum of $1,000,000 in general liability coverage and listing other appropriate insurance policies in force. (c.) Letter from primary institutional lender verifying current lending relationship. (d.) Letters from three primary product suppliers outlining purchasing volume over the last two years and its credit and payment history. (e.) Credit report from recognized credit rating organization.

Modify Requirement That Winning Supplier Must Repair Patient-Owned Equipment

It is appropriate for winning suppliers to be required to service any equipment they provide. However, this requirement should not be placed on equipment that is supplied by others. The current reimbursement rates for service and repair are inadequate and it is impossible for a bidding supplier to factor these unknown costs into their bids.

Do Not Require Wining Suppliers To Take On Beneficiaries That Are Currently Using Capped Rental Equipment From Another Supplier

Under a capped rental scenario, accepting a new beneficiary transfer after several months of rental with another supplier is unrealistic. It is impossible for a bidding supplier to factor in the cost of taking on beneficiaries that began service with another Medicare Supplier. If this requirement is to remain, then a new rental period should start when the beneficiary begins to receive an item from a wining supplier.

Allow Traveling Beneficiaries From Competitive Bidding Areas to Be Serviced At Standard Medicare Allowables

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

Different Alternatives To Gap Filling Must Be Used

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

Develop More Equitable System To Price HCPCs Changes

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

Please consider very seriously the comments submitted by all interested and concerned parties. The Competitive Acquisition rule has very drastic impacts on the industry and more importantly, on the patients we serve. The plan must be realistic, logical and implemented in an organized, efficient manner so that it is successful for all parties.

Thank you for the opportunity to provide comments on this important proposed regulation.

Respectfully submitted,

Melissa B. Cross
Business Manager
O.E. Meyer Co.

Submitter : **William Tobia** **Date: 06/30/2006**

Organization : **Home Medical Equipment**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-1270-P-1020-Attach-1.DOC

CMS-1270-P-1020-Attach-2.DOC

#1020

HOME MEDICAL EQUIPMENT, LLC
319 Nassau Blvd
Garden City South, NY 11530
516-505-1200 Fax 516-505-1211

June 29, 2006

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

Dear Dr. McClellan,

I am the owner of Home Medical Equipment (HME). We primarily provide custom rehabilitation products and services to the severely handicapped population. I would like to take this opportunity to provide comments on the Proposed Rule Making entitles " Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" published in the Federal Registrar on 5/1/06

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

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

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bidding agreement and post-sale that company continues to meet the contract requirement that contracted supplier and its new ownership should retain its contract.

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

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

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I appreciate the opportunity to submit these comments and remain available to discus with you in greater detail.

Respectfully Submitted

William Tobia, RPh
President

#1020

HOME MEDICAL EQUIPMENT, LLC
319 Nassau Blvd
Garden City South, NY 11530
516-505-1200 Fax 516-505-1211

June 29, 2006

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

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Respectfully Submitted

William Tobia, RPh
President

Submitter : **Mr. Michael Hamilton** **Date: 06/30/2006**

Organization : **ADMEA/GAMES**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

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These comments are submitted on behalf of the more than 500 suppliers represented by the Alabama Durable Medical Equipment Association (ADMEA) and the Georgia Association of Medical Equipment Services (GAMES). Members of both organizations are concerned that the prosed rule on competitive acquisition will unecessarily disrupt the market for home medical equipment, threaten beneficiary access to needed equipment and destroy currently viable businesses, all without producing significant savings for the program.

The chief concern is the lack of information provided in the proposed rule, especially with regard to quality standards. In order to provide potentially useful comments on competitve acquistion, it is necessary to understand the quality standards that would apply to a successful bidder. We urge publishing final quality standards and responding to other comments received on competitive acquistion, then publishing another proposed rule for comment. We also urge careful consideration and adoption of recommendations by the American Association for Homecare.

The most egregious content in the proposed rule is the proposal to allow for rebates. For the entire existance of the Medicare program, there have been constant efforts to avoid such behavior, and to introduce it with government approval is to invite widespread fraud on an unprecedented level. Reversing a long-standing policy by permitting the government to handle publicity, rather than the provider, is bad policy, a bad practice, and subjects the program to ridicule and derision. Suppliers can already compete on the cost to beneficiaries by charging a lower rate than the allowable charge for any item, and while it does happen, it is not a widespread practice, because the level of reimbursement at current rates does not encourage such behavior. The proposed practice is an invitation to cheat, and it will not benefit any beneficiary.

As proposed, the rule raises many more questions than it answers. Please resposnd to the commnets submitted by issuing a second proposed rule for comment, incorporating those changes accepted as a result of comments received, and add a review of both final quality standards and the new proposed rule by the PAOC before publication. This is too important to risk the results that may and probably would result from rushing the implementation of current plans.

Submitter : Ms. Linda Breakie **Date:** 06/30/2006

Organization : Complete Infusion Services

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1022-Attach-1.DOC

#1022

Complete Infusion Services

"Living Life To The Fullest"

June 29, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

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

Dear Dr. McClellan:

Complete Infusion Services is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

We are an independent home infusion company located in Metro Detroit Michigan. We have been in business for five years and are committed to serving the under-served population. Of our 295 patients, 66 or 22% have Medicare as their primary insurance.

CMS has the unenviable task of developing and implementing, within a limited time frame, a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program. We understand that this is a challenging undertaking. Our comments are designed to point out primary areas of concern related to the application of competitive bidding program for home infusion therapies covered under the durable medical equipment benefit or enteral nutrition therapies. In short, we believe that these product areas are not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

We urge you to carefully consider and adopt the detailed recommendations being sent to you under separate cover by our national organization, the National Home Infusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. We understand that new Part B quality standards for DMEPOS are still in development. These standards will apply not just to items selected for competitive bidding but also to other DMEPOS items that will continue to be reimbursed under current payment methodologies. We support quality standards for infusion and enteral therapies, but urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless

if Medicare p ayment levels are woefully i nadequate in relation to the costs as sociated w ith complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. The preamble to the proposed rule indicates that Medicare expenditures for DME infusion pumps and related drugs in 2003 were approximately $149 million. This number appears to include expenditures made for insulin and insulin pumps for patients with diabetes, which are not provided by infusion pharmacies and is largely a different market than infusion. In fact, we have never cared for an insulin pump patient in the 5 years we have been open. It also includes drugs that have sole or limited national distribution arrangements with particular pharmacies, where there would appear to be little savings to be gained from the imposition of competitive bidding. In addition, it includes drugs that are administered to the "sickest of the sick" patients who are very compromised and which require extraordinary expertise for safe and effective provision. These drugs should never be subject to a competitive bidding regimen. The more accurate amount of Medicare expenditures for 2003 for DME infusion pumps and related drugs was approximately $87 million.

5. Similarly, enteral nutrition is not a good candidate for competitive bidding. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services. It creates serious policy and operational issues for nursing homes as well as for CMS. CMS has the authority to exclude enteral nutrition from this phase of the competitive bidding program, and it should exercise that authority to do so.

   If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients. CMS should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.

6. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.

7. The proposed "gap-filling" provisions are too vague and undefined, and appear to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 734-425-2550.

Sincerely,

Linda M. Breakie, RN, CRNI
Managing Member

cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Submitter : Miss. Tracey Towlen **Date:** 06/30/2006

Organization : Norton Clinic For Lymphedema & Physical Therapy

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-1023-Attach-1.WPD

#1023

June 29, 2006

Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS

To Whom It May Concern:

I am a physical therapist in private practice who specializes in lymphedema. I am writing in response to the Proposed Rule for Competitive Acquisition of Certain DMEPOS. I treat many patients with the chronic diagnosis of lymphedema in upper or lower extremity, head/neck, or trunk.

I feel that it is necessary that a physical therapist fit and adjust compression garments whether it is a ready made or custom made garment. During an intensive phase of treatment (complete decongestive therapy), the patient is reduced to the smallest size limb with manual lymph drainage, compression bandaging and exercises. When they have reached their goals, they are then fit for a compression garment. The bandaging is very customized to the patient depending on the severity of lymphedema, limb contour, and sensitivity of skin. These findings need to be carried over when measuring for a compression garment and only the treating therapist has the knowledge of the patient's individual needs from the intensive phase of treatment.

I have worked in the hospital setting in the past and most of the patient cases that failed were from a direct result of insufficient compression garments that were not tailored or adjusted by the treating physical therapist. These patients were referred to a surgical supply store and not properly fitted causing fluctuations in their swelling and a need for further treatment and expenses for additional garments. Measuring and assessing self care is part of the monthly follow ups in my practice. The patients are measured and the compression garments are analyzed as to how well they are maintaining the achieved reduction at home. If these patients do not maintain a proper and steady reduction with these compression garments, they are at risk to swell and require further daily treatment or are at risk for cellulitis that would require additional medical attention, possibly even hospitalization.

Please consider all of these points when making a decision on the above proposed rule. I am in favor that physical therapists be able to measure and adjust for durable medical equipment such as compression garments, ready made or custom and I feel that these products should be reimbursable to the patient each year since it is the only self care treatment that is keeping them from getting worse and reflecting a large cost for medical attention and hospitalization.

Thank you for your time,

Tracey Towlen, MPT, CLT-LANA, CLM

Submitter : Mr. Dennis Strickland **Date:** 06/30/2006

Organization : Strickland's Pharmacy

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

This process is not fair to the small health care professional and more importantly, the patients he or she serves. I am in a small rual area in a city of >3000 and a county of >15000. We work hard for our patients and we do make money for our services, but we are not overcompansated for our actions.This proposed regulation will not allow me to care for my patients and pay my bills,must less make a living.

Submitter : **Ms. Catherine Cambridge** **Date: 06/30/2006**

Organization : **Hand Therapy of Delaware**

Category : **Physical Therapist**

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

see attached

CMS-1270-P-1025-Attach-1.DOC

#1025

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

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to supply upper extremity orthoses to beneficiaries in their care without additional constraints.

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

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

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

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

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

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

Finally, I would like to comment on the very small margin of profit I receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis.

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

Sincerely,

Catherine A. Cambridge, MS, PT, CHT

Submitter : Ms. Ellen Briley **Date:** 06/30/2006

Organization : Elba Nursing Home

Category : Long-term Care

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

I am an administrator of a 111 bed facility in rural southeast Alabama. I am concerned over the impact of patient care if having to subject to bidding and vendor changes. Not only will this be aptient health and safety concern, ultimately it will not be cost effective as it opens more opportunity for increased healthcare needs.

Regulatory Impact Analysis

Concern over the competitive bid proposal and its impact to nursing homes

Submitter :

Date: 06/30/2006

Organization :

Category : Private Industry

Issue Areas/Comments

Criteria for Item Selection

Criteria for Item Selection

See Attachment.

CMS-1270-P-1027-Attach-1.RTF

#1027

June 30, 2006

VIA EMAIL: www.cms.hhs.gov/eRulemaking

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

Re: CMS-1270-P
Issue Identifier: Criteria for Item Selection - Exclusion of mastectomy products from competitive bidding.

Centers for Medicare & Medicaid Services:

Including mastectomy products, such as breast prosthesis, in competitive bidding will have an adverse impact on the products and services beneficiaries receive. Further, at least two of the objectives of the proposed rule will not be satisfied: to assure beneficiaries access to quality DME, and to contract with suppliers who conduct business in a manner that is beneficial for Medicare beneficiaries.

Many small businesses, such as Women's Health Boutique, offer specialized and individualized consultation and assistance in the selection, fitting, proper use and care of mastectomy products in a physical setting that is comfortable, discreet and dignified. Due to the intimate nature of mastectomy products, such individualized and skilled care is extremely important to beneficiaries' comfort and well-being. The Women's Health Boutique system began in 1994 because this basic care was unavailable for its founder's mother.

It appears from the current draft of the rule that only the largest companies who offer the lowest prices will win bids. It is likely that mastectomy products will not be the focus or specialty of the companies that submit the winning bids, and, as a result, beneficiaries will not receive quality products or the needed individualized attention and skilled care. While such an outcome may be palatable for certain types of DME, given the intimate nature of mastectomy products and the skilled care required, such an outcome is harmful to the physical and psychological well-being of beneficiaries who use mastectomy products. Dissatisfied beneficiaries will negate any perceived financial savings derived from including mastectomy products in competitive bidding.

Beneficiaries need to have the ability to continue to receive the current high level of attention, care and skill they are accustom to from the mastectomy boutique they have chosen to patronize. Including mastectomy products in competitive bidding will frustrate this need as beneficiaries will be faced with the conditions that existed prior to 1994 when Women's Health Boutique and other similar business did not exist. Ultimately, the stated objectives of competitive bidding will not be satisfied.

For t hese r easons, I r espectfully s ubmit t hat mastectomy p roducts ar e n ot s uitable for competitive bidding and should be excluded.

Sincerely,

Daina Pitzenberger
President of WHB, Inc.

Submitter : **Mrs. Charlene Olds** **Date: 06/30/2006**

Organization : **Mrs. Charlene Olds**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I have been in physical therapy for approximately 7 months for a severe wrist break which has been diagnosed as shoulder-hand syndrome. I have had several splints - both prefabricated and those fabricated by the therapist. My experience has been first hand with the problem of having a chosen off the shelf splint not either fitting properly and after several months, not improving my condition (specifically - extension). Both the doctor and therapist were able to ascertain this problem and suggest that another splint would be more appropriate.

Throughout my treatment, the therapist has had to make at least (five) 5 splints with constant adjustments as my condition and progress changed. This would have been impossible if this bidding process had to be followed.

Another issue that was of concern was finding an appropriate splint in conjunction with my insurance coverage with an in-network approved company. This was not true of the first splint chosen.

As a patient, I would not want to go to to a third party to change the splint, or be fitted and/or adjusted by someone not trained in the medical field.

The bidding process proposed would dramatically impair the ability of therapists to appropriately treat and monitor, with changes, the progress of their patients.

I strongly urge you NOT to pass this rule. It would have adverse affects both on the therapists and specifically patients.

Submitter : Mr. Steven Perkins **Date:** 06/30/2006

Organization : Coldwater Pharmacy

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

Criteria for Item Selection

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolodate 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 urge CMS to take steps to ensure that small suppliers - which include the majority of pharmacy-based suppliers - can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOS. It would be extremely difficult, if not impossible, for small suppliers to be competitive in large metropolitan areas.
- After CMS establishes the single payment amount for each item of DMEPOS, any small supplier willing to accept that payment amount should also be allowed to join the competitive bidding program as a contracted supplier.
- CMS must take these steps to preserve beneficiaries' convenient access to DMEPOS supplies and to maintain established provider/patient relationships.
- I currently provide the following types of DMEPOS in my practice: diabetic testing supplies, diabetic shoes, ambulatory aides, commode chairs, respiratory drugs, and immunosuppressant drugs and without these resvisions to the final regulation, I will be unable to continue providing these valuable services to my patients.

Submitter : **Ms. Doug Westerdahl** **Date: 06/30/2006**

Organization : **Monroe Wheelchair**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#1030

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

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

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

Submitter : **Donald Manzullo** **Date: 06/30/2006**

Organization : **House Committee on Small Business**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1270-P-1031-Attach-1.PDF

#1031

DONALD A. MANZULLO, ILLINOIS
CHAIRMAN

NYDIA M. VELÁZQUEZ, NEW YORK

Congress of the United States

House of Representatives

109th Congress

Committee on Small Business

2361 Rayburn House Office Building

Washington, DC 20515-6515

June 30, 2006

Via Hand and E-Mail Delivery
The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; CMS-1270-P, 71 Fed. Reg. 25,654 (May 1, 2006)

Dear Administrator McClellan:

On May 1, 2006, the Centers for Medicare and Medicaid Services (CMS)[1] published a proposed rule to implement § 302 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) mandating competitive acquisition of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that are covered under Medicare Part B. Specifically, the proposed rule establishes a bidding mechanism to determine the price at which bidding suppliers will be entitled to provide DMEPOS to Medicare-covered beneficiaries. CMS correctly found that the proposed rule is significant under Executive Order 12,866 and prepared a regulatory impact analysis. The agency also accurately concluded that the proposed rule will have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act, 5 U.S.C. §§ 601-12 (RFA) and prepared an initial regulatory flexibility analysis proffering a number of alternatives designed to limit the adverse economic consequences of the proposed rule.[2] 71 Fed. Reg. at 25,690-96. CMS should be commended for this effort. These comments focus on alternatives that CMS can adopt to reduce burdens on

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[1] Section 302 of the MMA, 42 U.S.C. § 1395w-3, delegates the responsibility for implementing a competitive acquisition program to the Secretary. However, the Secretary delegated rulemaking authority to CMS. For ease of reference, these comments will refer to CMS rather than the Secretary.

[2] CMS combined the regulatory impact analysis with the initial regulatory flexibility analysis. This is permitted by statute. 5 U.S.C. § 605(a); *see Associated Fisheries of Maine v. Daley*, 127 F.3d 104, 115 (1st Cir. 1997) (noting validity of combining environmental impact statement and final regulatory flexibility analysis).

small business without undermining the efforts to institute a market-based solution for the supply of DMEPOS.

I. Use of Competitive Bidding Implementation Contractors (CBICs) will Create Gaps in Accountability to Small Businesses

The Committee has extensive experience in oversight of CMS's regulation of small healthcare providers. In particular, the Committee tried to resolve the problems that small providers have when caught between the Scylla of Medicare contractors and the Charybdis of CMS. For example, the Committee worked for three years to address reimbursements provided to small business portable X-ray providers. The providers were faced with three bureaucracies: skilled nursing facilities (SNFs), Part B carriers, and CMS. In attempting to redress the complaints of small businesses, the Committee found that SNFs blamed portable X-ray providers for their own problems, portable X-ray providers blamed SNFs and CMS, and CMS, including testimony by then Administrator Scully, laid some of the blame on Part B carriers. Small business owners, who have enough difficulties maintaining their businesses, have neither the time nor the appropriate resources to challenge the frequently contradictory assertions of multiple bureaucracies. The Committee fears that CMS, unfortunately, is going down that same well-trodden path in implementing § 302 of the MMA.

CMS proposes to designate one or more CBICs to provide the following functions: "preparing the request for bids (RFB), performing bid evaluations, selecting qualified suppliers, and setting single payment amounts for all competitive bidding areas."[3] *Id.* at 25,661. In the typical federal procurement, these functions are performed by federal employees with specialized training known as contracting officers whose decisions may be subject to challenge in a variety of arenas including the Government Accountability Office and federal court. CMS's delegation, combined with the foreclosure of judicial review on the contracting decisions,[4] essentially eliminates any accountability within this system.

When a small business has a complaint about the bidding process, the Committee expects that CMS will tell the DMEPOS small business provider to contact the CBIC. In turn, the CBIC will respond that the supplier contact CMS because the CBIC has no power or discretion to

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[3] Section 302 of the MMA does not establish a conventional federal procurement program in which winning bidders are the only suppliers. Rather, the system uses a bidding process as the primary mechanism for determining the single price for each item of DMEPOS. Then any supplier who submitted a bid and is willing to accept that single price will be eligible to supply DMEPOS to Medicare-eligible beneficiaries.

[4] Congress forbade judicial review of the establishment of payment amounts, award of contracts, areas designated for competitive acquisition, phased-in implementation, selection of items and services for competitive acquisition, and bidding structure and number of contractors selected. 42 U.S.C. § 1395w-3(b)(10). Since the only protection against irrational and ad hoc rulemaking is judicial review, *see Morton v. Ruiz*, 415 U.S. 199, 232 (1974); *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967), the Congressional decision to foreclose judicial and administrative review of these decisions enables CMS and the CBICs to make completely irrational decisions.

respond to the complaint. The delegation of a purely governmental function to a private contractor (the operation of a federal procurement system) leaves the small business owner without any recourse to simple errors or irrational actions. The faulty decisionmaking process may cost the small business the opportunity to provide goods and services to existing and future customers – the most severe burden imaginable to a small business owner. At that point, the only recourse is a complaint to Congress. When Congress investigates, the already delineated absence of accountability will again re-emerge with the CBIC and CMS each denying responsibility. If CMS does not delegate the bid selection process to a CBIC, Congress knows who is ultimately responsible.[5] CMS should reject the CBIC option and make competitive acquisitions decisions through its own contracting officers.

The Committee's antipathy to the CBIC process should not be interpreted as a complete rejection of CMS seeking contracts to advise it in the implementation of a DMEPOS competitive acquisition regime. The Committee concurs that CMS certainly must obtain necessary assistance from contractors to help it design the contracts, establish an appropriate bidding mechanism, and even develop options that reduce burdens on small businesses. However, such advice is a far cry from delegating the ultimate decisonmaking process to a private enterprise. Determination of awards must be made by qualified CMS employees and not CBICs or some other private entity.

Should CMS decide to go forward with CBIC proposal, the agency must develop some type of accountability and oversight of CBIC decisionmaking. The accountability must include person or persons at CMS that have the authority to override a CBIC decision. The appeal process contemplated by the Committee does not violate the bar against administrative review in § 302 of the MMA. Nothing in that section prohibits CMS from instituting an internal appeals process of a private company's decision because CMS delegated that initial decision to a private entity. The Committee opines that this alternative will give small businesses an easily navigable process to voice complaints and enable Congress to hold government officials accountable for the decisions made in the DMEPOS competitive acquisition program.

II. Appropriate Allowance of Joint Networks will Reduce Potential Burdens on Small Business Providers of DMEPOS

The current system allows any qualified supplier to offer DMEPOS to a Medicare-eligible beneficiary upon that person's presentation of a valid certificare of necessity and the supplier's willingness to accept the fee schedule payment for the particular item or service. 71 Fed. Reg. at 25,656. Thus, the existing system contains few limits on the total number of DMEPOS suppliers.

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[5] The argument that the system is better because it eliminates the possibility of political pressure on CMS is unavailing. The normal federal government procurement system resists political pressure and has done so for many years. CMS taking responsibility for contracting decisions in the DMEPOS acquisition program should be no different.

All competitive acquisition schemes used by the federal government limit the number of potential suppliers. The program mandated by § 302 of the MMA and the proposed implementation by CMS is no different. The most obvious adverse economic consequence to existing small business suppliers of DMEPOS is the loss of customers if they are not awarded a contract. CMS correctly recognizes the potential loss of business even though the agency found it "difficult to estimate how much revenue a losing supplier will lose because of the DMEPOS competitive acquisition program." *Id.* at 25,694.

CMS suggests that one means of reducing possibility of lost revenue is to allow suppliers to form networks for the purpose of submitting bids. *See* Proposed 42 C.F.R. § 414.418. The current CMS proposal allows any suppliers of DMEPOS to form a network as long as the network does not control more than 20 percent of the market. While the Committee appreciates CMS's concern over potential market power of a network, the Committee thinks a slightly modified approach to the network proposal will have greater utility in protecting small businesses.

Current size standard regulations for purposes of federal government procurement permit a joint venture to have as many small businesses within the joint venture and still not be considered a large business as long as each member is small for the industrial classification corresponding to the contract. 13 C.F.R. § 121.103(h)(3).[6] The standard does not incorporate a market share limitation because the purpose of the joint venture size standard[7] is to increase participation by small businesses in the federal procurement process. If CMS wants to ensure increased participation by small business suppliers of DMEPOS, then it should strongly consider adapting the joint venture definition set forth in Title 13 of the Code of Federal Regulations to the competitive acquisition program for DMEPOS. The Committee suggests that CMS allow small businesses to form joint ventures or networks for the purpose of bidding in response to a DMEPOS request for bids, without regard to market share, as long as all of the members of the network or joint venture are small business suppliers of the particular item of DMEPOS. In

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[6] The Small Business Act grants the Administrator of the Small Business Administration final authority to determine what constitutes a small business for the purpose of the Small Business Act or any other statute unless another statute contains a specific definition of small business. 15 U.S.C. § 632(a)(2)(A). This authority is explicit with respect to federal government procurement. *See* 48 C.F.R. §§ 19.301-.308. Nothing in § 302 of the MMA establishes a separate definition of small business so the Administrator's authority remain plenary with respect to the size of a business that is considered small for the purposes of implementing the competitive acquisition program.

[7] There are additional restrictions applicable to the joint venture size standard rule. However, those exceptions further support the applicability of the regulation to the DMEPOS competitive acquisition program. The joint venture is considered small if all the businesses are small and the joint venture is bidding on a bundled contract. The proposal established by CMS for competitive acquisition of DMEPOS would be considered a bundled contract as that term is defined in § 3(o)(2) of the Small Business Act, 15 U.S.C. § 632(o)(2). Even if the contract is not bundled, a joint venture containing only small businesses still will be considered small if the size of the contract exceeds $10 million. It certainly is not beyond the realm of reason to assume that many contracts for particular DMEPOS items in a geographic area may exceed in $10 million.

addition to the benefit to small businesses, the proposal reduces burdens on CMS because the agency will not have to calculate the market share of networks or joint ventures that consist solely of small business suppliers.

As a corollary to the Committee's suggested modification of the network standard, CMS should strongly consider whether the size standards DMEPOS suppliers developed by Small Business Administration (SBA) are appropriate. To be sure, the administratively simple solution is to adopt the existing size standards established by the SBA. However, those standards were designed to operate within the context of normal federal government procurement. The competitive acquisition program established by § 302 of the MMA is certainly not a conventional federal acquisition program.[8] Therefore, CMS should examine whether the SBA size standards are appropriate or whether different size standards are needed and those size standards may vary depending upon the DMEPOS item to be acquired.[9] The Committee reminds CMS that should it adopt a different size standard, it will need to comply with the procedural requirements of § 3(a)(2)(C)(i) and § 3(a)(3).

The Committee recognizes that there are instances in which it may prove beneficial for small businesses to enter into joint ventures or networks with large business suppliers of DMEPOS. The recommendation to allow small business suppliers of DMEPOS to form networks irrespective of market share should not be interpreted to exclude small and large suppliers an option to form networks or joint ventures. If CMS allows that option, the Committee concurs with the agency's preliminary determination to impose a cap on network size based on market share.[10] However, if it does so, the burden of demonstrating that the venture is below the market share cap should rest on the large business or CMS and not on the small suppliers. That would represent an unnecessary and expensive market research burden that would deter many small businesses from entering into a joint venture or network.

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[8] No further proof is needed than the fact that Congress authorized CMS to waive the application of the Federal Acquisition Rules. 71 Fed. Reg. at 25,661, citing 42 U.S.C. § 1395w-3(a)(1)(C). In this program, the government itself never takes possession of any good or utilizes a service. Rather, the competitive DMEPOS program establishes a single price and the universe of suppliers of DMEPOS to Medicare-eligible beneficiaries.

[9] Such variation in size standards is not uncommon for other federal auction/competitive bidding situations. The most closely analogous procedure was the sale of electromagnetic spectrum pursuant to the authority set forth in § 332 of the Federal Communications Act in which the Commission developed different standards for small businesses based on the specific spectrum that was to be auctioned.

[10] The Committee is not convinced that 20 percent share evidences market power. It also is possible that 20 percent may be appropriate for certain DMEPOS items and not others. If antitrust law teaches one thing, there are no bright line tests for determining market power. *See* 2A P. AREEDA & H. HOVENKAMP, ANTITRUST LAW ¶¶ 423, 515 (2004). While administratively useful, the bright line suggested in the proposed rule may be overbroad and prohibit network formation that raises no problem with respect to market power even though the network's market share exceeds the proposed 20 percent. The Committee recommends that CMS obtain the advice of the Antitrust Division of the Department of Justice and the Federal Trade Commission.

III. CMS Must Consider Small Business Participation in Establishing the Competitive Bidding Areas

Section 302 of the MMA does not specify the size of the competitive bidding areas that CMS must establish. If the sole goal of the program is government efficiency, then CMS would be constrained to establish the largest bidding areas possible given the item of DMEPOS to be acquired. However, efficiency is not the sole criterion for the program. CMS recognizes other important aspects of competitive acquisition including the need to ensure small business participation and the delivery of quality services to Medicare-eligible beneficiaries.[11]

This Committee's perspective on CMS's proposal to establish competitive acquisition areas must be filtered through the Committee's experience with other federal agency procurement activities through the utilization of contract bundling. Contract bundling is defined as the consolidation of two or more procurement requirements (be they for goods or services or a combination of both) that are consolidated into one contract previously provided under separate smaller contracts. The consolidation only becomes problematic bundling if the terms of the contract make it unlikely to be suitable for award to small businesses because of size of the contract, the dollar value of the contract, the geographical dispersion for performance, or any combination of these factors. 15 U.S.C. § 632(o). The Committee on Small Business has more than a decade-long record in opposition to contract bundling because it drastically reduces opportunities for small businesses. Furthermore, the use of bundled contracts runs counter to the Congressional policy set forth in § 15 of the Small Business Act that requires small business be given their fair share of opportunity to supply good and services to the federal government. 15 U.S.C. § 644(a).

With this history and concern in mind, it is not surprising that the Committee has significant concerns about the competitive acquisition program proposed by CMS. The program has all the characteristics of a bundled contract. Medicare-eligible beneficiaries now can select any supplier and that supplier is reimbursed; this is not dissimilar to a federal government contract currently performed by a small business. The proposed rule would consolidate these "separate contracts" into one metropolitan statistical area-wide contract. This is the type of consolidation that may not be suitable to award to small business because of the geographic dispersion of the contract. In many cases, small business suppliers of DMEPOS will not have the logistical or financial resources to provide service to an entire metropolitan area.[12]

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[11] This is particularly true with respect to DMEPOS that contain a significant component of service assoicated with the provision of the item such as respiratory technician monitoring of oxygen tanks.

[12] To some extent, the networking procedures will vitiate this concern. However, formation of networks to bid constitutes a significant transaction cost that will dissuade many small business suppliers. Furthermore, these smaller suppliers may be chary of entering into business partnerships with entities that they normally view as competitors creating potential difficulties in competition outside of the Medicare arena.

The Federal Communications Commission (FCC) was faced with a problem analogous to that currently facing CMS. In 1993, Congress mandated that the FCC auction spectrum it had previously simply licensed on a first-come first-serve basis or on the basis of which applicant would best serve the public interest. Congress also dictated that the FCC ensure that small businesses have the opportunity to participate in these auctions. This prevented the FCC from simply auctioning licenses for personal communications services (PCS)[13] on a national basis because small businesses did not have the financial resources to compete in an auction against giant telecommunications companies. The FCC then adopted a bifurcated strategy of separate PCS auctions. One auction involved large companies bidding for spectrum to serve major trading areas which generally included an entire state or multiple states. A series of auctions then were held for smaller businesses to purchase spectrum to serve smaller regions called basic trading areas which were generally contiguous with metropolitan statistical areas. *See High Plains Wireless, L.P. v. FCC*, 276 F.3d 599, 603 (D.C. Cir. 2002). Small businesses did not participate and were not expected to participate in the auctions for major trading areas. However, they did participate, and, in certain instances, were the only participants in the auctions for spectrum allocated to basic trading areas.

CMS can adapt the strategies employed by the FCC in a number of ways. The most obvious one is to reduce the size the of the geographic regions from metropolitan statistical areas to some smaller division of those areas.[14] In the alternative, CMS can allow bids for an entire metropolitan statistical area; then set aside for small businesses to bid on smaller regions such as cities or counties within the metropolitan statistical area.[15] Finally, CMS can use metropolitan statistical area bidding to establish the single price and then allow small businesses to make offers using that bid price but allowing the small businesses to designate their service

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[13] PCS is type of mobile communication similar to cellular service but operating in the 1.9 GHz band.

[14] It is important to note a prime distinction between DMEPOS and electromagnetic spectrum for use in PCS. In providing telecommunication services, it is vital that entire economic regions be covered otherwise no one will purchase the service. Dividing the United States into areas smaller than basic trading areas would not permit the establishment of a commercially-viable telecommunications service. *See Amendment of the Commission's Rules to Establish Personal Communications Services*, 8 FCC Rcd 7700, 7732 (1993). Given the difference between logistics of supplying DMEPOS and the physics of electromagnetic spectrum, CMS cannot use the FCC's adoption of basic trading areas as proof that metropolitan statistical areas constitute the appropriate geographic size for participation by small business suppliers of DMEPOS.

[15] Should CMS wish, it might use the bids on the metropolitan statistical area to establish the single price and if bids on smaller areas exceed the single price, reject any or all bids above that single price. On the other hand, bids of small suppliers may be even lower than the metropolitan statistical area bids. CMS then has the opportunity to blend the two prices in order to obtain a single bid price applicable to larger and smaller competitive bidding regions. The United States Department of Agriculture uses a variation of this blending strategy in the implementation of milk marketing orders which establish the price of various classes of milk in those regions of the country subject to a milk marketing order. *See* 7 C.F.R. § 1000.50; 7 C.F.R. Parts 1001-1135 (pricing for specific market order regions).

territories.[16] The Committee strongly urges CMS to consider these and similar alternatives that do not force small suppliers to bid on serving an entire metropolitan statistical area.

IV. Mandatory Subcontracting Plans

CMS determined that the federal acquisition rules should not apply to the implementation of the DMEPOS competitive acquisition program. 71 Fed. Reg. at 25,661. The Committee recognizes that the federal acquisition rules are complex and may reduce agency discretion in procurement. Furthermore, as already noted in these comments, the competitive acquisition program is not a typical federal procurement program. Nevertheless, CMS should strongly consider adopting one aspect of the federal acquisition rules – the requirement for subcontracting plans.

Section 8(d) of the Small Business Act, 15 U.S.C. § 637(d), mandates that prime contractors give small businesses the maximum opportunity practicable to participate as subcontractors. *Accord* 48 C.F.R. § 19.702. The regulations implementing § 8(d) require that prime contractors, other than those that are small businesses, submit a subcontracting plan, *id.* at § 19.702(a)(1)-(2), that among other things, contains "a description of the principal types of supplies and services to be subcontracted." *Id.* at § 19.704(a)(3). Subcontracting plans, despite this Committee's ongoing concern about compliance,[17] do provide significant opportunities for small businesses to participate in the federal contracting arena.

The Committee recommends that CMS adapt the federal acquisition rule subcontracting regime to the competitive acquisition DMEPOS program. The Committee does not expect that CMS will impose an identical subcontracting plan requirement that is imposed on federal prime contractors.[18] However, CMS may require that large bidders submit subcontracting plans after

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[16] Under this regime, CMS must bar the small business from designating a service territory contiguous with the metropolitan statistical area. If the small supplier wants to serve an area contiguous with the entire metropolitan region than it must participate in the bidding process for the entire area. Any other result enables some small businesses to game the system in their favor and the Committee is requesting CMS examine methods to reduce burdens on small suppliers not provide them with an unfair advantage.

[17] *See* H.R. REP. NO. 108-325 at 180 (2003) (describing changes made by H.R. 2802 to improve prime contractor compliance with their subcontracting plans).

[18] Federal subcontracting plans are designed to achieve a variety of economic opportunity goals including the increased utilization of small businesses owned by women, minorities, veterans, service-disabled veterans, and those operating in historically underutilized business zones. The primary purpose of the competitive acquisition DMEPOS is to replace the current fee schedule arrangement for reimbursement of DMEPOS items while maintaining quality provision of services to Medicare-eligible beneficiaries. Given the significantly different underlying purposes of the two regimes, CMS should not be required to develop subcontracting plans that focus on particular subgroups within the small business community.

the winning bidders are determined[19] as a condition of their continued participation in the program. The plans should include the following items: 1) the type of goods and services that they will utilize small business subcontractors;[20] 2) the type of outreach that the they will perform to identify potential subcontractors; and the 3) the recordkeeping that will be done by the prime contractor to ensure that subcontractors comply with CMS quality standards in the delivery of services to Medicare-eligible beneficiaries. CMS also may condition the use of subcontractors on the basis that such utilization will not modify the single price reimbursement to the prime contractor. Adaptation of the subcontracting plan requirement from the federal acquisition rules will provide opportunities for small business suppliers of DMEPOS to obtain some revenue from the competitive acquisition program even if they decide not to bid on a particular item or are not awarded a contract.

V. Conclusion

CMS does not have an enviable task in the development of a competitive acquisition scheme for DMEPOS. The Committee commends CMS for recognizing at an early stage that implementation may have significant adverse consequences for small businesses. Adoption of the alternatives set out in these comments will ameliorate some of the adverse consequences to small business suppliers of DMEPOS. The Committee recommends that CMS work with the Office of Advocacy of the United States Small Business Administration, RTI (its contractor for developing the small business focus groups that the agency convened prior to the issuance of the proposed rule), and the small supplier community to develop other alternatives that will reduce the adverse economic consequences of the DMEPOS competitive acquisition program.[21] The

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[19] If CMS determines that a sufficient number of awards in a particular area have been made to small businesses, CMS may elect to waive the subcontracting plan requirement for that specific DMEPOS item in that geographic bidding area. Should CMS select this procedure, the Committee would expect that a sufficient number of small business awardees represent a not insubstantial amount of the market share in a given region for the DMEPOS.

[20] As an example, a large supplier of power wheelchairs, might utilize smaller, local businesses to provide delivery or maintenance of the wheelchairs.

[21] The courts recognize that an agency "may develop additional information in response to comments without starting anew [a new comment period]...." *Personal Watercraft Indus. Ass'n v. Department of Commerce*, 48 F.3d 540, 544 (D.C. Cir. 1995). This stems from two aspects of the Administrative Procedure Act. First, and unlike an adjudicatory proceeding, there is no concept of ex parte contacts or communications because there are no specific parties in an informal rulemaking. *Sierra Club v. Costle*, 657 F.2d 298, 400-02 (D.C. Cir. 1981). Second, as long as the rulemaking constitutes a logical outgrowth of the proposed rule, the use of additional information is neither inappropriate nor prejudicial. *E.g.*, *Texas Office of Pub. Util. Coun. v. FCC*, 265 F.3d 313, 327 (5th Cir. 2001); *Solite Corp. v. EPA*, 952 F.2d 473, 481 (D.C. Cir. 1991) whether produced by the agency or the agency's consultants. *Burke v. Board of Governors of the Federal Reserve System*, 940 F.2d 1360, 1367 (10th Cir. 1991), *cert. denied*, 504 U.S. 916 (1992); *United Steelworkers v. Marshall*, 647 F.2d 1189, 1220-22 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981). In this instance, all parties are on notice that CMS is considering the development of a competitive acquisition program that seeks participation by small suppliers and minimizes the potential of lost revenue. No person interested in the rulemaking then will be surprised if CMS adopts a competitive acquisition

(continued...)

Committee staff stands ready to assist CMS in the continued development of this competitive acquisition program. Should your staff have any comments about this letter, please contact the Committee's Chief Counsel, Barry Pineles at 202-225-5821.

Sincerely,

Donald A. Manzullo
Chairman

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[21](...continued)
program that utilizes techniques not set forth in the proposal that achieve its regulatory objective concerning small suppliers even though it might include alternatives not specifically raised in the notice. *See Association of Battery Recyclers v. EPA*, 208 F.3d 1047, 1058-59 (D.C. Cir. 2000).

Submitter : **DeAnn Mullins** **Date: 06/30/2006**

Organization : **Mullins Pharmacy, Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1032-Attach-1.DOC

#1032

WeCare
"FOR BETTER HEALTH"

June 30, 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 from my perspective as a practicing pharmacist, certified diabetes educator, and an owner of two pharmacies, a medical supply company and a diabetes education company. I am also a regular columnist for *Retail Pharmacy Management* magazine writing on how community pharmacy can improve diabetes care and education. My column reaches every retail pharmacy in the United States totaling more than 60,000 pharmacies and has an estimated 120,000 readers.

Requiring accreditation for pharmacy participation would create unnecessary bureaucracy and impose prohibitive costs in terms of monies and time. Prohibiting pharmacists who submit a bid above a "pivotal bid:" – i.e. reimbursement ceiling might reduce initial costs to the government, but enactment of CMS-1270-P would result in loss of access and greater costs and inconvenience to patients, loss of personalized attention from community pharmacists, and higher health care costs associated with deteriorating health of patients. For a serious, yet largely manageable, disease that already inflicts great harm through under treatment, discouraging patient access and care through implementation of CMS-1270-P would have tragic results.

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 will compromise patient health outcomes.

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Phone 850-271-8426 Fax 850-271-8189

WECARE
"FOR BETTER HEALTH"

Criteria for Item Selection

The competitive bidding program should not include common DMEPOS supplies such as diabetes 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 be a central supplier. **The demonstration projects in Florida and Texas did not explore the benefits of CB for diabetes related supplies and services.**

Diabetes Self Management Training (DSMT) - Beneficiary Access Compromised

Pharmacists provide Diabetes Self Management Training (DSMT). The Balanced Budget Act (BBA) of 1997 provided coverage for diabetes self-management training (DSMT) for beneficiaries in a variety of settings -- including community pharmacies. The final regulations were published in the Federal Register dated December 29, 2000.

Under the law, a certified provider must meet CMS and American Diabetes Association (ADA) quality standards to provide DSMT. Through DSMT, pharmacists and other professionals provide beneficiaries the necessary training and skills to self administer testing and medications, handle diabetes crisis, and make lifestyle changes to effectively manage the disease. DSMT has been proven to decrease the overall cost of diabetes care.

DSMT providers typically maintain a supplier billing number to provide beneficiaries convenient access to diabetes supplies. This supplier number also enables a pharmacy with American Diabetes Association (ADA) Recognition to supply Diabetes Self-Management Education and Training.

Referring to critical language in CMS-1270-P on page 25658:

Suppliers of DMEPOS must comply with quality standards in order to furnish ANY item which payments are made under Part B AND to retain a provider or supplier billing number used to submit claims for reimbursement for ANY such items made under Medicare.

CMS-1270-P minimizes the value of DSMT by discouraging pharmacists and other providers from completing rigorous CMS and ADA quality standards to provide this training. Beneficiaries that receive DSMT services from a non participating or losing CAP bidder will have to visit multiple locations to take advantage of both Medicare benefits.

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Accordingly, to continue to allow beneficiaries convenient access to DSMT AND diabetes testing supplies from the same provider I strongly urge CMS to exempt pharmacists from CMS 1270-P requirements to obtain accreditation and requests CMS remove diabetes supplies from CB consideration.

The Medicare Therapeutic Shoe Bill (TSB) of 1993 – Beneficiary Access Compromised

Therapeutic Shoes are not subject to competitive bidding. CMS has deemed pharmacists qualified to dispense therapeutic shoes to persons with diabetes. On May 1, 1993, CMS determined that therapeutic footwear and protective insoles were effective methods for preventing foot problems among diabetes. The extra levels of protection will help keep beneficiaries out of the hospital and off of the operating table. According to the ADA, 86,000 lower limb amputations occur annually due to diabetes. Experts agree that most of these amputations would not have to happen if properly fitted, appropriate footwear were dispensed and worn.

The Medicare Therapeutic Shoe Bill of 1993 and Diabetes Self Management Training programs were enacted to prevent complications in persons with diabetes. Unfortunately, access to these benefits is not supported through CMS 1270 P proposals to: 1) mandate mail order of diabetic supplies; 2) subject diabetic supplies to CB; and 3) require DSMT providers and pharmacists to accredit.

In addition, however, if CMS includes Part B drugs, the potential exists that beneficiaries will have to travel to **three** different Part B suppliers to buy shoes, strips, and receive DSMT. Limiting beneficiaries with diabetes access to these valuable services will increase healthcare expenditures.

Pharmacists are already licensed and regulated by State Boards of Pharmacy (BOPs) and dispense DMEPOS as a routine course of business. Pharmacists maintain professional and product liability insurance and beneficiaries may seek disciplinary action through BOPs for inadequate pharmacist services.

Additionally, CMS did exempt pharmacists from industry surety bond requirements imposed on DMEPOS dealers in the late 1990s. This exemption is a clear precedent in distinguishing pharmacists that maintain supplier numbers from dealers.

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WeCare
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For these reasons, I

1) recommend that CMS exempt pharmacists providing part B drugs, DSMT, and diabetes testing supplies from obtaining accreditation

2) strongly urge CMS to remove diabetes supplies from competitive bid consideration.

3) Oppose <u>any</u> CMS mail order proposal that would mandate beneficiaries use mail order suppliers as their <u>only choice</u> when purchasing DMEPOS and replacement supplies in 2010.

I currently provide the following types of DMEPOS in my pharmacy practice:

- Diabetes Testing Supplies
- Therapeutic Shoes
- Diabetes Self-Management Education and Training

Without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients in a community that desperately needs them.

Thank you for considering my view.

DeAnn Mullins

DeAnn Mullins, BSPharm, RPh, CPh, CPT, CDE
Owner/Clinical Coordinator

WeCare Mullins Pharmacy
WeCare Pharmacy
WeCare Diabetes Education Company
WeCare Wellness and Medical Supplies

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Submitter : **Mr. Michael Reinemer** **Date: 06/30/2006**

Organization : **American Association for Homecare**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1033-Attach-1.DOC

#1033

Via Hand Delivery and Electronic Submission

June 30, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

Re: AAHomecare Comments on the Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues [CMS-1270-P]

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') notice of proposed rulemaking (NPRM) on the implementation of a national competitive bidding program for DMEPOS. Congress authorized national competitive bidding for DMEPOS under the Medicare Modernization Act of 2003 (MMA).

AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include home health agencies and suppliers and manufacturers of DMEPOS, rehab and assistive technologies, and pharmacies that provide home infusion and inhalation drug therapies to patients in their homes. Our membership reflects a cross-section of homecare providers, including national, regional, and local providers and suppliers. With approximately 800 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home. AAHomecare members service thousands of Medicare beneficiaries who use DMEPOS items. Our members are committed to providing beneficiaries with high quality DMEPOS items and services that promote positive health outcomes. Consequently, AAHomecare is uniquely qualified to comment on the issues raised under the NPRM.

As you know, competitive bidding will be an unprecedented departure from the traditional fee-for-service Medicare DMEPOS benefit. We hope that CMS appreciates the experimental nature of this program, especially in light of the limited scope of the two demonstrations. While we understand your desire to meet the deadlines specified under the MMA, we urge you to proceed with caution, especially during the initial implementation phase in 2007. Given the scale of this undertaking and the interests that are at stake, it is more important to protect beneficiary access and the interests of all bidders than to rush through the implementation.

The NPRM predicts that the bid process will begin in 2006, with prices taking effect in October of 2007. This timeline is aggressive in light of the many critical steps that remain to be done. We urge CMS to publish a revised timeline that identifies each of these steps with more realistic target dates for their implementation:

- Publish the supplier standards
- Select accrediting bodies
- Publish regulations
- Publish the initial 10 MSAs
- Publish the initial product categories
- Publish the RFB
- Evaluate bids
- Select contract suppliers
- Educate beneficiaries and referral sources
- Publish program instructions for a transition
- Implement the program in each MSA

We also want to emphasize our concern that the information in the NPRM is inadequate to serve as a basis for public comments on several important issues. A rulemaking procedure must provide notice of a proposed agency action with reasonable specificity to solicit informed public comments. The NPRM falls short of this standard with respect to how §5101 of the Deficit Reduction Act of 2005 (DRA) and the final quality standards will apply under competitive bidding. As you know, §5101 forces Medicare beneficiaries to own their capped rental or oxygen equipment at the end of a statutory period of continuous use. Without establishing the scope of this new requirement and how it will dovetail with competitive bidding, the NPRM is incomplete and vague, limiting our ability to comment.

AAHomecare is aware that CMS will publish regulations to implement the DRA in the future. However we need an opportunity to assess and comment on how the new rules will apply under the framework for competitive bidding. We suggest that CMS issue an interim final rule to allow additional comments on this issue prior to publishing a final rule implementing competitive bidding. In addition, because the NPRM fails to identify the Metropolitan Statistical Areas (MSAs) and the DMEPOS items that will be subject to competitive bidding, we request that CMS also schedule a meeting of the Program Advisory and Oversight Committee (PAOC) when it publishes this information. The

PAOC can provide CMS with additional comments before it begins to implement the program.

It is also imperative that CMS allows stakeholders an opportunity to comment on the quality standards before they become final. We are sensitive to your concerns about meeting the deadlines in the NPRM, but we believe that allowing time for additional comments is unlikely to significantly delay the program. We also believe that it is required given that CMS chose to issue the standards in a program memorandum rather than through a rulemaking proceeding. As a result CMS avoided the requirements under the Administrative Procedure Act (APA) and the oversight of the Office of Management and Budget (OMB) that would otherwise be part of rulemaking. CMS should allow the comment period on the NPRM to remain open for an additional 30 days following the publication of the quality standards. CMS should include a response to any comments it receives on the quality standards in its response to the public on the NPRM.

In any event, as we stated above, competitive bidding is a radical departure from the traditional DMEPOS benefit, and CMS has no experience with this program on a wide scale. The quality standards and accreditation will protect beneficiaries by requiring all bidding suppliers to meet an objectively verifiable level of service and quality. The standards and accreditation will also ensure that bidders compete on a "level playing field" by requiring that all bidders factor into their bids the costs of providing the same level of service and quality. Because the standards are at the center of a successful bidding program, CMS should tolerate delays and not rush the quality standards -- or any other aspect of competitive bidding.

Payment Basis

Inflation Update

CMS states that providers do not have to factor inflation into their bids because the competitive bid price will be updated by the CPI-U. Providers have no assurance that Congress will not override the update through subsequent legislation in any given year. CMS needs to address how it plans to assure providers that the inflation update to the competitive bid price will not be subject to subsequent freezes in the CPI-U. If CMS cannot provide this assurance, then it should instruct bidders to include an inflation adjustment in their bids.

Grandfathering Medicare Advantage

The NPRM does not address the impact of competitive bidding on Medicare Advantage patients who leave their plan to reenter traditional Medicare. These patients may have a provider who is part of the MA plan network, but that may not be a contract supplier. What rules will apply to this patient population under competitive bidding? Will these patients have the opportunity to continue to use their existing supplier when they reenter the traditional Medicare program? AAHomecare recommends that patients moving from an MA plan to traditional Medicare be given the option of remaining with their existing provider under the grandfathering provisions proposed in the NPRM.

Beneficiary Switch to Contract Suppliers

The NPRM states that a beneficiary can decide to use a contract supplier at any time. Contract suppliers will be required to furnish capped rental or oxygen equipment to beneficiaries in the competitive bidding area regardless of the rental months remaining on the equipment. CMS states that suppliers must factor these additional costs into their bids. Suppliers will be unable to include these additional costs in their bids, because it is not possible to predict whether beneficiaries may decide to switch to a grandfathered supplier and how many rental months remain on a piece of equipment. Moreover, CMS states that suppliers may not submit bids higher than the current fee schedule amount for an item. This artificial ceiling on the bids further complicates bidding under this scenario. AAHomecare appreciates CMS' desire to preserve the beneficiary's freedom to change suppliers even under a competitive bidding program. We recommend that CMS initiate a new period of continuous use if a beneficiary decides to switch from a grandfathered supplier to a contract supplier.

We also suggest that CMS allow contract suppliers access to the common working file or some other streamlined mechanism for determining when a piece of equipment will convert to a sale or that a claim might be subject to a "same or similar" denial. Contract suppliers need to know this information upfront. Not having access to this information will increase suppliers' administrative costs and impact the amount of their bids. CMS should state whether this type of mechanism will be available so that suppliers can factor it into their bids.

Application of DRA to Oxygen Patients

It is unclear from the NPRM how CMS intends to apply the DRA provisions on oxygen to grandfathered suppliers and beneficiaries. Will the "grandfathered" relationship terminate at the conclusion of 36 months? S imilarly, how will CMS apply the DRA requirements to beneficiaries who move from one MSA to another? As noted above, the implementation of the DRA forced-ownership provisions on oxygen and capped rental equipment will have important ramifications for competitive bidding. We cannot provide meaningful comments on many issues in the NPRM without understanding how CMS will administer the DRA requirements.[1] Consequently, it is important that CMS publish an interim final rule before it publishes the final rule on competitive bidding.

Authority to Adjust Payment in Other Areas

The NPRM states that CMS has the authority, with respect to items included in a competitive bidding program, to use the payment information obtained through competitive bidding to adjust the payment amounts for those items in areas outside the competitive bidding area. With respect to DME, the authority is based on §1834a(1)(F)(ii). CMS states that the authority under §1834(h)(1)(H)(ii) is the basis for using the information obtained through competitive bidding to adjust the payment amounts for "prosthetic devices and orthotics." CMS should note that the authority under

[1] AAHomecare submitted a letter to CMS in April requesting clarification on how the DRA would apply to a number of scenarios involving oxygen and capped rental equipment. We have not received a response to our question as of the date of these comments. A copy of our correspondence to CMS is attached.

§1834h(1)(H)(ii) applies only to orthotics as defined under §1847a. Specifically, the authority to adjust payment amounts in other areas applies only to "off-the-shelf" orthotics and not also to prosthetic devices as CMS contends.

In implementing its authority under §1834a(1)(F)(ii), CMS should adhere to the inherent reasonableness (IR) methodology authorized by Congress under the Benefits Improvement and Patient Protection Act (BIPA). The IR methodology includes procedural steps to protect stakeholders and requires an analysis of the factors that influence a determination to make a payment adjustment. In using information derived form competitive bidding to adjust payment amounts in other areas, at least one of these factors is the comparability of the CBA to the areas where CMS intends to make a payment adjustment. Our ability to comment further on this issue is limited because CMS has asked only for suggestions on how to implement this authority without publishing notice of a specific proposal. CMS must initiate a separate notice and comment rulemaking to solicit comments on a specific proposal before implementing this authority in a final rule.

Limitation on Beneficiary Liability

We understand that Medicare will not cover DMEPOS items subject to competitive bidding furnished to a beneficiary in a competitive bidding area by a non-contract supplier. Under current Medicare rules, a supplier may furnish the beneficiary with an ABN notifying him that Medicare will not pay for an item. Other portions of the NPRM specifically state that ABNs will be permitted under a competitive bidding program, and the MMA requires that CMS continue to allow suppliers to use ABNs. CMS should clarify what it means when it states that a beneficiary will have no financial liability to a non-contract supplier for competitively bid items furnished by that supplier.

Competitive Bidding Areas

Staggered Implementation

The NPRM is silent on whether CMS will commence competitive bidding in 10 MSAs at the same time, or stagger the initial implementation of competitive bidding in 2007. We recommend that CMS phase-in the first 10 MSAs. This will allow CMS to identify and correct problems as competitive bidding commences before the problems become widespread.

Nationwide or Regional Mail Order Competitive Bidding Program

It is unclear why CMS proposes a separate competitive bidding program for mail order suppliers in 2010. Since mail order suppliers are not excluded from participating in competitive bidding during 2007 and 2009, a separate program for them in 2010 would be unnecessary. Further, there is no definition for a "mail order" supplier under Medicare program rules. Many local or regional suppliers provide some items to beneficiaries by mail order yet also provide retail or delivery services to homes. As a result, we are also unsure who would qualify to participate in a national competition for mail order supplies.

There are many complicating factors such as changes in a beneficiary's level of supply needs that may inhibit the supplier's ability to deliver reorder supplies to a beneficiary within the required time frame. With glucose monitors, the type/brand that a beneficiary is initially prescribed may change based on the beneficiary's medical status and required changes in the brand of test strips supplied. For example, a beneficiary may develop arthritis and be unable to open the packages of test strips, requiring that they be switched to a different brand in order to comply with the prescribed testing.

While mail order is an appropriate and cost effective vehicle for delivery of some replacement supplies such as test strips and lancets, it may not meet the needs of all beneficiaries who require such supplies. Mail order, while efficient, is subject to the ability to get the supplies to the beneficiary by commercial carrier. Whether or not a beneficiary receiving such supplies lives in a competitive bidding MSA, he or she should have the option of being able to obtain these supplies locally. The Medicare program must allow multiple distribution channels to meet beneficiary needs.

Finally, we note that this proposal represents another example of CMS' failure to provide the level of detail necessary for notice and comment rulemaking. CMS should publish an interim final rule to solicit additional public comment before implementing a national or regional competitive bidding program.

Establishing the Competitive Bidding Area

CMS has no authority to extend competitive bidding areas outside an MSA in 2007 and 2009. The MMA clearly states that the competitive acquisition areas will be established ***in*** an MSA. Moreover, including a patchwork of areas within a competitive bidding area will make it difficult for contract suppliers to administer competitive bidding from an operations perspective. Finally, CMS must identify the MSAs in which it will commence competitive bidding in 2007 at the time it publishes an interim final rule and schedule a PAOC meeting to solicit additional comments.

Criteria for Item Selection

Items Included in Competitive Bidding

CMS identifies three categories of items that are subject to competitive bidding consistent with the requirements of §1847(a)(2): Covered items as defined under §1834a(13) for which payment would otherwise be made under §1834(a) and supplies used in conjunction with durable medical equipment; enteral nutrition, equipment, and supplies; and off-the-shelf orthotics (OTS). CMS should clarify whether prosthetic devices such as ostomy products and related supplies that were not expressly included under §1847(a)(2) by Congress are subject to competitive bidding.

Potential for Savings

CMS should explain and clarify what specific measures will be used to decide an item's potential savings as a result of competitive bidding. Specifically, CMS should address the following:

- *Annual Medicare DMEPOS allowed charges*: Is there a threshold expenditure level that will trigger competitive acquisition for a product category?
- *Annual growth in expenditures*: Is there a threshold growth percentage and does it vary by the dollar size of the category?
- *Number of suppliers*: How will CMS determine the appropriate number of suppliers for a product category in each MSA? What supplier capacity thresholds will be used to determine this and how were those thresholds determined?
- *Savings in DMEPOS demonstrations*: How will savings be determined for the vast majority of product categories not included in the Demonstration Projects?
- *Reports & studies*: Which ones and types will be considered? Who will review the studies and determine their validity and applicability for modeling Medicare program savings?
- *Allowed Charges*: Does this mean paid claims?

Additional Criteria for Item Selection

Under the proposal in the NPRM, item selection is driven by costs and utilization only. There is a risk that by focusing exclusively on cost and utilization criteria, CMS will allow competitive bidding to become a substitute for appropriate coverage policies as a way of controlling expenditures. In deciding to include a product under a competitive bidding program, CMS should also consider clinical and service factors specific to the product. Some products will be inappropriate for competitive bidding because of the clinical condition of the beneficiaries who use them. For example, invasive ventilator patients have clinical conditions that require clinical monitoring and oversight, making invasive ventilators inappropriate for competitive bidding.

CMS should publish the items it will include in the initial competitive bidding program when it publishes an interim final rule. CMS should also schedule a meeting of the PAOC to solicit additional public comment after it announces the product selections.

Brand-Specific Requirements

The NPRM proposes to allow physicians and practitioners to prescribe a specific brand or type of equipment. According to CMS, this type of provision would preserve beneficiary access to equipment. Although contract suppliers will not be required to carry all brands/models of equipment included in competitive bidding, if a physician orders a brand/model the supplier does not carry, the supplier must choose whether to fill the order, refer the beneficiary to another supplier, or ask the physician to change the order. Medicare will not pay for another item if the supplier failed to provide the brand name item the doctor ordered.

AAHomecare believes it is unnecessary for CMS to include this requirement as part of a competitive bidding program because a physician is always free to order a specific item he/she wants the beneficiary to have. Importantly, this requirement will promote a demand for premium or brand name items based on direct to consumer advertising, even though the "brand name" product has the same clinical benefit as other products. Physicians often are not well-informed about the features and benefits of new

technologies; the homecare supplier is responsible for matching the patient's needs to the equipment or supplies. The proposal is also contrary to how suppliers do business, not only under the Medicare program, but with all payers. Suppliers carry items and equipment that the FDA deems to be functionally equivalent to other products. Forcing suppliers to carry all possible items and equipment will be costly and burdensome and will reduce potential savings from competitive bidding. Finally, the current HCPCS codes do not support brand specificity. A comprehensive overhaul of the HCPCS codes would be necessary to successfully implement this provision. Inasmuch as CMS' authority to implement this requirement is discretionary under the MMA, we recommend that CMS not include this provision in the final rule.

Coding Issues and Item Selection

The methodology that CMS proposes for item selection relies on historical data and does not take into account recent changes in a benefit that will affect utilization. For power wheelchairs, recent changes in the HCPCS codes, a new LCD, and new fee schedules will significantly change utilization for these items. Specifically, CMS would lack the cost and volume data required under the formula in the NPRM to select an item. CMS would be unable to determine which codes within this product category are the highest cost and highest volume for Medicare using current data. Moreover, assuming that the coding, pricing and coverage changes result in accurate utilization for these products, in future years there may not be a rationale for including power wheelchairs in competitive bidding under the formula CMS has proposed. AAHomecare recommends that CMS not include power wheelchairs in the initial rounds of competitive bidding because it would lack recent data from which to determine the HCPCS codes that represent the highest costs and highest volume for CMS. We also recommend that CMS exclude new products that come on the market in the middle of a bidding cycle from competitive bidding.

Submission of Bids

General Issues

Clear definition of the product categories must be outlined for bidding suppliers. All HCPCS codes and their typical quantities should be identified for each product category that the supplier bids. For example, glucose monitors and supplies should include glucose monitors, test strips, lancets, lancing device, and replacement batteries. Glucose monitors for visually impaired (i.e.: E2100) should be identified and bid separately because their cost is drastically different. If the bid pricing is related to the product category and not each HCPCS code that makes up the category, then it may be cost prohibitive to service visually impaired beneficiaries with the monitors, resulting in service issues for beneficiaries. Further, CMS needs to break down the product categories for manual wheelchairs and seating systems so that appropriate seating systems can be included with the wheelchair base.

Weighing Criteria

The request for bid must identify the weighing factors the CMS will apply to the bids.

Requirements to Bid on all Products in a Category

Suppliers may choose to bid on one, some, or all of the product categories, but if a provider bids on a category, that provider must bid on each item included in the category. CMS must define product categories narrowly, to make sure that they are consistent and representative of the products that a supplier might actually furnish. Including a broad category for wheelchairs or power wheelchairs could be very problematic. Suppliers who do not specialize in rehab may not carry power wheelchairs under certain codes. Similarly, suppliers who do specialize in providing equipment to patients with complex needs may not carry all of the power wheelchairs designated by that product category.

- Power wheelchair codes are in the process of being revised. A high probability exists for compromise of patient care due to the breadth of the category combined with the complexity of needs for the high-end rehab patient. Complex rehab wheelchairs are predominantly custom-configured, and they utilize a minimal amount of standard in-stock components. Due to the high probability of inappropriate equipment being provided to the complex rehab patient in the first level of review as well as subsequent provision of appropriate equipment, it is highly probable that a categorical bidding process will be more costly in the long run for complex rehab and assistive technology.
- Manual wheelchairs HCPCS codes will be subjected to a similar recoding process beginning in 2007. Due to its greater breadth as a category, manual wheelchairs will probably cost more to bid categorically for similar reasons. Complex rehab technology patients require wheelchairs that are fitted and adjusted to meet their individual needs and therapeutic goals. Under the proposal in the NPRM, a provider who bids on the category of manual wheelchairs must be prepared to provide all types of manual wheelchairs including standard, ultra lightweight, bariatric, or manual tilt-in-space. In many cases complex Rehab manual wheelchairs require multiple components from multiple manufacturers to achieve appropriate fit and function for the individual.
- Those providers who are awarded a winning bid in a category for "Wheelchairs" could end up not being a winning bidder for the associated seating. In effect, many patients may need to deal with two or more providers for a single rehab wheelchair. This situation could lead to access issues in areas of the country where a winning provider is not equipped to provide the complexity of multiple seating and positioning services required in that area.
- Current HCPCS codes are too broad, encompassing items that represent vastly different technologies. CMS should develop narrow product categories so that providers may submit proposals for more standard bases with general purpose seating and positioning products compared to high end complex rehab technology services. It is dangerous to the end user for non-qualified providers to be submitting bids for services that they do not provide.

Skilled Nursing Facilities and Physicians

CMS proposes that only skilled nursing facilities (SNFs) and physicians selected as contract suppliers would be eligible to provide DMEPOS in a competitive biding area. Physicians and SNFs can limit their services to their own residents or patients and would not be required to service all beneficiaries in an MSA. In contrast, DMEPOS suppliers awarded contracts, cannot refuse to serve any beneficiary. This means that contract suppliers would be required to accept beneficiaries regardless of the costs the supplier may have to absorb (*e.g.*, assuming a caped rental in the 10th rental month) whereas SNFs and physicians could limit their service costs. Including SNFs and physicians in the same competition with DMEPOS suppliers will distort the bid evaluation and selection of the pivotal bid because SNFs and physicians will have significantly lower costs to operate under the bidding program. We recommend that CMS conduct separate competitions for those items that will be furnished by SNFs or physicians such as enteral nutrition, equipment and supplies.

Conditions for Awarding Contracts

Quality Standards and Accreditation

The NPRM states that CMS will allow a "grace period" during which unaccredited providers can participate in the bidding process. Unaccredited providers who are winning bidders may complete accreditation during this unspecified grace period. If it fails to get accredited during the grace period, the bidder will loose its contract supplier status. Whether a supplier is accredited influences its bid amount inasmuch as accredited suppliers must bear the cost of complying with the quality standards. Including bids from accredited and unaccredited suppliers in the same bid pool distorts the selection of a pivotal bid, because unaccredited suppliers do not factor the costs of complying with quality standards into their bids. These costs are unknown until CMS publishes final quality standards. Consequently, unaccredited suppliers who lack experience with accreditation will not be able to accurately project those costs, skewing the pivotal bid point and the median bid downward. We strongly recommend that CMS allow only accredited suppliers to submit bids. In other words, accreditation must be a minimum eligibility requirement to submit a bid. CMS should not proceed with competitive bidding in an MSA until it is sure that that all suppliers who want to submit bids have had an opportunity to get accredited.

Financial Stability

The evaluation of the supplier's financial stability must take place *before* the bid prices are arrayed and the pivotal bid is selected. Bids from disqualified providers should not be considered in selecting the winning bid point or setting the payment amount. Again, suppliers who do not meet financial standards are likely to have a different cost structure from those that do. It is unfair to include the bids from these suppliers in the bid pool from which the pivotal bid is selected or a payment amount established. CMS should publish the criteria it will use to assess the supplier's financial stability and how it will rank the supplier based on the criteria. The information on rankings should be published in the interim final and final regulations as well as in the request for bids (RFB).

To assess a supplier's financial stability and capacity, CMS should require as a minimum *reviewed* financial statements. This will ensure that the financial statements have been examined by an outside accounting firm. CMS may also want to evaluate the supplier's cash flow. Cash flow can be measured by examining the balance sheet and confirmed by looking at banking statements from the last six months (or longer period). As a practical matter, including bank statements as a requirement may prove burdensome for suppliers and CMS. Consequently, CMS may want to limit its request for bank statement to those situations where it needs to resolve doubts about the supplier's other submissions. In any case, CMS would have to define the period for the bank statements it is requesting, *e.g.*, third and fourth quarters of the previous year, in order to ensure consistency in its analysis across suppliers.

To assess capacity to meet increased demand under competitive bidding, CMS should consider the supplier's debt-to-equity ratio (long term debt divided by shareholders equity). The debt-to-equity ratio provides a measure of the extent of the supplier's leverage which, in turn, is a measure of a company's capacity to borrow. This measure may have significant drawbacks when applied to private firms because it is difficult to place a value on equity, making the formula easy to manipulate. An alternative ratio is the EBITDA (earnings before interest taxes depreciation and amortization)-to-debt-ratio, because EBITDA may be more difficult to manipulate. To simplify the analysis, CMS could use the quick ratio (current assets minus inventory divided by current liabilities) which some AAHomecare members have indicated is favored by their lending institutions.

CMS representatives have stated that there was great variability in how suppliers booked their accounts receivables (A/R) when supplier financial criteria were assessed during the demonstrations. As a result, A/R was not a useful measure of supplier financial health (because it could not be used to compare suppliers). To address this issue, CMS should define A/R under the quick ratio as less than 180 days sales outstanding (DSO). DSO is a measure of how long it takes the company to collect money it is owed. The quick ratio provides a measure of the supplier's liquidity, *i.e.*, its ability to meet short term operating needs.

Additionally, the bidding supplier should identify for CMS all of its interest bearing debt which, in combination with the quick ratio, would give CMS a picture of the supplier's capacity to borrow. Finally, CMS should look at the Dunn & Bradstreet accounts payable ratings by the supplier's creditors. The D & B information provides an additional measure of whether the supplier is in fact able to meet its current obligations because creditors will report on the length of the supplier's accounts payable cycle.

Accreditation

CMS needs to identify the criteria it will use to select accrediting bodies *now*. CMS should be encouraging accreditation rather than discouraging it and should grandfather all providers accredited by organizations that meet the criteria CMS identifies. We recommend that CMS "fast track" accreditation in the manner that was suggested during

the PAOC meeting so that CMS can publish a notice soliciting public comments on the organizations that are seeking designation as an accrediting body. CMS' goal should be to promote an aggressive accreditation campaign to assure that providers in any MSA with a competitive bidding program are accredited *before* the bid solicitations are published. As we stated above, CMS should not commence competitive bidding in any MSA until all potential bidders have been accredited.

Market and Supplier Capacity

The NPRM states that CMS will evaluate market capacity and supplier capacity to determine the number of suppliers necessary to service beneficiaries in an MSA. We agree that CMS must carefully evaluate capacity issues to ensure adequate access to DMEPOS items in a competitive bidding area. Under the methodology proposed in the NPRM, CMS would array the composite bids from lowest to highest and count up from the bottom until it identifies the point where the bidders' cumulative capacity is sufficient to service the MSA. This will be the winning, or "pivotal" bid. This methodology does not include any mechanism to "rationalize" the bids to ensure that there are no unreasonably low bids. Although competitive bidding is premised on the theory that suppliers will submit their "best bid," in fact there will be suppliers with small individual capacity who may submit a very low bid speculating that they will end up in the winning bid range based on other bidders' capacity.

AAHomecare recommends that the bid solicitation and evaluation process include safeguards against this type of bidding strategy. At the very least, CMS should eliminate outlier bids to discourage suppliers who might submit unreasonably low bids. If these safeguards are not part of the process, CMS can have no assurance that the competitive bidding payment amounts are sustainable over time.

The NPRM also states that if at least two suppliers are at or below the pivotal bid amount, CMS would designate the two suppliers as winning bidders. We urge caution in adopting this minimalist approach. CMS should select more suppliers than necessary to meet minimum capacity requirements in the competitive bidding area. Any number of circumstances, such as a natural disaster, could create unanticipated access problems for beneficiaries in the MSA. It is unlikely that CMS could address these types of access problems quickly enough to avoid serious disruption to patient care. Additionally, CMS should at least consider other variables beyond capacity that may affect the selection of winning bidders. For example, beneficiary convenience and proximity to contract suppliers would greatly diminish under a scenario where CMS selects only two or three contract suppliers. We recommend that CMS use 130% of anticipated Medicare volume as the threshold for the number of suppliers needed in a competitive bidding area.

Supplier Evaluation

CMS must describe what criteria it will use to compare bidders (aside from the amount of their bid) and how CMS would apply the criteria. As we have stated before, this evaluation must take place before the composite bids are arrayed and the pivotal bid is selected. The supplier evaluation should include, at a minimum, three hurdles that a

bidder must clear, before its bid is included in the final array. First, is the company accredited? If not, the bid is rejected. Second, does the company meet the financial standards? If not, the bid is rejected. Third, is the claimed "capacity" realistic? If not, the capacity is lowered to an appropriate number. Only bids from bidders who clear these hurdles should be included in the final array.

Assurance of Savings

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstrations. CMS should look for savings in the overall product category even though a single payment amount for a specific item may be higher than its current fee schedule amount.

Determining the Single Payment Amount

CMS proposes to set the single payment amount for any competitively bid item at the median of the array of bids of the "winning suppliers." This means that almost 50% of the winning bidders will have to accept less than their bids to participate in the program, even if those bidders above the median will be providing most of the items and services in the competitive bidding area due to a higher level of capacity. This methodology is contrary to basic principles of contracting and competitive bidding and is also significantly different than the method used in the Polk County, Florida and San Antonio, Texas demonstration projects. More importantly, we believe Congress did not have this methodology in mind when it authorized competitive bidding under the MMA. CMS should set the payment amount at the pivotal bid level, which is defined as the highest bid for a product category that will include a sufficient number of suppliers to meet beneficiary demand for the items in that product category. This method was used in the two demonstration projects. No contract supplier should be forced to accept a payment amount that is lower than its bid.

Rebate Program

The NPRM describes a rebate program that would allow contract suppliers to give the beneficiary a rebate in an amount equal to the difference between their bid and the single payment amount. CMS proposes to make the rebate program voluntary and would not allow suppliers to advertise the rebate to beneficiaries. Instead, CMS would distribute program materials in the competitive bidding area that would identify contract suppliers that offer rebates. We have grave concerns about the program integrity ramifications surrounding this proposal and do not understand how CMS can reconcile a rebate program of this type with the statutory prohibition on beneficiary inducements under §1128A(a)(5) of the Act.

Specifically, §1128A(a)(5) prohibits the offering or transfer of remuneration when an individual or entity knows or should know that it is likely to influence the beneficiary's selection of a provider or supplier. Remuneration includes anything of value and would apply to the rebate proposed by CMS. While the statute contains exceptions to the

definition of the term "remuneration," the rebate program proposed in the NPRM does not fit any of the statutory exceptions. For example, "remuneration" does not include unadvertised waivers of coinsurance or deductible amounts for individuals who have been determined to be in financial need. The rebate offered by contract suppliers under the CMS program would not fit into this exception or any of the other exceptions under §1128A(a)(5). We are also unaware of any guidance from the Office of Inspector General (OIG) of the Department of Health and Human Services that would authorize the program CMS proposes. In light of the statutory prohibitions of §1128A(a)(5), CMS lacks the authority to implement a rebate program. Consequently, CMS should withdraw the proposal.

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

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

Bulletin at 1.

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

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

unlikely to approve of a rebate program like the one CMS proposes even if the supplier did not advertise the rebate:

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

Bulletin at 5 (Emphasis supplied).

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

Terms of Contract

Repair or Replacement of Equipment

CMS will require contract suppliers to accept a ll beneficiaries within the competitive bidding area. CMS will also require contract suppliers to repair or replace beneficiary owned equipment under the competitive bidding program. As we mentioned above, we recommend that CMS allow a new period of continuous use to begin when a beneficiary switches to a contract supplier. This preserves the beneficiary's choice and protects the contract supplier who may have to furnish equipment to the beneficiary without adequate compensation for the item or the service it requires. The repair of patient owned equipment should be treated as a separately bid item on the RFB. In other words, CMS should solicit bids for the repair of patient owned equipment. We assume that replacement equipment will be provided and paid for in an amount equal to the single payment amount.

Different Contract Terms

CMS states that the length of the contract may be different for different product categories. We strongly urge CMS to have the same length contract for all products in a competitive bid area to minimize confusion among beneficiaries, referring physicians and suppliers. As it is, there are numerous variables that these stakeholders will have to understand (which products are part of the competitive bid; the boundaries of the

competitive bid, etc.), and it will simply create confusion if there are different lengths of contracts for different product categories in the same MSA.

Termination of Contract

CMS must include procedural safeguards for contract suppliers prior to terminating their contract. Minimum requirements for the process are notice that CMS believes the supplier is in breach, an opportunity for the supplier to cure the breach, and a review or appeal mechanism if the supplier is terminated. The contract terms should also include a provision to allow a supplier to terminate the contract without breaching it.

Judicial and Administrative Remedies

CMS should include a procedure for debriefing suppliers who did not win a bid as well as an opportunity for a review to determine, at a minimum, whether an error on the part of CMS or its contractors was the reason the supplier lost the bid.

Change of Ownership

It is reasonable for CMS to review a change of ownership to determine whether the new entity meets the quality standards before granting the new company contract supplier status. However, CMS cannot unreasonably withhold its approval of a change of ownership and should not deny contract supplier status to the new entity on the basis that its capacity is not necessary within the competitive bidding area. CMS' proposal would improperly restrict an owner's right to transfer its property and greatly diminish the value of winning a bid. We are aware from the discussion at the last PAOC meeting of CMS' concerns that some suppliers will use acquisition as a strategy to gain contract supplier status. While this may have been successful in the demonstrations, it is unlikely that a supplier with business interests in an MSA would rely on an acquisition strategy outside a demonstration environment. In any event, the new entity would be forced to bid in any subsequent rounds of bidding to maintain its contract supplier status. We recommend that CMS approve changes of ownership if the new entity will meet applicable quality standards and conform to other requirements of competitive bidding. CMS' approval should not be withheld based on a determination that the new entity's capacity is not necessary.

Participation of Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS' proposal for allowing networks does not consider the practical hurdles involved in creating a new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also include meaningful small supplier set asides in the competitive bidding areas. We again request that CMS schedule a PAOC meeting as soon as it identifies the products and the MSAs so that stakeholders can provide additional comments on issues pertaining to small supplier participation.

New Gap-Filling Methodology

CMS proposes to implement a new gap-filling methodology that would rely on a technology assessment process to establish fee schedule amounts for new HCPCS codes and for new DMEPOS products. CMS has used gap-filling since 1989 to estimate what the average reasonable charges would be for a new item if the item had been paid for under Medicare during the fee schedule base period. Under the current gap-filling methodology, CMS "deflates" the current manufacturer suggested retail price (MSRP) for an item using the CPI-U to estimate its 1989 MSRP. CMS then trends that price forward using the legislatively mandated covered item update for the item through the current year. Because the gap-filling methodology assumes that the MSRP increases are consistent with increases in the CPI-U, and because the covered item update has been 0% or "frozen" numerous times by Congress since the fee schedules were created, gap-filling can result in Medicare payment amounts that are too high or unrealistically low.

According to the NPRM, CMS has engaged contractors to evaluate technologies for the purpose of making payment and HCPCS coding decisions for new items. CMS states that its purpose in engaging the contractors was to identify technologies that provide demonstrated clinical benefits and recognize those benefits over existing technologies. Although the NPRM does not identify what products CMS assessed, they were assessed in three main areas:

- Functional Assessment – to evaluate the device's operations, safety, and user documentation relative to the Medicare population. Health care providers were asked to determine how and under what circumstances they would prescribe the product for a Medicare beneficiary.
- Price Comparison Analysis – to evaluate the costs of the product compared to similar products on the market or alternative treatment modalities.
- Medical Benefit Assessment – to evaluate the effectiveness of the product. Scientific literature reviews and interviews with health care providers were conducted to determine if the product significantly improved clinical outcomes compared to other products and treatment modalities.

CMS is proposing to use these three types of assessments to help set fee schedule amounts when new HCPCS codes are created for a category of items. CMS would also use the technology assessment to determine whether new HCPCS codes need to be established for new products and to determine the payment amount for new items. CMS intends to use the technology assessment process any time after January 1, 2007, to adjust payment amounts that were previously established using the gap-filling methodology if it determines that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.

We are encouraged to know that CMS recognizes that the current gap-filling methodology can have arbitrary results. We also agree that CMS should depart from the practice of "deflating" current MSRP to arrive at a gap-filled amount and that CMS

should use the median current retail price for new items to establish the payment amount. We remain concerned, however, because the proposal for a technology assessment process is vague and lacks any opportunities for stakeholder participation. More importantly, CMS' only authority to adjust payment amounts for an item or a category of items is the IR authority under §1842(b)(8) and (9), and CMS is not authorized to depart from the authority.

Under the IR methodology established by Congress, CMS must make a determination that using the "standard rules for calculating payment" results in a payment amount that is not inherently reasonable. Congress explicitly directed the Secretary to identify the factors that it would use to determine when a payment amount is not "inherently reasonable" because it is either grossly excessive or grossly deficient. CMS must use "valid and reliable data" in making this determination and in establishing a new payment amount.[2] Importantly, IR includes specific procedural safeguards that apply to determinations to adjust a payment amount by more than 15%. For payment adjustments greater than 15%, CMS must consider (among other factors) the "potential impact of such a determination on quality, access, and beneficiary liability, including the likely effect on assignment rates and participation rates."

Under the proposal in the NPRM, CMS could avoid complying with the IR methodology simply by migrating existing products into new HCPCS codes. Congress specifically required notice and comment and the use of valid and reliable data under the methodology to protect beneficiaries and providers from poorly conceived payment reductions that affect access. CMS cannot use a technology assessment to make a payment adjustment based on a determination that a payment amount does not "reflect the cost of furnishing the item" because those factors cannot serve as the basis for a special payment adjustment under §1842b (8) and (9).[3]

We do not disagree that CMS should establish fee schedule amounts for new products using the median retail price for the item. However, to the extent that CMS intends to use a technology assessment to establish a payment amount or a new HCPCS code for new products, we cannot provide meaningful comments without additional information. At a minimum CMS must identify the factors it would consider in deciding to initiate a technology assessment and establish mechanisms to solicit participation from interested stakeholders. M ore im portantly, t his p roposal h as r amifications b eyond t he D MEPOS competitive bidding program and CMS may have limited stakeholder input by including

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[2] 42 C. F. R. §405.502 (g).

[3] We also note that we do not understand how the technology assessment CMS proposes can be used to arrive at a determination that the payment amount for an item does not reflect the cost of furnishing an item. The criteria proposed for the technology assessment focus on a cost benefit analysis of the technology relative other similar products. This analysis is different from an analysis of provider costs to furnish the product which would include not only the acquisition cost of the product, but also the cost of servicing the beneficiary, the cost of accreditation and other regulatory compliance, as well documentation, billing, and other similar costs.

it in this NPRM. Consequently, CMS should initiate a separate rulemaking proceeding to address this issue and allow broader stakeholder participation.

Changes in HCPCS Codes During A Bidding Cycle

We disagree with the proposals for paying new HCPCS categories that are established during a competitive bidding cycle. The rationale for establishing new codes during a competitive bidding cycle would be to create codes that are more representative of specific technologies. Thus it would be unfair to pay new codes for more expensive technology at the same payment amount applicable to older codes that included products spanning a broader spectrum of technology. CMS should re-bid these codes, assuming they are appropriate for bidding.

Impact Analysis

We believe that CMS has minimized the impact of competitive bidding on beneficiaries and small businesses. According to the CMS Regulatory Impact Analysis, about half of bidding suppliers will not be selected as contract suppliers, adversely affecting the majority of suppliers in this country. These non-contract suppliers will therefore not likely be able to sustain their businesses based upon the items not included in competitive bidding. We believe the proportion of adversely affected suppliers will be significantly greater for smaller suppliers, given the fact that price will be the key factor in determining which suppliers become contract suppliers. Competitive bidding will force about half of the current suppliers to go out of business.

CMS predicts that impact on beneficiaries who will be forced to switch suppliers will be minimal. We are not sure how CMS can arrive at the conclusion in light of its estimates that 50% of bidding suppliers will loose their bids. Moreover, CMS is allowing "grandfathering" for a very limited subset of products, again impacting those beneficiaries who will be unable to elect a "grandfathered" status.

CMS' Regulatory Impact Analysis is limited in terms of the scope of the real economic impact throughout the country. CMS has not considered the larger macroeconomic impacts of forcing half of the DMEPOS suppliers out of business; these impacts include lost jobs, lost personal and corporate taxes, and other direct losses to communities across the country that will result from a large number of small business entities being forced to close their doors.

Further, CMS' Regulatory Impact Analysis overstates the potential savings from implementing competitive bidding. CMS cannot assume that competitive bidding will achieve the same level of savings as were experienced in the demonstration projects in Polk County, Florida, and San Antonio, Texas. Congress has imposed a series of significant cuts on the major product categories. For example, the Medicare Modernization Act imposed significant cuts to oxygen (11-13%, hospital beds 20%, nebulizers 22%, etc.). Further, there have been CPI freezes imposed on the DMEPOS fee schedules, which are in reality a cut as labor, fuel and other costs have increased

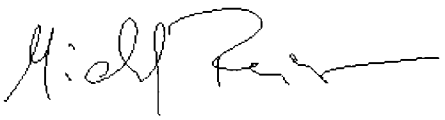
dramatically over the last few years. As a result of this series of significant cuts, we strongly recommend that CMS re-calculate the potential savings; and recommend that the Administration request Congress to request that the Congressional Budget Office revise its estimate of savings in light of these facts that will have a direct impact on the potential savings associated with implementing competitive bidding.

Finally, we believe that CMS has significantly under-estimated the administrative costs associated with developing and implementing the competitive bidding program. The administrative costs to review all bidders' information to ensure compliance with quality, financial and other standards, physical site visits to potential contract suppliers, bid review, calculation of pivotal bids and single payment amounts, and ongoing oversight in the competitive bidding areas will be enormously complex and resource intensive. CMS should re-examine its assumptions, and based upon comments received, recalculate the anticipated costs of administering this program. CMS should then provide that information to the Congress, along with its revised estimate of the potential for savings associated with the program. Looked at together, the administrative costs will not be able to be rationalized, given the meager potential savings that the program might yield.

Conclusion

For the reasons we stated above, AAHomecare requests that CMS adopt the recommendations we make in these comments. We appreciate the opportunity to submit these comments and remain available to discuss them with you in greater detail.

Sincerely,



Michael Reinemer
Vice President, Communications & Policy

Enclosure

Via E-Mail and Federal Express

April 20, 2006

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Implementation of the Deficit Reduction Act of 2005 to Medicare Reimbursement to Oxygen and Durable Medical Equipment**

Dear Mr. Kuhn:

As you are aware on February 8, 2006, the President signed into law the Deficit Reduction Act (DRA) of 2005, P. L. 109-171. Section 5101 of the DRA amends the provisions of the Social Security Act (SSA) that govern Medicare payment for home oxygen therapy and rental of certain items of durable medical equipment (DME). Beneficiaries who use home oxygen or rent DME now have a higher burden to manage their care and coordinate service and maintenance for their medical equipment. The DRA provisions also significantly impact the operations of suppliers who furnish oxygen and DME to beneficiaries. The American Association for Homecare (AAHomecare) is writing to request clarification on how the Centers for Medicare and Medicaid Services (CMS) intends to implement these new requirements, especially with respect to the specific questions we raise below. For your easy reference, we have also included the questions in an appendix attached to this letter.

By way of background, prior to February 8, 2006, Medicare reimbursed oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. The monthly rental payment for oxygen is a modality neutral bundled payment that covers ongoing service and maintenance for the equipment. In contrast, under §5101, Medicare will pay for the rental of oxygen equipment over a period of "continuous use" of 36 months, after which title to the equipment transfers to the beneficiary. Medicare will pay only for "oxygen" after 36 months. Further, after the statutory period of continuous use, Medicare will pay only for service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Prior to the DRA, Medicare paid for certain DME items under a "capped" rental payment methodology. This means that beneficiaries could elect to own or rent the medical equipment after a rental period of 10 months. If the beneficiary chose to continue the rental, Medicare payments for the equipment would "cap" after 15 months, and the supplier would receive a maintenance and service fee every six months. Otherwise, title to the equipment transferred to the beneficiary after 13 months.

Section 5101 eliminates the capped rental payment methodology. Instead, Medicare will rent most items of DME for 13 months of continuous use, after which title to the equipment will transfer to the beneficiary. Medicare will pay only for service and maintenance the Secretary determines to be reasonable and necessary after the 13 month rental period. This new "rent-to-purchase" payment methodology is effective for rental periods beginning on or after January 1, 2006.

I. Questions on the Application of the DRA Provisions

The DRA fundamentally revises the payment structure for oxygen and capped rental DME. As a result, existing billing, payment, and documentation rules for oxygen and DME are inadequate to address the changes imposed under the DRA. CMS will need to revise the current rules and establish new HCPCS codes to capture the services and products that are no longer bundled into the monthly fee schedule amount for oxygen and DME. AAHomecare's questions pertain to CMS' plans for making these changes and the timeline for their implementation.

A. Medical Necessity and Documentation

How will CMS apply "break-in-service" rules to oxygen and DME under the new payment provisions? For capped rental DME, Medicare rules allow for temporary interruptions in the period of "continuous use." An interruption of no more than 60 days plus the days remaining in the rental month in which the use ceases is a temporary interruption, regardless of the reason for the interruption. When there is a temporary interruption in continuous use, medical necessity for the rented equipment is presumed to continue.[4] If the interruption is not temporary, then a new rental period begins, subject to the requirements specified in the rule.[5]

We expect these rules to remain in effect for DME and request that you confirm whether that is correct. For example, if a beneficiary using a support surface is "healed" within the meaning of the medical policy, but "breaks down" again after 60 days, will a new period of continuous use begin?

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[4] 42 C. F. R. §414.230 (c) (3) (2006).

[5] The provider must submit a new prescription, new medical necessity documentation and a statement explaining the reason for the interruption and demonstrating that the medical necessity for the prior episode ended.

Importantly, §5101 (b) authorizes the Secretary to determine how he will define "continuous use" for oxygen and oxygen equipment. We believe CMS must issue regulations to define "continuous use" and what constitutes a "break in service" for beneficiaries on oxygen. Specifically, when will a break in service for an oxygen patient commence a new period of "continuous use"?

In the past, if a beneficiary experienced a change in condition that resulted in the need to change his or her oxygen equipment (such as a change from stationary oxygen only to both stationary and portable oxygen), the provider would simply switch the beneficiary's existing equipment to other equipment consistent with the doctor's prescription. For example, a beneficiary on liquid oxygen during the first 30 rental months requires a medically necessary change in equipment in the 31st rental month, and the physician orders a stationary concentrator or a portable concentrator for the beneficiary. In this example, will the beneficiary's change in condition start a new 36 month period of continuous use?

Moreover, after a beneficiary owns the equipment, will Medicare pay for new equipment on the basis of a change in condition? Medicare program rules for capped rental DME contemplate that a new period of continuous use begins when the beneficiary has a new prescription or requires additional equipment;[6] these rules were not intended to apply to oxygen because oxygen was reimbursed as a continuous rental under the original fee schedules. Consequently, CMS must issue new regulations to address these questions. What is CMS' projected timeline for a proposed rule?

If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, is the beneficiary responsible for paying for the new equipment (assuming there has been no change in condition)?

The DRA contemplates that Medicare will continue to pay for medically necessary oxygen after title to the equipment transfers to the beneficiary. How will the medical necessity documentation for oxygen change? Currently, the Medicare program requires a "lifetime" certificate of medical necessity (CMN). Will lifetime CMNs be valid for beneficiaries who own their own equipment?

B. Reimbursement Questions

Some beneficiaries have dual systems. That is, they have both a concentrator and a stationary liquid system or a stationary concentrator and a portable concentrator. Under Medicare's modality neutral payment methodology, providers only bill the Medicare program for one system. At the end of the period of continuous use, what equipment will these beneficiaries own? Will the beneficiary be responsible for purchasing one of the two systems?

We interpret §5101 (b) to require the transfer of title to oxygen equipment, including portable equipment, after 36 months of continuous use. As you are aware, portable

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[6] 42 C. F. R. §414.230 (f) (2006).

equipment may include an oxygen cylinder equipped with a flow meter and a cannula. The DRA requires Medicare to pay for medically necessary oxygen after title to oxygen equipment transfers to the beneficiary. How will CMS pay for refills on oxygen cylinders? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow? How will CMS address payment for patients who have both a concentrator and a liquid system where the liquid system is being used primarily for ambulatory portable requirements? Will Medicare pay for additional portable cylinders after the 36 months, or will the patient be responsible for purchasing these items? Will beneficiaries be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or items such as humidifiers?

May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the beneficiary's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for contents once these cylinders are used? Finally, will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

As you are aware, oxygen is a prescription drug, and oxygen equipment, including oxygen cylinders, is highly regulated by several Federal agencies including the United States Department of Transportation (DOT) and the United States Food and Drug Administration (FDA). An important safety concern for the FDA is the provider's ability to test oxygen cylinders and to verify their chain of custody. This will be very difficult to do for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). This also raises significant liability issues for patient-owned equipment, especially if the beneficiary changes supplier after he or she owns the equipment (e.g., the beneficiary moves out of the provider's service area). There may be instances where beneficiaries purchase cylinders second-hand from non-providers (eBay®, for example). As a consequence, there may be instances where providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing new oxygen cylinders under these circumstances?

The local coverage determination (LCD) for oxygen states that the beneficiary is responsible for coordinating travel oxygen needs. The beneficiary's existing oxygen provider may service the beneficiary's travel oxygen needs, but is not required to do so. For short-term travel, the beneficiary pays for the oxygen out-of-pocket, and the primary provider may reimburse all or a part of those costs.[7] We anticipate that this rule will not change. That is, the beneficiary will continue to be responsible for arranging and paying for short-term travel oxygen. Please confirm that our understanding is correct with respect to the 36-month period of continuous use. After title to the equipment transfers to the beneficiary, will Medicare pay the beneficiary directly for short-term travel oxygen?

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[7] See DMERC Region B Bulletin, Spring (1999).

Beneficiaries who spend the winter or summer months away from their primary residence may have more than one supplier. Similarly, beneficiaries who move out of a provider's service area will have more than one provider. How will CMS determine the period of continuous use in these scenarios? Will rental months at the second residence apply towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary? We foresee significant access issues for beneficiaries if providers are forced to transfer title to equipment that they have rented for only a few months. Beneficiaries who move or change providers "midstream" may have difficulty finding a new provider for the same reason.

The Medicare Claims Processing Manual states that Medicare will not make a separate payment for pick-up and delivery of oxygen equipment because these charges are included in the monthly fee schedule payment for oxygen.[8] After title to oxygen equipment transfers to the beneficiary, will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills? If not, what data does CMS propose to use to arrive at an appropriate payment amount? The Medicare Claims Processing Manual also states that pick up and delivery charges are included in the Medicare fee schedule payment amount for capped rental DME. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount?

Finally, does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent to purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

C. Service and Maintenance

Section 1834 (a) (7) of the SSA states that the reasonable useful lifetime for capped rental DME is five (5) years, unless the Secretary specifies otherwise.[9] This statutory provision does not apply to oxygen and oxygen equipment. How will CMS define the useful life of oxygen equipment? If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment? Importantly, does CMS have a timeline for issuing regulations that address these questions? Finally we anticipate that the useful life for capped rental DME will remain 5 years consistent with §1834 (a) (7). Please confirm that our understanding is correct.

Providers are required to perform extensive maintenance checks on liquid oxygen equipment furnished to beneficiaries. These checks include testing for purity of content, performing a visual inspection for dents, performing a pressure check and checking for appropriate labels. Until now, these checks have been reimbursed under the monthly fee

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[8] Chapter 20 §60, Medicare Claims Processing Manual, 100-4.
[9] 42 U. S. C. 1395 (m) (7).

schedule payment for oxygen and oxygen equipment. Similarly, oxygen cylinders must undergo hydrostatic testing. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

Section 5101 requires Medicare to pay for maintenance and service not covered under warranty. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient-owned equipment? When maintenance and service on oxygen equipment is reasonable and necessary, what documentation will providers be required to submit? Will CMS require different documentation depending on whether the provider repairs the equipment it furnished or repairs equipment furnished by another provider? Importantly, after title to equipment transfers to the beneficiary, what will be the impact on the beneficiary if the manufacturer is no longer in business and replacement parts are needed? If the original provider is no longer in business, who will provide service and maintenance on the equipment?

In order to facilitate payment for repairs, we recommend that CMS issue specific HCPCS codes to account for the need to have skilled technicians perform extensive maintenance with specialized tools. Will CMS issue temporary HCPCS codes for this purpose, or will providers have to apply for the codes?

Finally, how will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices, oxygen titrating devices, or technology that allows beneficiaries to fill their own cylinders? Will providers bill the beneficiary for these services?

D. Other Questions

Leased Equipment and Outstanding Patient Balances

The DRA provisions for oxygen and oxygen equipment impact provider's business operations in other ways. For example, leasing is a common means of financing medical equipment. It's likely that in many cases providers will need to reconcile lease terms with the statutory period of continuous use. Under this scenario, understanding the implementation date is very important for providers. Does CMS intend to apply these new payment rules as of January 1, 2006 even though their actual implementation is delayed for administrative reasons such as the need to issue carrier instructions and make system changes? In addition, we are concerned about any requirement to transfer title to oxygen equipment to a beneficiary with unpaid balances for co-pays and deductibles. Title to oxygen equipment should remain with the provider until the beneficiary has paid any outstanding deductible and co-payment amounts.

Clinical Assessments for Respiratory Patients

The change in reimbursement for oxygen and oxygen equipment also raises questions about the provider's obligation to furnish continuing care and monitoring. Although ongoing care, monitoring, and assessment of the beneficiary are not explicitly covered by Medicare, most private sector payers and national accrediting bodies expect providers of

oxygen to furnish these services. Moreover, providers are required in several states to perform respiratory assessments for patients who receive conserving devices. Other states require the oxygen provider to furnish the patient with a clinical visit shortly after the oxygen is set-up. For Medicare beneficiaries, providers have included these services within the monthly fee schedule payment for oxygen. Will payment for these services now become the beneficiary's responsibility? Will beneficiaries be required to pay for the services of respiratory therapists and other services that CMS considers non-covered?

Parenteral and Enteral Equipment

Finally, AAHomecare interprets the DRA to apply only to medical equipment in the capped rental Medicare payment category. As you know, parenteral and enteral (PEN) pumps are reimbursed under the prosthetic device benefit, and the payment rules that apply to them differ from the rules that apply to capped rental DME. Consequently, this new rent-to-purchase payment methodology does not apply to PEN pumps. Specifically, PEN pumps fall under the fee schedule category for "parenteral and enteral." PEN pumps can be purchased or rented whereas capped rental items can only be rented. Although rental payments for PEN pumps "cap" after 15 months, subsequent payment for service and maintenance on PEN pumps do not follow the capped rental billing rules. To avoid confusion among the carriers, we request that CMS confirm that PEN pumps are not subject to the DRA's new rent to purchase payment methodology.

Medicare Advantage Plans

As you know, beneficiaries may choose from a number of Medicare Advantage plans, some of which do not follow the payment and coverage policies of traditional Medicare. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

II. Conclusion

AAHomecare understands that these new payment methodologies do not take effect immediately. However, their impact on our member's operations is immediate because they must begin to structure their operations to respond to the changes. Moreover, providers must plan now for their implementation in order to ensure a smooth transition for Medicare beneficiaries. AAHomecare and its members are prepared to work closely with CMS to address these issues, and we would like an opportunity to meet with you and your staff to discuss these issues further. We will contact you next week to arrange for a mutually convenient time for us to meet.

Sincerely,

Thomas Ryan
Chairman

Michael Reinemer
Vice President, Communications & Policy

AMERICAN ASSOCIATION FOR HOMECARE

APPENDIX

Deficit Reduction Act of 2005 Provisions on Medicare Reimbursement for Oxygen and Durable Medical Equipment

Implementation Questions

I. Medical Necessity and Documentation

1. Will current regulations defining "continuous use" for capped rental DME remain unchanged?

2. How will CMS define "continuous use" for oxygen equipment? What will constitute a break in service so that a new period of continuous use commences for beneficiaries on oxygen?

3. When a beneficiary owns his or her oxygen equipment, will Medicare pay for new equipment on the basis of a change in condition? Does the change in equipment begin a new period of continuous use?

4. Will CMS issue regulations to address the issues raised in questions 1 and 2 above? If so, what is the projected timeline for a proposed rule?

5. If new technology becomes available that is medically appropriate and has the potential to improve health outcomes, will the beneficiary be responsible for paying for the new equipment (assuming there has been no change in condition)?

6. How will CMS define "oxygen" after the 36-month period of continuous use ends? How will the medical necessity documentation for oxygen change? Will lifetime CMNs be valid for beneficiaries who own their own equipment?

II. Reimbursement Questions

7. Will beneficiaries who have both a concentrator and stationary liquid or a concentrator and a portable concentrator be responsible for purchasing one of the two systems after 36 months?

8. How will CMS pay for refills on an oxygen cylinder? Will the payment amount differ between patients who require more refills because they have a greater need for mobility or a higher prescribed liter flow?

9. How will CMS take into consideration those patients who have a concentrator and a liquid system, where the liquid system is being primarily used for ambulatory/portable requirements? Will the Medicare program pay for additional portable cylinders after the 36-month rental period, or will it be the beneficiary's responsibility to purchase these items?

10. Will the beneficiary be responsible for purchasing supplies such as cannulas and tubing for their oxygen equipment or other items such as humidifiers?

11. May providers charge beneficiaries a rental or purchase for a back-up emergency cylinder that is not used to meet the patient's portable oxygen needs? These units would be used solely in the event of an emergency such as a power outage, a natural disaster, or a malfunction of the beneficiary's primary equipment. Will Medicare pay for the contents once these cylinders are used?

12. Will the payment amount differ based on different oxygen technologies that may be more or less costly for the provider to furnish?

13. Providers may be unable to service a patient-owned portable oxygen cylinder that they did not furnish. Will the beneficiary be responsible for purchasing a new oxygen cylinder under these circumstances?

14. Will rental months at a beneficiary's second residence apply towards the 36 months of continuous use? If so, which provider is responsible for transferring title to the beneficiary (i.e., the primary provider, or the provider at the second residence)? Similarly, if a beneficiary moves during the period of continuous use, which provider is responsible for transferring title (the new provider or the original provider)?

15. For short-term travel, the beneficiary pays for the oxygen out-of-pocket and the primary provider may reimburse all or a part of those costs. AAHomecare anticipates that this rule will not change for beneficiaries who own their oxygen equipment. That is, the beneficiary will continue to be responsible for arranging and paying for travel oxygen. With respect to the period of continuous use, please confirm that our understanding is correct. After title to the equipment transfers, will Medicare pay the beneficiary directly for short-term travel oxygen?

16. Will the beneficiary be responsible to pay charges for pick up and delivery of oxygen refills after title to oxygen equipment transfers to the beneficiary? If not, what data does CMS propose to use to arrive at an appropriate payment amount for pick up and delivery charges?

17. For beneficiary-owned equipment that requires servicing, will Medicare pay pick up and delivery charges? If so, what data will CMS use to arrive at an appropriate payment amount for pick up and delivery charges?

18. Does CMS intend to apply any of the billing rules that applied to capped rental equipment to rent-to-purchase DME? A purchase option letter is unnecessary inasmuch as the beneficiary no longer has the "option" to purchase the equipment. Consequently, we see no need to use the BP, BR, or BU modifiers in the 11th, 12th, and 13th rental months.

III. Service and Maintenance

19. How will CMS define the useful of life of oxygen equipment?

20. If oxygen equipment is "irreparably damaged" after title has transferred to the beneficiary, but before the end of the equipment's "useful life," will Medicare pay for new equipment? If so, will this commence a new period of "continuous use," or will CMS pay a lump sum amount for the new equipment?

21. Does CMS have a timeline for issuing regulations that address questions 17 and 18 above?

22. Oxygen cylinders must undergo hydrostatic testing and other checks periodically. Though technically these tests are not "repairs," will they be reimbursed as repairs to account for the more extensive service they involve?

23. Will the Medicare program pay for emergency service calls for beneficiary-owned equipment that is still under warranty? If not, can providers contract with beneficiaries to provide on-call services for patient owned equipment?

24. If the manufacturer of equipment that is under warranty is no longer in business, will the beneficiary be responsible for paying for replacement parts? If the provider who furnished the equipment to the beneficiary is no longer in business, who is responsible for the repairs?

25. How will providers document that the maintenance and service they performed on oxygen equipment were reasonable and necessary? Will CMS require different documentation depending on whether the provider

repairs the equipment it furnished or equipment furnished by another provider?

26. Will CMS issue temporary HCPCS codes to identify the service, maintenance and repairs for oxygen equipment, or will providers have to apply for the codes?

27. How will providers be reimbursed for service or maintenance to non-covered oxygen equipment such as conserving devices or oxygen titrating devices? Will providers bill the beneficiary for these services?

28. Will CMS issue temporary HCPCS codes to identify service and maintenance repairs and parts for equipment in the capped rental category, such as motor and hand controls for a bed, or will providers have to apply for the codes?

IV. Other Questions

29. Will the requirements of the DRA apply retroactively to January 1, 2006, regardless of whether the need for systems changes result in administrative delays in implementation?

30. Will CMS require providers to transfer title to beneficiaries who have unpaid deductible and coinsurance balances?

31. After title to the oxygen equipment transfers to the beneficiary, will beneficiaries be responsible for paying for clinical assessments required under state law? Will the beneficiary be responsible for paying for respiratory assessment ordered by the physician?

32. Please confirm that parenteral and enteral pumps are not subject to the rent-to-purchase methodology established under the DRA.

33. How will providers be reimbursed if beneficiaries begin to use oxygen or capped rental equipment under a Medicare Advantage plan? Will CMS begin a new period of continuous use each time the beneficiary has a payer change in or out of traditional Medicare?

Submitter : **Dr. Lawrence Harkless** **Date: 06/30/2006**

Organization : **University of Texas Health Science Center, SA**

Category : **Physician**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am a podiatric physician and surgeon and presently the Division Chief of Podiatry in the Department of Orthopaedics at the University of Texas Health Science Center at San Antonio (UTHSCSA). University Hospital is the primary teaching hospital of the UTHSCSA. The Podiatry Division sees over 12,000 outpatients with over 300 admissions annually. At least 60% of the patient visits are related to diabetes and all of the admissions are diabetes related.

My primary clinical interest has been in the evaluation and management of diabetic foot problems and lower extremity amputation prevention. Patients with problem diabetic wounds have benefited immensely from VAC therapy from KCi, San Antonio, TX as often times these wounds are very complex. We were one of the first centers to become involved with the VAC and I have had the opportunity to have tremendous experience. I have watched wounds that would have failed in the past to granulate and thus heal with appropriate skin grafting techniques where previously they would have ended up in an amputation. Clearly, we are preventing more below-the-amputations and salvaging the feet at a more distal level with this adjunctive technology that has played a significant role in wound healing.

I am writing in concern that competitive bidding will not be appropriate for this particular modality as there are no studies to support the efficacy of the competition in this regard. This will have a deleterious effect on patient care as it will be removing choices of known therapy; increase the amputation rate, increase length of stay, and ultimately increasing cost. I urge you that the VAC should not be included in the competitive bidding which you are contemplating. I believe patient wound care will suffer and the likelihood for the amputation rate to increase will significantly rise.

I hope this information will be of assistance to you in making the correct decision for continued improved patient care.

If I can provide additional information, please advise.

Sincerely,

Lawrence B. Harkless, D.P.M.
Professor, Department of Orthopaedics
and Louis T. Bogy Professor of
Podiatric Medicine and Surgery

LBH:mg

Submitter : **Mr. Bryan Schneider** **Date: 06/30/2006**

Organization : **Walgreens Health Services**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1035-Attach-1.DOC

#1035

Government and Community Relations Department

June 30, 2006

VIA ELECTIONIC SUBMISSION

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
P.O. Box 8013
Baltimore, MD 21244-1850

Dear Sir or Madam:

Walgreen Co. together with its home care and mail service division, Walgreens Health Services (collectively, "Walgreens"), are writing to comment on the proposed rule concerning the competitive acquisition program ("CAP") for certain durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). Through its more than 5,000 home care, mail service and retail pharmacy locations, Walgreens is a leading supplier of DMEPOS to Medicare beneficiaries.

Walgreens is a member of the National Association of Chain Drug Stores and the American Association for Homecare and we join their detailed comments concerning these standards. We write separately to highlight certain issues.

Elimination of Unnecessary Administrative Burdens to Make Part B Program More Comparable to the Commercial Marketplace

Walgreens supports the efforts of CMS to harness marketplace forces through the CAP in order to provide Part B beneficiaries with quality items in an efficient manner and at a reasonable cost. We note initially, however, that the Medicare Part B program imposes considerably more administrative burdens on suppliers than most payers in the commercial marketplace. These burdens, in turn, add costs which will, in the end, be passed through to the Part B program in terms of higher bids under the CAP. Because we believe that certain of these administrative burdens do not add any corresponding value to the Part B benefit in terms of enhanced patient care or elimination of fraud, waste or abuse, we urge their elimination.

Eliminate Requirement for a Separate Written Order Following Receipt of a Telephonic Prescription at a Licensed Pharmacy

Licensed pharmacies are permitted to dispense products on the basis of either (a) a prescription handwritten by the prescriber or (b) a telephonic prescription from the prescriber, which is reduced to writing by pharmacy staff. After a telephonic prescription is reduced to writing, it functions, and is maintained in the same manner, as a prescription handwritten by a prescriber. Licensed pharmacies are responsible to the state pharmacy boards that license them for the adequacy of their controls concerning telephonic orders. Both Part B regulations and state pharmacy laws allow community pharmacies to dispense Part B items to patients on the basis of an oral (telephonic) order. Requiring licensed pharmacies to obtain written orders to be able to bill for Part B items when they already have obtained valid telephonic orders is superfluous and adds unnecessary costs. CMS can be assured of the integrity of oral, telephonic orders as the dispensing pharmacy risks the loss of its pharmacy license if such orders are falsified or improperly maintained. All third-party payers, including the various Medicaid programs and Medicare Part D plans, allow pharmacies to dispense **AND** bill for claims on the basis of oral, telephonic orders that comply with applicable state pharmacy laws.

Thus, in sum, in order to achieve closer parity with the commercial marketplace, which is the goal of the CAP, CMS should allow claims for pharmacy-dispensed items to be dispensed and billed on the basis of an order (either handwritten by the prescriber or telephonic) valid in the state in which the dispensing pharmacy is operating.

Eliminate Assignment of Benefits ("AOB") Form

We are not aware of any commercial, Medicaid or Medicare Part D program that requires AOB forms for claims submitted on behalf of their beneficiaries. Indeed, virtually all claims in those programs are submitted on an assigned basis. As a result, in those situations assignment is implied by the very fact that the patient asks the supplier to submit a claim and the patient and supplier are able to identify those few claims that must be handled on unassigned basis. In the past, CMS has taken steps to reduce the number of claims subject to the AOB requirement in the Part B program, but it has done so in a patchwork manner that hinders efficient implementation by suppliers. If CMS desires to move the Part B program toward closer parity with the commercial marketplace, it is imperative that CMS promptly eliminate the AOB requirement for all claims.

Quality Standards and Accreditation of Suppliers for DMEPOS

Walgreens supports the efforts of CMS to ensure that all Part B beneficiaries receive care from high quality suppliers. Although many DMEPOS suppliers lawfully operate without considerable oversight by state regulatory agencies, pharmacies (both retail and mail service) are subject to a multitude of state regulations that are designed to

protect patients. The scope of such regulations is set forth in the comments of the National Association of Chain Drug Stores concerning this proposed rule and we adopt and support those comments. Requiring licensed pharmacies to obtain separate accreditation would only add costs to the Part B program, which is inconsistent with a successful CAP. Accordingly, we urge CMS to (a) require that all suppliers – including licensed pharmacies – comply with the DMEPOS quality standards for the items that they supply but (b) exempt licensed pharmacies from the separate accreditation requirement.

Alternatively, in the event that CMS concludes that licensed pharmacies cannot be exempted from the accreditation requirement, we urge CMS specifically to provide that approved accreditation organizations may develop accreditation programs and standards that are implemented at an enterprise level. Many DMEPOS supplies are provided by suppliers that are part of national and regional chains, both large and small. Such chains typically create a set of operating procedures which are deployed throughout all of their individual locations. By so doing, such chains are able to ensure the efficient delivery of a consistent standard of care in a variety of locations and through a variety of delivery channels.

An accreditation organization would be able to ensure that each individual chain location is meeting applicable quality standards by (1) confirming that the chain entity has adopted policies and procedures adequate to satisfy the quality standards, (2) evaluating the chain entity's internal control procedures to ensure that such standards are consistently followed at all locations and (3) periodic surveys of selected chain entity locations to ensure compliance with the applicable policies and procedures. Such a process would ensure that pharmacy suppliers are accredited by an approved organization, reduce costs by eliminating redundant accreditation processes and help reduce the inevitable accreditation backlog that will occur as thousands of presently unaccredited supplier seek to become accredited.

Payment Basis (proposed § 414.408)

Authority to Adjust Payment in Other Areas (proposed § 414.408(e))

We believe that the CAP is a unique program and that its results cannot be replicated, nor reliably implemented, outside of the competitive bidding process. For example, CAP bidders may be willing to accept a lower reimbursement amount solely in return for the possibility of greater volume as a result of a smaller set of eligible suppliers in the competitive bidding area. Accordingly, we strongly oppose the use of payment information determined under the competitive bidding program in areas not subject to competitive bidding.

Competitive Bidding Areas

Nationwide or Regional Mail Order Competitive Bidding Program (proposed § 414.410(d)(2)

Walgreens strongly opposes the creation of any program that *requires* diabetic patients to use mail service suppliers to obtain their glucose testing monitors and strips. Moreover, Walgreens urges CMS specifically to ensure that all suppliers in a mail order competitive bidding program are in compliance with Administration Quality Standard # 4, which requires that "mail services are not used for the initial delivery, set-up, and beneficiary education /training" for DME equipment and supplies.[1]

Although diabetic patients receive certain training in the care and monitoring of their condition from their treating physician, they cannot receive particularized training in the use of a diabetic testing system until they select a system to use. Such training can effectively be delivered only in a face-to-face setting where the patient can see the system demonstrated by a trained professional and ask questions concerning its proper use. To ensure that such training is provided to all Part B patients, even those electing to use mail service suppliers, CMS must require that such suppliers be able to provide initial delivery and training through face-to-face patient meetings at their own facilities, through affiliated locations or with subcontractor relationships.

Criteria for Item Selection

Walgreens believes that certain supply product categories are especially unsuited for competitive bidding. For example, the significant adverse clinical consequences, and attendant costs, flowing from improper or inadequate training in the use of diabetic testing systems and the inability to access needed testing supplies in a timely fashion, strongly counsel against inclusion of such items in the CAP. We join the National Association of Chain Drug Stores in its comments urging the exclusion of diabetic testing supplies from the CAP.

Alternatively, in order to balance the needs of CMS to operate a robust CAP across many product categories with the concerns that the competitive bidding process has not been adequately tested for certain supply items, we recommend that CMS limit the inclusion of individual supply product categories to no more than one-third of all competitive bidding areas in 2007 and no more than one-half of all competitive bidding areas in 2009. Such a phased-in approach would (a) limit any adverse results, (b) allow CMS to study the effects of competitive bidding for particular supply items in a measured fashion and, (c) allow CMS to compare the results of competitive bidding – both in terms of clinical outcomes and cost savings – with the experiences of patients and suppliers in

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[1] Because the quality standards apply to all competitive bidders, and to ensure that all diabetic patients receive proper training in the use of their testing systems, we also urge CMS specifically to require that successful bidders provide initial face-to-face dispensings during the 2007 and 2009 implementation phases.

other selected competitive bidding areas where the particular supply item was not included in the CAP.[2]

Conditions for Awarding Contracts (proposed § 414.414)

Market Demand and Supplier Capacity (proposed § 414.414(e))

In addition to the factors described in the proposed rule, Walgreens believes that bidders should also be able to support their expected capacity in the Part B competitive bidding area by submitting data that demonstrates its previous capacity to serve patients in other programs – commercial, Medicaid and Medicare Part D – operating within the competitive bidding area.

Determining the Single Payment Amounts for Individual Items (proposed § 414.416)

Improve Methodology for Determining Single Payment Amounts

Walgreens recognizes the competing pressures confronting CMS in establishing the single payment amount under the CAP. We are concerned, however, that the proposed methodology may encourage bidders to submit unsubstantiated and unrealistically low bids simply to ensure being selected as a contract supplier. Assume, for example, under the proposed rule, the following array:

Bidder	Weighted Bid[3]		Supplier Capacity	Cumulative Capacity
A	120		62	179
B	115		15	117
C	110	Pivotal Bid ⇨	40	102
D	108		42	62
E	107		13	20
Single Payment Amount (median of successful bids) = 106				
F	105		5	7
G	62		1	2
H	57		1	1

[2] Because competitive bidding areas will share many demographic and market characteristics, a comparison between patients in different competitive bidding areas will be generally unbiased.

[3] For purposes of this example, assume a product category containing one item so that the weighted bid is equal to the bid for an individual item.

In this situation, it is highly likely that bidders G & H submitted bids that are not based on realistic assessments of the true costs of providing services to Medicare beneficiaries simply to ensure that their bids fall below the pivotal amount. However, under the proposed methodology, their bids are weighted equally with all other bidders at or below the pivotal bid for the purpose of setting the single payment amount. We suggest that CMS consider a methodology for determining a single payment amount that takes into account the possibility of such manipulative bid practices.

We believe that CMS should consider only those bids that tend toward the midpoint of the successful bidders. For example, CMS could choose to calculate the single payment amount only from among those bids that lie within one standard deviation of the mean of the bids at or below the pivotal bid. Continuing with the sample data above, the mean successful bid is 91.5, with a standard deviation of 24.8.[4] Using this proposed methodology, CMS would consider only those bids at or below the pivotal bid in the range of 116.3 (91.5 + 24.8) to 66.7 (91.5 – 24.8). Thus, only bids C, D, E, and F would be used in calculating the single payment amount. Using the weighted average of these bids results in a single payment amount of 108.52 ((110 x .40) + (108 x .42) + (107 x .13) + (105 x .05)).

This approach would give effect to both of CMS's stated principles in setting the single payment amount -- (1) bidding amounts from all winning bids be used to set the single payment amount[5] and (2) single payment amounts cannot be higher than current fee schedule amounts – while at the same time ensuring that the single payment amount is not excessively influenced by outlier bids.

Alternatively, CMS could set the single payment amount at the average bid price of those bidders at or below the pivotal bid, with each bid weighted according to the bidder's capacity to serve beneficiaries within the competitive bidding area.[6] Thus, continuing with the example above, the single payment amount would be calculated as follows:

C	110	x	.39	=	42.90
D	108	x	.41	=	44.28
E	107	x	.13	=	13.91
F	105	x	.05	=	5.25

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4 The arithmetic mean is calculated (110 + 108 + 107 + 106 + 62 + 57) ÷ 6 = 91.5. The standard deviation is the square root of the average squared deviation from the mean.

5 By including all bidders at or below the pivotal bid in the calculation of the standard deviation, we believe that this methodology satisfies the statutory requirement that payment for competitively bid items be "based on bids submitted and accepted." 42 U.S.C. § 1395w-3(b)(5)(A). We do not believe that this statutory language must or should be interpreted to require CMS to include outlier bids in the final calculation of the single payment amount.

6 In calculating the weighting factors, each bidder's capacity is adjusted to reflect its portion of the total capacity served by bidders at or below the pivotal bid. Hence, bidder C is weighted at .40 ÷ 1.02=.39.

G	62	x	.01	=	0.62
H	57	x	.01	=	0.57
	Weighted Average			=	107.53

While this approach also would give effect to both of CMS's stated principles in setting the single payment amount, it, unlike the standard-deviation methodology described above, continues to give effect to bids that are significant outliers and, therefore, allows bids that bear indicia of not having been submitted in good faith to influence the single payment amount. Thus, while this approach mitigates some of the effects of outlier bids inherent in CMS's proposed rule, and thus should be preferred to that proposal, we believe that the final calculation of the single payment amount should be based only on non-outlying bids. As a result, we urge CMS to adopt a methodology that excludes outlier bids from the final calculation of the single payment amount.

Prevent Mail Order Rebate and Discount Disparities

CMS has stated that mail order suppliers may submit bids for the 2007 and 2009 implementation phases. However, by including mail order and non-mail order suppliers in the same array for calculating a pivotal bid and single payment amount, CMS may be conferring a distinct advantage on mail order suppliers, which often receive rebates, discounts and other price concessions not available to other suppliers. To eliminate this disparity, we recommend, for those product categories notably served by mail order suppliers, that CMS create separate, but coterminous, competitive bidding areas: one to be served by mail order suppliers and another to be served by non-mail suppliers. Each of these competitive bidding areas would be subject to its own bid process, including the determination of a single payment amount.[7] By so doing, CMS would ensure a fair playing field for both types of suppliers and would also allow patients the opportunity to select the type of supplier that best suits their needs. Moreover, by comparing overall savings between the two groups of suppliers – taking into account reduced hospitalization and other medical costs through proper testing compliance – CMS will be in a better position to determine the feasibility of nationwide or regional mail order networks for 2010 and beyond.

Rebate Program (proposed § 414.416(c))

We support the inclusion of this provision in the CAP as an innovative means to control patients' out-of-pocket expenses and to reward bidders that submit good faith, competitive bids.[8] We suggest the following specific modifications to this program:

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[7] Section 414.410(d)(2) – establishment of nationwide or regional mail order competitive bidding areas – contemplates this same arrangement, *i.e.*, overlapping, but distinct, competitive bidding areas. Because mail order will not be mandatory in nationwide or regional bidding areas, *i.e.*, patients will not be required to use a mail order supplier, the mail service competitive bidding area (whether national or regional) must exist together with, and overlap, other competitive bidding areas that include non-mail suppliers for the same items. We urge an identical process for the 2007 and 2009 implementation phases.

[8] We respectfully disagree with, and do not adopt, the comments of the American Association for Homecare to the extent that they urge CMS to eliminate the proposed rebate program.

1. The maximum rebate allowable should not exceed patients' applicable co-payment amounts for particular items dispensed, irrespective of their satisfaction or non-satisfaction of the annual Part B deductible.

2. We support CMS's proposal that rebates may not be implemented on a case-by-case basis. However, we believe that contracted suppliers should be given flexibility to determine when such rebates are offered during the contract period. For example, a bidder eligible to provide patient rebates may need to evaluate actual market conditions after competitive bidding has taken effect to determine whether such conditions are consistent with offering rebates. Similarly, market conditions in a competitive bidding area may change over time and cause a bidder that previously offered rebates to reevaluate that decision. Hence, we recommend that suppliers not be required to commit at the time of contracting to offer or not to offer rebates. Instead, we suggest that suppliers eligible to offer rebates be required to give CMS reasonable advance notice of any decision to offer or discontinue patient rebates under this provision.

3. To encourage good faith bidding, we suggest, consistent with our recommendations concerning the calculation of the single payment amount, that only successful bidders whose bids tend toward the midpoint of all successful bidders be allowed to offer rebates. Thus, only bidders whose bid for a particular item is within one standard deviation of the mean successful bid would be entitled to offer rebates.

4. We recommend that suppliers offering rebates under this provision be allowed to engage in direct advertising of the rebates. CMS should adopt appropriate policies to ensure that such direct advertising is confined only to items subject to competitive bidding.

Terms of Contract (proposed § 414.422)

Qualifications of Subcontractors

In order to prevent abuse of the bidding process, we recommend that competitive bidding contracts limit the participation of subcontractors only to entities that satisfy applicable quality and accreditation standards.

Disclosure of Ownership Information

Some competitive bidders are likely to be large nationwide or regional entities that are publicly traded companies. Accordingly, for such bidders we encourage that CMS limit information concerning ownership to those owners required to be disclosed in regular filings with the Securities Exchange Commission.

Change of Ownership

We share CMS's concern that changes of ownership could be used to circumvent the competitive bidding process. However, we believe that relatively flexible rules concerning changes in ownership are likely to increase participation in the competitive bidding process. Consequently, we encourage CMS to revise its proposed rule to provide that successor entities which meet all of the requirements to become a contract supplier are presumptively entitled to function as a contract supplier following a merger with or acquisition of a contract supplier. CMS should retain the authority to disallow a successor entity from becoming a contract supplier if it determines that allowing the successor entity to participate as a contract supplier would have significant anti-competitive effects.

In addition, we are concerned that the 60-day prior notice provision may be inconsistent with standard commercial practices involving mergers and acquisitions. We recommend a notice period of no more than 30 days. In addition, because of the confidential nature of merger and acquisition discussions and negotiations, we request clarification that any such notices to CMS will remain confidential until the successor entity notifies CMS that the transaction has been completed.

Physician Authorization/Treating Practitioner (proposed § 414.420)

Walgreens recognizes that some patients' physicians may determine that a particular brand or mode of delivery of an item within a particular HCPCS code is required in order to achieve optimal clinical results. However, it is very likely that successful bidders will not offer all product brands within a HCPCS code. In the event that a physician requests a specific item, brand or mode of delivery, and no contract supplier offers such product, a contract supplier may be forced to dispense an item the cost of which was not included in its bid nor taken into account in its decision to participate in the CAP. This uncertainty is likely to cause bids under the CAP to rise. In order to avoid such a result, we urge CMS to exercise its discretion under 42 U.S.C. § 1395w-3(a)(5) not to permit such brand-specific prescribing within competitive bidding areas.

Alternatively, we suggest that CMS consider making a finding that under such circumstances the CAP is not likely to result in significant savings and, accordingly, exempt such items from the CAP under 42 U.S.C. § 1395w-3(a)(3)(B). As a result of this exemption, such items would be reimbursed at the then current fee schedule amount. In order to prevent abuse, we recommend that such an exception apply only if all of the following criteria are satisfied: (1) the supplier has not offered the specific item, brand or mode of delivery to any Part B patient in the competitive biding area during the CAP, (2) no other contracted supplier within the competitive bidding area offers the item, brand or

mode of delivery, and (3) the patient's physician, after consultation with the supplier, refuses to revise his or her order.

We appreciate the opportunity to comment on this proposed rule. We request that the rule be modified as discussed above so that Part B patients are assured of obtaining high quality care in a cost-effective manner.

Very truly yours,

Bryan A. Schneider
Director, Governmental Affairs
Walgreens Health Services
(847) 964-6747
Bryan.Schneider@walgreens.com

Submitter : **Ms. Fran Kahn** **Date: 06/30/2006**

Organization : **Hand Therapy Specialists, Inc.**

Category : **Occupational Therapist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1036-Attach-1.TXT

#1036

docdispatchserv[2].txt

June 26, 2006 Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P

P.O. Box 8013 Baltimore, MD 21244-8013 Re: Proposed Rule for Competitive Acquisition of Certain DMEPOS CMS-1270-P

Position: Request that Medicare revise the proposed regulation to establish a process that will enable therapists to continue to

supply upper extremity orthoses to beneficiaries in their care without additional constraints. Thank you for the opportunity to

comment on a regulation that will significantly affect my quality of service to Medicare beneficiaries. My name is Fran Berger Kahn,

OTR/L, CHT, and I am an occupational therapist specializing in the treatment of upper extremity disorders. I am also a certified hand

therapist, having passed a certification exam that requires at least 4000 hours of upper extremity patient treatment and over 5 years

experience in the treatment of these patients prior to sitting for the exam. I have specialized in the treatment of hands and upper

extremities for 20 years. I currently own and operate Hand Therapy Specialists, Inc., with three locations in Virginia and one in

Florida. We frequently treat Medicare and Medicaid beneficiaries that require custom and/or off the shelf orthoses. Therapists are

unique from other suppliers of DMEPOS. We work as both a provider and a supplier, and it is difficult to divide the two aspects of our

profession. As a hand therapist, while orthoses are a critical component in the treatment of my patients, they are just one part of

their overall management. When supplying an orthoses, we also look at the disease process, functional and ADL needs,

ergonomics, precautions, future orthotic needs, etc. The provision of an orthosis is usually performed as part of a complete

treatment plan, and I feel that the proposed competitive bidding system will pose a serious threat to my ability to effectively treat

these patients. Hand therapists typically treat very acute patients, and the need to be able to immediately dispense and adjust an

orthosis is crucial to the final outcome of these patients. In the course of treatment of these patients, we will often see changes in

stability, edema, inflammation, and wound healing that require immediate attention. This regulation, as stated, could significantly

interfere with my ability to react to these changes, putting repairs and patients at risk. In addition, I feel that this

system has the

potential to place me in an untenable legal and ethical position. If a patient appears in my clinic with an inappropriate orthoses,

supplied by another entity, am I to adjust this orthosis, assuming some of the liability for a device that I did not supply or charge for?

Or should I let them leave my office and drive to another facility, with its possible delay, knowing that they are inadequately fitted

and/or unprotected? This very possible scenario has both legal and ethical considerations. A patient's needs are thoroughly

evaluated by a therapist to determine the appropriate orthosis for beneficiary use. In many cases, a specific brand may be the only

one that will appropriately meet the needs of a patient. Should this rule be enforced as written, suppliers will not be required to bid on

all brands of a certain orthosis. As a result, there is no guarantee that a beneficiary will be able to find a specific orthosis in their

area, potentially limiting their access to an important orthosis. As a hand therapist, I routinely stock those off the shelf orthoses that

I know the beneficiary and the referring physician will require. Finally, I would like to comment on the very small margin of profit I

receive from these prefabricated orthoses. In fact, CMS, in their report on the demonstration projects, supports my contention that

the savings to Medicare from upper extremity orthoses would be minimal. With many upper extremity OTS orthoses, there is no

profit at all. This would severely affect my ability to bid for a contract to supply these orthoses. There are many DMEPOS items

that do provide significant profit, allowing large and multiple item suppliers to possibly marginally discount their upper extremity

orthoses. However, when a supplier is limited to upper extremity orthoses only, such as the case with hand therapists, they would

be unable to provide a sufficient discount to win a bid. You would be loosing an important component in the treatment of the upper

extremity beneficiary; the therapist input and expertise in the supply of an OTS orthosis. In conclusion, I request that Medicare

revise the proposed regulation to allow therapists to continue to supply critical OTS orthoses unimpeded by a competitive bidding

process. Thank you again for the opportunity to comment on this proposed regulation. Sincerely, Fran Berger Kahn, OTR/L, CHT

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HP Sample Letter Chelli Johnson□Mark

Submitter : **Randall Myers** **Date: 06/30/2006**

Organization : **Harry's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I strongly object to this proposal that would require beneficiaries to get their supplies for designated providers. This would restrict the choice of the patient especially in rural and underserved areas such as the one our pharmacy is located. We are the only provider of basic DME supplies in our community.

Criteria for Item Selection

Criteria for Item Selection

I do not feel the bidding process should include basic supplies such as diabetes testing supplies and basic DME items. We provide as part of our pharmacy service to our diabetes pateints all of their supplies and this bidding process will prevent us from caring for the "whole" patient.

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

I urge CMS to take steps to ensure that small suppliers, like my pharmacy, be able to participate in the competitive bidding program. We need to be able to provide supplies to our patients in our rural market.
We provide diabetes supplies and small DME items to our patients at this time. CMS must take steps to preserve the beneficiaries' convenient access to DMEPOS supplies and maintain our established provider/patient relationships. If a patient has to travel (if they can drive) to obtain supplies they may not be as healthy as possilbe and may cost the system more over time.

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

I feel that accreditation is a valuable process for LARGE organizations. The process of accreditation for a small DMEPOS provider such as my pharmacy would be an extreme burden in time and money. I have thoroughly studied the process and it would cost our pharmacy approximately $3500 in fees and $4000 in additional labor to get accredited. This may not be a large expense for a large business but it would be extremely difficult for our pharmacy to absorb. The type of DME supplies we provide are basic diabetes testing supplies and small DME items such as canes, walkers & wheelchairs. We also provide transplant medications for three patients and inhaled medications for twelve patients through CMS. The profit on the items we provide would not begin to cover these additional costs of operation. I feel setting a minimum volume level with CMS for DMEPOS supplies of $1,000,000 and a separate volume level of $2,000,000 for medications such as transplant and inhaled products with indexing for inflation before accreditation would be required. Many small pharmacies especially in rural areas will be eliminated from the DMEPOS process if CMS requires accreditation. I strongly urge CMS to limit accreditation to large DMEPOS providers and preserve the access of the patient to DMEPOS supplies through small providers such as pharmacies.

Submitter : **Dr. John Rafetto** **Date: 06/30/2006**

Organization : **Twin Rivers Podiatry**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1270-P-1038-Attach-1.DOC

#1038

June 30, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,

John Rafetto, DPM

Submitter : **Ms. Robin Kriegel** **Date: 06/30/2006**

Organization : **American Society for Parenteral & Enteral Nutritio**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1039-Attach-1.PDF

#1039

Via E-Mail

DATE: June 30, 2006

TO: Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 314 G, Hubert H. Humphrey Building
Washington, DC 20201

FROM: Robin Kriegel, CAE
Executive Director

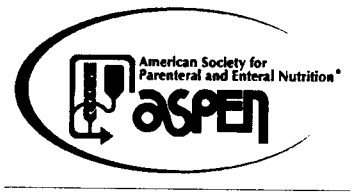
Dear Dr. McClellan:

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is a professional society of physicians, nurses, dietitians, pharmacists, and researchers dedicated to assuring that every patient receives optimal nutrition care. A.S.P.E.N.'s is dedicated to patient-centered, clinical practice worldwide through advocacy, education, and research in the field of specialized nutrition support for patients with inability to consume or assimilate adequate nutrition.

Attached to this letter are our comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies as issued in the Federal Register on May 1, 2006.

With approximately 5,000 members including providers of hospital and home nutrition support to patients, many of who are covered under Medicare Part B, A.S.P.E.N. is keenly interested in insuring that Medicare coverage allows for safe, appropriate and effective home nutrition support. Recognizing that the issue of the proposed rule on competitive bidding is broad in scope, A.S.P.E.N. will confine its comments to the issue of competitive bidding for enteral nutrition.

Please feel free to contact me at 301-920-9127, or email at robink@aspen.nutr.org, for further information.



COMMENTS ON PROPOSED RULE ON COMPETITIVE BIDDING

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is pleased to submit these comments on the proposed rule to implement the new Medicare Part B competitive bidding program for durable medical equipment, prosthetics, and supplies as issued in the Federal Register on May 1, 2006.

The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) is a professional society of physicians, nurses, dietitians, pharmacists, and researchers dedicated to assuring that every patient receives optimal nutrition care. A.S.P.E.N.'s mission is to serve as the preeminent, interdisciplinary nutrition society dedicated to patient-centered, clinical practice worldwide through advocacy, education, and research in the field of specialized nutrition support. With approximately 5,000 members including providers of hospital and home nutrition support to patients, many of who are covered under Medicare Part B, A.S.P.E.N. is keenly interested in insuring that Medicare coverage allows for safe, appropriate and effective home nutrition support. Recognizing that the issue of the proposed rule on competitive bidding is broad in scope, A.S.P.E.N. will confine its comments to the issue of competitive bidding for enteral nutrition.

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

That said, the proposed rule is unlike most proposed rules in that this rule lays out a number of unanswered questions without CMS having committed to a concrete proposal on particular topics. The preamble section regarding criteria for product selection, wherein CMS seeks comment on very general criteria for subsequent product selection, and the preamble discussion regarding the application of competitively bid rates in other areas of the country, are two examples of this practice. At this juncture, it is difficult to project what the final rule will look like on a number of important issues where CMS did not propose a specific course of action. For that reason, we suggest that CMS issue the final rule as an interim final rule with comment period, so that the public will see, for the first time, CMS' directions on an array of issues and thus will have an opportunity to comment on concrete proposals.

Executive Summary

1. Enteral nutrition is not a good candidate for inclusion in the first phase of the competitive bidding program. The differing quality standards between the nursing home and home care settings make fair and equal competitive bidding impossible for the enteral market. In addition, most enteral nutrition patients are residents of nursing homes, a factor that distinguishes enteral nutrition from the other Part B items and services within the scope of the competitive bidding program. It creates serious policy and operational issues for nursing homes as well as for CMS itself. CMS has the authority to exclude enteral nutrition

from this phase of the competitive bidding program, and it should exercise that authority to do so.

2. If CMS ultimately subjects enteral nutrition to competitive bidding, it should provide the same grandfathering protections for enteral patients that are proposed for DME patients.
3. If CMS ultimately subjects enteral nutrition to competitive bidding, it should also modify the proposed payment structure for enteral pumps and, consistent with current law, ensure that the monthly rental payment is one-tenth of the purchase price for each of the fifteen months in the rental period.
4. The competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas.
5. The proposed gap-filling provisions are too vague and undefined, and appear to be in conflict with the limitations on CMS' authority to modify existing payment rates. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders as to how existing payment levels can and should be adjusted when existing codes are modified.

Criteria for Item Selection

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

Both, obviously, are admirable goals. For the reasons described herein, however, we believe that enteral nutrition covered under the prosthetic device benefit is a poor candidate for inclusion in the competitive acquisition program, particularly in the initial phase of the program.

Enteral nutrition involves more than the delivery of enteral nutrition products to patients. Of particular concern to A.S.P.E.N. are patients receiving home enteral nutrition since they do not reside in a health care facility with competent caregivers and practitioners surrounding them. Home enteral nutrition patients still require an array of professional services, including the following:

- Initial patient evaluation and assessment
- Development and implementation of the patient care plan
- Dispensing of enteral formulas, equipment and supplies appropriate for the patient's specific needs

- On-going clinical monitoring and treatment plan oversight to minimize complications, insure that nutritional intake is adequate, and insure that concomitant drug therapies for other medical conditions are both medically and physically compatible with the patient's plan for enteral nutrition.
- Provision of on-call services and patient discharge services.

These services should be provided by specialized home infusion pharmacies with pharmacists, nurses and dietitians that must satisfy licensing and other regulatory requirements imposed by state boards as well as accreditation standards required by most third-party payers. Since home enteral nutrition patients do not reside within facilities staffed with these professional

caregivers, the home infusion provider must be staffed such that these professionals can provide the appropriate level of care to meet the patient's needs.

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

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

Enteral Nutrition

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

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

Factors Determining Product Selection

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

I. Level of Medicare Expenditures:

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

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

Historically, a clear majority of Medicare Part B enteral patients are residents of LTC facilities. The percentage of enteral patients who are in LTC facilities increased from 2003 to 2004 to

approximately 56 percent, based on the data described below. This fact is extremely relevant to CMS' ultimate decision of whether to include enteral nutrition in the 2007 phase of competitive bidding. Based on our involvement with CMS in the development of the new Part B quality standards, we understand that the enteral-specific quality standards will not apply to these enteral patients, and thus will not apply to the majority of Part B enteral patients. Enteral patients in LTC facilities are and will continue to be treated pursuant to the nursing home conditions of participation, not the Part B standards on enteral nutrition.

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

II. Rate of Growth

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

III. Demonstration Project Experience

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

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

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

IV. Studies and Reports

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

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

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

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

If CMS wishes to use outside sources to gather information about enteral nutrition functions and costs, we urge CMS to consult with organizations like A.S.P.E.N. Our organization has developed quality guidelines as to the functions and services required for enteral nutrition. A.S.P.E.N. also believes that the development of a national database or registry of home enteral nutrition patients is needed to properly develop data regarding the patient population, both privately insured and government funded, who need and require home enteral nutrition. A.S.P.E.N. further believes that it is only through the development of such data that the true needs of this patient population can actually be identified and analyzed, and will support the assumption that the services necessary to provide proper care to these patients cannot be met by competitive bidding. Likewise, we suggest CMS consult with the Joint Commission on the Accreditation of Healthcare Organizations and other accrediting organizations as to their perspective on what is involved in the provision of enteral nutrition.

In addition, the OIG studies could not have reflected the costs associated with accreditation, either in terms of the administrative costs of seeking and maintaining accreditation or the costs of complying with the quality standards that are the bases of accreditation. In light of this clear

discrepancy, we urge CMS not to rely heavily on OIG reports in determining product selection for the competitive bidding program.

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

Enteral Patients in Long-Term Care Facilities

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

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

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

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

The proposed rule also does not account for Part B suppliers whose entire business is treating beneficiaries who are residents of nursing homes. Nursing home suppliers have very different businesses than home care suppliers. They are not interchangeable, and definitely should not

be combined into a single grouping to demonstrate that an area has a certain number of suppliers.

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

Application of Quality Standards

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

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

As described above, most of the enteral patients are in long term care facilities. Most of these patients receive enteral nutrition from suppliers that focus only on the long term care market. The proposed rule would require these enteral nutrition suppliers to be accredited for compliance with the Part B standards, even though those standards do not apply to the patients they serve. The absurdity of that result is evident.

Likewise, the provision of enteral nutrition to patients who qualify for the home health benefit would not be subject to the new Part B standards.

It would be highly illogical to subject all of enteral nutrition to the competitive bidding program at this point, because of the involvement of the three different sets of quality standards. The costs of compliance with the standards differ, due in large part to the fact that the settings of care differ. On the other hand, we do not believe it is a feasible option to simply limit the competitive bidding program to homecare enteral patients, since those patients make up less than half of the enteral patient population and thus CMS would not achieve the savings envisioned by the MMA. Regardless, the administrative costs of sorting out the various enteral patient populations and standards within the context of the competitive bidding program would be disproportionate to any value derived from applying competitive bidding to this area.

Enteral HCPC Codes

The enteral formulas within particular billing codes are not interchangeable, which would thwart one an objective of the competitive acquisition program to achieve cost savings by forcing competition not only among Part B suppliers but also among medical manufacturers as well. One of the basic tenets of the competitive acquisition program appears to be an assumption that the program can generate additional savings by limiting coverage to particular products within billing codes that may be cheaper than other products within those codes. For this approach to work, the products within a billing code must be interchangeable. That is not the case for several of the enteral formula billing codes, which were updated within the past few months.

B4153 contains enteral formulas that are described as "nutritionally complete, hydrolyzed proteins." This category contains enteral formulas that meet this definition but which are not used for the same purposes. For example, the Nestle product *Crucial Complete Elemental Diet* is a B4153 enteral formula that is used for advanced wound healing. Another Nestle product in B4153, *Peptamen,* is used for patients suffering from malabsorption. No physician would consider the two products to be clinically interchangeable in all situations.

B4154 contains enteral formulas that are designed for patients with special metabolic needs. Formulas in this category are used to treat particular disease states. Thus, for example, Novartis Nutrition's *Novasource Pulmonary* is a B4154 product that is intended for patients with respiratory disease. Novartis Nutrition's *Diabetisource AC,* however, is another B4154 product that is engineered for patients with diabetes. It should be obvious that these products cannot be substituted clinically for each other.

These two codes, B4153 and B4154, are among the two growing codes among the enteral formula codes. In the future, it is reasonable to expect the introduction of additional enteral formulas for specific diseases and conditions which will have to be added to these codes. As these codes will contain a growing number of the enteral formulas used in the care for Medicare beneficiaries, this is additional evidence that enteral nutrition is not as suitable for the competitive acquisition program as would be other products that: (1) are clinically interchangeable within their HCPCS codes, (2) do not involve the nursing home resident population, and, (3) do not involve services and other functions that the Medicare program has yet to cover explicitly.

Enteral Nutrition Pumps

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

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

Submitter : **Ms. Barbara Crane** **Date: 06/30/2006**

Organization : **Clinician Task Force**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached Word Document

CMS-1270-P-1040-Attach-1.DOC

#1040

Clinician Task Force Co-coordinators

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Clinician Task Force

June 29, 2006

The enclosed comments are being submitted on behalf of a national clinician group known as the Clinician Task Force (CTF). The CTF was formed in 2004, and involves over 30 clinicians from around the country with special expertise in wheelchair assessment.

CTF's purpose is to support the development of policies that will improve access to assistive devices, technologies, and related services for people of all ages with disabilities and chronic conditions.

The following comments address the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues (CMS-1270-P).

Contents: Comments on CMS-1270-P

CTF Draft comments on CMS-1270-P

General Comments:
The Clinician Task Force is gravely concerned about the impact of Competitive Acquisition of DMEPOS on beneficiaries who require use of high end rehab equipment for their daily mobility needs. To avoid an adverse medical outcome for the beneficiary, certain DMEPOS require a particular mode of delivery that utilizes qualified providers to determine the clinical efficiency and value of said items.

Misapplication of devices or absence of necessary services required for effective training in the use of devices may cause harm. Individuals with neuromuscular conditions or with diagnoses resulting from trauma are at highest risk of harm based on the application of the proposed policy. These individuals require higher levels of service provision by DME suppliers to maximize the benefits of the equipment supplied. The Clinician Task Force believes the bid system will not allow suppliers to provide the high levels of service required for some clientele they serve. Suppliers will have to cut services to remain competitive in this system and beneficiaries will be harmed by this lack of service.

CTF further supports the specific comments submitted by NCART regarding the many proposals within the entire NPRM. CTF also strongly supports carving out products that are evaluated, fitted, configured, adjusted or programmed to meet the specific and unique needs of an individual with a primary diagnosis resulting from injury or trauma or which is neuromuscular in nature as these items are not appropriate for delivery in a competitive bidding system.

Comments regarding Section D. "Competitive Bidding Areas"
The Clinician Task Force recommends that one MSA be selected from each DMERC region for consideration in 2007. Further, we recommend one product group be selected for each MSA to gain further experience with different product groups without trying to manage multiple product groups in any one area. Power wheelchairs should be excluded from the first round due to the fact that new powered wheelchair coding was not even completed until 2006. There is still no pricing information for these new codes and it will be impossible to determine cost savings potential for this item.

Comments regarding Section E. "Criteria for Item Selection"
The Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule lists five objectives, one to assure beneficiary access to quality DMEPOS.

The Clinician Task Force (CTF) believes that to avoid an adverse medical outcome for the beneficiary, certain DMEPOS require a particular mode of delivery that utilizes qualified providers to determine the clinical efficiency and value of said items.

The CTF recommends that support surfaces and mobility assistive equipment meeting the following criteria NOT be subject to competitive acquisition:

1. Skin protection, positioning, skin protection and positioning seat cushions; positioning back cushions; custom fabricated seat and back cushions.
2. Manual wheelchairs with adjustable configurations.
3. Power wheelchairs with one or more of the following: expandable controllers, alternative controls, power seating or customized seating.

Comments regarding Section H part 2 – "Rebate Program"
CTF is strongly opposed to the use of rebates in any form.

Comments regarding Section V. "Regulatory Impact Analysis"
CTF believes competitive acquisition will cause closure of small business providers of wheelchairs and adaptive seating, further limiting access of beneficiaries to devices.

Submitter : DAVID HOSEMANN **Date:** 06/30/2006

Organization : HOMETOWN MEDICAL, LLC

Category : Individual

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

BENEFICIARY WILL RECIEVE LESS PRODUCT/ LESS SERVICE/ IN AN UNACCEPTABLE TIME FRAME

Regulatory Impact Analysis

NOT IDENTIFYING SPECIFIC PRODUCTS TO BE INCLUDED IN THE COMPETITIVE ACQUISITION PROCESS MAKE IT VERY DIFFICULT TO EVALUATE COST ASSOCIATED WITH THE DELIVERY OF THE PRODUCT. DILIVERY AND SERVICE OF THE PRODUCT CAN ONLYY BE GUESSED AT WITHOUT SPECIFICS.

Regulatory Impact Analysis

Regulatory Impact Analysis

I OWN A HME COMPANY IN MISSISSIPPI. I'VE BEEN IN BUSINESS FOR 25 YEARS. WHEN I FIRST STARTED THERE WAS 1 HME IN OUR TOWN. THERE ARE NOW 4 HME COMPANIES. WE ALL COMPETE FOR THE SAME REFERRAL. IN MY OPINION THERE HAS NEVER BEEN A BETTER ENVIROMENT FOR COMPETITION IN THE MEDICARE BENE'S FAVOR. I'M CONCERNED THAT COMPETITIVE BIDDING COULD ACTUALLY MEAN (ANTI COMPETITIVE MARKETPLACE) BECAUSE IT COULD CREATE AN ENVIROMENT OF ANTI-TRUST STATUES IF JUST A FEW VENDORS CONTROL THE MARKET. SINCE 2002, OUR COMPANY HAS CONCENTRATED HELPING MEDICARE BENEFICARIES WITH DISEASE MANAGEMENT. WE ARE PROUD OF OUR RESULTS, AND WE KNOW WE HAVE HELPED IN PREVENTING UNNECCESSARY HOSPITAL STAYS, AS WELL AS UNNESSESSARY E.R. ROOM VISITS. I'M CONCERNED THAT COMPETITIVE BIDDING MAY SAVE $75MIL ON THE FRONT END, BUT COST $1BIL ON THE FLIP SIDE DUE TO HOSPITILIZATIONS THAT ARE UNWARRANTED, OT PREVENTABLE. PLEASE FEEL FREE TO CONTACT ME IN THIS REGARD. I HAVE MANY MORE IDEAS, BUT I'M OFF TO SERVICE RESPIRATORY HOMECARE PATINTS AND MAKE SURE THEIR NOT COSTLY TO THE MEDICARE PROGRAM.

Submitter : Mr. Ed Rivalsky **Date:** 06/30/2006

Organization : Clinical Specialties, Inc.

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See attachmnet

CMS-1270-P-1042-Attach-1.DOC

#1042

June 30, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244

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

Dear Dr. McClellan:

Clinical S pecialties Inc, db a C SI Infusion and Network S ervices is p leased t o submit t hese c omments on t he p roposed r ule t o im plement t he ne w M edicare P art B competitive bidding program for durable medical equipment, prosthetics,. and supplies (DMEPOS) as issued in the Federal Register on May 1, 2006.

Clinical Specialties Inc (CSI) is currently in it's 19th year of serving infusion therapy patients throughout Ohio! CSI has been a Medicare provider since our inception. We currently serve nearly 3500 new patients annually.

Realizing that CMS has the unenviable task of developing and implementing within a limited time frame a congressional mandate for a nationwide competitive bidding program for a large portion of the Medicare program, my comments are designed to p oint o ut C SI's p rimary areas o f c oncern r elated t o t he a pplication o f c ompetitive bidding program for home infusion therapies. In short, I believe that this product area is not well-suited to successful implementation of competitive bidding and in many significant respects do not meet the criteria for inclusion.

I urge you to carefully consider the detailed recommendations being sent to you under separate cover by our national organization, the National Home I nfusion Association. Below is a summary of the major points we would like to emphasize:

1. CMS should issue the final rule as an interim final rule with comment period, so that stakeholders can provide comments on a range of issues that were not subject to concrete proposals from CMS in the proposed rule.

2. I understand that new Part B quality standards for DMEPOS are still in development. I support quality standards for infusion and enteral therapies, but

urge CMS to recognize that Medicare payments both within and outside the competitive bidding program need to be at a level sufficient for efficient suppliers to comply with the quality standards. These standards will be meaningless if Medicare payment levels are woefully inadequate in relation to the costs associated with complying with the quality standards. CMS should affirm this point in the final rule.

3. Home infusion therapy is one of the most service-intensive therapies covered under Medicare Part B. However, current Part B coverage of home infusion therapy is extremely limited, and overall Medicare coverage of home infusion therapy is now divided between Part B and the new Part D prescription drug benefit. There are serious and still unresolved coordination issues between Part B and Part D involving infusion therapy coverage. In light of these factors, infusion therapy is a poor candidate for competitive bidding at this time; implementation of competitive bidding for these therapies will exacerbate existing confusion and complications for beneficiaries, physicians, discharge planners, pharmacies, and other clinicians, and could result in different infusion drugs being provided concurrently from different pharmacies, raising significant medication safety concerns. CMS has the authority to exclude infusion therapies from this phase of the competitive bidding program, and it should exercise that authority to do so.

4. If adopted the competitive bidding areas should be limited to the geographic scope of the selected MSAs, and should not encompass contiguous areas, primarily due to the intensive service needs of these patients at a local level.

5. The proposed "gap-filling" provisions are too vague and undefined, and appear to to circumvent the statutory "inherent reasonableness" review and allow CMS to act independently to modify reimbursement of some already covered products and supplies. CMS should withdraw the gap-filling proposal and engage in a separate dialogue with stakeholders regarding how existing payment levels can and should be adjusted when existing codes are modified.

Thank you for the opportunity to comment on these important issues. If you wish to discuss these comments further with me, please contact me at 440.717.1700

Sincerely,

Edward J Rivalsky
President and CEO

Cc: Lorrie Kline Kaplan, Executive Director, National Home Infusion Association

Submitter : Mr. Jody Wright

Organization : Rocky Mountain Medical Equipment

Category : Other Health Care Professional

Date: 06/30/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

I am against national competitive bidding (NCB). Being the owner of a small business that supplies DME equipment, I'm being told that the objective of NCB is to obtain lower costs for DME. If that is the case, why doesn't CMS simply lower the allowables for products on a supply and demand basis, continuing to lower the pricing until there are relatively few companies that can provide the products. Under this scenario, it will be my decision whether or not to supply the products, which is as it is right now. There are many products I don t supply because the reimbursement isn t high enough. Instead, NCB is designed to eliminate providers from the Medicare system by sending out particular products for bid, and if a provider s bid is not accepted, then the provider is eliminated from providing the product. Since the majority of DME providers have a significant amount of their business derived from Medicare recipients, many of them will be put out of business. It seems to be the goal of NCB to eliminate as many as 50% of the existing providers. I'm sorry, but this sounds anti-American. As a consumer, I don't want to be sent to the cheapest provider; instead, I want the option of going to the provider who supplies the best quality products and services at competitive prices. With NCB, my parents will be forced to go to providers who can supply cheap products, but with limited (if any) services to support those products. My view of NCB is that fraud and abuse will run rampant in the DME business. Companies will have to find ways of making money outside of the normal means of buying a product at a reasonable cost, supplying the product, servicing the product, billing appropriately for that product, and receiving a fair profit for the products provided. As companies become desperate(because the reimbursement is to low), they will be forced to make decisions they normally wouldn t make. The criteria to submit a bid under NCB is designed for the larger national providers. My response: For the past 14 years, I have owned my DME equipment company, and you have never read my name in the paper for any wrongdoings, and yet I read about Apria, Lincare, Hanger and many of the other national and regional companies using business practices that I deem immoral and illegal. The difference is that my staff knows I don t want the money bad enough to chance going to jail, and yet the larger companies pay their fines and business continues as usual. If I were you, I would design NCB for smaller dealers. A small dealer has more to lose when everything we own and everything we can borrow is invested in our businesses, and we must service our customers with the highest degree of professionalism because we need every customer to come back. Please feel free to contact me for any additional information you may need. Jody R Wright, President, Rocky Mountain Medical Equipment, Inc.; 303-806-8001 x 130

Submitter : Dr. Jay Rosenberg **Date:** 06/30/2006

Organization : Dr. Jay Rosenberg

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#1044

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

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

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

Submitter : **Ms. Mary Jo Carden** **Date: 06/30/2006**

Organization : **Transplant Pharmacy Coalition**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

See attachment for comments from the Transplant Pharmacy Coaliton.

CMS-1270-P-1045-Attach-1.PDF

#1045

MEMORANDUM

Transplant Pharmacy Coalition

Date: June 30, 2006

To: Linda Smith, Quality Standards and Accreditation
Centers for Medicare & Medicaid Services

From: Mary Jo Carden, RPh, JD
On behalf of the Transplant Pharmacy Coalition

Re: **CMS-1270-P**, Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule

The Transplant Pharmacy Coalition (TPC) is pleased to submit comments regarding the competitive acquisition program for DMEPOS. Specifically, TPC submits comments regarding Quality Standards and Accreditation. TPC understands that CMS' goal in accrediting all Medicare suppliers is to assure high quality of care, services, integrity, professionalism, and oversight in the program but believes that this accreditation is unnecessary for pharmacies that provide pharmaceuticals and diabetic testing strips but not DMEPOS. TPC believes that existing state Board of Pharmacy requirements provide sufficient oversight to meet CMS' goals of providing high quality care with oversight from an appropriate organization. CMS recently affirmed its confidence in the credibility and integrity of pharmacies that provide immunosuppressant and oral anti-cancer agents by eliminating the need for submission of the assignment of benefits (AOB) form and DMERC information form (DIF)(42 CFR Parts 402, *et seq.* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005), paperwork still for DMEPOS suppliers.

TPC is a coalition of eight specialty transplant pharmacies that are both independently owned and public companies. The members of the coalition are Amber Pharmacy (Omaha, NE); BioScrip, Inc (Minneapolis, MN); Echo Drugs (Flushing, NY); F&M Specialty Pharmacy (Jackson, MS); PharmaCare, Inc (Lincoln, RI); Skyemed Pharmacy (Pompano Beach, FL); Transcript Pharmacy (Jackson, MS); and Two Thousand Ten (2010) Pharmacy (Los Angeles, CA). These companies supply immunosuppressant medications and associated, necessary pharmacy services to approximately 30% of all US organ transplant recipients and approximately 40% of Medicare Part B beneficiaries who have received an organ transplant. TPC is the largest organization of specialty transplant pharmacies in the United States.

State Boards of Pharmacy impose stringent requirements for both pharmacies and pharmacists and perform many of the functions that CMS accrediting organizations would perform. State Boards of Pharmacy require that both pharmacists and pharmacies meet stringent licensing and registration requirements. State Boards of Pharmacy also

have the authority of exclusion and revocation of non-conforming pharmacist practitioners and pharmacies. State Boards of Pharmacy authority extends to all activities of pharmacy dispensing and practice regardless of payer source.

Specific Board of Pharmacy functions similar to those performed by an accrediting organization include:

- Regular inspection of inventory and records on disposition and acquisition of medications and devices stored in the pharmacy and provided to the public;
- Inspection of physical premises to ensure that a pharmacy meets minimum requirements for sanitation and drug storage; and
- Registration and licensing of pharmacists and other personnel permitted to be employed in a pharmacy and the standards required for this employment.

Requiring pharmacies to become accredited for purposes of providing Medicare Part B medications would be superfluous and might discourage the provision of immunosuppressants and oral anticancer agents. Many pharmacies do not participate in the Medicare Part B program because of the cumbersome billing practices coupled with insufficient reimbursement. Accreditation would further increase pharmacies' costs and could eliminate some suppliers from the market.

TPC also supports accreditation exclusion for suppliers of diabetic testing supplies that also provide patients with prescription drugs. Many pharmacies serving diabetic patients provide testing strips to patients who receive diabetic medications. Blood glucose monitoring is a critical element to ensure overall health of diabetic patients and pharmacies should be encouraged, not discouraged to provide these supplies. Some pharmacies only participate in the Medicare program through provision of diabetic testing supplies. If these pharmacies are required to become accredited just for this purpose, then some might not continue to provide these supplies. The cost of purchasing these supplies is often greater than the Medicare allowable and therefore these products are already supplied at a loss. The cost of accreditation would increase overall losses for providing these products. At a time when CMS is encouraging payment for outcomes, it should be encouraging its partners, including community pharmacies, to provide products and services that assist in improving outcomes, not creating barriers to care.

TPC thanks CMS for the opportunity to provide comments on the quality and accreditation standards and looks forward to working with CMS on this issue in the future. If you have questions regarding TPC or require further assistance or support, please contact TPC's Washington, DC representative Mary Jo Carden (Mcarden@CardenAssociates.net; 202-904-2482).

Submitter : **Ms. Eve Zartman-Ball** **Date: 06/30/2006**

Organization : **Vision Council of America/Better Vision Institute**

Category : **Health Plan or Association**

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

Thank you for this opportunity to comment on the CMS proposed ruling regarding the exclusion of low vision aids.

The Vision Council of America (VCA) is a non-profit trade association dedicated to the promotion of eye care in America. VCA membership is comprised of 225+ optical related Member Companies. These members along side our Exhibitor Members support the Vision Expo Trade shows which educates over 15,000 eye care professionals each year and provides the resources to support important programs such as the Check Yearly. See Clearly. which educates millions of Americans on the importance of vision health. VCA advocacy activities work to ensure that children and all Americans are given access to vision care. All VCA public health related programs are vetted through the Better Vision Institute (BVI), a 501(c) 3 medical advisory board with nearly 100 years of history and is the only group in the US that represents all three of the optical professions (opticians, optometrists and ophthalmologists). The BVI helps to ensure that our positions on public health related issues are medically sound and patient based.

While we appreciate the attention that the CMS has given to the low vision device matter, as well as the desire to clarify the policy, we believe that process by which this proposed ruling was made and the associated deadlines given do not allow CMS to make the best ruling on the matter. We therefore respectfully request that CMS extend the deadlines and expand the process to allow for a more fully vetted process prior to any rule for or against the low vision device matter.

Our rationale for this request is that this decision will affect in perpetuity the coverage for thousands of Americans, and the gravity of this decisions mandates that all issues, including the medical grounds and the court ruling, be more fully explored in a pubic decision process.

We have also discussed this important issue with the leadership of other national vision health care organizations who also believe that there is need for more public discourse on this topic. An extension of the deadlines will permit these groups to provide CMS with their views and data on this issue in more detail.

We again greatly appreciate you addressing an area which we feel clearly needs clarification, but hope that you agree with our finding that a more fully fledged process will serve all those involved in this for the better. Thank you for your time and consideration and we look forward to hearing from you. The Vision Council of America's offices are at 1700 Diagonal Road #500 Alexandria, VA 22314 Tel: 703-548-4560 or email ezb@visionsite.org.

Submitter : **Mrs. Laurie Dykema** **Date: 06/30/2006**

Organization : **Durable Medical Supplier**

Category : **Nurse**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Re: CMS-1270-P
Dear CMS: 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 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 severly restrict beneficiaries' access to needed items and supplies and may compromise patient health outcomes.
*Criteria for Item Selection
The competitive bidding program should NOT include common DMEPOS supplies such as diabetic testing supplies. If CMS intends to centralize and consolidate the provision of DMEPOS items and supplies, the Agency should limit the competitive bidding program to those unique products that could be provided be a central supplier.
*Opportunity for Participation by Small Suppliers
I urge CMS to take steps to ensure that small suppliers which include the majority of pharmacy-based suppliers can participate in the competitive bidding program. Small suppliers should be allowed to designate a smaller market in which to provide DMEPOs. It would be extremely difficult, in 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 the following types of DMEPOS in my practice wheelchair, hospital beds, nebulizers, diabetic supplies, walkers, canes, lift chairs, scooters, power wheelchairs, and other ADL suppies, and without these revisions to the final regulation, I will be unable to continue providing these valuable services to my patients.
* In conclusiion, I urge CMS to revise the regulation to:
exclude common DMEPOS supplies, and make it easier for the small supplier to be included instead of making us close our doors and not beable to serve the people we so deeply care about in our community!

Thanky you for considering my view.

Sincerely,

Laurie Dykema, RN Manager

Submitter : Chris Houston

Date: 06/30/2006

Organization : RLS, Inc., dba Lane's Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

CMS has taken a very narrow view of its obligation to ensure that small suppliers are adequately represented among contract suppliers. CMS proposal for allowing networks does not consider the practical hurdles involved in creating a new entity. Under the timelines that CMS has announced, it will be difficult to establish networks that can meet the eligibility requirements for submitting bids. Consequently, this may not be a viable option for most small suppliers. CMS has also stated that the market share for supplier networks cannot exceed 20%. CMS should expand this to allow greater participation by small suppliers. CMS should also consider small supplier set asides in at least some MSAs. The quality of service provided by small suppliers should not be overlooked by CMS. Smaller communities in more rural areas of the country rely heavily upon the level of care and expertise that many smaller suppliers provide and should be afforded an opportunity of the same caliber as the larger national chains.

Submitter : **Mr. James Frederick** **Date: 06/30/2006**

Organization : **Mitchell Home Medical**

Category : **Other Practitioner**

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Because of the enormous amount of "unknowns" in the bidding process and the agressive time frame in which CMS is implementing I seriously question the transition from a 30 plus year fee for service system to CB will be smooth, rather it implement within the proposed time frame there will be multiple problems and disruptions impacting carrier, providers and ultiamtely beneficiaries.

I also have serious concerns over the payment issues where as the original purpose of saving Medicare health care dollars are lost in an over-complicated adminstrative system. Also not factored in the CB process is the DRA that has already slashed cuts in oxygen and recently changed the payment modality where a Medicare beneficiary is forced to purchase their oxygen equipment in 36 months. Besides issues related to patient endangerment and liability related to this legislation it also poses the question as to how much savings will actually be realized from the oxygen services in the bidding process since there is are no profit margins available?

Being a independent supplier and considered small business, I have considerable concerns as to how CMS will insure fairness in the bidding process for small independent providers. From where I stand CMS has taken a very lackidaisical positions to ensure that small providers are represented with contract suppliers. CMSs's network proposal to allow networking with other providers doesn't take into account the legal and practical issues involved in establishing a new entity on top of trying to meet the timelines to submit bids. Also, the 20% market share network limitation should be expanded to allow greater participation by small providers.

Jim Frederick, R.R.T., B.Ed.

Submitter : **Dr. Janet Faghihi** **Date: 06/30/2006**

Organization : **Dr. Janet Faghihi**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-1050-Attach-1.DOC

#1050

DR. JANET M. FAGHIHI
55 Main Street, Suite 202
Hastings-on-Hudson, NY 10706
Tel: (914) 478-8120
Fax: (914) 478-1818
Medicare Provider #: P95421
DME #: 5137190001

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

June 30, 2006

Dear Dr. McClellan:

I request that the Centers for Medicare & Medicaid Services (CMS) modify the physician definition used for the new competitive acquisition program from 1861(r)(1) to 1861(r). I am a podiatric physician and prescribe and supply select durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items to my patients only. If I am instead required to bid to supply to an entire Metropolitan Statistical Area (MSA), my patients may no longer be able to get medically appropriate and necessary DMEPOS items from me even though they are integral to the care I provide.

Additionally, I want to be able to execute a physician authorization when I determine that a particular brand of item is necessary for my patient.

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

For example, if I treat a patient with an ankle injury, I may determine that an ankle brace is necessary to stabilize the ankle and crutches are necessary to limit weightbearing on the injured extremity. If I am not a DMEPOS supplier in the new competitive acquisition program because I was unsuccessful in competing to bid to supply to the entire MSA rather than just to my patients, the patient will need to go elsewhere to obtain the

medically necessary items. The patient risks converting the existing injury into one that is more severe, with greater recovery time and increased risks for complications.

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

Sincerely,
Dr. Janet M. Faghihi

Submitter : **Dr. Edward Williams** **Date: 06/30/2006**

Organization : **Foot and Ankle Associates, Inc.**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

FOOT AND ANKLE ASSOCIATES, INC.
1 CALLE MEDICO
SANTA FE, NM 87505
505-982-0123 FAX 505-982-5714

June 22, 2006

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

Dear Dr. McClellan:

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

I prescribe and supply select DMEPOS items as part of patient care. I do not supply items to individuals who are not my patients and believe that requiring me to do so would harm Medicare beneficiaries who are my patients. I am a current supplier with a valid supplier number and I adhere to the existing 21 supplier standards. I am subject to the Stark requirements, as well as other regulatory requirements that apply to MD and DO suppliers.

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

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

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

Sincerely,

Edward D. Williams, D.P.M.

EDW/md

Submitter : **Ms. Evelyn Herndon** **Date: 06/30/2006**

Organization : **Ellis County Home Medical Equipment**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

#1052

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

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

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

Submitter : **Dr. Jay Rosenberg** **Date: 06/30/2006**

Organization : **Dr. Jay Rosenberg**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-1270-P-1053-Attach-1.DOC

#1053

DR. JAY R. ROSENBERG
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Medicare Provider #: P25491
DME #: 5395910001

June 22, 2006

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

Dear Dr. McClellan:

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

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

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

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

Sincerely,
Dr. Jay R. Rosenberg